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Gary S. Wolfe

Autism: A Real Challenge

Autism spectrum disorder (autism) is a complex, lifelong developmental condition that typically is diagnosed in early childhood and can impact a person's social skills, communication, relationships, and self-regulation. Autism is different for everyone and affects people differently and to varying degrees. Autism consists of a certain set of behav-

low-income, or non-English primary language.

- Boys are approximately 4 times more likely to have an autism diagnosis than girls of the same age.
- Girls may display characteristics of autism differently than boys and might go undiagnosed because of their different presentation.

The cause of autism is unknown. The

For the first time, more Black, Hispanic, Asian, or Pacific Islander children were identified with autism than were White children.

iors, which is why it is referred to as a spectrum condition.

In 2023, the Centers for Disease Control and Prevention (CDC) issued a Community Report on Autism revealing the following:

- Prevalence of autism rose to 1 in every 36 eight-year-olds in 2020, more than twice as great as the 2004 rate of 1 in 125.
- The Covid-19 pandemic interrupted the identification of children with autism, which may have long-lasting effects resulting from delays in identification and initiation of services.
- Children who receive an autism diagnosis by the age of 4 are 50% more likely to receive services.
- For the first time, more Black, Hispanic, Asian, or Pacific Islander children were identified with autism than were White children.
- Children of color may receive their diagnosis later than White children because of stigma, lack of access to health care services, noncitizenship,

disease is very complex and no two people are exactly alike. Autism probably results from multiple causes. Some of the causes of or contributors to autism might be genes, environmental factors, problems with growth of certain areas of the brain, and problems with metabolism.

The CDC recommends all children be screened for autism 3 times—at 9 months, 18 months, and 24 or 30 months. Early identification is associated with better outcomes. Intervention should start as soon as an autism diagnosis is suspected. Children who receive early intervention can show marked strides in their overall development and quality of life and receive the needed educational and home care support.

It is important to remember people present at different ages and with different behaviors. Although signs and symptoms of autism usually are seen by age 2 years, some children show signs earlier and some later. Each person has a unique pattern of behavior and level of severity.

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Catherine M. Mullahy

It's All About Engagement!

Issues of Engagement: Patient, Staff and Professional

As I contemplated possible topics for this issue's column, I scanned various blogs, journals, and other publications, but it was through my discussions with colleagues that a common and concerning issue kept bubbling to the surface. Frequently, we hear the term "engagement," which most of us working in health care associate with patient engagement. The discussions about this are endless, raising more questions and eliciting more recommendations, but they are often given without a considered exploration of the factors that contribute to a lack of engagement by patients with members of the health care team. Among the factors responsible for a less than ideal engaged patient are:

- Patient demographic characteristics and health literacy
- Severity of the patient's health condition
- Knowledge and attitudes of health care professionals
- Patient behaviors that may challenge a health care professional's clinical abilities
- Type of health care setting (eg, primary or secondary care)

We also see the terms *patient engagement* and *patient activation* used interchangeably. The Center for Advancing Health in Washington, DC, defines patient engagement as "...actions individuals must take to obtain the greatest benefit from the health care services available to them...." It defines patient activation as "...the knowledge, skills, and confidence a person has in managing their own health and health care...."

Case managers increase the likelihood for successful outcomes when their patients are fully engaged in their intervention. A growing body of evidence supports that patients who are actively engaged in managing

Disengagement can be caused by a variety of internal and external factors, and it's important not just to identify the factors, but also to address them on an individual and organizational basis.

their own health are less likely to be hospitalized or visit the emergency department. Most important, they are more likely to report better health care experiences and outcomes.

Those in leadership roles in health care may be experiencing another troubling element of engagement, which is staff disengagement. The COVID-19 pandemic has resulted in major changes in staffing and concern regarding those who have "quietly quit" or "silently resigned" (ie, those individuals who give the minimum possible effort to their job, as opposed to just resigning). This is problematic across our nation's health care workforce and can have devastating consequences across the care continuum.

Disengagement can be caused by a variety of internal and external factors, and it's important not just to identify the factors, but also to address them on an individual and

organizational basis. COVID-19 surges left staff emotionally and physically exhausted. Staff in critical care units became increasingly anxious when patients were transferred to their units knowing that the likelihood of death was imminent. In the earlier days of the pandemic, staff in hospitals were viewed as heroes and accorded demonstrable appreciation for their efforts. They received dinners, baked cookies, applause, and sirens and church bells ringing at the end of shifts as folks lined the streets near hospitals. Those accolades eventually subsided, but the physical and emotional demands and stress remained.

The Gallup Corporation, which has studied engagement for over 3 decades, identified several factors that have an impact on team engagement. They include:

- Staff turnover
- Sick leave and Family and Medical Leave Act
- Medical error occurrence
- Patient loyalty to a health system
- Nurse well-being
- Staff productivity

External staff engagement factors come from the organization and direct leadership. Poor communication among the organization, leadership, and staff can hinder shared governance, which then increases staff disengagement. Shrinking funds and the resulting limited resources leave staff feeling like they can't provide safe and effective care. This, of course, further exacerbates the situation leading to more problems. Over the past several

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Federal Anti-Kickback Statute Applies to Medicare Providers and Others, Including Private Duty Companies

Elizabeth Hogue, Esq.

There seems to be a myth among home care companies that the federal anti-kickback statute applies to Medicare-certified providers only. On the contrary, the anti-kickback statute applies to providers who receive funds from any state or federal health care program, including the Medicaid Program, Veterans Administration, TRICARE, and others. Attention private duty providers: This means many of you!

There is a federal law that prohibits illegal remuneration. This law is often called the *anti-kickback statute*. It generally says that anyone who either offers to give or actually gives anything to anyone to induce referrals has engaged in illegal conduct. A recent enforcement action reinforces this point.

In this case, a doctor and a medical sales representative were charged in a scheme to pay and receive kickbacks to generate expensive prescriptions for compound drugs. TRICARE paid over \$12 million for the prescriptions. The indictment alleges that recruiters identified TRICARE beneficiaries to receive the drugs, promising to secure their prescriptions without consultation with physicians and sometimes offering money to sign up. On receipt of beneficiary information from recruiters, the leader of the scheme sent prefilled prescriptions with drugs to be dispensed, refills authorized and lists of names of patients to medical professionals who signed them without

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Claims submitted for services provided to patients who were referred in violation of applicable prohibitions are “false claims.”

consulting patients or without regard to medical necessity. Prescriptions were sent to a pharmacy in Mississippi that shipped drugs nationwide and billed TRICARE for reimbursement.

Once again, as is clear from the indictment, the alleged perpetrators were “done in,” in part by their own text messages:

“When the ringleader joked about being hounded for payouts by texting Clifton, ‘Hashtag for the day... [Ringleader], is my check ready? #Lol.’ Clifton replied, ‘Haha! Meeeee toooo Jay already called asking this morning too...even the rich Man[s].’” Later, Clifton lamented falling TRICARE reimbursement rates by texting the ringleader, ‘\$210 minus half for Tax\$105 [sic] then dr’s cut then patients cut...Yike[s].’”

In addition, it is important for providers to note that if referrals are obtained illegally in violation of the anti-kickback statute and claims are submitted for services provided to patients referred inappropriately, such claims may also violate the federal False Claims Act.

The Office of the Inspector General (OIG) of the US Department of Health and Human Services, the primary enforcer of fraud and abuse prohibitions, has clearly stated that claims submitted for services provided to patients who were referred in

violation of applicable prohibitions are “false claims.” Submission of false claims may also result in criminal prosecution and/or civil liability, amounting to many thousands of dollars and suspension or exclusion from participation in the Medicare and Medicaid Programs and other federal and state health care programs.

In addition to the necessity to avoid payment of kickbacks, therefore, providers must be scrupulous about avoiding all illegal strategies for obtaining referrals. When referrals are obtained by any unlawful means, the consequences can be extremely adverse for providers.

Consequently, as part of the development of new marketing strategies, management must always explore the legal boundaries of proposed methods of marketing before implementation. To do so, marketing staff cannot be allowed to implement new marketing arrangements and programs without review and approval by management. Review must include a thorough examination of whether the marketing program or arrangement, as proposed, violates applicable prohibitions and, if so, whether it can be changed so that it passes muster. **CM**

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A Pathway to Explore Disability Management: Core Knowledge Curriculum Updated, Certificate Offered

By Stan Scioscia, MEd, CDMS

A unique learning resource is offered for professionals interested in exploring the field of disability management: the [Core Knowledge Curriculum \(CKC\)](#). The CKC offers a pathway into the domains, or areas of practice, of disability management that are associated with the Certified Disability Management Specialist (CDMS) credential.

As a professional development opportunity, the CKC may be of particular interest to case managers and other health and human resource professionals who work in workers' compensation or disability case management or who want to learn more about promoting independence, self-sufficiency, and return to work, and about advocating for individuals with disabilities.

The CKC is the first comprehensive online learning program broadly focused on disability management and leaves of absence. It consists of an introductory module and four domain modules. In 2022, a subcommittee of the CDMS Professional Development

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more than 50,000 professional case managers and disability management specialists. Stan is also a long-time disability management professional and chairs the CDMS Professional Development and Education Committee.



Within the disability management field, there is increased demand for those who possess the knowledge and skills to enter this field of practice. The CKC and its various benefits can build knowledge and open pathways to new opportunities.

and Education Committee reviewed and, where necessary, updated the content and resources provided within each module.

The four domains, which were first identified in the 2009 CDMS Role & Function study and confirmed in the 2020 study, are:

- 1. Disability and Work Interruption Case Management**, including gathering relevant case information, synthesizing information, interpreting case-specific local, state, and federal regulations, and developing a case management plan.
- 2. Workplace Intervention for Disability Prevention**, including conducting organizational assessments, evaluating policies and procedures, presenting the business rationale for disability management programs, managing human resources, applying labor relation laws, and managing financial resources.
- 3. Program Development, Management, and Evaluation**, including organizing and planning disability management programs, applying qualitative and quantitative measurements, interpreting financial risk data, designing programs with rewards and incentives, and tracking cost, operational, and outcomes data.
- 4. Employment Leaves and Benefits Administration**, including managing

health-related employment leaves, administering health and welfare plans, managing payroll and systems data, and identifying risks associated with interruptions and leaves.

Each module consists of tools for developing skills, interactive exercises, and case studies. Pre- and posttests are administered to assess knowledge and measure improvement.

Additionally, as a learning resource, CKC must reflect current practice. To ensure relevancy, feedback is elicited from those who use the CKC, and content is reviewed and updated as needed on an ongoing basis.

Earning CEs and a Certificate

The newly updated CKC offers several continuing education and professional development benefits. First, the CKC's four domains have been preapproved by the Commission for Case Manager Certification (CCMC) to provide continuing education (CE) credit to certified case managers (CCMs). Each domain is approved for 8 CE contact hours, for a total of 32 contact hours for completion of all domains.

Second, completion of the CKC can culminate in the achievement of the Associate Disability Management Specialist ([ADMS](#)) designation. The certificate is awarded to those who

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What Is an Advocate?

Colleen Morley, DNP, RN, CCM, CMAC, CMCN, ACM-RN, FCM

Advocate (noun): a person who publicly supports or recommends a particular cause or policy.

“Public policy work—also known as political activism—is a crucially important activity for any professional organization in the United States.” (Bergman & Morley 2022) The authors continue, “One way to accomplish this important challenge is for professional organizations to model and demonstrate the ways we can be



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Board of Directors and Principal of Altra Healthcare Consulting in Chicago, IL. She has held positions in acute care as director of case management at several acute care facilities and managed care entities in Illinois for over 14 years, piloting quality improvement initiatives focused on readmission reduction, care coordination through better communication, and population health management.

Her current passion is in the area of improving health literacy. She is the recipient of the CMSA Foundation Practice Improvement Award (2020) and ANA Illinois Practice Improvement Award (2020) for her work in this area. Dr Morley also received the AAMCN Managed Care Nurse Leader of the Year in 2010 and the CMSA Fellow of Case Management designation in 2022. She has recently authored her first book, *A Practical Guide to Acute Care Case Management*, published by Blue Bayou Press.

politically active that allow for civil and pleasant disagreement, resulting in productive conversation and reasonable compromise. We must recognize that this level of active, civil engagement is the only way to preserve our democratic system.” (Bergman & Morley 2022)

This type of advocacy has many faces. Read on for some examples.

1. Recently, the CMSA blog featured a piece by Dr. Ronald Hirsch highlighting CMSA proposed new rule CMS-4201-P, “Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications.” Dr. Hirsch provided an excellent summary of the 957-page rule with proposed changes to the Medicare Advantage program, noted that the Centers for Medicare & Medicaid Services (CMS) has opened the proposed rule to public comment and provided resources to make it easier for all (especially professional case managers) to have their voices heard on this important rule that directly affects case management practice. As Dr Hirsch observed, “Count on your advocacy organizations to read the rules and find the

pertinent sections and summarize them for you.”

2. Another CMSA blog, by Laura Ostrowsky and Joan Westgor reporting on the work the CMSA Public Policy committee, highlights the role of the professional case management in public policy as it relates to micro and macro levels. They report that in addition to continuing advocacy for the Nurse Licensure Compact, the Public Policy Committee of CMSA is currently focusing on three legislative areas:
 - a. Workforce development (including compact licensure)
 - b. Telehealth (including video, telephonic, and computer platforms)
 - c. Mental health (private insurance to cover same in-person service in equal terms via telehealth)

Laura and Joan also report that there are “no less than 89 bills in Congress encompassing our three domain foci.” Did you know that you can also place comments on state and federal Bills (support or not support)? Just a simple log in to your state site or at [Congress.gov](https://www.congress.gov) for federal legislation. This is a simple way to have your voice heard.

3. For a more active form of advocacy, CMSA Virtual Hill Day took place on March 7–9. During this advocacy event, case managers met virtually with members of Congress or their health policy staff from their respective areas of the country to educate

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Six Ways to Develop Cultural Sensitivity

By Jeannie LeDoux, RN, BSN, MBA, CCM, CPHQ, CTT+

Professional case managers, particularly those of us who are board certified, are ethically obligated to maintain our objectivity. As the [Code of Professional Conduct](#) for case managers, published by the Commission for Case Manager Certification (CCMC), states, case managers “will not impose their values” on others.

Our professional objectivity in serving clients (known in some care settings as “patients”) is supported by cultural sensitivity. In other words, we seek to build our understanding of the clients, groups, and populations for whom we advocate: their values, backgrounds, and cultures. In fact, cultural sensitivity is recognized in the CCMC Role and Function study of case management practice. The most recent study affirmed the importance of knowing the “[multicultural, spiritual, and religious factors](#) that may affect the health status of the individual receiving case management services.”

Jeannie LeDoux, RN, BSN, MBA, CCM, CPHQ, CTT+, is a Commissioner and former Chair of the Commission for Case Manager Certification, the first and largest nationally accredited



organization that certifies more than 50,000 professional case managers and disability management specialists. Her professional experience includes working with clients from diverse cultures and with special needs and complex medical issues. She also has extensive experience working with the military.

The more we understand and appreciate the groups and populations in our community and practice setting, the better we can advocate for them with respect and objectivity.

Having this knowledge is crucial when advocating for individuals whose backgrounds, values, and cultures differ from our own.

In my case management career across the US and in military hospitals abroad, I have had the privilege of serving a wide variety of individuals and their support systems and families. While knowledge provided the foundation, to become more culturally sensitive, I needed to put what I knew and learned into practice. Though the following list is hardly exhaustive, here are six tips I have found helpful in becoming culturally aware and sensitive:

1. Expose our biases and assumptions.

As case managers, we learn early about active interviewing: asking open-ended questions to reveal deeper answers. To become culturally sensitive, we need to apply that same questioning to ourselves: What biases do I have? What knowledge base do I draw from? What do I want and need to learn more about, particularly as it relates to the population of clients I serve? Such questions point out where and how we need to address our biases and assumptions (and everyone has them). We recognize that any lack of sensitivity on our part could contribute to poor health outcomes; therefore, it is very important to know where we stand.

2. Know the populations we serve.

Within a particular practice setting or geographic location, case managers most likely serve specific populations. We need to know the ethnicity, religious, and cultural contexts of these groups and understand their norms and practices. For example, is it acceptable or forbidden for a woman from a particular culture to be treated by a male physician? Is eye contact considered respectful or challenging? Is physical contact—for example, touching an individual’s arm to convey empathy—welcome or intrusive? Know the client’s gender identity and preferred pronouns: he/him/his, she/her/hers, they/them/theirs. Be aware of the nuances within a particular group or culture; for example, there are dialects within American Sign Language (ASL) that differ from region to region. When we don’t know, we need to ask and share our insights with our colleagues.

3. Ask questions. The clients, colleagues, and others with whom we interact will welcome our questions when we sincerely want to know more and improve our understanding. When advocating for a client whose culture is less familiar to me, I have found it helpful to ask respectful,

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Predictive Modeling and Embracing Digital Technology

By Ruth D. Grenoble, LCSW, CCM; June Callasan, MSN, RN, CCM; Rachele Misiti, LCSW-S, CCM

In a fully integrated system, care coordination staff will understand the value of predictive technology to clinical practice and identify opportunities to integrate it into care planning. Staff will be empowered to find veterans before an adverse event occurs and intervene to prevent avoidable episodes of care that could have a negative impact on a veteran's health and quality of life. The veteran experience can improve through enhanced system navigation afforded via proactive care coordination practice.

Historically, risk stratification in the Veterans Health Administration (VHA) has required significant time commitment from care coordination staff and managers. Clinicians perform data mining across different data sources,

which offer both predictive modeling for adverse events as well as retrospective patterns of care data dashboards. Many health care systems offer a data-rich environment although approaches may be inefficient, time consuming, and fragmented given that data sources are housed on various platforms. Additionally, care coordinators might not understand how predictive modeling can improve care of veterans, create workflow efficiency, or connect with facility population health priorities. The Care Coordination and Integrated Case Management (CC&ICM) framework was developed to proactively identify and engage cohorts of veterans who could benefit from care coordination or case management services.

The Case Management Society of

America (CMSA) Standards of Practice for Case Management (2022) include "Client Selection" and outline the requirement of processes that would appropriately identify clients who can benefit from case management services including the application of predictive algorithms. Through CC&ICM, the VHA has embarked on an enterprise-wide effort to integrate the use of risk stratification tools (predictive analytics and retrospective pattern of use) to identify veterans most in need of support and to match their needs through targeted interventions.

A brief review of literature suggests that predictive modeling strengthens a system of care's ability to perform effective population health management. (Handmaker & Hart 2015; Harris &



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clinical and leadership roles within VHA and the private sector starting in 2010, including with various client populations experiencing both traumatic and nontraumatic brain injury and spinal cord injuries and disorders.



June Callasan, MSN, RN, CCM, (she/her/hers) currently serves as a care coordination and integrated case management (CC&ICM) lead for the Veterans Health Administration (VHA) Western States Network Consortium (WSNC). She has 28 years of VA Federal

Nursing Service. Ms. Callasan has 20+ years of nursing management experience in acute care, primary care, surgery, and case management program oversight. She has been involved in the inception of CC&ICM since 2016, co-leading two charters and serving in CC&ICM leadership committees and workgroups.



Rachele Misiti, LCSW-S, CCM, (she/her/hers) currently serves as a CC&ICM lead for the VHA WSNC. She has provided case management in various settings to include justice involving the population with serious mental illness, combat veterans, homeless individuals, and women services. Ms. Misiti has served in a leadership capacity as an M2VA program manager and assistant chief of social work at Central Texas VA. In 2016, Ms. Misiti was appointed social work site lead for CC&ICM Central Texas where, in partnership with Ms. Dorothy Sanders in nursing, Ms.

Misiti co-developed the innovative RACETIME operational model that has served as the gold standard for implementing an integrated approach to care coordination within the VA. Ms. Misiti's M2VA team was the recipient of the 2015 Transition and Care Management Team of the Year awarded by VHA Care Management Social Work Service and is a proud 2021 graduate of Leadership VA (LVA).

Popejoy 2019; Hodgman 2008; Miller et al 2021; Sy et al 2022) Additionally, use of artificial intelligence (AI) and machine learning (ML) can enhance the processes by which systems of care identify clients most in need of targeted case management services. (Newman 2021) When applied strategically, predictive modeling can function as a compass to guide case managers to the cohort of patients who can benefit the most from services.

VHA currently offers several predictive models:

- Care Needs Assessment Score (CAN Score): designed to predict hospitalization and mortality within 90 days or 1 year (Ruiz et al 2018)
- Ambulatory Care Sensitive Conditions (ACSC) Risk 3M score: represents the predicted probability that a patient will be admitted within the next 3 months (Gao et al 2014)
- Recovery Engagement and Coordination for Health–Veterans Enhanced Treatment (REACH VET): suicide risk prediction statistical model (Matarazzo et al 2022)
- Stratification Tool for Opioid Risk Mitigation (STORM): uses predictive analytics to determine the risk for opioid-related serious adverse events (SAEs) for each VHA patient with an opioid prescription (Oliva et al 2017; STORM Policy Brief 2022)
- Jen Frailty Index (JFI): predicts risk of long-term care placement or institutionalization (Kinosian et al 2018)
- Nosos (Nosos is the Greek word for chronic disease): predicts future costs on an individual patient level (Wagner et al 2022)

Artificial intelligence (AI) is rapidly evolving into health care clinical operations. AI is described to be “a variety of emerging technologies designed to analyze and interpret data, automate

repetitive manual processes, and deliver personalized experiences.” (Newman 2021) In partnership with the Veterans Administration’s National Artificial Intelligence Institute (NAII), case management subject matter experts are providing insight on how social determinants of health and case management practices contribute to the delivery of safe, quality, patient-centered care.

As VHA facilities implement CC&ICM, they identify key health care system patient safety priorities, such as reducing avoidable hospital admissions. Social work and nursing co-champions select the best predictive models to efficiently identify the cohort of veterans who could benefit from targeted interventions. Next, they develop an implementation plan to map out where predictive modeling can be integrated into ongoing care coordination programming. Successful CC&ICM implementation requires that case managers and care coordinators become proficient navigators of the tools that promote quality patient outcomes. **CM**

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An Exploration of Ethical Issues Associated With Prosthetics

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Prosthesis have helped many people regain independence and improve their quality of life. The most common reason for prosthetics is limb loss due to amputations, and the incidence of amputations has been increasing over the past few decades. Surveys have shown that over 100,000 amputations are performed in the United States annually. This increase is largely due to the rise in diabetes, vascular diseases, and trauma, as well as an aging population. (Amputee Coalition 2015) Amputations can have a significant impact on a person's quality of life and their ability to function in everyday life.

During the '70s, two TV shows, "The Six Million Dollar Man" with Steve Austin and "The Bionic Woman" with Jaime Summer, introduced us to the idea that people could be rebuilt with bionic limbs and implants (prostheses). We have most recently been presented with a character called Cyborg in the movie "Justice League," who was rebuilt with bionic limbs and implants after being injured in a car accident. Another cinematic cyborg we can always remember is The Terminator. Although bionic limbs and implants seem fantastical and futuristic, they are more common than ever thanks to advances in biomedical engineering. In fact, Emeritus Professor Kevin Warwick, an expert of cybernetics at the University of Reading in Britain, claims to be the world's first cyborg. In 1998 he implanted a microchip in his left arm to control a remote arm. (Coventry University) A Canadian filmmaker, Rob Spence, lost his right eye in a shooting accident and had it replaced with a wireless video camera. (Dickinson 2011) Prostheses can help people with disabilities lead a more independent and fulfilling life, as well as improve their quality of life. But with the current advances in prosthetics come questions and concerns about how they should be used responsibly.

Ethical considerations range from whether people should have access to certain types of prostheses to whether it is ethical for a person to use them for purposes other than what they were designed for. Many difficult questions regarding medical ethics need further exploration if we hope to make informed decisions on issues related to human enhancement technologies in the future. In this article, we will explore what

constitutes a prosthesis and why one would need a prosthesis. We will additionally discuss ethical considerations that can arise with care coordination for an individual obtaining a prosthesis.

Prosthesis Defined

Prostheses and orthoses are both externally applied devices used to assist people with physical impairments. Prostheses are commonly used to replace lost limbs, such as an arm or leg, but they can also be used to replace lost eyes, ears, and other body parts. Prostheses can also be used to correct congenital defects, such as a cleft palate or a missing finger. Orthoses are used to modify the structural and functional characteristics of the neuromuscular and skeletal system. Both prostheses and orthoses can be used to improve the quality of life for those with physical impairments, allowing them to perform activities that they may not have been able to do before. For this article, the focus will be on prostheses.

Prosthetic rehabilitation is the use of artificial devices and technology to improve physical ability and functioning, often after a limb amputation or other disability. This type of rehabilitation typically involves fitting the patient with a prosthetic device and then teaching them how to use it. This can be done through physical therapy, occupational therapy, or even in some cases, psychological counseling. A prosthetist is an



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“The key to improving outcomes for those who have lost limbs is to ensure that they receive appropriate and comprehensive interdisciplinary care to address both their physical and psychosocial needs.”

—Colonel Paul F. Pasquina, USA (Ret), MD; Antonio J. Carvalho; and Terrence Patrick Sheehan, MD

allied health professional who specializes in the design, manufacture, fitting, and application of externally applied devices (prosthetics and orthotics) used to reduce pain or modify or substitute for a missing body part. Prosthetists are trained in anatomy, biomechanics, kinesiology, and materials science so they can effectively assist people with physical disabilities.

Types of Prostheses

When choosing a prosthesis, one must think about function, feedback, control, and rejection as well as preservation of physical appearance. The individual's physical needs, personal preferences, and functional needs should also be considered when determining the appropriate prosthesis. (Carey et al 2017) There are three major types of prostheses: body powered, motor powered, and myoelectric powered. The body-powered prosthesis is powered by the body. It is the common choice for individuals with upper limb amputation. (Huinink et al 2016) These types of prostheses are more durable and require fewer adjustments. The motor-driven prosthesis has buttons that initiate and control movement. These types of prostheses are used for both upper and lower limb amputations. Myoelectric- (or electric-) powered prostheses are becoming more popular. Motors are driven by electromyographic (EMG) signals generated from the stump of the limb. The benefits of this choice include reduction of contralateral overuse, easier control by the individual, increased comfort, and both functional and cosmetic restoration. (Uellendahl 2017)

Another type of prosthesis that is becoming increasingly popular is a neuroprosthesis. These devices use electrodes to communicate with the nervous system. Motor, sensory, and autonomic functions are enabled by innervating the nervous system to produce muscle contractions, restore motor function, and provide sensory feedback. (Collinger et al 2013) They are considered a brain-computer (or brain-machine) interface. Common neuroprostheses include cardiac pacemakers, hearing aids, deep brain stimulation, and spinal cord stimulators.

Cyborgs, or cybernetic organisms, are gaining attention also. The benefits of cybernetic extensions is the ability to monitor physiological impulses, restore lost tissue functions, and stimulate tissue. Some are even able to give the individual superhuman abilities. (Mehrali et al 2018). In the case of Kevin Warwick, neurons were grown in a laboratory and were

attached to nerve fibers in his arm, thus connecting him to a computer. The components of a cybernetic human include brain implants to provide a memory boost and obtain access to the internet. Other components are wearable exoskeletons, spinal implants, interchangeable limbs, and access control chips. (House 2014)

Case Management Considerations

Psychological Focus

The psychological impact of amputation and prosthesis can include a range of emotions, such as shock, disbelief, anger, sadness, and grief. These feelings can be compounded by phantom pain and discomfort associated with the amputation or prosthesis-fitting process. Long-term mental health issues such as depression, anxiety, and posttraumatic stress disorder may develop in individuals who have experienced limb loss due to trauma or illness. It is also common for amputees to experience body image issues or a sense of loss of identity due to their altered appearance. Regaining mobility with a prosthetic device can help an individual adjust emotionally to the changes brought on by limb loss; however, some amputees may struggle with adjusting physically to using the device, including learning how to walk again or even using fine motor skills such as writing or typing. Neuropsychological therapies are available for individuals who find it difficult to adjust psychologically or physically to their new life with a prosthetic device. Professional counseling is often recommended for an individual to come up with coping strategies that best suit their needs during this time of transition.

Before exploring the ethical implications associated with prosthesis, let's discuss a unique plight that the board-certified case manager could encounter. The board-certified case manager should endeavor to obtain a thorough history from all treating providers of the individual. Two diagnoses to consider are body integrity dysphoria (BID) or apotemnophilia. BID is a condition in which the individual feels there is a discrepancy between their desired body (mental body image) and their current physical body. The individual desires to amputate a healthy limb and replace it with a prosthesis or sever the spinal cord to become paralyzed. The treating physician usually reports no sensory deficits in the targeted limb, and the neurological examination shows no abnormality. The individual reports emotional, but not physical, discomfort

with the body part. (Blom et al 2012; Sedda & Bottini 2014) The individual may resort to unusual methods to correct what they perceive is a defective body part. One option for this individual could be biohacking.

Biohacking is a relatively new concept that has been gaining traction in recent years. It involves using technology to modify or enhance the body to improve physical and mental performance. This issue can arise if an individual suffered an injury and is not back to their preinjury functioning level. Their treating physician may not recommend an amputation or insertion of the brain-computer interface device, but the individual desires to get it to improve their functioning level. While biohacking can have a variety of positive outcomes, it also raises a few ethical concerns. For instance, biohackers may be exposed to unknown risks, and the modifications they make could have unforeseen consequences. Additionally, biohacking may lead to a disparity between those who have access to these technologies and those who do not. Finally, there is the potential for biohackers to modify themselves in ways that could be considered unethical, such as to gain an unfair advantage over others. It is important to consider the ethical implications of biohacking before engaging in any modifications because the consequences could be far-reaching and difficult to undo.

Return to Work Focus

Returning to work after obtaining a prosthesis can be a complicated process. Some factors to bear in mind with coordinating return to work with a prosthesis: age, gender, amputation level, the time from injury to obtaining a permanent prosthesis, and stump issues. Depending on the type and degree of amputation, some individuals may require additional physical and/or occupational therapy to help develop strength and muscle control in the affected limb. Additionally, many people find they require modifications at their workplace to successfully return to work with a prosthesis. This may include changes such as additional seating or desk space, modified tools or equipment, or even special accommodations such as wheelchair access. Finally, many individuals who use prosthetics report feeling more confident if they can take breaks throughout the day for rest or physical activity that helps them keep their mobility levels up. Careful planning and support from health professionals, employers, family members, and friends can facilitate return to work.

Ethical Implications

There are different ethical dilemmas that present with prostheses, especially with the integration of humans and machines. The board-certified case manager would benefit greatly from reviewing the guidelines in the Code of Professional Conduct for Case Managers and Certified

Disability Management Specialist (CDMS) regularly to guide their care coordination (Table 1). (CCMC 2015)

TABLE 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.

Advocacy

For an advocate to be effective, they must understand the rights of the client they are representing. People with prosthetics can often face discrimination in the workplace, the community, and their everyday lives. This discrimination can take many forms, from people making assumptions about their capabilities to employers refusing to hire them. The care coordinator should have knowledge of the Americans with Disabilities Act (ADA), a civil rights law that prohibits discrimination against people with disabilities. It requires employers to provide reasonable accommodations for people with disabilities, including access to prostheses. The ADA also requires public places to be accessible to people with disabilities, including those who use prostheses.

Informed Consent

Informed consent is an important part of the process for receiving prosthetics. It is a legal document that outlines the risks, benefits, and alternatives of the prosthetic device. It also outlines the rights of the patient, such as the right to refuse or withdraw consent at any time. It is important for the patient to understand the information provided in the informed consent document before signing it. The prosthetist

should explain the document in detail, answer any questions the patient may have, and ensure that the patient fully understands the information before signing. Informed consent is necessary to ensure that the patient is aware of the risks and benefits associated with the prosthetic device and can make an informed decision about their care.

Included with informed consent is the concept of shared decision making. Shared decision making is a process that involves both the patient and the health care provider in making decisions about the patient's care. This process allows the patient to be an active participant in their treatment and to be informed about the risks and benefits of the various options. In the case of prosthetics, shared decision making can help to ensure that the patient and their health care provider are both making an informed decision about the best type of prosthetic to use. The patient's individual needs and preferences, as well as any potential risks or benefits associated with the different types of prosthetics, should be considered when making the decision.

Veracity

Providing an accurate picture of the pros and cons of the prosthesis is essential for the individual to make an informed decision about whether to proceed with obtaining a prosthesis. This can also assist in helping with determining which prosthesis to obtain. The prosthetist and board-certified case manager should be open and honest about any potential risks or complications associated with the prosthesis, so that the individual can make an informed decision about the best course of action for their individual situation. Honesty and truthfulness are essential in helping the individual make the best decisions for their health and well-being.

Autonomy

Individuals have the right to make decisions concerning their care. With this principle, people can decide what they feel is best for them. However, biohackers may be exposed to unknown risks, and the modifications they make could have unforeseen consequences. Another point concerning biohacking is if an individual chooses biohacking for themselves without a prescription from their treating provider. There is a lack of true informed consent and oversight. If individuals are choosing biohacking, they cannot obtain a clear understanding of the risks involved. The board-certified case manager and others involved in care coordination should point out the risks with using a device that is not approved by the US Food and Drug Administration.

A special population group that can present challenges are youth under the age of 18 years old. These individuals are considered to lack the aptitude to make decisions about their care. Unless special circumstances are present, they are

unable to provide consent for medical care. The child's parent or legal guardian is considered the medical decision maker. Issues can arise if the child is not in agreement with implantation of a brain-computer interface or does not wish to have a limb amputated. It is important to provide a safe and supportive environment for youth to gain trust and ensure their comfort throughout care. Finally, health care providers should strive for open communication with both the child and parent/guardian to provide quality care that meets both parties' needs. (Bieber et al 2020)

Beneficence

The ethical principle of beneficence is an important consideration when it comes to prosthetics. This principle states that medical professionals should act in the best interest of their patients, promoting their well-being and protecting them from harm. When it comes to prosthetics, this means that medical professionals should strive to provide the best care possible, including helping patients find the most suitable prosthetic for their needs and providing them with the necessary information to make an informed decision. Additionally, medical professionals should ensure that the prosthetic is properly fitted and adjusted to meet the patient's individual needs and to monitor the patient's progress to ensure that the prosthetic is providing the desired outcome. By following the ethical principle of beneficence, medical professionals can ensure that their patients receive the best care possible when it comes to prosthetics.

Nonmaleficence

Nonmaleficence is the ethical principle of avoiding any action that may harm others. When it comes to prosthetic devices, this means that the device should be designed in such a way that the person using it does not experience any physical or psychological harm. With neuroprosthetics, nonmaleficence presents a distinctive situation in which some may argue that implanting the brain-computer interface can potentially cause harm to the patient. The individual may need to have multiple surgeries to replace a defective or nonworking chip. The brain-computer interface could additionally change the personality of the recipient. Heat from the brain-computer interface could cause thermal damage to the brain. (Glannon 2016) The device should be tested for safety and efficacy before being used by patients, and manufacturers should take steps to minimize risks and potential complications associated with its use. Additionally, prosthetic devices should be tailored to each individual patient's needs to maximize both comfort and function.

With brain-computer interfaces, the safety of others could be an issue. There is a risk that the brain implant can be hacked or manipulated by a third party with malicious intent.

“Geographical barriers, gender, age, socioeconomic position, race, education, and cost all affect a patient’s access to appropriate rehabilitation and prosthetic care.”

—Colonel Paul F. Pasquina, USA (Ret), MD; Antonio J. Carvalho; and Terrence Patrick Sheehan, MD

Perhaps someone with a prosthetic hand that is controlled by a brain-computer interface shakes someone’s hand and grips it too tightly, resulting in serious injury. If someone is harmed, who ultimately is responsible for the injury? (Davidoff 2020) Regular communication needs to transpire between the board-certified case manager, prosthetist, and treating physician to ensure that all parties are aware of risks to the individual receiving the prosthetic as well as possible risks to others.

Privacy and Confidentiality

Security and data protection are topics of great ethical concern in the field of technology. Security is necessary to protect users’ privacy and their data, while data protection laws are needed to ensure that any personal or sensitive information they provide remains confidential. It is imperative that these standards be upheld; failure to do so could have serious consequences for individuals, companies, and governments alike. Furthermore, the use of body control and brain-controlled interfaces has stirred debate about ethical issues such as consent, accuracy of results, privacy concerns regarding user data collection and storage, potential impacts on human rights, and freedom from discrimination—particularly when used for decision making processes in areas like health care or law enforcement. Companies must ensure that appropriate safety protocols are in place when developing these products to protect users from harm. Another point of consideration is the mental capacity of the individual obtaining the prostheses. The board-certified case manager should be prepared to possibly discuss the appropriate referral to a neuropsychologist or psychiatrist to determine the psychological state of the individual. Additionally, transparency should be a priority; users need to be made aware of how their information is used by companies with clear language they can access easily.

Justice

Patient access to health care and medical equipment is an imperative issue to consider. Everyone should have access to quality health care and prosthetic devices, regardless of their financial or insurance situation. Consequently, for individuals with disabilities to live a full and healthy life, they must have access to the resources they need. Prosthetics, especially neuroprosthetics, are often expensive and difficult to obtain. How

does one ensure fair distribution? Who decides who should or should not get a neuroprosthetic? If individuals do get the neuroprosthesis, will they then be able to access the appropriate specialist for maintenance care? A payor may decide that they will pay for a prosthesis that costs less but the individual may want a prosthesis “with all the bells and whistles.” An individual could obtain the prosthesis with one payor, switch payor source, and the new payor source may not wish to pay for prosthesis maintenance. Materials for the neuroprosthesis could become proprietary, making it harder for the individual to get regular maintenance. If a person decides to biohack and there is malfunction, the individual’s payor source may decide to not cover the costs to avoid responsibility for continuing to maintain the prosthesis. Additionally, biohacking may lead to a disparity between those who have access to these technologies and those who do not. Finally, there is the potential for biohackers to modify themselves in ways that could be considered unethical, such as to gain an unfair advantage over others. It is important to consider the ethical implications of biohacking before engaging in any modifications because the consequences could be far-reaching and difficult to undo.

This type of situation can be challenging. The board-certified case managers’ greatest assets are their communications skills and integrity. The board-certified case manager should regularly remind the individual that they are independent of the payor source. Being forthcoming with all case parties and consistent in providing all involved with accurate, objective information are key. Helping the individual to understand the short- and long-term advantages and disadvantages of a particular prosthesis can help with decision making about the prosthesis.

Conclusion

Ethical considerations related to prosthetics are important to consider because they can have a significant impact on the quality of life of those who use them. Some ethical issues to consider include the cost of prosthetics and the potential for unequal access to them, the potential for harm to the user and others, and the potential for the prosthetic to be used for unethical purposes. The biggest concern with prosthetics is the potential misuse of them in situations where they weren’t meant to be used. For example, while prosthetic hands can be a great

aid to someone who needs one, they can also be abused by criminals who wish to commit crimes undetected. Additionally, there are privacy concerns related to how data from smart prosthetics is stored and used. Finally, there are questions about how insurance should cover or not cover certain kinds of prosthetic devices. All these ethical considerations must be considered when contemplating the use of prosthetics. **CE1**

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The Relationship Between Patient Adherence, Advocacy, and Health Outcomes in Clients With Autism

Jennifer Andrea Genson-Pat, RN, BSN, CCM

Autism spectrum disorder (ASD) is a developmental disability that can cause significant social, communication, and behavioral challenges. People with ASD can behave, communicate, or learn in unusual ways. Some individuals with ASD require extra help daily. (CDC 2022)

Alvin's Background Story

Alvin, a 7-year-old first-grader, is the subject of this case. English is his first language although he is originally from Mexico. Alvin's parents speak only English in front of him. The family relocated to New Jersey in March 2021. Although Alvin had attended preschool for a month before the move, he needed one-on-one assistance. However, there was no intervention for him at that time. When they settled in New Jersey, Alvin's parents sent him for a special education evaluation in Fall 2021 because they were concerned about his communication and social abilities. After a comprehensive evaluation, he met the requirements for an autism spectrum condition.

In December 2021, Alvin completed the initial special education eligibility standards to qualify for services under the ASD category. His mother voiced her reluctance because they did not yet have a car, and transportation was one of the hurdles to complying with the therapy. In addition, Alvin was on the waiting list for speech and occupational treatment. The parents were struggling to meet their basic needs. Their immediate family lived in Mexico, and they did not have any close relatives that resided nearby.

They lived in a 3-bedroom apartment they rented in a suburban community distant from the bus and rail station. They were very close to their families, devout Roman Catholics, and able to communicate in English without an interpreter. Both parents expressed that they were still working through accepting their child's situation.

Alvin has tried to leave their apartment. To keep Alvin secure, they installed a lock chain that works well to lower Alvin's danger of leaving their apartment. Alvin doesn't naturally reach out or point at objects in his environment. He can wave goodbye, but he needs to be reminded or taught often before he does. He is seen employing typical motions

like shaking his head yes or no. He usually "whines" when he needs something.

Because they had only recently received the diagnosis, they were still learning about Alvin's condition. The mother stated that her family wished to learn more about autism and was willing to do so. She was slowly conducting some research on the topic. They were interested in finding out more and receiving more help for the whole family, not just for Alvin.

Physician Assessment

After conducting an assessment, the doctor's plan of care included referrals to case management for the coordination of treatment for speech and occupational therapy, and to locate resources for the family's fundamental needs. In addition to needing help with winter clothing and groceries until they could acclimate and find full-time jobs, the family also needed help with transportation.

During assessment, various difficulties and care-related obstacles were noted. The distance between the family's home and the bus stop is about a quarter of a mile. Alvin has sensory issues that make walking difficult for him. What's more, traveling to the bus stop in freezing weather would not be safe for Alvin. He struggles to express his fundamental needs verbally, lacks a sense of danger, and has a propensity for getting lost while out and about. Moreover, the family may need a support group, help to find resources, and therapy to help them better understand Alvin's illness.



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When establishing the outcomes, the case manager will first determine how to assess achievement using various ways such as before and after comparisons with established standards.

Case Management Needs

The case manager seeks to address barriers to care by providing referrals to outpatient occupational and speech therapy, nonemergency medical transportation for each therapy session, behavioral counselors to help the family cope with the new diagnosis, autism support groups, food pantries for adequate groceries, and foundations that could provide them with necessary winter clothing. The case manager will assist the patient and their family in locating the resources they require to take care of their Social Determinants of Health (SDOH) necessities. In this circumstance, without the case manager, the client would feel alone, overburdened, and disheartened.

Council for Case Management Accountability

In response to rising demand for accountability in health care through outcomes reporting, the [Case Management Society of America \(CMSA\)](#) established the Council for Case Management (CCMA) in 1996. They solicited opinions on case management outcomes from a wide range of stakeholders and discovered the following direct case management outcomes.

Client Knowledge

By asking the client how well they understand their condition, the process of case management, the interventions, and how they can promote health before interventions are started and then comparing those answers with the same questions or survey answers after the case is closed, a better understanding of the outcome can be obtained.

Client Involvement in Care

One technique to determine the result of client involvement in care is based on the case manager's or other family members' assessments.

Client Empowerment

If clients are given information about how to control their disease, they will feel more empowered. One technique to determine client empowerment is to ask the client how comfortable they feel managing their health at the beginning and end of the case.

Improved Adherence

If individuals are empowered, they are more likely to adhere to care; consequently, the client empowerment outcome would be related to the outcome of adherence.

Improved Coordination of Care

Coordination of care is critical in case management because it connects clients to the services they require for their health. The outcome will be evaluated based on the number of referrals made and the overall health outcome as a result of linking the client to services.

When establishing the outcomes, the case manager will first determine how to assess achievement using various ways such as before and after comparisons with established standards. The CCMA created the accountability dimension, which provides a framework for tying fundamental case management responsibilities such as assessment, planning, facilitation, evaluation, and advocacy to direct case management results and health system end objectives such as improved health status, higher quality of treatment, and lower costs. (Tahan & Treiger 2016)

Outcome Indicators

Quality of life, mortality, and morbidity are three of the client outcome indicators that I will cover in this study. Everyone values their quality of life. Although the World Health Organization (WHO) defined health broadly more than a half century ago, health in the United States has generally been assessed narrowly and from a deficit perspective, frequently using morbidity or mortality indicators. However, the public health community views health as a multifaceted construct that comprises physical, mental, and social dimensions. As medical and public health advances have resulted in cures and better treatments for existing diseases, as well as delayed mortality, it is natural for those who measure health outcomes to begin to assess the population's health not only in terms of saving lives but also improving the quality of lives.

Quality of life is a multifaceted notion that often comprises subjective assessments of both good and negative elements of life. It is difficult to quantify because, while quality of life has distinct meanings for different people, and across disciplines, people and organizations might interpret it differently. Although health is an important component of

People with autism have the right to live their own lives, and they should be supported if they require assistance in caring for themselves; they should feel empowered to achieve their goals.

overall quality of life, there are others, such as quality pertaining to schools, jobs, community, and housing. (CDC 2016)

The prevalence and severity of various illnesses or ailments are described by morbidity and mortality. Morbidity is the presence of a certain sickness or condition. Although morbidity can relate to an acute ailment, such as a respiratory infection, it most commonly refers to a chronic condition. Diabetes, high blood pressure, heart disease, and obesity are examples of prevalent morbidities. Morbidity data are displayed in two ways: incidence and prevalence. The occurrence of new cases of a sickness or condition within a population during a specified time period is referred to as *incidence*. It can be stated as a percentage or as a rate. Simultaneously, *prevalence* is defined as the percentage of a population that has a disease or ailment. It contains both new and current instances, unlike incidence. It can be computed at a given point in time or over a specified period. (Healthline 2022)

The Importance of the Outcome Indicators

Quality of life, morbidity, and mortality for clients with autism can be viewed as follows. First, the quality of life has a considerable impact on the success of therapy and the recovery process. Patients who react well to treatment and are at ease with their current lifestyle will find it simpler to strive to enhance their physical and mental health. (Chicago Insurance Online 2018)

The [Autism Society](#)'s aim is to improve the quality of life for all people with autism. It refers to basic human rights that allow individuals to engage with one another and the rest of the world on their own terms. The capacity to communicate, choose a vocation, and engage with the community are all important parts of the human experience. The Autism Society advocates for treatments, accommodations, and social acceptability. Respect, dignity, inclusiveness, and communication are all values promoted by the society. People with autism should be valued by their peers and encouraged to participate fully in their schools, workplaces, and communities. They should also be able to express themselves and communicate with others meaningfully. (Autism Society 2022)

The society's goals include health and well-being, safety, and academic performance. People with autism should be healthy and have access to the resources they require to be

well; they should also be safe and able to seek assistance from their communities, law enforcement, and others as required. They should have the chance to engage fully in school and study in an atmosphere and manner that allows them to achieve. People with autism have the right to live their own lives, and they should be supported if they require assistance in caring for themselves; they should feel empowered to achieve their goals. (Autism Society 2022)

According to numerous studies, individuals with ASD have higher rates of health concerns throughout infancy, youth, and adulthood, which may culminate in an increased risk of early mortality. One study (Smith DaWalt et al 2019) looked at the timing, rate, and causes of mortality in a large community-based cohort of autistic adolescents and adults. During the 20-year study period, 6.4% of people died at an average age of 39. Chronic diseases such as heart disease and cancer were among the causes of mortality, as were accidents such as choking on food and unintentional poisoning, and health difficulties caused by drug side effects. The findings point to the need for functional self-sufficiency and social engagement throughout the life course, as well as proper access to health care for people with autism spectrum conditions.

Outcomes Planning for Alvin

The following outcomes were planned for Alvin by the case manager and his family:

1. By providing transportation resources, the family will be able to attend all therapy sessions or at least 80% of them.
2. Alvin will be able to express fundamental needs, such as for food and water, as well as convey discomfort.
3. By establishing safety kid locks and alarms and fulfilling goals with social stories from therapy about danger, Alvin will no longer wander outside his home.
4. The family's concern over Alvin's condition will progress from highly to less concerned.
5. The family's awareness of Alvin's situation will develop from uncertainty to complete comprehension.

Indicator

Gastrointestinal difficulties caused by hunger or being underweight will form the morbidity indicator. If there are no accidents connected to elopement, this would be a sign of zero mortality. The indicator of quality of life will be whether

The purpose of measuring, reporting, and comparing health care outcomes is to meet health care's Quadruple Aim: to enhance patient experience of treatment, population health, per capita cost of health care, and clinician and staff burnout.

Alvin's family and Alvin can enjoy life, such as going to school safely, playing with other kids successfully, and attending therapy sessions regularly.

Goals

Within 5 months of therapy, Alvin will have attended at least 15 of the 16 scheduled sessions and be able to communicate effectively enough to request food and water and answer questions with a yes or no. After 15 sessions of family therapy, with 4 being the most severe, the family's stress level will also decrease from 4/4 to 1/4, and Alvin won't experience any incidents of wandering outside the apartment.

Alvin's Plan of Care

Alvin struggles more with vocally expressing his fundamental needs. The case manager's role as an advocate is to support the client in developing fundamental communication skills to reduce tantrum episodes brought on by a failure to articulate wants and thoughts; a referral to a speech therapist can aid in achieving this objective. The client will benefit by being directed to transportation providers who could offer Alvin a ride for his treatment sessions. Because he lacks awareness of the risk, Alvin can wander away without realizing he is lost. The family's basic requirements are met through referrals to community support organizations such as nongovernmental organizations. Because the family is unfamiliar with Alvin's condition, sending them to family counseling might assist them emotionally. Support and guidance in locating resources (especially because the family is new to the country and have no close relatives in the state) will help solve this challenge.

Potential Variance to the Clinical Pathway and Treatment Plan

Nonadherence with treatment appointments and the failure to complete at least 15 sessions might constitute variations from the plan of care. This will also have an impact on another objective, which is teaching Alvin a word that he can use to express fundamental needs. As a result, the family's stress level will increase if they don't observe any improvement. The accessibility of the therapy, the family's perception of the treatment's value, and Alvin's readiness for the change might all be contributing reasons for this variation. Alvin could perhaps be resistant when he enters the facility and

refuse to participate in any therapies. One recommendation would be to prepare the child and have a social story about what to expect during the therapy. To familiarize and prepare Alvin for what to anticipate, the therapist can assist by providing social stories with images of the actual facility, car, personnel, and therapist.

The inability to get the resources for nonmedical transportation is another potential deviation from the treatment plan for this client and affect how well the family can adhere to their therapy appointments. A number of circumstances can affect ease of finding transportation, such as an agency lacking sufficient employees. But case managers are excellent problem solvers and will figure out how to get around such an obstacle. One option to get through the barrier is to use telehealth treatment, which involves video conferencing. Involving the parent in the sessions may also give them a sense of empowerment towards their son's condition and enable them to put what they learned from the therapy to use. By finding some resources for volunteers to help drop off and pick up Alvin for his therapy, the case manager may be able to remove this obstacle. In addition, the case manager can help the family earn their drivers' licenses as well as find them an affordable car.

Caseworkers coordinate with various service systems to ensure the delivery of appropriate services and evaluate the effectiveness of those services. Additionally, family members are asked to fully participate in programs and monitor progress. Family members can offer suggestions for services that will be most helpful to them, help to define desired outcomes, and set timeframes for the plan's implementation. Continuous case management demands frequent, planned communication with the family to track progress toward goals. (Child Welfare Information Gateway 2022)

Family Support Services

Community-based family support programs help and encourage parents in their position as caregivers. Depending on the needs and strengths of the family, these services might take many different forms. However, their main objective is to support parents in developing their abilities and resolving issues to encourage the best possible child development. The ideas of family support should be incorporated into casework along the continuum of child welfare services

since all families can benefit in some manner from help. (Child Welfare Information Gateway 2022)

Family support programs may target specific groups, such as family caregivers; teenage parents; or families dealing with health, mental health, or drug use concerns; in addition to the general community. They may be all-inclusive or narrowed to a particular objective. The United Way and [2-1-1.org](#), for example, provide a free, confidential hotline to connect people with local resources for food, employment, crisis support, health, and housing assistance. [FamilyFirstAct.Org](#) offers an overview of the Family First Prevention Services Act as well as resources on related subjects, communication tools for promoting the website, and a community calendar. (Child Welfare Information Gateway 2022)

Conclusion

Health care systems must construct a strong governance and team structure, incorporate best practices, and develop a robust analytics system while ensuring organizational and financial alignment. These are just a few of the challenges systems confront as they strive to improve results. The path to better results is littered with obstacles in each of the above areas. Throughout the journey, reducing variance is important because it identifies areas where health systems may make improvements. (Ferguson 2017)

The purpose of measuring, reporting, and comparing health care outcomes is to meet health care's Quadruple Aim: to enhance patient experience of treatment, population health, per capita cost of health care, and clinician and staff burnout. Health care outcomes cannot be improved without accurate outcomes measurement. Health systems report on hundreds of outcomes each year in an environment of administrative and regulatory constraints. They also track outcomes to ensure that they are giving the best possible treatment to patients while also maintaining a transparent, efficient, and accessible environment for all health care practitioners. (Tinker 2022) **CE II**

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Understanding Reinsurance: Opportunities, Challenges, and Insights for Case Managers

By Mary Paquette, RN, BSN, CCM

Executive Director, RGA ROSE® Consulting Group, Reinsurance Group of America, Incorporated

Introduction

I have been a certified case manager for 25 years, observing and supporting the growth of the profession. I have worked in reinsurance and provider excess insurance, and, as such, my role has been a bit of an enigma. Many outside the industry may have heard of or worked with case managers. However, few people have heard of or understand reinsurance. A role that combines case management and reinsurance further confuses most people. My family still has difficulty explaining what I do for a living. The common response is, “Oh... they insure insurance companies.” I guess that is actually a pretty good start. However, it’s valuable for case managers to go beyond that definition and truly understand the role and purpose of reinsurance and the challenges and opportunities that health plans and reinsurers can face.

What Is Reinsurance?

Reinsurance really is insurance for insurance companies. In the group health space, employers pay a health plan a set amount per insured/member per month for insurance coverage. The health plan is then responsible for all the costs outlined in the plan benefit. To ease the financial burden of unexpected, high-cost claims and assist with leveling out the balance sheet, health plans pay a portion of the per member per month fee from employers to a reinsurer who will assume part of the risk. The agreements are generally written on an incurred basis over a 12-month period and are renewed on an annual basis. Claims are required to be paid and submitted to the reinsurer within a deadline that is usually 6 months after the agreement terminates.

For example, the coverage may run from January 1, 2023 to December 31, 2023; paid claims for 2023 must then be submitted by June 30, 2024 to be covered by the reinsurer. The coverage could be comprehensive—including all health care–related services, such as inpatient, outpatient, transplant, gene and cell therapy, homecare, and physician services. Other health plans may select more limited coverage, for example inpatient only. In most cases, the coverage does not include retail pharmacy.

Before 2011 and the enactment of the Affordable Care Act

(ACA), most health plans had an annual or lifetime limit of benefits per individual. (eHealth 2022) With the enactment of the ACA, health plans were required to offer unlimited benefits. This created more risk for health plans, and in turn, new opportunities for reinsurers. Some health plans that previously did not seek reinsurance suddenly were fearful of unlimited risk and sought protection.

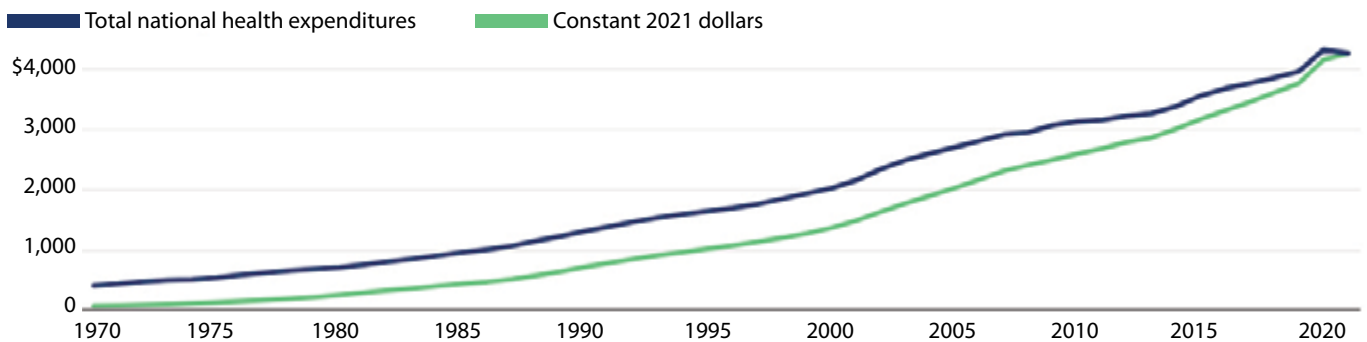
When I started in reinsurance in 1987, it was considered almost impossible for someone to survive after receiving \$1 million in medical services. Back then, the most frequent high-cost diagnoses were premature infants and traumatic brain and spinal cord injuries. Well, that has certainly changed. In 2006, RGA ROSE Consulting Group reported that claims in excess of \$1 million had tripled over the previous 3 years. The top diagnoses over \$1 million in 2006 were premature and complex infants, cancer, pulmonary diseases, and cardiac diseases. In 2018, it was reported that million-dollar medical claims leapt 87% from the previous 3 years. (Lagasse 2018) Figure 1 demonstrates the increase in expenditure since 1970. (Telesford et al 2023)

Today, although costs associated with premature infants, hemophilia care, oncology, and complicated transplants remain high on the list, costs have risen for other diagnoses because new therapies are now used. Specialty pharmacy and gene therapy have brought treatments to rare conditions that previously had few or no treatment options. Gene therapy is the newest high-cost treatment with associated costs ranging from \$1 million to \$3.5 million for single treatments. Patients with spinal muscle atrophy (SMA) benefited from both FDA

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FIGURE 1 TOTAL NATIONAL HEALTH EXPENDITURE INCREASES, US \$BILLIONS, 1970 TO 2020



Note: A constant dollar is an inflation adjusted value used to compare dollar values from one period to another.

Source: KFF analysis of National Health Expenditure (NHE) data

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approval of a specialty drug, Spinraza, in 2016 and gene therapy, Zolgensma, in 2019. We rarely, if ever, saw claims for SMA before 2016. Since 2019, we have been notified of over 25 cases of SMA being treated with Spinraza and/or Zolgensma. For many health plans, one or more such claims could cause financial hardship. This is where the reinsurer steps in.

How Does Reinsurance Work?

Reinsurance works in a couple of ways. The first type is excess reinsurance, or use of a deductible where the reinsurer is at risk for all or a percentage of the claims that exceed the deductible. Deductibles can range from as low as \$200,000 to as high as \$2 million or more. For example, Client A has a reinsurance deductible of \$700,000 with a 90% coinsurance. They have a member who received \$1.5 million in eligible health care services. The health plan pays all the claims and then submits the expenses to the reinsurer for reimbursement. The reinsurer will reimburse the health plan \$720,000, which is 90% of the amount over the deductible as demonstrated in this calculation: $(\$1.5 \text{ million} - \$700,000) \times 90\% = \$720,000$.

The other type of reinsurance is quota share. In quota share, the health plan aggregates all their claim losses, and the reinsurer is responsible for a percentage of the total claims—like taking a piece of the pie. For example, if the health plan's claims totaled \$10 million, and the reinsurer was taking 20% of the risk, the reinsurer would reimburse the client \$2 million.

What About Stop Loss Coverage?

You may be familiar with stop loss coverage, which is similar to reinsurance, but has different legal requirements

and partnerships. Reinsurers are limited to business that is already written on insurance paper, hence the name reinsurance. Stop loss applies to employer groups who self-insure and take on the risk of their employees' medical costs. Stop loss is different from reinsurance in that employers are not insurance entities and, thus, are required to work through a licensed insurance company to write their business. Like health plans, those employers seek protection from high-dollar claims and purchase stop loss coverage at a certain deductible level or specific insurance retention (SIR). A reinsurer may provide coverage on top of the stop loss.

The premise is that the reinsurer reduces the health plan's risk. In turn, the reinsurer has a large block of business in which all their clients' losses and gains can offset each other.

For more information on reinsurance, please see the resources section below. (NAIC 2022)

Managing Reinsurance Risk

To further the management of risk, some reinsurers have created medical and claim management programs to assist clients. These programs are staffed by nurses and claims personnel. As reinsurers, we encounter rare, complex, and high-cost claims daily, while a health plan may only experience a few of these types of claims in a year. Through these large or complex claims, reinsurers identify opportunities to mitigate costs and can share that experience with clients to assist them in reducing costs. Clients also benefit in decreasing overall client claim experience to potentially reduce future reinsurance premiums paid by the client to the reinsurer.

In the early days of case management, most health plans did not have internal case managers. Payers contracted with external case management companies or independent case managers. As a reinsurer, we assisted clients by identifying

Once a new reinsurance deal has been completed, it is ideal for the reinsurer to meet with the client to review reporting and claim submission processes, as well as present their menu of value-added services.

specialty case managers to manage clients' complex cases, which were mostly brain injury and spinal cord injuries. Health plans began to understand the multiple benefits of case management and started to develop their own internal programs or contracted directly with case management companies. The role of the reinsurer then changed from providing access to case managers to assisting plans with resources to provide quality case management to their members.

Today, case management consultation and education are important resources provided by many reinsurers. As case managers are keenly aware, both cost and quality of care are key factors to monitor. Quality care can increase costs or may actually provide cost savings because it may prevent complications. A reputable reinsurer would not risk quality care for lower costs. One example is reinsurers' early adoption of centers of excellence and transplant networks.

Starting in 2009, reinsurers began collaborating with national transplant networks to offer their services and access to clients. Transplants were new to health plans, and the contracting was very complex with new terms and nuances. Access to networks was a perfect example of how reinsurers provided access to quality providers, coupled with beneficial and thorough contracting. Many health plans now directly contract with transplant networks as they have become more knowledgeable about the details of transplantation services.

Who Exactly Are You?

Reinsurance is a financial decision generally made by C-suite individuals in finance or actuarial science. The terms of the agreement and premium are negotiated annually. Many health plans use a broker to represent them and assist with the process of selecting a reinsurer, identifying the appropriate coverage, and negotiating rates. Usually, claims and medical management units within health plans are not involved in the decision.

Once a new reinsurance deal has been completed, it is ideal for the reinsurer to meet with the client to review reporting and claim submission processes, as well as present their menu of value-added services. The meeting is sometimes the first introduction to reinsurance for the heads of claims and medical management. Because they did not seek assistance, it is understandable that they may be skeptical

of the reinsurer's intentions, possible intrusion, or level of expertise. Additionally, the breadth of the reinsurer's desired partnership may be an unwelcome surprise.

The health plan staff may have questions and concerns. Will the reinsurer attempt to control the management of claims or medical services? Will they be another watch group making demands? Will the reporting and questions require a massive time commitment for our already taxed health plan staff? These are all reasonable responses and may even be based on previous experience.

These concerns are certainly valid, and addressing them is something the reinsurance consultants face with every new client. It is the consultant's responsibility to understand the client and their concerns, break down those barriers, and begin to build a relationship. Ultimately, a strong relationship between the health plan's claims/medical management teams and the reinsurer results in collaboration that improves health care services and reduces unnecessary costs.

How to Work With a Reinsurer

Understand the reinsurance agreement and reporting/management requirements

A reputable reinsurer should allow the health plan to maintain the responsibility of the management of their insureds'/members' medical services. Health plans are knowledgeable about the local providers, cultural considerations, and available networks. Federal, state, and accreditation organization requirements vary among health plans, and internal staff have the knowledge and experience to ensure compliance.

Additionally, reinsurers differ in terms of their requirements of health plans. Some may have rules restricting the health plan's audit or case management practices, whereas others have incentives encouraging clients to access experienced vendors but not requiring compliance, and still other reinsurers may be less involved with managing care or costs.

Regardless, nearly all reinsurers require reporting. Just as the financial staff within health plans require notification of potential high-dollar cases, so does the reinsurer. Many require monthly reporting of claims that have met 50% of the reinsurance deductible. Clinical information may be requested to better understand the case and determine if there will be financial risk to the reinsurer. Early

Early identification also gives the reinsurance consultant the opportunity to identify any areas where they can provide assistance or strategies for the management of health care services or the claim costs.

identification also gives the reinsurance consultant the opportunity to identify any areas where they can provide assistance or strategies for the management of health care services or the claim costs. There are several examples of this, and a few are noted in sections below. The reinsurer may then estimate the health care costs for the year and set up reserves (funds that are used to reimburse client claim expenses).

Ask about the experience and depth of the reinsurance medical management program

Level of reinsurance nurse consultant expertise and depth of resources vary by reinsurer. It is appropriate to ask about the education, training, and experience of the reinsurance consultants and overall program offerings. Some programs are well established with vast resources, and others are newer with limited strategies to offer.

An experienced reinsurance medical management team can bring value to a client that is open to collaboration. Reinsurance programs can offer consultation, education, and research services, mostly on a complimentary basis. These services can supplement the health plan's available resources. As previously mentioned, reinsurers work almost exclusively with high-dollar medical cases. They can provide insight into the management of care (including centers of excellence), information on the diagnosis and treatment guidelines, potential complications, and research services. The information is provided to the health plan, but it is up to the health plan to decide how to move forward with the case.

Take, for example, the following infant transplant case wherein the reinsurer provided information to the client that likely improved the outcome of the case and assisted in controlling costs. A 4-month-old infant was approved for a lung transplant. The health plan's practice was to keep members in state, thinking they could better control the care and costs. The plan was to refer the care of this infant to a local facility. The reinsurance consultant reviewed the experience and outcomes of the local facility only to discover that they had never performed a lung transplant on an infant. The consultant reviewed available transplant network facilities and identified an out-of-state center of excellence that had performed hundreds of such procedures with a high success rate.

A reasonable discount was also in place. The information was provided to the health plan, which, grateful for the insight, agreed that the out-of-state facility was the most appropriate for the referral. The reinsurance consultant assisted with connecting the health plan to a specialty case manager, who provided the services at the cost identified by the reinsurer. The case manager provided support and education to the family. Savings were also achieved by using the reinsurer's recommendation for an air ambulance service. After the transplant was performed, the infant had a positive outcome and was discharged home to their family.

Does the reinsurer offer claim management services?

From the claim perspective, reinsurers can offer a broad review of claim payments and identify claims that may have slipped through the cracks. Identification and retrospective action can save considerable financial impacts for health plans and, sometimes, the reinsurer. Once issues are identified, health plans can institute process changes to prevent the issue from reoccurring. The types of claim consulting you should expect from your reinsurer include specialty pharmacy. There are examples of cases in which substantially higher than average amounts have been paid on specialty pharmacy claims.

Health plans may have great discounts in place for standard formulary medications. However, standard discounts may be automatically applied to new, specialty pharmacy drugs that would otherwise qualify for much greater discounts. This may occur because specialty pharmacy is commonly applied to the medical benefit instead of the pharmacy benefit that may have more controls in place. In the following case example, the health plan's claim processing system did not flag the claims because a discount had been applied, as minimal as it may have been.

The client's monthly report to the reinsurer included claim details showing the amount paid per dose. The reinsurance consultant identified that the drug was paid at an unusually high cost and notified the health plan. The health plan contacted the provider and negotiated a higher discount. The cost reduction was applied to retrospective and prospective claims. This action reduced the total cost to below the reinsurance deductible and resulted in savings of

After recognizing the change to internal case management, reinsurers shifted from identifying outside case managers to ensuring that health plans had the resources necessary to best manage their members' care.

over \$1 million per year on a drug that would be continued for several years. In these types of cases, cost savings are experienced by both the health plan and the reinsurer without disturbing the member's medical services.

The reinsurer can also partner with the plan to work with vendors by bringing their years of experience and relationships into play. In one such instance, a reinsurer used their long-standing relationship with a transplant network to assist a client. A member was on an immunotherapy, which was paid based on the Medicare fee schedule. The member had a stem cell transplant under a transplant network contract. Although unusual, the member resumed taking the medication after the transplant. The medication was then billed under the transplant contract at a discount but was still six times higher than what the plan previously paid. The claims were paid by the health plan and submitted to the reinsurer for reimbursement. The reinsurer identified the high costs and worked with the transplant network to renegotiate the agreement for this case. The drug claims were excluded from the agreement and rebilled at the previous Medicare rate. Over \$1 million was saved, reducing the liability for the health plan and the reinsurer.

In another case, the reinsurer identified higher than expected claims for cancer diagnoses. The reinsurance consultant and actuary identified that the price the plan was paying for chemotherapy was significantly higher than the average and was the main cost driver of the claims. Specific chemotherapeutic drugs were identified that were the farthest out of line with the expected costs. The reinsurer consulted with their specialty pharmacy vendor and provided the client with a range of average costs for the drugs. The information was shared with the client, who intended to use it during the next contract negotiation cycle with the providers.

What professional educational opportunities are provided?

Educational offerings vary by reinsurer. After recognizing the change to internal case management, reinsurers shifted from identifying outside case managers to ensuring that health plans had the resources necessary to best manage their members' care. Education is offered on new therapies and trends. Staff turnover can be difficult to manage, and not all new case managers have had the opportunity to

complete an in-depth case management training program. At least one reinsurer provides comprehensive case management training for the new and experienced case managers that includes the core components, essential activities of case management, latest developments, and preparation for the certified case management exam. This is crucial training, especially for health plans that require their case managers to become certified.

Both Can Benefit

Health plans and reinsurers can collaborate to benefit both parties and the members they serve. It is important for the health plan management to understand both the contractual obligations in terms of reporting, and how to access the reinsurer's expertise to the advantage of the health plan and their members.

The reinsurer can assist health plans especially related to high-cost claims, new therapies, and education. Reinsurers should be available as resources and not dictators of health care services. They should also be mindful of the workload that the reinsurance reporting requires of the health plans and be efficient in their inquiries.

The reinsurer and health plan can benefit if both accept that the reinsurance agreement provides more opportunity than just being a financial agreement. The collaboration can provide resources to improve health care services and reduce unnecessary costs. **CM**

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PharmaFacts for Case Managers



Orserdu™ (elacestrant) tablets, for oral use

INDICATIONS AND USAGE

Orserdu is indicated for the treatment of postmenopausal women or adult men with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

DOSAGE AND ADMINISTRATION

Patient Selection

Select patients for treatment of ER-positive, HER2-negative advanced or metastatic breast cancer with Orserdu based on the presence of ESR1 mutation(s) in plasma specimen using an FDA-approved test [.

Information on FDA-approved tests for detection of ESR1 mutations in breast cancer is available at: <http://www.fda.gov/CompanionDiagnostics>.

Recommended Dosage

The recommended dosage of Orserdu is 345 mg taken orally with food once daily until disease progression or unacceptable toxicity occurs.

Take Orserdu at approximately the same time each day. Take with food to reduce nausea and vomiting.

Swallow Orserdu tablet(s) whole. Do not chew, crush, or split prior to swallowing. Do not take any Orserdu tablets that are broken, cracked, or that look damaged.

If a dose is missed for more than 6 hours or vomiting occurs, skip the dose and take the next dose the following day at its regularly scheduled time.

See Product Insert for dose modifications for adverse reactions.

Dosage Modifications for Use with Concomitant CYP3A4 Inducers and Inhibitors

Avoid concomitant use of Orserdu with strong or moderate CYP3A4 inducers and inhibitors.

Dosage Modifications for Hepatic Impairment

Avoid use of Orserdu in patients with severe hepatic impair-

ment (Child-Pugh C). Reduce the Orserdu dosage to 258 mg once daily for patients with moderate hepatic impairment (Child-Pugh B). No dosage adjustment is recommended for patients with mild hepatic impairment (Child-Pugh A).

DOSAGE FORMS AND STRENGTHS

Tablets: Elacestrant 345 mg (equivalent to 400 mg elacestrant dihydrochloride) and 86 mg (equivalent to 100 mg elacestrant dihydrochloride):

- 345 mg: light blue, unscored, oval film-coated biconvex tablet, imprinted with “MH” on one side and plain on the other side.
- 86 mg: light blue, unscored, round film-coated biconvex tablet, imprinted with “ME” on one side and plain on the other side.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Dyslipidemia

Hypercholesterolemia and hypertriglyceridemia occurred in patients taking Orserdu at an incidence of 30% and 27%, respectively. The incidence of Grade 3 and 4 hypercholesterolemia and hypertriglyceridemia were 0.9% and 2.2%, respectively.

Monitor lipid profile prior to starting and periodically while taking Orserdu.

Embryo-Fetal Toxicity

Based on findings in animals and its mechanism of action, Orserdu can cause fetal harm when administered to a pregnant woman. Administration of elacestrant to pregnant rats resulted in adverse developmental outcomes, including embryo-fetal mortality and structural abnormalities, at maternal exposures below the recommended dose based on area under the curve (AUC).

Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with Orserdu and for 1 week after the last dose. Advise male patients with female partners of reproductive potential to use



effective contraception during treatment with Orserdu and for 1 week after the last dose].

ADVERSE REACTIONS

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

- Dyslipidemia

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of Orserdu was evaluated in 467 patients with ER+/HER2- advanced breast cancer following CDK4/6 inhibitor therapy in EMERALD, a randomized, open-label, multicenter study. Patients received Orserdu 345 mg orally once daily (n=237) or standard of care (SOC) consisting of fulvestrant or an aromatase inhibitor (n=230). Among patients who received Orserdu, 22% were exposed for 6 months or longer and 9% were exposed for greater than one year.

Serious adverse reactions occurred in 12% of patients who received Orserdu. Serious adverse reactions in >1% of patients who received Orserdu were musculoskeletal pain (1.7%) and nausea (1.3%). Fatal adverse reactions occurred in 1.7% of patients who received Orserdu, including cardiac arrest, septic shock, diverticulitis, and unknown cause (one patient each).

Permanent discontinuation of Orserdu due to an adverse reaction occurred in 6% of patients. Adverse reactions which resulted in permanent discontinuation of Orserdu in >1% of patients were musculoskeletal pain (1.7%) and nausea (1.3%).

Dosage interruptions of Orserdu due to an adverse reaction occurred in 15% of patients. Adverse reactions which resulted in dosage interruption of Orserdu in >1% of patients were nausea (3.4%), musculoskeletal pain (1.7%), and increased ALT (1.3%).

Dosage reductions of Orserdu due to an adverse reaction occurred in 3% of patients. Adverse reactions which required dosage reductions of Orserdu in >1% of patients were nausea (1.7%).

The most common (>10%) adverse reactions, including laboratory abnormalities, of Orserdu were musculoskeletal pain, nausea, increased cholesterol, increased AST, increased triglycerides, fatigue, decreased hemoglobin, vomiting, increased ALT, decreased sodium, increased creatinine, decreased appetite, diarrhea, headache, constipation, abdominal pain, hot flush, and dyspepsia.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Based on findings in animals and its mechanism of action, Orserdu can cause fetal harm when administered to a pregnant woman. There are no available human data on Orserdu use

in pregnant women to inform the drug-associated risk. In an animal reproduction study, oral administration of elacestrant to pregnant rats during organogenesis caused embryo-fetal mortality and structural abnormalities at maternal exposures below the recommended dose based on AUC (see Data). Advise pregnant women and females of reproductive potential of the potential risk to a fetus.

The background risk of major birth defects and miscarriage for the indicated population is unknown. In the

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

Lactation

Risk Summary

There are no data on the presence of elacestrant in human milk, its effects on milk production, or the breastfed child. Because of the potential for serious adverse reactions in the breastfed child, advise lactating women to not breastfeed during treatment with Orserdu and for 1 week after the last dose.

Females and Males of Reproductive Potential

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

Pregnancy Testing

Verify the pregnancy status in females of reproductive potential prior to initiating Orserdu treatment.

Contraception

Females

Advise females of reproductive potential to use effective contraception during treatment with Orserdu and for 1 week after the last dose.

Males

Advise male patients with female partners of reproductive potential to use effective contraception during treatment with Orserdu and for 1 week after the last dose.

Infertility

Based on findings from animal studies, Orserdu may impair fertility in females and males of reproductive potential].

Pediatric Use

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

Geriatric Use

Of 237 patients who received Orserdu in the EMERALD trial, 43% were 65 years of age or older and 17% were 75 years of age or older. No overall differences in safety or effectiveness of Orserdu were observed between patients 65 years or older of age compared to younger patients. There are an insufficient number of patients 75 years of age or older to assess whether there are differences in safety or effectiveness.



Hepatic Impairment

Avoid use of Orserdu in patients with severe hepatic impairment (Child-Pugh C). Reduce the dose of Orserdu in patients with moderate hepatic impairment (Child-Pugh B). No dosage adjustment is recommended for patients with mild hepatic impairment (Child-Pugh A).

CLINICAL STUDIES

The efficacy of Orserdu was evaluated in EMERALD (NCT03778931), a randomized, open-label, active-controlled, multicenter trial that enrolled 478 postmenopausal women and men with ER+/HER2- advanced or metastatic breast cancer of which 228 patients had ESR1 mutations. Patients were required to have disease progression on one or two prior lines of endocrine therapy, including one line containing a CDK4/6 inhibitor. Eligible patients could have received up to one prior line of chemotherapy in the advanced or metastatic setting.

Patients were randomized (1:1) to receive Orserdu 345 mg orally once daily (n=239), or investigator's choice of endocrine therapy (n=239), which included fulvestrant (n=166), or an aromatase inhibitor (n=73; anastrozole, letrozole or exemestane). Randomization was stratified by ESR1 mutation status (detected vs not detected), prior treatment with fulvestrant (yes vs no), and visceral metastasis (yes vs no). ESR1 mutational status was determined by blood circulating tumor deoxyribonucleic acid (ctDNA) using the Guardant360 CDx assay and was limited

to ESR1 missense mutations in the ligand binding domain (between codons 310 to 547). Patients were treated until disease progression or unacceptable toxicity.

The major efficacy outcome was progression-free survival (PFS), assessed by a blinded imaging review committee (BIRC). An additional efficacy outcome measure was overall survival (OS).

A statistically significant difference in PFS was observed in the intention to treat (ITT) population and in the subgroup of patients with ESR1 mutations. An exploratory analysis of PFS in the 250 (52%) patients without ESR1 mutations showed a HR 0.86 (95% CI: 0.63, 1.19) indicating that the improvement in the ITT population was primarily attributed to the results seen in the ESR1 mutated population.

Among the patients with ESR1 mutations (n=228), the median age was 63 years (range: 28-89); 100% were female; 72% were White, 5.7% Asian, 3.5% Black, 0.4% Other, 18.4% unknown/not reported; 8.8% were Hispanic/Latino; and baseline ECOG performance status was 0 (57%) or 1 (43%). Most patients had visceral disease (71%); 62% had received 1 line of endocrine therapy and 39% had received 2 lines of endocrine therapy in the advanced or metastatic setting. All patients had received prior treatment with a CDK4/6 inhibitor, 24% had received prior fulvestrant, and 25% had received prior chemotherapy in the advanced or metastatic setting.

Efficacy results are presented below.

EFFICACY RESULTS FOR EMERALD (PATIENTS WITH ESR1 MUTATIONS)

	Orserdu (N = 115)	Fulvestrant or an Aromatase Inhibitor (N=113)
Progression-free Survival (PFS)^a		
Number of PFS Events, n (%)	62 (54)	78 (69)
Median PFS months ^b (95% CI)	3.8 (2.2, 7.3)	1.9 (1.9, 2.1)
Hazard ratio ^c (95% CI)	0.55 (0.39, 0.77)	
p-value ^d	0.0005	
Overall Survival (OS)		
Number of OS Events, n (%)	61 (53)	60 (53)
Hazard ratio ^c (95% CI)	0.90 (0.63, 1.30)	
P value ^d	NS ^e	

CI=confidence interval; ESR1=estrogen receptor 1.

^aPFS results based on blinded imaging review committee.

^bKaplan-Meier estimate; 95% CI based on the Brookmeyer-Crowley method using a linear transformation.

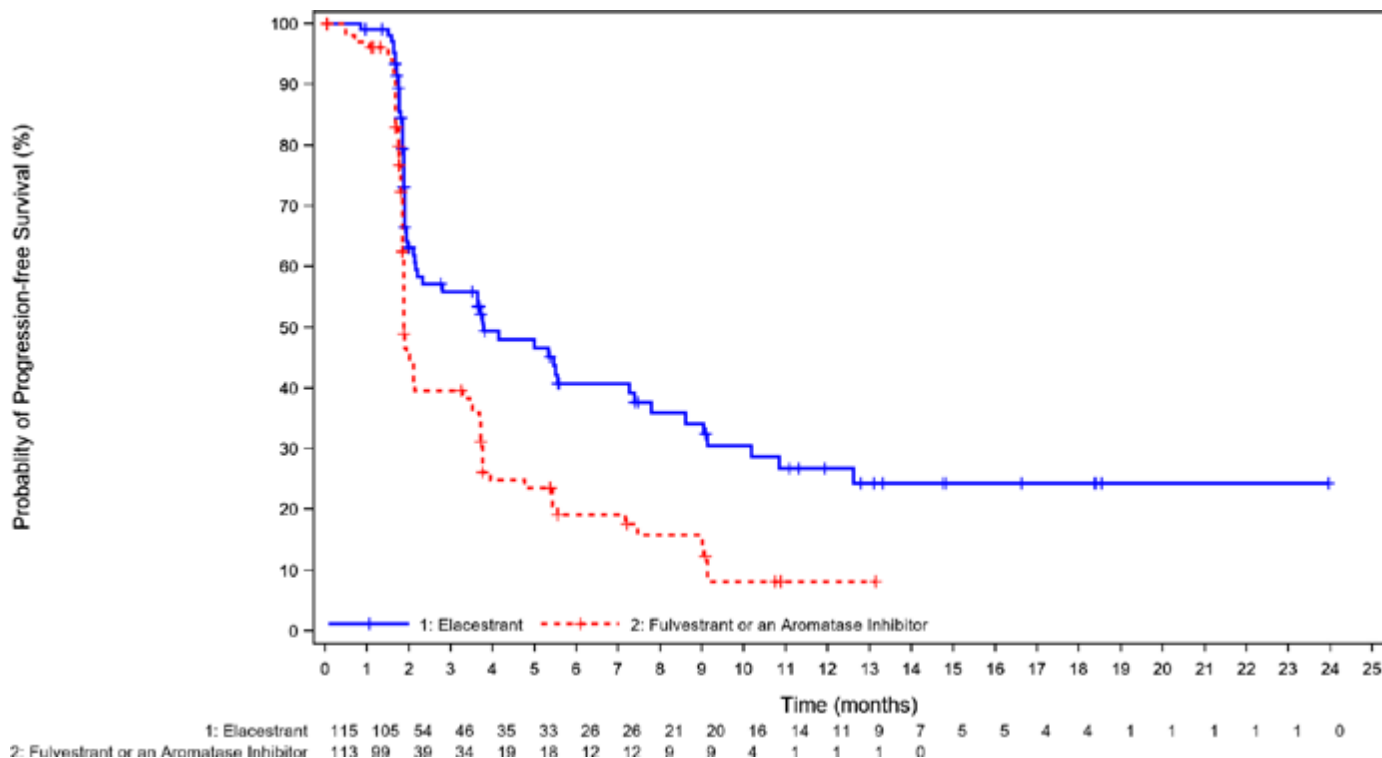
^cCox proportional hazards model stratified by prior treatment with fulvestrant (yes vs no) and visceral metastasis (yes vs no).

^dStratified log-rank test two-sided P value.

^eNS – Not statistically significant.



FIGURE 1 KAPLAN-MEIER CURVE FOR PFS IN EMERALD (PATIENTS WITH ESR1 MUTATIONS, BIRC ASSESSMENT)



HOW SUPPLIED/STORAGE AND HANDLING

Orserdu (elacestrant) film-coated tablets for oral use are supplied as follows:

Tablet Strength	Tablet Color and Shape	Tablet Markings	Pack Size	NDC Code
Elacestrant 345 mg (equivalent to 400 mg elacestrant dihydrochloride)	Light blue; Oval	"MH"	Bottle of 30 Tablets with Child Resistant Closure (CRC).	NDC 72187-0102-3
Elacestrant 86 mg (equivalent to 100 mg elacestrant dihydrochloride)	Light blue; Round	"ME"	Bottle of 30 Tablets with Child Resistant Closure (CRC).	NDC 72187-0101-3

Storage and Handling

Store at 20°C to 25°C (68°F to 77°F). Excursions permitted from 15°C to 30°C (59°F to 86°F). [see USP controlled room temperature].

Cost is estimated to be \$7,500 for 30 86 mg tablets and \$22,500 for 30 345 tablets.

For full prescribing information see Product Insert.

Orserdu is manufactured by the Menarini Group Stemline Therapeutics, Inc.



New Indications

Tafinlar (dabrafenib) Capsules

Tafinlar is a kinase inhibitor for the treatment of melanoma, non-small cell cancer, thyroid cancer, and solid tumors with BRAF V600 mutations and has now been approved for pediatric patients with BRAF V500F low grade glioma.

Kenzara (sarilumab) Injection

Kenzara is an interleukin -6 (IL-6) receptor antagonist for the treatment of rheumatoid arthritis and polymyalgia rheumatica is the first and only biologic indicated for patients with polymyalgia rheumatica.

Eylea (aflibercept) Injection

Eylea is a VEGF inhibitor indicated for the treatment of patients with neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, diabetic retinopathy, and retinopathy of prematurity has now been approved as the first pharmacologic treatment for preterm infants with retinopathy of prematurity.

Keytruda (pembrolizumab) for Injection

Keytruda is a human PD-1 blocking antibody indicated for the treatment of melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high or mismatch repair deficient cancer, instability high or mismatch repair deficient colorectal cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutation burden-high cancer, cutaneous squamous cell carcinoma and triple-negative breast cancer has now been approved as

adjuvant treatment following surgical resection and platinum based chemotherapy for patients with Stage IB, IIA, or IIIA Non-Small cell Lung Cancer.

Tukysa (tucatinib) Tablets

Tukysa is a kinase inhibitor used for the combination treatment of HER2 positive breast cancer and RAS wild type HER2 positive colorectal cancer and now has received accelerated approval in combination with Trastuzumab for people with previously treated RAS wild type, HER2-positive metastatic colorectal cancer.

Brulinsa (zanubrutnib) Capsules

Brulinsa is a Bruton's tyrosine kinase inhibitor used for the treatment of mantle cell lymphoma, Waldenstrom's macroglobulinemia, marginal zone lymphoma and chronic lymphocytic leukemia or small lymphocytic lymphoma is now approved for chronic lymphocytic leukemia.


Rybelsus (semaglutide) Tablets

Rybelsus is an oral glucagon like peptide 1 receptor agonist indicated for the treatment of adults with type 2 diabetes mellitus and has been approved as a first-line option for adults with type 2 diabetes.

Wegovy (semaglutide) Injection

Wegovy is a glucagon like peptide 1 receptor agonist used as an adjunct to diet and exercise for chronic weight management has now been approved for the treatment of obesity in teens ages 12 years and older.

Vraylar (cariprazine) Capsule

Vraylar is an atypical antipsychotic for the treatment of schizophrenia bipolar 1 disorder has now been approved for major depressive disorder. 

Write for CareManagement

CareManagement welcomes articles that explain, illuminate, interpret, and advance case management in all practice settings. Topics include case management models and trends, care plans, business and legal aspects of case management, medical treatments and medications, case management education, outcomes measurement, developments in certification and legislation, ethical issues, advancements in managed care, and new products and equipment.

Manuscripts are accepted for publication with the understanding that they are contributed solely to *CareManagement* and are reviewed by members of *CareManagement's* peer review panel for accuracy, relevancy, and readability.

Style guidelines for manuscripts are as follows:

- Manuscript length is 3,000+ words
- Number all pages of manuscript including reference list, tables, and figure legends
- Use APA style for references

Please send manuscripts or inquiries to:

Catherine Mullahy at cmullahy@academycm.org.



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. 2023 Mar 6. doi: 10.1097/QAD.0000000000003531.
Online ahead of print.

[Postural instability in HIV infection: relation to central and peripheral nervous system markers](#)

Sullivan EV, Zahr NM, Sassoon SA, Pohl KM, Pfefferbau A

OBJECTIVES: Determine the independent contributions of central nervous system (CNS) and peripheral nervous system (PNS) metrics to balance instability in people with HIV (PWH) compared with people without HIV (PWoH).

METHODS: Volumetric MRI (CNS) and two-point pedal discrimination (PNS) were tested as substrates of stance instability measured with balance platform posturography.

DESIGN: 125 PWH and 88 PWoH underwent balance testing and brain MRI.

RESULTS: The PWH exhibited stability deficits that were disproportionately greater with eyes closed than eyes open compared with PWoH. Further analyses revealed that greater postural imbalance measured as longer sway paths correlated with smaller cortical and cerebellar lobular brain volumes known to serve sensory integration; identified brain/sway path relations endured after accounting for contributions from physiological and disease factors as potential moderators; and multiple regression identified PNS and CNS metrics as independent predictors of postural instability in PWH that differed with the use of visual information to stabilize balance. With eyes closed, temporal volumes and two-point pedal discrimination were significant independent predictors of sway; with eyes open, occipital volume was an additional predictor of sway. These relations were selective to PWH and were not detected in PWoH.

CONCLUSION: CNS and PNS factors were independent contributors to postural instability in PWH. Recognizing that myriad inputs must be detected by peripheral systems and brain networks to integrate sensory and musculoskeletal information for maintenance of postural stability, age- or disease-related degradation of either or both nervous systems may contribute to imbalance and liability for falls.

AIDS. 2023 Mar 6. doi: 10.1097/QAD.0000000000003536. Online ahead of print.

[Closing the gaps in the continuum of depression care for persons with HIV: modeling the impact on viral suppression in the United States](#)

Koenig LJ, Khurana N, Hafizul Islam MD, Gopalappa C, Farnham PG

OBJECTIVE: Depression is prevalent among persons with HIV (PWH) and is associated with poorer adherence and lack of viral load suppression (VLS). When treated for depression, PWH are more likely to stay in HIV care and adhere to medications; however, for many PWH, depression is not adequately diagnosed or treated. We adapted Progression and Transmission of HIV (PATH 3.0), a U.S. agent-based dynamic stochastic simulation model, by incorporating a continuum of depression care and estimating the impact on VLS of an enhanced depression diagnosis and care scenario (EDC).

METHODS: We compared EDC-whereby every PWH is assessed for depression, gets treatment if diagnosed, and of those, half achieve remission-to a status quo scenario (SQ) on VLS. Based on published findings, assumptions for SQ were: 34.7% depressed, 45% diagnosed, 55.3% treated and 33% of treated achieving remission. Compared to PWH without depression, we assumed the probability of being non-virally suppressed increased by 1.57 times for PWH with depression (PWH-D), and by 0.95 times for PWH with remitted depression.

RESULTS: There was an average increase of 14.6% (11.5-18.5) in the proportion of PWH-D who achieved VLS in EDC compared to SQ. Among all PWH, there was a 4.7% (3.4-6.0) increase in the proportion who achieved VLS in EDC compared to SQ.

CONCLUSIONS: Fully diagnosing and adequately treating depression would improve health and quality of life for a substantial proportion of PWH-D and result in a nearly 5% increase in expected rates of VLS in the United States, supporting national prevention goals.

J Viral Hepat. 2023 Mar 5. doi: 10.1111/jvh.13826. Online ahead of print.

[Impact of hepatitis C treatment status on risk of Parkinson's disease and secondary parkinsonism in the era of direct-acting antivirals](#)

Ranya SR, Zhou Y, Gordon SC, et al.

BACKGROUND: Research suggests a possible link between chronic infection with hepatitis C virus (HCV) and the development of Parkinson's Disease (PD) and secondary Parkinsonism (PKM). We investigated the impact of antiviral treatment status (untreated, interferon [IFN] treated, direct acting antiviral [DAA] treated) and outcome (treatment failure [TF] or sustained virological response [SVR] regimens) on risk of PD/PKM among patients with HCV.

METHODS: Using data from the Chronic Hepatitis Cohort Study (CHeCS), we applied a discrete time-to-event approach with PD/PKM as the outcome. We performed univariate followed by a multivariable modeling that used time-varying covariates, propensity scores to adjust for

RESULTS: Among 17,199 confirmed HCV patients, we observed 54 incident cases of PD/PKM during a mean follow-up period of 17 years; 3753 patients died during follow-up. There was no significant association between treatment status/ outcome and risk of PD/PKM. Type 2 diabetes tripled risk (hazard ratio [HR] 3.05; 95%CI 1.75-5.32; $p < .0001$) and presence of cirrhosis doubled risk of PD/PKM (HR 2.13, 95%CI 1.31-3.47). BMI >30 was associated with roughly 50% lower risk of PD/PKM than BMI <25 (HR 0.43; 0.22-0.84; $p = 0.0138$).

CONCLUSION: After adjustment for treatment selection bias, we did not observe a significant association between HCV patients' antiviral treatment status/outcome on risk of PD/PKM. Several clinical risk factors-diabetes, cirrhosis, and BMI-were associated with PD/PKM.

Am J Obstet Gynecol. 2023 Feb 28;S0002-9378(23)00132-1. doi: 10.1016/j.ajog.2023.02.022. Online ahead of print.

[Risk for stillbirth among pregnant individuals with SARS-CoV-2 infection varied by gestational age](#)

Lyu T, Liang C, Liu J, M, Yi H, Li X, et al; of the National COVID Cohort Collaborative Consortium.

BACKGROUND: Despite prior research findings on higher risks of stillbirth among pregnant individuals with SARS-CoV-2 infection, it is unclear whether the gestational timing of viral infection modulates the risk for stillbirth.

OBJECTIVES: This study aims to examine the association

between the timing of SARS-CoV-2 infection during pregnancy and the risk of stillbirth.

STUDY DESIGN: This is a retrospective cohort study that used multilevel logistic regression analyses of nationwide Electronic Health Records in the United States. Data were from 75 healthcare systems and institutes across 50 states. A total of 191,403 pregnancies among 190,738 individuals of reproductive ages (15-49) who had childbirth between March 1, 2020 and May 31, 2021 were identified and included. The main outcome is stillbirth occurred at or after 20 weeks of gestation. Exposures are the timing of SARS-CoV-2 infection: early pregnancy (< 20 weeks), mid-pregnancy (21-27 weeks), the 3rd trimester (28-43 weeks), any time before delivery, and never infected (reference).

RESULTS: We identified 2,342 (1.3%) pregnancies with COVID-19 in early-pregnancy, 2,075 (1.2%) in mid-pregnancy, and 12,697 (6.9%) in the 3rd trimester. After adjusting for the maternal and clinical characteristics, increased odds of stillbirth were observed among pregnant individuals with SARS-CoV-2 infection only in early pregnancy (OR=1.75, 95% CI, 1.25-2.46) or mid-pregnancy (OR=2.09, 95% CI, 1.49-2.93), compared to pregnant individuals never infected. Older age, Black race, hypertension, acute respiratory distress syndrome or acute respiratory failure, and placental abruption were found to be consistently associated with stillbirth across different trimesters.

CONCLUSIONS: The increased risk of stillbirth is associated with COVID-19 only when pregnant individuals were infected during early and mid-pregnancy, not any time before the delivery or during the 3rd trimester, suggesting the potential vulnerability of the fetus to the SARS-CoV-2 infection in early pregnancies. Our findings underscore the importance of proactive COVID-19 prevention and timely medical intervention for individuals infected with SARS-CoV-2 during early and mid-pregnancy.

J Card Fail. 2023 Mar 13; S1071-9164(23)00067-2. doi: 10.1016/j.cardfail.2023.02.011. Online ahead of print.

[Multidisciplinary care in heart failure services](#)

Sokos G, Kido K, Panjraht G, et al.

The American College of Cardiology/American Heart Association / Heart Failure Society of American 2022 guidelines for heart failure (HF) recommend a multidisciplinary team approach for patients with HF. The multidisciplinary HF team-based approach reduces the hospitalization rate for HF and healthcare costs and improves adherence to self-care and utilization of GDMT. This manuscript proposes the optimal multidisciplinary team structure and each team member's delineated role to achieve institutional goals and metrics for HF care. The proposed HF-specific multidisciplinary team comprises cardiologists, surgeons, advanced practice providers,

clinical pharmacists, specialty nurses, dieticians, physical therapists, psychologists, social workers, immunologists, and palliative care clinicians. A standardized multidisciplinary HF team-based approach should be incorporated to optimize the structure, minimize redundancy of clinical responsibilities among team members, and improve clinical outcomes and patient satisfaction in their HF care.

Clin Transplant. 2023 Mar;37(3):e14843. doi: 10.1111/ctr.14843. Epub 2022 Dec 29.

[Impact of 2016 UNOS pediatric heart allocation policy changes on VAD utilization, waitlist, and post-transplant survival outcomes in children with CHD versus non-CHD](#)

Das BB, Blackshear CT, Lirette ST, et al.

AIMS: We analyzed the impact of the revised pediatric heart allocation policy on types of ventricular assist device (VAD) utilization, and waitlist (WL) and post-heart transplant (HT) survival outcomes in congenital heart disease (CHD) versus non-CHD patients before (Era-1) and after (Era-2) pediatric heart allocation policy implementation.

METHODS: We retrospectively reviewed the UNOS database from December 16, 2011, through March 31, 2021, for patients < 18 years old and listed for primary HT. We compared the differences observed between Era-1 and Era-2.

RESULTS: 5551 patients were listed for HT, of whom 2447(44%) were in Era-1 and 3104(56%) were in Era-2. CHD patients were listed as status 1A unchanged, but the number of patients listed as status 1B decreased in Era-2, whereas the number of non-CHD patients listed as status 1A decreased, but status 1B increased. In Era-2 compared to Era-1, both temporary (1% to 4%, $p < .001$) and durable VAD (13.6% to 17.8%, $p < .001$) utilization increased, and the transplantation rate per 100-patient years increased in both groups. The median WL period for CHD patients increased marginally from 70 to 71 days ($p = .06$), whereas for non-CHD patients it decreased from 61 to 54 days ($p < .001$). Adjusted 90-day WL survival increased from 84% to 88%, $p = .016$ in CHD, but there was no significant change in non-CHD patients ($p = .57$). There was no significant difference in 1-year post-HT survival in CHD and non-CHD patients between Era-1 and Era-2.

CONCLUSIONS: In summary, after the revised heart allocation policy implementation, temporary and durable VAD support increased, HT rate increased, waitlist duration marginally increased in the CHD cohort and decreased in the non-CHD cohort, and 90-day WL survival probability improved in children with CHD without significant change in 1-year post-HT outcomes. Future studies are needed to identify changes to the policy that may further improve the listing criteria to improve WL duration and post-HT survival.

PLoS One. 2023 Mar 13;18(3):e0283045. doi: 10.1371/journal.pone.0283045. eCollection 2023.

[Validity of ICD codes to identify do-not-resuscitate orders among older adults with heart failure: a single center study](#)

Callahan K, Acharya Y, Hollenbeak CS

BACKGROUND: Observational research on the advance care planning (ACP) process is limited by a lack of easily accessible ACP variables in many large datasets. The objective of this study was to determine whether International Classification of Disease (ICD) codes for do-not-resuscitate (DNR) orders are valid proxies for the presence of a DNR recorded in the electronic medical record (EMR).

METHODS: We studied 5,016 patients over the age of 65 who were admitted to a large, mid-Atlantic medical center with a primary diagnosis of heart failure. DNR orders were identified in billing records from ICD-9 and ICD-10 codes. DNR orders were also identified in the EMR by a manual search of physician notes. Sensitivity, specificity, positive predictive value and negative predictive value were calculated as well as measures of agreement and disagreement. In addition, estimates of associations with mortality and costs were calculated using the DNR documented in EMR and the DNR proxy identified in ICD codes.

RESULTS: Relative to the gold standard of the EMR, DNR orders identified in ICD codes had an estimated sensitivity of 84.6%, specificity of 96.6%, positive predictive value of 90.5%, and negative predictive value of 94.3%. The estimated kappa statistic was 0.83, although McNemar's test suggested there was some systematic disagreement between the DNR from ICD codes and the EMR.

CONCLUSIONS: ICD codes appear to provide a reasonable proxy for DNR orders among hospitalized older adults with heart failure. Further research is necessary to determine if billing codes can identify DNR orders in other populations.

Am J Med Sci. 2023 Mar 13;S0002-9629(23)01061-3. doi: 10.1016/j.amjms.2023.03.002. Online ahead of print.

[Pulmonary hypertension inhaled therapies: an updated review](#)

El-Kersh K, Jalil BA

Treatments of pulmonary hypertension (PH) continue to evolve with approval of new therapies. The currently FDA approved inhaled PH therapies include inhaled iloprost for group 1 pulmonary arterial hypertension (PAH), inhaled treprostinil solution and treprostinil dry powder inhaler for both group 1 PAH and group 3 PH associated with interstitial lung disease (PH-ILD). Inhaled treprostinil was recently approved for group 3 PH-ILD based on the

results of INCREASE trial and the newer formulation of treprostinil dry powder that comes with a new inhaler was recently approved for both group 1 PAH and group 3 PH-ILD based on BREEZE study. The pipeline for inhaled PH therapies includes several promising molecules that can enrich the current PH therapeutic era and mitigate several systemic side effects by directly delivering the drug to the target organ. In this review article we summarize the evidence for the currently approved inhaled PAH/PH therapies, discuss the available inhalation devices, present a roadmap for successful treatment strategy, and present several inhaled PAH/PH therapies in the pipeline.

BMC Cancer. 2023 Mar 9;23(1):220. doi: 10.1186/s12885-023-10650-7.

[Spatial characterization and quantification of CD40 expression across cancer types](#)

Bates KM, Vathiotis I, MacNeil T, et al.

BACKGROUND: CD40, a TNF receptor family member, is expressed by a variety of immune cells and is involved in the activation of both adaptive and innate immune responses. Here, we used quantitative immunofluorescence (QIF) to evaluate CD40 expression on the tumor epithelium of solid tumors in large patient cohorts of lung, ovarian, and pancreatic cancers.

METHODS: Tissue samples from nine different solid tumors (bladder, breast, colon, gastric, head and neck, non-small cell lung cancer (NSCLC), ovarian, pancreatic and renal cell carcinoma), constructed in tissue microarray format, were initially assessed for CD40 expression by QIF. CD40 expression was then evaluated on the large available patient cohorts for three of the tumor types demonstrating high CD40 positivity rate; NSCLC, ovarian and pancreatic cancer. The prognostic impact of CD40 expression on tumor cells was also investigated.

RESULTS: CD40 expression on tumor cells was found to be common, with 80% of the NSCLC population, 40% of the ovarian cancer population, and 68% of the pancreatic adenocarcinoma population displaying some degree of CD40 expression on cancer cells. All of three of these cancer types displayed considerable intra-tumoral heterogeneity of CD40 expression, as well as partial correlation between expression of CD40 on tumor cells and on surrounding stromal cells. CD40 was not found to be prognostic for overall survival in NSCLC, ovarian cancer, or pancreatic adenocarcinoma.

CONCLUSIONS: The high percentage of tumor cells expressing CD40 in each of these solid tumors should be considered in the development of therapeutic agents designed to target CD40.

Clin Lung Cancer. 2023 Feb 8;S1525-7304(23)00017-7. doi: 10.1016/j.clcc.2023.01.012. Online ahead of print.

[Current and emerging treatment options for patients with relapsed small-cell lung carcinoma: a systematic literature review](#)

Bernabé-Caro R, Chen Y, Dowlati A, Eason P.

Second-line treatment options are limited for patients with small-cell lung cancer (SCLC). We conducted a PRISMA-standard systematic literature review to evaluate the treatment landscape for patients with relapsed SCLC (PROSPERO number: CRD42022299759). Systematic searches of MEDLINE, Embase, and Cochrane Library were performed (October 2022) to identify publications (prior 5 years) from prospective studies of therapies for relapsed SCLC. Publications were screened against predetermined eligibility criteria; data were extracted to standardized fields. Publication quality was assessed using GRADE. The data were analyzed descriptively, grouped by drug class. Overall, 77 publications involving 6349 patients were included. Studies of tyrosine kinase inhibitors (TKIs) with established cancer indications accounted for 24 publications; topoisomerase I inhibitors for 15; checkpoint inhibitors (CPIs) for 11, and alkylating agents for 9 publications. The remaining 18 publications featured chemotherapies, small-molecule inhibitors, investigational TKIs and monoclonal antibodies, and a cancer vaccine. According to GRADE assessment, 69% of the publications reported low-/very-low-quality evidence; quality limitations included lack of randomization and small sample sizes. Only 6 publications/6 trials reported phase 3 data; 5 publications/2 trials reported phase 2/3 results. Overall, the clinical potential of alkylating agents and CPIs remained unclear; investigations of combination approaches and biomarker-directed usage are warranted. Phase 2 data from TKI trials were consistently promising; no phase 3 data were available. Phase 2 data for a liposomal formulation of irinotecan were promising. We confirmed an absence of promising investigational drug/regimens in late-stage development; thus, relapsed SCLC remains an area of high unmet need.

Am J Surg. 2023 Mar;225(3):577-582. doi: 10.1016/j.amjsurg.2022.11.037. Epub 2022 Nov 30.

[Trends and benefits of prophylactic ureter catheters in the era of minimally invasive surgery](#)

William C Cirocco

BACKGROUND: The recent spike in ureter injury (UI) amidst the rise of minimally invasive surgery (MIS) has focused attention on the propriety of prophylactic ureter catheters (PUCs) for abdominopelvic operations.

METHODS: A retrospective review of PUCs for rectal cancer resection following neoadjuvant therapy, combined with a comprehensive literature review.

RESULTS: There were zero UI in the current study. Literature review revealed a nationwide spike in PUCs in the last 30 years, dependent on operation: 1) colorectal resection-increased from 1.1% to 4.4%, 2) sigmoid colectomy for diverticulitis-increased from 6.7% to 16.3%. This 2-4 fold increase parallels the rise of MIS: 15 of the 20 latest studies (75%) either combined open operations and MIS (4 studies) or focused solely on MIS (11 studies). Medial-to-lateral dissection identified as a UI risk factor. Only 20-30% of UI identified intraoperatively.

CONCLUSIONS: Intraoperative UI is missed in 70-80% of cases. The prevention, identification, ease of ureter repair, and net decrease in operative time support the use of PUCs. Medial-to-lateral dissection is identified as a potential contributing factor to UI.

Clin Transplant. 2023 Mar 17;e14960. doi: 10.1111/ctr.14960. Online ahead of print.

[Center expansion of liver transplants using donation after circulatory death organs is associated with reduced overall waitlist mortality](#)

Kathawate RG, Abt PL, Bittermann T

INTRODUCTION: Waitlist outcomes in liver transplantation (LT) for individual recipients are improved by use of allografts procured through donation after circulatory death (DCD). However, the impact of increased DCD acceptance on overall center outcomes is unknown.

METHODS: Using the United Network for Organ Sharing database, 88 centers performing an average of ≥ 10 LTs/year between 1/2004 and 12/2019 were compared by percent DCD use quartile and categorized into four phenotypes according to temporal usage trends. Overall center median Model for End-stage Liver Disease at LT (MMA_T), waitlist mortality, and waiting time were evaluated.

RESULTS: The overall DCD rate was 6.1% (N = 4906/80,709), ranging from 0% to 25.5%. Centers in the top DCD use quartile had lower MMA_T (24 vs. 26; p < .001) and shorter overall waiting times (median 66 days vs. 90 days; p < .001) compared to bottom quartile centers. MMA_T increased less over time at centers with increasing DCD use and was lower than at centers with declining DCD use (27 vs. 32; p = .017). Overall waitlist mortality between 2016 and 2019 was lower at increasing DCD use centers (17.8% vs. 22.5%, p = .034), yet did not affect 1-year mortality (p = .747).

CONCLUSIONS: The improved waitlist outcomes at centers with expanded DCD use extend beyond DCD recipients alone without negative consequences to overall post-LT center metrics.

Am J Nephrol. 2022;53(11-12):826-838. doi: 10.1159/000528602. Epub 2022 Dec 9.


[Domains for a comprehensive geriatric assessment of older adults with chronic kidney disease: results from the CRIC study](#)

Chiu V, Gross AL, Chu NM; CRIC Study Investigators

INTRODUCTION: A comprehensive geriatric assessment (CGA) tailored to the chronic kidney disease (CKD) population would yield a more targeted approach to assessment and care. We aimed to identify domains of a CKD-specific CGA (CKD-CGA), characterize patterns of these domains, and evaluate their predictive utility on adverse health outcomes.

METHODS: We used data from 864 participants in the Chronic Renal Insufficiency Cohort aged ≥ 55 years and not on dialysis. Constituents of the CKD-CGA were selected a priori. Latent class analysis informed the selection of domains and identified classes of participants based on their domain patterns. The predictive utility of class membership on mortality, dialysis initiation, and hospitalization was examined. Model discrimination was assessed with C-statistics.

RESULTS: The CKD-CGA included 16 domains: cardiovascular disease, diabetes, five frailty phenotype components, depressive symptoms, cognition, five kidney disease quality-of-life components, health literacy, and medication use. A two-class latent class model fit the data best, with 34.7% and 65.3% in the high- and low-burden of geriatric conditions classes, respectively. Relative to the low-burden class, participants in the high-burden class were at increased risk of mortality (aHR = 2.09; 95% CI: 1.56, 2.78), dialysis initiation (aHR = 1.63; 95% CI: 1.06, 2.52), and hospitalization (aOR = 2.00; 95% CI: 1.38, 2.88). Model discrimination was the strongest for dialysis initiation (C-statistics = 0.86) and moderate for mortality and hospitalization (C-statistics = 0.70 and 0.66, respectively).

CONCLUSION: With further validation in an external cohort, the CKD-CGA has the potential to be used in nephrology practices for assessing and managing geriatric conditions in older adults with CKD. 

Autism: A Real Challenge

continued from page 2

Because of the unique mixture of symptoms in each person, severity can be difficult to determine. Severity is based on the level of impairments and how they affect the ability to function.

The signs and symptoms of autism fall into two categories:

Social communication and interaction. The individual:

- Fails to respond to his or her name or appears not to hear at times
- Resists cuddling and holding and seems to prefer playing alone
- Lacks eye contact and facial expression
- Doesn't speak or has delayed speech
- Can't start a conversation or keep one going
- Repeats words or phrases verbatim
- Doesn't appear to understand simple directions
- Doesn't point to objects that have interest

Patterns of behavior. The individual may:

- Perform repetitive movements
- Perform activities that could cause self-harm

- Develop specific routines or rituals and become disturbed at the slightest change
- Have problems with coordination or have odd movements
- Be sensitive to light, sound, or touch and may be indifferent to pain or temperature
- Not engage in make-believe play
- Fixate on an object or activity with abnormal intensity

People develop at their own time line and no one follows exactly the same time line. If signs and symptoms are present, then an evaluation is indicated. Remember that most children with autism show signs of delayed development by the age of 2.

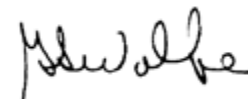
Treatment for autism should start as soon as it is diagnosed or even before when symptoms are suspected. Early treatment along with proper care and services can reduce an individual's difficulties while helping them build on their strengths and learn new skills.

People with autism face a wide range of issues, meaning there is no single best treatment. Working with a health care team, including a case manager, is an important part of finding the right combination of treatment

and services. The two broad categories of treatment include medication and behavioral, psychological, and educational interventions.

After a treatment plan is established, the real work begins. Although there may be a case manager assigned to the client with autism, the real case managers are the parents. The parents are present every day and recognize what is needed, what is working, and what isn't working. It's important to identify how the assigned case manager can support and provide respite for the parents. I salute all parents of children with autism.

In this issue, I am pleased to publish "The Relationship Between Patient Adherence, Advocacy and Health Outcomes in Autism" by Jennifer Andrea Genson-Pat, BSN, RN, CCM.



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

ACCM: Improving Case Management Practice through Education

What Is an Advocate?

continued from page 6

them about the importance of case managers and our role in improving patient health outcomes. This important event helped elevate the professional practice of case management and the immediate needs of case managers nationwide. With more than 60 case management professionals registered, we had opportunities to reach a wider group of legislators, getting the word out and advocating for our profession.

Advocacy takes many forms; find the one that is right for you and make

sure your voice is heard. You are not only advocating for the profession but for our patients, clients, and members as well. And that is our primary role as "advocate." **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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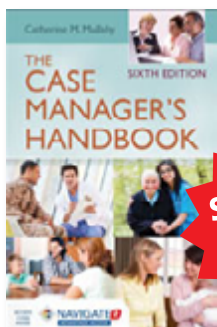
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Six Ways to Develop Cultural Sensitivity *continued from page 7*

open-ended questions such as: What is comfortable for you? This invites the individual to express a preference or cultural norm, rather than defend the choices or values of their culture, religion, or other background.

4. Engage in storytelling. Together with respectful questioning is the use of storytelling to invite the individual to explain previous incidents and experiences, both positive and negative. What happened the last time you had surgery? Can you tell me about when your first child was born? How do you feel about a particular treatment (one example is physical therapy or rehabilitation)? The request to “tell me a story about...” is a nonthreatening way to explore cultural context and perceptions without assumptions or judgment.

5. Navigate intergenerational differences. This scenario is no doubt familiar to many case managers: The client (or patient) is an elderly parent from another country or culture. Their adult son or daughter who was born or raised in the US is weighing in with opinions and recommendations. These intergenerational differences within families can influence the decisions made—and the client’s comfort level with those choices. One example is when an elderly parent wants to be treated at a particular hospital or care setting that is “close to home” while the adult children prefer a different care setting that is larger, has a wider array of medical specialties, or is a teaching hospital. In my experience, engaging the elderly parent in the discussion (using a third-party interpreter, when necessary) keeps the focus on the client. At the same time, it’s essential to engage

the family/support system to provide additional insights and information—for example, to explain an elderly parent’s stoic attitude toward pain or certain tests or treatments.

6. Keep curious. Learn all you can about other cultures and their norms and practices beyond the health care setting. Read literature written by international authors or nonfiction books that explore a different culture. Visit museums to learn about cultural heritage. Curiosity can open our minds to the rich diversity of the human experience.

Becoming more culturally sensitive is an ongoing process as part of our lifelong learning and personal development. The more we understand and appreciate the groups and populations in our community and practice setting, the better we can advocate for them with respect and objectivity. **CM**

ACCM has partnered with Pfizer to bring our members special access to ArchiTools, a centralized resource to help case managers deliver value-driven health care with interactive training modules, downloadable tools, annotated and detailed article reprints, and more.

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CE3

Understanding Reinsurance: Opportunities, Challenges, and Insights for Case Managers

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It's All About Engagement!
Issues of Engagement: Patient, Staff and Professional *continued from page 3*

months, we have seen health care professionals launch massive strikes in protest of conditions they felt were unsafe for their patients. Clearly, health care leadership needs to deploy new strategies to reengage staff and demonstrate support for their concerns. Some viable strategies to consider include:

- Reconnect staff with their purpose: Allow staff to share their stories and acknowledge their accomplishments.
- Create psychological safety and reassure staff of their value.
- Rebuild trust: Many staff believed that policies and practice changes were being made by those who might have lacked the needed expertise and insights.
- Reinvolvement staff in unit governance, which likely decreased during the pandemic.
- Promote peer-to-peer recognition.

In this very brief overview of patient and staff engagement, it's also important to address professional engagement because a lack of it will have a direct impact on the future of case management. It's concerning that too many individuals who yearn for recognition

and respect in their role as case managers are often engaged in the mentality of "what's in it for me?"—surely a short-sighted view. Not everything that we do as case management professionals translates to a tangible end result. It saddens me that professional case managers won't attend an educational conference that provides CEs to maintain licensure or certification, subscribe to journals, and join a professional association that will enrich their knowledge and facilitate the development of a network of professional colleagues—that is, unless and until their employer reimburses them.

As professionals, we do have a heightened sense of responsibility, not just to provide case management intervention on behalf of those patients who have been referred for our care, but to our colleagues. Together, we can usher in change, build a better future for this practice, and ensure a high quality of care for our patients. We can make a difference ... one patient at a time!

Wishing each of you a Happy Spring!
Catherine

Catherine M. Mullahy

Catherine M. Mullahy, RN, BS, CRRN, CCM, FCM, Executive Editor
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A Pathway to Explore Disability Management: Core Knowledge Curriculum Updated, Certificate Offered *continued from page 5*

purchase access to CKC and successfully complete the four domains. Although not a certification, such as CCM or CDMS, this certificate does attest to completing the CKC and learning the basics of disability management. Successful completion of the CKC with a cumulative passing score of 80% across all module posttests is required to receive the ADMS designation. The ADMS is increasingly recognized as a step along the path toward developing expertise in disability management and, for those who then meet the eligibility requirements, can provide necessary knowledge for the pursuit of the CDMS credential.

Within the disability management field, there is increased demand for those who possess the knowledge and skills to enter this field of practice. The CKC and its various benefits can build knowledge and open pathways to new opportunities. **CM**

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