CareManagement

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Gary S. Wolfe

Spirituality, Faith, Religion, and Health

t is the holiday season, which provides us with an opportunity to talk about spirituality, faith, and religion. For Christians, Christmas is a religious holiday celebrated on December 25 deemed the birth of Jesus. It is interesting that there is no

people in a Pew Research Center Study said they were spiritual.

Let's define the terms. Elaine Bruner, MSN, RN, CMGT-BC, in the article, "Spirituality in HealthCare: A Primer for Case Managers," in this issue, defines the terms as follows:

Surveys show that most patients have a spiritual life and feel their spiritual life and physical health have equal importance.

record of the date of the birth of Jesus in the *Bible*. The church in the 4th century chose December 25 as it coordinated with the Solstice on the Roman Calendar. Christmas is one of the most important Christian and cultural holidays of the year. The meaning of Christmas can vary for different people and cultures. Beyond its religious roots, Christmas has evolved into a widely celebrated cultural and festive occasion in many parts of the world. It often involves exchanging gifts, spending time with family and friends, decorating homes with festive ornaments, and partaking in special meals and traditions. Many people are celebrating based on their beliefs at this time.

There is a lot of discussion about spirituality, faith, and religion. I would suggest from a case management point of view, it doesn't matter which term you use. We have seen tremendous changes in how people identify when asked about religion. From a statistical standpoint, the United States is moving from religion to spirituality. Attendance at organized churches is decreasing, but when asked, 70% of

- **Religion**: Personal set or institutionalized system of religious attitudes, belief, and practices with sacraments, ceremonies, prayers, and traditional observances.
- Faith: Trusting in something you cannot explicitly prove. Strong or unshakeable belief without proof.
- Spirituality: A broad concept of belief in something beyond the self. A holistic belief in an individual connection to others and the world that gives meaning, purpose, and hope to life.

For the purpose of my writing, I will use spirituality interchangeably with religion, faith, and spirituality.

What does spirituality have to do with healthcare and case management? Surveys show that most patients have a spiritual life and feel their spiritual life and physical health have equal importance. Frequently during illness, patients have greater spiritual needs. Spirituality is part of the holistic approach to value-driven, patient-centered care. If we are developing a care plan for the whole person, we must

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Catherine M. Mullahy

Passion in Case Management: An Essential Connection

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

s I contemplated my column topic for this last issue of 2024 and first of 2025, I thought about how striving for a heightened awareness improves outcomes for your patients while also giving you a greater sense of satisfaction in a job that is admittedly challenging and often discouraging. Far too many professionals are leaving their roles in case management, frequently citing feeling "burned out" and wondering just how this happened. They share a desire to reawaken the passion they felt initially when entering this practice setting.

"Passion in case management" refers to a deep, genuine enthusiasm and desire to actively help individuals facing complex challenges by providing support, advocating for their needs, and facilitating positive change in their lives through the structured process of case management. Essentially, it means having a strong drive to make a meaningful impact on people's well-being through this specific career path. Frequently, individuals share that when others on the team determine something can't be done, they believe it can be accomplished and want to be the person to do it!

When individuals consider embarking on a career in case management, they often wonder if they have what it takes to be successful. Of course, knowledge and experience in one's profession as a nurse, social worker, therapist, or other healthcare profession is very important. However,

"Passion in case management" refers to a deep, genuine enthusiasm and desire to actively help individuals facing complex challenges by providing support, advocating for their needs, and facilitating positive change in their lives through the structured process of case management.

passion is equally important but difficult, if not impossible, to teach. As an individual who created a case management company, I needed to hire and train staff. However, I was often frustrated by an inability to determine a candidate's ability to truly connect with patients...and their passion for the work they would be doing. There are essential skills for case managers, and whether you are an entry-level case manager or a more experienced one seeking to improve your performance, recognizing the following skills is imperative:

- · Effective communication
- Assessment skills
- Problem-solving abilities
- · Organizational skills
- Empathy and compassion

There are specific strategies to develop proficiency in each of these aforementioned skills, but how can we evaluate passion, and is passion something that can be taught? Or is passion something that can be encouraged? Let's take a look at some components that would describe passion, specifically passion in case management:

• **Desiring to help others:** The specific desire needed is to work

- with diverse populations especially those who have significant medical challenges, mental health issues, chronic diseases, substance abuse, or homelessness. These are the individuals who often fall through the cracks in our increasingly complex systems. It is the case manager who often possesses the determination and expertise to respond to and resolve their problems.
- Solving problems: Facing problems, challenges, and barriers is frequently what motivates the passionate case manager, and the exploration of creative and "out of the box" solutions that are identified for the best possible outcome.
- Learning new things: Case managers enjoy and seek the process
 of continuous learning and recognize that it's often the discovery
 of new resources in related fields
 that expand one's knowledge and
 expertise.
- Building relationships: Establishing collaborative relationships with the various stakeholders, especially those outside of one's practice

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CERTIFICATION OF DISABILITY MANAGEMENT SPECIALISTS COMMISSION

THE COMMISSION FOR CASE MANAGER CERTIFICATION

Advocating for Clients With Chronic Health Issues and Disabilities Into Retirement and Other Career Transitions

By Ed Quick, MA, MBA, CDMS; Stan Scioscia, MEd, CRC-R, CDMS; and Jeannie LeDoux, RN, BSN, MBA, CCM, CPHQ, CTT+

Note: This article is based on a group presentation made by the authors at the Commission for Case Manager Certification's 2024 Virtual Symposium held in mid-October.

etirement is a highly personal decision made in the context of several factors, including one's age, health status, and financial resources such as retirement savings or pensions. These same factors come into play when advocating for clients with disabilities, chronic health issues, or other conditions and who wish to explore retirement and other career transitions.

What retirement looks like, and whether it is financially feasible, will vary from person to person. In addition, plans that people have made earlier in their lives may suddenly be set aside because of physical or mental health issues. For board-certified professionals such as Certified Case Managers (CCM) and Certified Disability Management Specialists (CDMS), empathy, awareness, and understanding are essential tools to help their clients weigh their options and navigate into the next phase of their lives.

Retirement goals and planning may not result in what becomes reality. Personal or family issues, changes in health status, or even a shift in perspective can trigger decisions around retirement. For example, research by the <u>Transamerica Center for Retirement Studies</u> revealed that nearly half (49%) of people identified as being

"middle class" say they plan to work beyond the traditional retirement age of 65, including 15% who say they do not plan to retire at all. Despite those expectations, however, the study also showed that, among middle-class people who have retired, the median age at which they entered retirement was 62.

One of the reasons people cited for retiring sooner than expected was health issues. According to other research older workers with chronic health conditions are more likely to pursue early retirement. What happens when they leave the workforce, however, is often determined by their financial stability and available income, including retirement savings in the form of pensions or 401(k) accounts.

Under Social Security rules, age 62 is considered "early retirement" and monthly Social Security payments will be lower than if an individual delays retirement until age(s) 66 (for those born from 1943 to 1954); up to 67 (for those born from 1955 to 1960); and 67 (for those born in 1961 and later). As a result, individuals who want to pursue early retirement must rely on retirement savings or other financial resources to bridge the gap.

Some people, however, face a significant financial burden because of insufficient retirement savings. It may be that their health status has made it hard for them to work full-time or they have experienced several work interruptions because of their health—all of which reduce their retirement savings and the amount they potentially receive from Social Security.

As Certified Case Managers and Certified Disability Management Specialists, our role is not to provide financial or retirement planning advice. However, as advocates, we do



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

Stan Scioscia, MEd, CRC-R, CDMS, is a former CCMC Commissioner and has spent more than 40 years in the disability management



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Jeannie LeDoux, RN, BSN, MBA, CCM, CPHQ, CTT+, is a former Commissioner and a past Chair of the CCMC. She has worked with diverse

cultures and with special needs and complex medical issues and has extensive experience working with the military.

Even when someone has reached retirement age, it cannot be assumed that they have sufficient resources to provide for themselves and their families/dependents.

need to look at the whole person. When workers have chronic health issues or disabilities and are considering retirement, it's important to take financial stability into account as part of our assessment and planning. For example, clients should be encouraged to also seek assistance from financial counselors when making informed decisions to provide a "soft landing" for themselves into retirement.

Retirement Resources Vary by Demographics

We cannot make assumptions about our clients' retirement plan participation or retirement savings. Demographic factors, including race and gender identity, can contribute to disparities in retirement account balances. A U.S. Government Accountability Office (GAO) report found that 63% of white households had a retirement account balance in 2019 compared to about 41% across households of all other races. Among those with retirement accounts, white households had median balances of about \$164,000, about twice the amount held by households of all other races (about \$80,000). One potential reason for this disparity, the GAO report stated, was the significantly higher median income among white households compared to other races.

In addition, according to the <u>Center for LGBTQ Economic Advancement</u> & <u>Research</u>, 49.8% of LGBTQ+ individuals have assets in a 401(k) or other employer-sponsored retirement plan, compared with 58% of individuals in the general population. The National Council on Aging and the LeadingAge LTSS Center at UMass

Boston reported that LGBTQ+ older adults often earn less money and face greater difficulty paying their bills than non-LGBTQ+ counterparts. The National Council on Aging also reported LGBTQ+ individuals are more likely to be forced into retirement due to lack of available work or health problems.

Awareness that such disparities exist is an important starting point for case managers and disability managers who are advocating for individuals contemplating retirement or other career transitions, such as from full-time to part-time work. Even when someone has reached retirement age, it cannot be assumed that they have sufficient resources to provide for themselves and their families/dependents. In addition, those retiring before age 65 may not be able to afford to participate in employer-sponsored health plans offered through COBRA.

Employer Resources

When navigating retirement and other career transitions, employer resources such as an Employee Assistance
Program (EAP) can be very helpful and informative. EAPs are offered by many companies, particularly large employers, and provide confidential help in such areas as mental health counseling, financial planning, wellness, childcare and eldercare, and referrals to services. Encouraging individuals to reach out to their EAPs is an excellent starting place to determine what help may be available.

For individuals with a chronic health issue or a disability, who are not able to be accommodated at work and who cannot retire at this time, other benefits may help provide a cushion (after accrued sick leave and vacation/PTO are exhausted). Short-term disability is, as the name implies, a short-term income replacement benefit that provides a percentage of an individual's earnings. However, not all employers offer short-term disability as part of their benefits package or on a voluntary/contributory basis. In some states, state disability insurance is a statutory requirement, and all workers participate via payroll deduction. Overall, voluntary plan designs can vary significantly, such as 100% of base earnings for a period of time, after which benefits drop to 50-70%, for up to a total of 26 weeks.

Similarly, long-term disability provides a percentage of wage replacement (normally 50% to 70%) when an individual cannot work for an extended period of time due to a non-occupational injury or illness. These benefits can also serve as a bridge to secure Social Security Disability Income (SSDI) benefits, and many long-term disability carriers will help employees with the SSDI application. Once SSDI is received, many long-term disability benefits will be reduced. Once individuals (under age 65) are approved for SSDI because of a recent disabling condition, they have a two-year waiting period for Medicare benefits, during which time they need to explore other health coverage.

In addition, 13 states and the District of Columbia have enacted mandatory paid family leave systems, and an additional nine states have voluntary programs. These leaves can be most beneficial to clients whose

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CMSA's CM Week 2024 Wrap-Up

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

he Case Management Society of America (CMSA) recently celebrated Case Management Week (CM Week) 2024 with a series of virtual events, uniting case managers under the theme "Case Managers...Powering the Future of Healthcare." This week-long celebration recognized and empowered case managers across the healthcare continuum, emphasizing their essential roles in patient advocacy, care coordination, and improving healthcare outcomes. If you missed the October festivities, CMSA has scheduled additional events for December, alongside a special announcement for their 35th-anniversarv celebration in 2025.

CM Week 2024 offered diverse opportunities for case managers to learn, network, and develop professionally. The week began with the Case Manager Mixer on October 14, hosted by CMSA President Janet Coulter, where participants reflected on their achievements and celebrated their impact on healthcare over the past year. On October 15, Michael Garrett, MS, CCM, CVE, and Ellen Fink-Samnick, DBH, MSW, LCSW, ACSW, CCM, presented Advancing DEIB and Health Equity in Professional Case

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In celebration of CMSA's 35th anniversary, CMSA members can enjoy a \$35 discount on registration for the CMSA National Conference in Dallas, Texas, scheduled for June 24–27, 2025.

Management Practice, emphasizing the need for equitable care. The Primary Care and Behavioral Health: "Better Together" webinar, presented by Jin Yoon-Hudman, MD, on October 16, highlighted the importance of integrating behavioral health into primary care to provide holistic, patient-centered support.

On October 17, the AI & Ethics: Exploring Intelligence and Integrity in Case Management panel tackled the ethical considerations of using artificial intelligence in case management, discussing how AI can enhance decision-making while maintaining data privacy. The week also offered a focus on self-care with a Chair Yoga Mini-Webinar on October 18, led by Sarah Stevenson, LICSW, NSW-C, CCM, reminding busy case managers of the importance of prioritizing their well-being. The celebration concluded with the Case Manager Collaboration session on October 19, where professionals shared best practices, insights, and personal stories, reinforcing the importance of collaboration in achieving high-quality patient care.

In addition to the main CM Week events. CMSA offered bonus sessions in October for those interested in furthering their knowledge. These included Making the Case: Strategies

to Showcase Your Value on October 9, Transforming Healthcare: The Legislative Impact on Client Care on October 22, and Navigating Client Access to Care in Rural Communities on October 30, each addressing crucial challenges and skills for today's case managers.

Looking ahead, CMSA continues to support the case management community with new opportunities and resources. Applications are now open for the prestigious CMSA Fellow designation, which honors individuals who have made significant contributions to case management through leadership, research, or e0ducation. Please take some time to review the Fellow application and thoughtfully consider applying!

Additionally, in celebration of CMSA's 35th anniversary, CMSA members can enjoy a \$35 discount on registration for the CMSA National Conference in Dallas, Texas, scheduled for June 24-27, 2025. This conference will offer workshops, keynotes, and networking sessions, marking a milestone in CMSA's history. This event is always a highlight of my year, both professionally and personally and I would love to see everyone there!

Legal Updates

By Elizabeth E. Hogue, Esq.

Connecticut Takes Action to Protect Workers Who Provide Services in Patients'/Clients' Homes

year after registered nurse Joyce Grayson was killed while visiting a client who was a convicted sex offender at a halfway house, the Connecticut legislature has taken action to help ensure the safety of workers who provide services in patients' homes. Public Act 24–19, Substitute Senate Bill No. 1, became effective on October 1, 2024, and provides as follows:

- · Home healthcare and home health aide agencies, except for hospices, must collect certain information during patient/client intake for both the patient/client and the location where services will be provided. Information collected must be given to employees assigned to the patient/client. Agencies may not, however, deny services based solely on the information provided, or the inability or refusal of patients/clients to provide requested information. Agencies must gather information about patients'/ clients' history of violence against healthcare workers, domestic abuse, and substance abuse. Intake staff must also prepare a list of patient/client diagnoses, including psychiatric history, whether the diagnoses or symptoms have been stable over time, and information on violent acts involving patients/ clients from judicial records or sex offender registries. Regarding services location, agencies must
- Elizabeth E. Hogue, Esquire, is an attorney who represents healthcare providers. She has published 11 books, hundreds of articles, and has spoken at conferences all over the country.

- gather information about the municipality's crime rates; presence of hazardous materials, including used syringes, firearms, or other weapons; other safety hazards; and the status of fire alarm systems.
- Home health agencies, except for hospices, must conduct safety assessments at monthly staff meetings with staff who provide direct care and comply with other workplace training requirements related to safety. Agencies must provide annual training based on curriculum endorsed by the Centers for Disease Control and Prevention, National Institute of Occupational Safety and Health, and Occupational Safety and Health Administration. This training includes how to recognize and manage common home care workplace hazards, and practical ways to manage risks and improve safety. Reimbursement from the Medicaid Program is conditioned on compliance with the training requirements. The Medicaid Program may give "rate enhancements" to those agencies that report workplace violence incidents on a timely basis.
- Home health agencies, except for hospices, are required to report patients'/ clients' verbal threats, abuse, or similar incidents to the Department of Public Health on an annual basis. Agencies must report every instance of patients'/ clients' verbal abuse that staff members perceive as threats of danger, physical or sexual abuse, or any other abuse of staff

- members. Agencies must also report actions taken to ensure affected staff members' safety.
- The state is required to create a grant program for home health agencies to provide escorts and to purchase technology for staff safety checks. By January 1, 2025, the state must establish a program to give incentive grants on or before January 1, 2027, for home health agencies to provide safety escorts for staff providing home visits and ways for staff to perform safety checks. The latter may include mobile devices that allow staff to communicate with local police and others in emergencies or GPSenabled wearable devices that allow staff to contact local police.
- Public Health Committee chairpersons are required to convene working groups on staff safety issues for home health agencies and hospices. The Committee must report its findings no later than January 1, 2025.

Providers in states other than Connecticut may wish to use this new law as a "road map" for their efforts to protect workers.

Referral sources, including discharge planners/case managers, clearly have an important role to play in assisting providers of services to patients/clients in their homes to obtain complete, accurate information to help ensure clients'/patients' safety.

These requirements place potentially significant financial burdens on providers of services to patients in their homes. Whether these requirements will improve the safety of workers remains to be seen. Surely, however, the protection of workers is high on the list of every agency's obligations.

Legal Updates

By Elizabeth E. Hogue, Esq.

What To Do When Patients/Clients Don't Want Caregivers of Certain Races or Nationalities

he Equal Employment Opportunity Commission (EEOC) sued ACARE HHC, Inc. doing business as Four Seasons Licensed Home Health Care Agency in Brooklyn, New York. The EEOC claimed that the Agency removed home health aides from work assignments based on their race and national origin to accommodate patients'/ clients' preferences in violation of the Civil Rights Act of 1964 /EEOC v. ACARE HHC d/b/a/ Four Seasons Licensed Home Health Care, 23-cv-5760 (U.S. District Court for the Eastern District of New York)].

This case recently settled, and Four Seasons will pay \$400,000 in monetary relief to affected home health aides. The Agency must also update its internal and training processes related to requirements of the Civil Rights Act, stop assigning home health aides based on patients'/ clients' racial or nationality preferences, and provide semi-annual reports to the EEOC about any reports or complaints received about discrimination.

According to the EEOC, Four Seasons routinely responded to patients'/clients' preferences by removing African American and Latino home health aides based on clients' preferences regarding race and national origin. Aides removed from their assignments were transferred to new assignments, if available, or, if no other assignments were available, would lose their employment altogether. The lawsuit asked for both compensatory and punitive damages and for an injunction to prevent future discrimination based on race and national origin. The EEOC says, "Making work

assignment decisions based on an employee's race or national origin is against the law, including when these decisions are grounded in preferences of the employer's clients."

As many providers know, patients'/ clients' preferences for or against caregivers of certain races or nationalities are common. Experienced managers have been asked by patients not to provide caregivers who are, for example, "foreign." Such requests should generally be rejected, especially when they involve discrimination based on race, national origin, religion, or any other characteristic commonly used to treat groups of people differently. Legally and ethically, providers should not engage in such practices.

There is one exception to this general rule that occurs when patients ask for caregivers of the same sex as the patient/client based on concerns about bodily privacy. It is then acceptable to assign only same-sex caregivers to patients who have made such requests.

In addition to concerns about discrimination, providers must also be concerned about risk management when they honor such requests. Especially in view of increasing staff shortages, limitations on available caregivers may mean that patients'/ clients' needs cannot be met by staff members who are acceptable to patients. In view of staffing shortages, the fewer caregivers who are permitted to care for certain patients/clients, the more likely it is that patients'/clients' needs will go unmet. Unmet patient needs are, in turn, likely to significantly enhance the risk associated with providing care to patients.

Perhaps the pressure to honor

patients'/clients' requests is at its greatest when patients receive services at home. Patients who will accept any caregiver assigned to them in institutional settings somehow feel that they have the right to decide who may provide services in their homes. On the contrary, with the exception noted above, staff assignments should be made without regard to patient/client preferences for services rendered at home, just as assignments are made in institutional settings.

How should managers respond when patients tell them not to assign any "foreign" nurses to them? First, they should explain that the organization does not discriminate and that to avoid assignments based on cultural or racial background may constitute unlawful discrimination. Then staff should explain that if limitations on caregivers were acceptable, the provider may be unable to render services to the patient at all because they may not have enough staff. The bottom line is that staff will be assigned without regard to patient/client preferences to prevent discrimination and to help ensure quality of care.

Patients'/clients' requests and managers' responses must be specifically documented in patients'/clients' charts. Documentation that says patients/clients expressed preferences for certain caregivers or rejected certain caregivers is too general. Specific requests and responses of management must be documented.

After patients have expressed what may amount to prejudice against certain groups of caregivers, managers must follow up and monitor for inappropriate behavior by patients directed at caregivers who are not preferred. Managers should be alert to the potential for this problem and should follow up with patients/clients

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Exam expires on June 15, 2025



Spirituality in Healthcare: A Primer for Case Managers

Elaine Bruner, MSN, RN, CMGT-BC

Scenario

Jim is living with malignant melanoma and has received multiple treatments over the last two years. His caregiver and support system includes his wife, three adult children, his golf buddies, and his Christian faith community. During your home visit, Jim states, "I feel like God has abandoned me." How would you respond? Are you comfortable exploring this feeling with Jim? Or are you unsure how to proceed?

Overview

Let's discuss the spiritual influences that may affect an individual's health, care choices, and outcomes. Seventy-seven percent (77%) of patients want their healthcare team to incorporate their spiritual needs into the care plan, according to the National Cancer Institute (NCI, 2023). Spirituality is a key element in whole-person-centered care, not just an end-of-life issue. Elements to consider are:

- Acknowledgement of your religion, faith, and spirituality traditions
- Sensitivity to a person's religion, faith, and spirituality traditions
- Advocacy for those with differences

Assessing spirituality is more than "checking the religious preference" box on an intake or admission assessment, and it can be a hard conversation. Preparing yourself includes understanding the definitions of religion, faith, and spirituality, acknowledging directives and codes that address spirituality, plus exploring beliefs regarding mortality, suffering, and healthcare decision-making.

Defining Religion, Faith, and Spirituality

There are plenty of definitions; these are offered as a starting point:



Elaine Bruner, MSN, RN, CMGT-BC, is a Nurse Case Manager with the Navy Special Warfare Development Group, Virginia Beach, VA, and a recognized leader in case management.

Spirituality is a key element in whole-personcentered care, not just an end-of-life issue.

Religion: Personal set or institutionalized system of religious attitudes, beliefs, and practices

Sacraments, ceremonies, prayers, and traditional observances

Faith: Trusting in something you cannot explicitly prove

- Strong or unshakeable belief without proof **Spirituality**: A broad concept of belief in something beyond the self. A holistic belief in an individual connection to others and the world as a whole
- Refers to that which gives meaning, purpose, and hope in life

Consider that a person can be spiritual and not religious. Religion includes clerical hierarchies, sacred language, religious texts, feasts, and rituals. Spirituality can be whatever or whoever gives ultimate meaning and purpose to one's life. Another description is a connection to others and the world. Faith is more fluid in its definition; it is believing in something you cannot see, hear, or touch. This belief does not need evidence or proof. Case managers aren't experts in every religious, faith, or spiritual tradition. However, these traditions affect coping with health challenges and an individual's response to care and treatment. Acknowledge what you don't know and be willing to broaden your scope of learning.

Next, what regulations and codes address spirituality? CCMC Code of Conduct and Ethics, Principle 2, states, "Board-certified case managers will respect the rights and inherent dignity of all their clients" (CCMC, 2022). Self-determination means that individuals exercise autonomy in decision-making, including spiritual influences. The Case Management Body of Knowledge (CMBOK) reinforces autonomy as the heart of an American's citizens' cultural identity; honoring it means that you respect one another's choices, decisions, and behaviors as long as they are lawful and don't pose an unreasonable risk of injury to the individual and others (CCMC, 2018).

Assessing spirituality is more than "checking the religious preference" box on an intake or admission assessment, and it can be a hard conversation.

The American Nurses Association (ANA) Code of Ethics with Interpretive Statements states, "The nurse provides services with respect for human dignity and the uniqueness of the client unrestricted by considerations of social and economic status, personal attributes, or the nature of health problems" (ANA, 2023). The Code defines "optimal nursing care" as enabling the patient to live with as much physical, emotional, social, and religious or spiritual well-being as possible and reflecting the patient's values (ANA, 2023).

The National Association of Social Workers (NASW) Code of Ethics discusses that social workers treat each person with care and respect, mindful of individual differences and cultural and ethnic diversity. Social workers promote clients' socially responsible self-determination. Social workers seek to enhance clients' capacity and opportunity to change and address their own needs (NASW, 2021).

The Case Management Society of America (CMSA) Standards of Practice include Guiding Principles that outline a collaborative partnership that is responsive to the individual client's culture, preferences, needs, and values. These Principles focus on a comprehensive and compassionate approach to care delivery that integrates a client's medical, behavioral, social, psychological, functional, and other needs. Other needs certainly encompass religion, faith, and spirituality (CMSA, 2022).

The Joint Commission does not prescriptively require a spiritual assessment. It does state that hospitals and facilities are accountable for maintaining patient rights and providing accommodation for cultural, religious, and spiritual values.

Now that definitions, codes, and directives are outlined, what spiritual practices, beliefs, or traditions influence individual healthcare decisions or choices?

Decisions, Choices, and Beliefs

Case managers recognize that individuals base their healthcare decisions on cultural preferences, morals, and religious beliefs such as:

- Only female providers for women (Islam)
- No embalming or cremation (Judaism)
- No blood transfusions (Jehovah's Witness)

Additional beliefs surrounding suffering may influence individual choices. Perceptions of suffering influence decisions. Suffering is described as the state of undergoing pain, distress, or hardship. Christian beliefs acknowledge that suffering is real and attributed to the sinful nature of humanity. Muslims view suffering as both a punishment for sin and a test of faith. Jewish tradition holds that suffering is a result of one's actions. Hindus view suffering as a consequence of a person's actions, committed in this life or a past one (Brenner, 2017).

Understanding these choices, respecting spiritual practices, and being open to additional discussions enhance spiritual well-being and ensure that healthcare delivery doesn't violate an individual's religion, faith, or spirituality.

Two additional spiritual concepts are spiritual distress and moral injury. Spiritual distress is a conflict between an individual's beliefs and what is happening. It's a disturbance in their value system. Feelings of shame, grief, hopelessness, or abandonment are symptoms of spiritual distress. A person may ask why is this happening to me? What's the meaning of my suffering?

Moral injury is a deep emotional wound involving a cognitive or emotional response to events that violate a moral ethical code. Moral injury arises from exposure to situations that profoundly conflict with one's ethical or moral beliefs, often experienced through actions, decisions, or witnessed events that transgress one's moral framework (McGillivray, 2024). Moral injury has been associated with military members, but it affects healthcare professionals, too. Consider the impact of the pandemic on healthcare workers who had a professional obligation to provide care while experiencing threatening situations. They recognized the ethically correct action but were unable to act due to internal or external constraints. Anger, guilt, fear, shame, and exhaustion are common symptoms of moral injury.

By considering individuals' choices, decisions, and beliefs through a spiritual assessment, how can we initiate a comprehensive and compassionate conversation? Is there a tool or technique to guide us?

Guiding the Spiritual Conversation

The spiritual assessment and conversation are about what matters to the person. The FICA Spiritual History Tool is an example with sample questions to guide a conversation on spiritual issues. The transdisciplinary team can use the tool in diverse healthcare settings. The FICA acronym helps structure questions to cover a wide range of spiritual preferences (Pulchalski, 2002).

FICA SPIRITUAL HISTORY TOOL

Faith—Does the individual identify with a particular religion or spiritual belief?

- Do you have spiritual beliefs that help you cope with stress?
- If the patient responds "no," consider asking: what gives your life meaning?

Importance—Appreciate the influence of spirituality in the individual's life and healthcare decisions.

 Have your beliefs influenced how you take care of yourself in this illness?

Community—Is the individual connected to a religious or faith community? Do you rely on that community for support?

- Are you part of a spiritual or religious community?
- Does this offer you support, and how?

Address/Action in Care—Discuss and coordinate essential key issues with the individual and their healthcare team.

 How would you like me to address these issues in your healthcare?

Case managers acknowledge that open-ended questions deliver more complete and valuable answers. Consider how to offer these questions in the FICA conversation. Here are examples of other questions to ask:

- **F**-During a crisis, people look to all kinds of support, including faith or spirituality. What is your support? Where do you find meaning in your life? What gives you hope?
- **I–**How does your faith or spirituality influence your healthcare choices or decision-making?
- **C**–How does your faith community support you? What group of people are important to you and serve as support? (This question can be asked to those who don't identify with a faith community.)
- **A–**How would you like your healthcare team to address and include your spiritual issues in your care?

Whole person-centered care addresses the biological / psychological / social / cultural / spiritual issues of each individual. Respecting their spiritual practices establishes trust and awareness of what matters to the individual.

Next, consider how case managers can integrate a spiritual assessment and spiritual care interventions.

Integrating Case Management Strategies

The George Washington Institute for Spirituality and Health offers these guidelines when completing a spiritual assessment (Puchalski, 2024):

1. Regard spirituality as a potentially important component of every patient's physical well-being and mental health.

- Address spirituality at each complete physical examination and continue addressing it at follow-up visits if appropriate. In patient care, spirituality is an ongoing issue.
- 3. If a patient presents with distress, the clinician should always assess for psychosocial and spiritual distress as well as physical.
- 4. Respect a patient's privacy regarding spiritual beliefs; don't impose your beliefs on others.
- 5. Make referrals to chaplains, spiritual directors, or community resources as appropriate.
- 6. Be aware that your own spiritual beliefs will help you personally and will overflow in your encounters with those for whom you care to make the case manager-patient encounter a more humanistic one.

Whether using a spiritual history tool or asking appropriate open-ended questions, be an attentive listener. Be present—sit down to engage in conversation. Too many healthcare discussions occur with the team standing over the individual. This is not the posture for a spiritual discussion. A nursing colleague shared that her organization has implemented a "Commit to Sit" initiative; this seems to be a caring approach for many healthcare conversations. Direct eye contact is part of this presence. Making this connection says, "You are not just a patient but a human being." Another factor is sympathy. Sympathy is a mental understanding in which the case manager can facilitate appropriate spiritual interventions and resources. Case managers offer human contact and social connection where isolation and disconnections are common in the healthcare environment.

What about Jim and his feeling that he has been abandoned by God? Jim is experiencing spiritual distress. He may wonder where his strong, sustaining faith went, and if there is suffering, what good will result. Using the FICA Spiritual History tool, his case manager concludes that Jim's faith is central to his daily life. His family is involved with youth group, choir, and monthly potluck dinners. Due to his cancer treatments, Jim hasn't participated in these activities nor attended services in the last year. His Christian pastor visits monthly, and Jim wishes he would visit more frequently. He feels lonely and isolated, even though his family is attentive. Actions and opportunities for his case manager include:

- Acknowledging that cancer treatments can result in side effects that lead to social isolation
- Discovering how Jim's faith guided his treatment decisions and healthcare choices
- Exploring if services are offered in a virtual platform and if Jim's pastor can visit more frequently
- Involving Jim's family; do they enjoy reading together, board games, or playing cards?
- Encourage Jim to contact the church men's group, or his

Consider that a person can be spiritual and not religious. Religion includes clerical hierarchies, sacred language, religious texts, feasts, and rituals. Spirituality can be whatever or whoever gives ultimate meaning and purpose to one's life. Another description is a connection to others and the world.

golf buddies, to have social engagement. Even though he can't participate in in-person events, feeling like he still belongs addresses the disconnection and loneliness

Jim expresses gratitude to the case manager for their willingness to have this discussion about his spirituality and faith.

Summary

Mother Teresa said, "Listening when no one else volunteers to listen is no doubt a very noble thing." Case managers are consummate listeners, meaning that they can have hard conversations like religion, faith, and spirituality. These essential discussions reduce anxiety, offer comfort, decrease stress, and improve an individual's healthcare outcome. Spirituality will help people in (Astran, 2021):

- Maintaining a healthy mindset
- · Believing in the treatment plan
- · Believing in healing
- Creating a better quality of life

Unfulfilled spiritual needs lead to spiritual distress resulting in poor health outcomes. Case managers possess the knowledge, skills, and abilities to impact an individual's healthcare journey through spiritual assessment, care, and intervention.

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Music Therapy and Health Part 1

By Dawn A. Iwamasa, PhD, CCLS, MT-BC; and Flor del Cielo Hernandez, PhD, MT-BC

usic therapy is an allied health profession whereby a credentialed music therapist uses music to aid in growth and development, health maintenance, or recovery from health-related problems. For example, a music therapist will design music interventions to "promote wellness, manage stress, alleviate pain, express feelings, enhance memory, improve communication, promote physical rehabilitation, and more" (AMTA, 2005, para 1). While music therapy has been a profession since 1950 (Geist et al., 2018), it continues to be somewhat unrecognized and misunderstood in healthcare settings. This article is the first of a two-part series and will provide an overview of the profession, including the history of music therapy in the United States, training, certification, and benefits/outcomes of music therapy treatment.

History

The use of music for well-being has its roots in antiquity and its uses varied throughout history, depending on whether the cause and treatment of disease was magical, religious, or philosophical (Sigerist, 1943). The idea that music influences one's nervous system through emotions and mental states was first referenced in literature dating back to 1789, the same year George Washington took office as president of the United States (Heller, 1987). In 1796, the New York Weekly Magazine published an anecdotal story of a man whose fever-caused delirium disappeared while listening to a concert; however, symptoms returned once the music ended. The phenomenon occurred day-after-day until the symptoms eventually subsided (Heller, 1987). By the 19th century, physicians were treating physical and mental illnesses such as depression, mania, and pain with music (Heller, 1987).

Events of the 20th century were instrumental in the development of what is now the profession of music therapy. Between World War I (1914-1918) and World War II (1939-1945), the use of music in hospitals expanded as volunteer musicians played for convalescing soldiers in Veteran Administration Hospitals (Gilliland, 1944). In 1919, Columbia University offered the first university course in

"musicotherapy" to "cover the psychophysiological action of music and to provide practical training for sound therapeutic treatment under medical control" ("Columbia University to Heal Wounded by Music", 1919, p. 59). The course description indicated a strong alignment with medical practice and a prescriptive use of music for specific ailments. The curriculum was taught by the instructor Margaret Anderton, a musician who worked with Canadian soldiers who were prescribed music for war-neurosis, aphasia, temporary insanity, and paralysis ("Columbia University to Heal Wounded by Music," 1919). Anderton was also noted as saying that just "playing for soldiers" was not musicotherapy, suggesting the need for specific training and expertise.

After World War II, musicians continued to perform in Veteran hospitals to increase morale and provide recreation for recovering soldiers returning from war (Davis et al., 2018; Robb, 1999). Medical personnel noticed patients experienced positive physical and emotional responses (van de Wall, 1944), which created a demand for hiring staff musicians with additional training beyond musicianship (AMTA, n.d.-a). Thus, the first music therapy degree program was opened in 1944 at Michigan State University (AMTA, n.d.-a; Davis et al., 2018). However, music in the hospital setting continued to be viewed primarily as an "activity" rather than a treatment; medical professionals were cautious of making strong claims of music's effectiveness, and the use of music as therapy continued to be overlooked as a professional field (Boxberger, 1963). Leaders in the music therapy movement recognized the need for a governing body to eradicate the



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The use of music for well-being has its roots in antiquity and its uses varied throughout history, depending on whether the cause and treatment of disease was magical, religious, or philosophical.

"quackery and charlatanism" (Boxberger, 1963, p. 148) and to oversee curriculum requirements, scientific procedures, and dissemination of worthwhile literature (Boxberger, 1963).

The second half of the 20th century brought substantial developments in the organization and education of music therapists, including the formation of professional organizations, establishment of peer-reviewed journals in music therapy, formalized education and clinical training standards, and a national board certification. As medicine progressed to become more scientific through evidence-based practice, so did the use of music in the medical setting. An analysis of published articles about music therapy in peer-reviewed English language journals from 1964 to 2001 discovered 1,521 articles, 42% of which were either quantitative or qualitative research studies (Brooks, 2003). The analysis also found that the numbers of research studies published over time steadily increased. The growth in research and clinical reporting corresponded with the rise of evidence-based practice through the 1980s and 1990s.

Education and Training

In 1975, there were two professional organizations in music therapy, the National Association for Music Therapy (NAMT) and the American Association for Music Therapy (AAMT), each with different philosophical approaches, training models, and credentials. Having multiple credentials proved to be confusing for consumers to navigate, and advocacy efforts to promote the profession were diminished without a unifying voice. To unite the profession, streamline education and training, and create a single entry-level credential, the two organizations merged to form the American Music Therapy Association, (AMTA) in 1998 (Aigen & Hunter, 2018; Davis et al., 2018). Today, AMTA is the sole governing body that sets the standards for music therapy education and training in the United States.

The content and requirements for music therapy educational programs have continued to evolve since the first degree program began in the 1940s. Every university program must be approved by AMTA, and currently there are 90 approved university degree programs in the United States (V. Vega, personal communication April 10, 2024). Education and training consist of a multidisciplinary study of music, the biological sciences, psychology, anthropology, and sociology (Gfeller & Davis, 2008).

Students must achieve specific competencies set by AMTA, either through a bachelor's degree program or one of two equivalency routes. Equivalency programs were developed for students who already have a bachelor's degree in music (eg, music education, music performance, etc.) and wish to pursue the equivalent of a music therapy degree, either at the bachelor's or master's level. For the undergraduate equivalency, students take coursework at the undergraduate level to satisfy the Professional Competencies (AMTA, 2013) not met by their existing music degree. For example, most students will take coursework in music therapy, clinical foundations, and functional music skills (AMTA, 2013). Much like the undergraduate equivalency program, the master's equivalency allows students to take coursework that fulfills the Professional Competencies and graduate coursework that fulfills the Advanced Competencies (AMTA, 2015) while completing a graduate degree.

Students must have a strong foundation in musicianship to apply in the clinical setting. Music foundations include courses in music theory, music history, one-to-one instruction on a primary instrument, and competencies in voice, piano, and guitar. Students also take classes in anatomy, psychology, neuroscience, and research methods. Moreover, students develop specific music therapy expertise through the study of music therapy theories, methodology, and techniques. Lastly, students are required to engage in hands-on experiences in the clinical setting through practicum rotations in which they demonstrate the treatment process through the development and implementation of treatment plans, music-based interventions, assessment, and documentation of progress. Clinical rotations are supervised by a Board-Certified Music Therapist and generally take place in the community at hospitals, schools, behavioral health centers, hospice services, and music therapy private practices. A minimum of 180 practicum hours must be completed alongside the coursework. Once students complete the required coursework and meets pre-internship competencies, they are eligible for an internship (AMTA, 2021b). The internship takes 6 to 9 months, during which the student fulfills the final required clinical training to equal 1,200 combined (including practicum) clinical hours (AMTA, 2021b).

MT-BCs are trained to create therapeutic environments where patients and their families can feel empowered, find autonomy, and gain a sense of agency during treatment.

Certification

Once all education and training requirements are met, the student becomes a candidate for the board certification exam administered by the Certification Board for Music Therapists (CBMT). The exam consists of 150 multiple-choice questions, and candidates are allowed 3 hours to complete the test (CBMT, 2022). When the candidate passes the exam, they may use the credential MT-BC, or Board-Certified Music Therapist. Each certification cycle lasts 5 years, in which time the MT-BC must accrue 100 continuing music therapy education credits to recertify. At present, there are more than 10,000 MT-BCs in the United States (CBMT, 2024).

Benefits and Outcomes

MT-BCs are trained to create therapeutic environments where patients and their families can feel empowered, find autonomy, and gain a sense of agency during treatment. They assist patients in processing emotions and thoughts related to their diagnosis, care, and prognosis. MT-BCs often work within multidisciplinary or interdisciplinary teams. The collaborative approach not only enhances patient outcomes but also fosters a sense of inclusion and teamwork among healthcare providers. Through various music therapy assessments, approaches, and techniques, MT-BCs design interventions to address a wide range of goals, including pain management, emotional regulation, anxiety reduction, illness management, and improved motor skills, such as maintaining a steady gait while walking.

As a well-established, evidence-based practice, music therapy has been shown to be effective across various healthcare settings, such as neonatal care units, hospitals, mental health facilities, community health care, and hospice, among other care delivery settings (AMTA, n.d.-b). Research indicates that integrating a music therapist into the healthcare team offers numerous benefits, including improved patient health outcomes and overall patient satisfaction. These benefits positively impact not only the patients but also the healthcare staff and the general perception of hospital or clinic services (Mao, 2022; O'Brien et al., 2021).

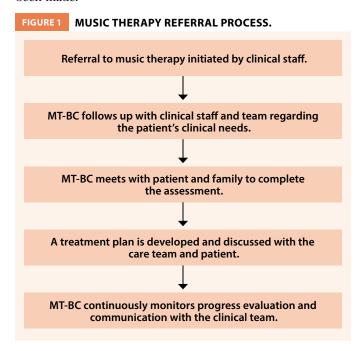
For example, a research team, including a music therapist and a nurse, found that patients in an emergency department who received music therapy reported lower pain levels

compared to those who did not receive music therapy (Mandel et al., 2019). Additionally, the emergency department staff reported improvement in their own caregiving experience and indicated they would recommend MT for use in the emergency department. Another study by Polascik et al. (2020) reported that listening to music before surgery helped reduce anxiety and pain perception in patients. Similarly, Stegemöller et al. (2017) found that singing interventions led by MT-BCs improved breathing, speech intelligibility, and mood in patients with Parkinson's disease. Music therapy also plays a significant role in enhancing social interaction and communication by providing a structured yet creative environment that encourages self-expression (Geretsegger et al., 2022).

Researchers have identified numerous benefits of music therapy, particularly in reducing anxiety and depressive symptoms, and enhancing emotional regulation and coping skills (AMTA, n.d.-b). Music therapy provides a valuable outlet for processing and expressing emotions, which can be particularly effective for individuals struggling with anxiety, depression, and PTSD. This therapeutic approach not only facilitates personal emotional expression but also promotes a sense of connection and community (Eyre, 2013; Silverman, 2022). Individualized therapy can target specific mental health challenges. Group sessions can help build social skills and create support networks (Eyre, 2013). The MT-BC's adaptability and their ability to provide different interventions, such as singing, active music making, improvisation, songwriting, and guided listening, makes music therapy an effective component for mental health care.

Referrals

Referrals to music therapy services need to closely align with specific clinical goals. The referral process for music therapy varies depending on factors such as the type of healthcare facility, the focus of care, the workload of the MT-BC, and the interdisciplinary team's communication processes and protocols. A healthcare provider, such as a doctor, nurse, or therapist, may refer a patient to music therapy after determining that the patient meets the clinical criteria for this intervention (Polen et al., 2017). The referral process for music therapy can vary depending on factors such as the type of healthcare facility, the focus of care, the music therapist's workload, and the communication dynamics within the interdisciplinary team. To enhance communication among team members, the music therapist might develop a referral form that includes key details such as the patient's diagnosis, reason for referral, suggested clinical goals, and proposed music therapy interventions (Polen et al., 2017). Figure 1 outlines the process of music therapy after the initial referral has been made.



Once the referral is made, the MT-BC will schedule and conduct a comprehensive assessment of the patient to determine whether music therapy is an appropriate and beneficial treatment option (CBMT, 2020). This assessment may consider factors such as pain management, emotional regulation, anxiety reduction, or the need for cognitive or motor skills enhancement. The decision-making process may also involve discussing the potential benefits and expected outcomes of music therapy with the patient and their family. During this initial session, the therapist evaluates the patient's needs, establishes therapeutic goals, and designs a personalized treatment plan tailored to the patient's unique circumstances.

Evaluating Progress

The MT-BC continuously monitors the patient's progress throughout music therapy and communicates the results to the referring healthcare provider. As an integral member of the care team, the MT-BC adjusts the therapy as needed to optimize treatment. The patient's progress is assessed through various methods, including observation,

physiological measurements, standardized tests, self-reports, and feedback from caregivers and other healthcare professionals (Polen et al., 2017). Each session is documented according to the facility's protocol (CBMT, 2020).

Funding

Funding for music therapy varies based on the location, type of facility where the music therapy service takes place, and the patient's diagnosis (Simpson, 2018). While there are many facilities that hire music therapists with "soft money" through donations and grants, there are examples of private and public sources of reimbursement as payment for music therapy services. The following is a list of possible funding sources for agencies and facilities that hire music therapists (Simpson, 2018):

- Medicare
 - Partial Hospitalization Programs (PHP)
 - Prospective Payment System (PPS): music therapy may be reimbursed through the bundle of services covered by the PPS
 - Minimum Data Set or Restorative Care in skilled nursing facilities
- Medicaid, Home and Community-Based Care Waivers: reimbursement is determined state-by-state
- Private insurance: Music therapists have successfully billed private insurance for music therapy interventions on a case-by-case basis

Music therapists are also employed by state and/or federal agencies such as school districts because music therapy is a related service under the Individuals with Disabilities Education Act, IDEA (AMTA, 2021a). Music therapists also work in some Veterans Affairs (VA) and military hospitals. Many music therapists are hired as part of a facility's operating budget and are generally included with support services such as social work and chaplains. Studies found that music therapy is cost effective (Chlan et al., 2018; DeLoach Walworth, 2005) and increases patient satisfaction (Mercier et al., 2023; Yinger & Standley, 2011), providing justification of services.

Music therapy is a recognized allied health profession where credentialed therapists use music to support various health-related goals, such as promoting wellness, managing stress, alleviating pain, and enhancing memory and communication. This article outlined the history of music therapy, tracing its roots from ancient practices to its formal establishment as a profession in the 20th century, including key developments like the first higher ed course at Columbia University and the creation of a unified professional organization. It also detailed the education and training requirements for music therapists, emphasizing the multidisciplinary studies and hands-on clinical experience. Additionally, the benefits of music therapy were highlighted, showing its

Music therapy provides a valuable outlet for processing and expressing emotions, which can be particularly effective for individuals struggling with anxiety, depression, and PTSD.

effectiveness in various healthcare settings and its positive impact on patient outcomes and satisfaction. Part II will dive deeper into music therapy clinical practice with specific intervention and case examples. CE2

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Wheelchair Seating Options: A Guide for Case Managers

By John V. Rider, PhD, MS, OTR/L, MSCS, ATP

Introduction

Selecting appropriate wheelchair seating options for clients is a critical task that directly impacts the comfort, mobility, and overall well-being of individuals with mobility impairments. As a case manager, understanding the various seating systems available is essential for making informed recommendations tailored to each client's unique needs. This knowledge is crucial because the right seating can prevent secondary complications, such as pressure sores and postural deformities, and improve functional abilities. This article provides an overview of the different wheelchair seating options, highlighting collaboration with appropriate rehabilitation professionals and key factors to consider.

The Interprofessional Team

In healthcare, providers can hold many credentials, signifying their specialized knowledge and expertise. Recognizing specific credentials among the interprofessional team is particularly important when addressing wheelchair seating, as it ensures that the most qualified professionals are involved in assessing, prescribing, and optimizing seating solutions to meet each client's needs. Rehabilitation professionals, such as occupational and physical therapists, play a pivotal role in the complex process of wheelchair seating, ensuring that individuals with mobility impairments receive the most appropriate seating solutions. Alongside occupational and physical therapy practitioners, Assistive Technology Professionals (ATPs) and Seating and Mobility Specialists (SMS) collaborate to enhance patient health and quality of life and prevent complications such as pressure sores. Occupational and physical therapy practitioners can attain certifications as an ATP and SMS; however, these examinations are also available for nonclinicians with certain levels of education and training in assistive technology and seating and mobility services. Professionals with the ATP credential are certified experts who specialize in assessing and providing assistive technology solutions including wheelchair seating and provide training in using the selected devices. While the ATP credential includes advanced knowledge and training in assistive technology in broad terms, the SMS credential is designated for those specializing in seating and

mobility. It recognizes demonstrated competence in seating and mobility assessment, funding resources, and outcome assessment and follow-up. A professional with the SMS designation is preferred when dealing with more complex seating issues. Case managers may also work directly with suppliers and manufacturers of wheelchairs and seating systems, including custom and over-the-counter options.

Importance of Proper Wheelchair Seating

Proper wheelchair seating significantly impacts health and well-being by promoting good skin integrity, ensuring comfort, preventing secondary complications, promoting positive self-esteem, and optimizing posture for daily activities. Inappropriate seating can lead to severe health issues, including pressure ulcers, spinal and postural deformities, and compromised respiratory and digestive functions. Effective seating solutions also help manage pain and enhance quality of life by allowing individuals to participate fully in social, recreational, and vocational activities, fostering optimal independence.

Pressure sores, also known as decubitus ulcers or bedsores, form when sustained pressure restricts blood flow to the affected area, leading to tissue damage and necrosis. These sores commonly develop over bony prominences such as the sacrum, coccyx, heels, and hips, where prolonged pressure can significantly impede circulation. However, they can develop anywhere, such as the back of the thighs or knees, with consistent pressure or friction due to improper seating. In addition to properly fitting wheelchairs and cushions, factors such as microclimate control, moisture management, friction and shear forces minimization, and regular repositioning to alleviate prolonged pressure can help reduce the risk of pressure sores.

Pressure sores can severely impact an individual's life,

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causing intense pain, infection, prolonged hospital stays, multiple surgeries, excessive financial strain, and reduced quality of life. They can also lead to severe and life-threatening complications such as sepsis and osteomyelitis. Effective wheelchair seating is a key component in preventing pressure sores by distributing weight evenly, reducing pressure points, and promoting proper posture, thereby maintaining skin integrity and overall health. Proper training on pressure relief methods, common pressure points, skin inspection, wheelchair and cushion maintenance, and transfer techniques is also necessary to prevent pressure sores and can be provided by rehabilitation professionals, such as occupational and physical therapists. Advanced pressure mapping techniques and specialized cushions can further enhance prevention strategies.

General Assessment of Client Needs

A comprehensive assessment of the client is essential for determining the most suitable wheelchair cushion. Factors to consider include those listed here.

Patient Mobility Level: Assessing the client's ability to reposition themselves is important. Those with limited mobility may require more supportive pressure-relieving cushions to prevent sores and maintain comfort. They may also require increased assistance from care partners.

B Assessing the skin condition and risk of pressure sores is fundamental. Clients with a history of pressure sores or fragile skin may need advanced pressure-relieving cushions. Several assessments, such as the Braden Scale, Norton Scale, and Waterlow Score, can be used to evaluate skin integrity and risk of pressure sores. Additionally, the Skin Changes at Life's End (SCALE) assessment helps evaluate skin changes and the potential for pressure sore development in terminally ill clients and can be useful for end-of-life care.

Postural Support Requirements: Assessing the client's posture and alignment helps determine the type of support needed to maintain an upright and functional position. Occupational or physical therapists will perform a MAT evaluation in which the individual's posture is assessed outside of a wheelchair to help determine appropriate postural supports while maintaining optimal levels of independence.

Comfort and Pain Management: Comfort is key, particularly for those spending extended periods in their wheelchair. Proper cushioning can alleviate discomfort and reduce

pain associated with prolonged sitting. Individuals should have the opportunity to test out different cushion types. ATPs or SMSs often have various cushion types for the client to try before making a final decision.

Lifestyle and Daily Activities: Understanding the client's lifestyle and daily activities helps to select a cushion that supports their functional needs. Active users may require different solutions compared to those with more sedentary lifestyles. It is also important to consider how long the individual will be in the wheelchair daily, what types of activities they will do in the wheelchair, and in what environments.

Functional Abilities: The client's functional abilities, such as transferring in and out of the wheelchair, should also be considered. Cushions facilitating easy transfers can enhance independence and safety, decreasing the need for care partner assistance. In contrast, some cushions may make it more difficult for clients to transfer independently, depending on their functional abilities. Considerations regarding whether the client or a care partner can maintain cushion maintenance are also important, as some cushions require high maintenance or daily adjustments to retain their pressure-relieving properties.

Pressure Mapping: For clients with complex needs, pressure mapping can provide detailed insights into pressure distribution and identify areas at risk for sores. Pressure mapping is a technology used in wheelchair seating that visually displays the distribution of pressure on a person's body when seated, typically appearing as a color-coded map on a computer screen, with different colors indicating varying levels of pressure intensity. During an evaluation, the client sits on a thin, flexible, pressure-sensitive mat placed on the wheelchair seat, which captures real-time data on pressure distribution to help clinicians identify high-pressure areas and optimize cushion selection and positioning to prevent pressure sores. Pressure mapping can also help clinicians modify existing cushions or create custom cushions for clients with asymmetrical or atypical sitting postures due to their medical condition. This technology has become less expensive over the years and is more readily available upon request. As costs continue to decrease, more clinics and therapists will have the ability to use this technology. Case managers can advocate for pressure mapping when working with complex cases, as most professionals specializing in wheelchair evaluations will have access

to a pressure mapping system.

Contexts: Multiple contexts can impact seating options. For example, the physical context, including direct sunlight, temperature, and moisture, can affect various cushion materials. In the social context, assistance from family, care partners, school or work personnel, and transportation must be considered. Lastly, sometimes referred to the institutional context, available funding, insurance coverage, and applicable legislation must also be given consideration. These contexts should be discussed with the client and within the interprofessional team.

Wheelchair Seating Options

In general, wheelchair cushions range from prefabricated planar and custom cushions to custom-contoured cushions, depending on the postural support needed. For most clients, prefabricated cushions are available and effective. In complex cases, custom-contoured cushions may be necessary. Planar cushions are flat cushions that rely on the material properties to conform to the body's shape. Contour cushions have prefabricated curved surfaces that more closely match the body's shape. Lastly, custom-contoured cushions are molded to fit an individual body, providing the greatest body contact. This article has categorized cushions as foam, gel, air, and hybrid for simplicity. However, it is important to note that there are various subtypes of cushions (eg, viscoelastic foam and viscous fluid gel cushions) beyond the level of content provided in this article).

Foam Cushions

Description and Costs

Foam cushions are among the most common and affordable options and are available in various densities and contoured designs. Prices typically range from \$20 to \$150 (costs vary depending on private pay, insurance coverage, and suppliers). They are generally designed for someone not sitting in their wheelchair all day, such as someone using them for transportation or limited use.

Pros

- · Lightweight and easy to transport
- Inexpensive and widely available
- Customizable to different shapes and sizes

Cons

- · Limited durability, may compress over time
- · If too soft or thin, the cushion may "bottom out," and the client will be in contact with the wheelchair seating base, increasing discomfort and risk of skin breakdown
- Less effective in pressure distribution compared with advanced options
- Require frequent replacement

Gel Cushions

Description and Costs

Gel cushions contain gel-filled compartments that provide excellent pressure distribution and comfort. Prices generally range from \$50 to \$200. These are typically designed for someone using their wheelchair for more than just transportation or limited use. General-use gel cushions provide less postural support than foam cushions. Advanced gel cushions with skin protection and positioning gel provide additional postural support at a higher cost.

Pros

- Better pressure distribution
- Good for temperature regulation
- · Enhanced comfort

- · Heavier than foam cushions
- Potential for gel leakage
- Gel often needs to be manually kneaded to ensure uniform distribution
- Can be affected by extreme hot and cold temperatures (viscous fluid gel cushions)
- Higher cost than foam cushions, especially when individuals need additional positioning

Air Cushions

Description and Costs

Air cushions use air cells to provide adjustable support and pressure relief and typically cost between \$100 and \$500. These are highly adjustable. Air cells can be added to the cushion, and users can adjust the level of inflation in the cushion. Clients will need training in adjusting and maintaining air cushions for proper pressure redistribution. These are designed for individuals sitting in wheelchairs most of the day and offer the greatest pressure relief.

- Excellent pressure relief
- Adjustable firmness for personalized comfort
- · Lightweight and portable

Cons

- Susceptible to punctures and
- Requires regular maintenance and air pressure checks
- Pressure varies with altitude
- Higher cost than foam or gel cushions

Hybrid Cushions

Description and Costs

Hybrid cushions combine materials such as foam, gel, and air, offering the benefits of multiple technologies. Prices vary widely, typically ranging from \$100 to \$600. These are designed for individuals sitting in their wheelchairs most of the day.

Pros

- Customized support and pressure relief
- Versatile and adaptable to different needs
- Enhanced comfort and durability

Cons

- · More expensive than singlematerial cushions
- Can be heavier and bulkier
- Requires maintenance and adjustment

In addition to the above categories, custom-molded cushions are available. Custom-molded cushions are designed specifically for an individual's body shape and postural needs, with costs often exceeding \$600. They provide optimal pressure distribution and maximum postural support and are highly customized for comfort and function. They are often utilized when a client has fixed deformities that need to be accommodated by the cushion. Custom-molded cushions have a high cost, longer production time, and limited adaptability to changes in body condition.

Cushion Covers

Another consideration with cushions is the cushion cover. Most clients will want at least two covers to wash one while having one on the cushion. There are also covers designed for individuals with incontinence to resist moisture and prevent the cushion from absorbing liquids, extending its life and making for easier cleanup. Covers must be replaced when worn or torn, as they can contribute to skin breakdown.

Cushion Lifespan

Wheelchair cushions typically have a lifespan of 2 to 4 years, though this can vary based on factors such as usage frequency, user weight, and the cushion's material and construction. Evidence suggests that user characteristics and how the cushion is used have a greater influence on cushion performance than the age of the cushion (Sprigle & Delaune, 2017). Over time, cushions can lose their structural integrity, leading to decreased pressure relief and increased risk of pressure ulcers. Clients and the healthcare team should regularly assess the cushions by looking for signs of wear, such as flattening, loss of support, or visible damage. Insurance coverage for cushion replacement generally requires documentation of medical necessity, which may include evidence of cushion wear, changes in the user's condition, or the development of pressure sores. Case managers should coordinate with therapists and wheelchair specialists to ensure timely replacement, leveraging proper documentation to support insurance claims and prevent gaps in essential seating support. A good rule is to replace cushions every 3 years unless the cushion is compromised earlier. While many factors influence a cushion's integrity, lifespans can differ for each cushion type. If properly maintained, air cushions often last

the longest, followed by gel and foam. Air cushions can last for many years as long as they can still hold air and do not have any material breakdown. Gel cushions may begin to feel uneven and rocky over time, indicating a replacement is necessary. Foam cushions can have permanent compression over time. If you pick up a cushion and an imprint of the person stays in it, it is probably time to get a new one.

Positioning Support in Cushions

In addition to foam, gel, air, and hybrid cushions, there are specialized cushions for additional postural support beyond the typical contoured cushion.

- Anti-Thrust Cushions: Anti-thrust cushions prevent the individual from sliding forward, promoting better posture and reducing the risk of pressure sores in the sacral area.
- Wedge Cushions: Wedge cushions are angled to promote anterior pelvic tilt, improve posture, and reduce pressure on the lower back and ischial tuberosities.
- Pommel Cushions: Pommel cushions feature a raised area between the thighs to prevent the user from sliding forward and to maintain hip alignment, reducing the risk of adduction contractures.
- Sacral Cut-Out Cushions: These cushions have a cut-out area at the sacrum to relieve pressure on the coccyx and sacral region, which is ideal for individuals with sores or pain in that area.
- Amputee Cushions: Amputee cushions are designed to accommodate individuals with limb amputations, providing support and balance by redistributing weight and pressure.
- Additional Positioning Aides: Additional positioning aides, such as arm/trunk supports, side supports, and lateral hip guides, can be added to the wheelchair to enhance stability and postural alignment, further reducing the risk of pressure sores and improving comfort.

Considerations for Selecting a Wheelchair Cushion

When exploring wheelchair and cushion options for a client, consider the following questions as a starting point:

- How long will the client be sitting on the cushion daily?
- Is the cushion comfortable enough for extended use? Stability
- Does the cushion provide sufficient stability to prevent
- Can the client perform movements like reaching without losing balance?

Skin Protection

- Does the cushion offer adequate pressure relief and reduce friction to prevent pressure sores?
- Is the cushion suitable for the client's skin condition and risk factors?

It is considered best practice and required for many insurance companies paying for wheelchairs and cushions to collaborate with an occupational or physical therapist and a professional holding the ATP or SMS credential.

Microclimate

- Does the cushion promote a cool, dry microclimate to prevent skin breakdown?
- Is there good airflow to manage temperature and moisture?

Cushion Weight

- How heavy is the cushion?
- Will the weight affect the client's ability to self-propel in a lightweight wheelchair?

Cushion Height

- Does the cushion height allow for easy transfers and the client to fit under tables or desks?
- Does it provide adequate height for the client to reach surfaces?

Maintenance

- What maintenance does the cushion require?
- Is the client or caregiver able to perform the necessary maintenance?

Price

- Does the cushion fit within the client's budget?
- What is the average lifespan of the cushion, and what features does it offer?

Case managers are not expected to have a comprehensive knowledge of every wheelchair or cushion available; however, it is helpful to know the basics. It is considered best practice and required for many insurance companies paying for wheelchairs and cushions to collaborate with an occupational or physical therapist and a professional holding the ATP or SMS credential. This collaborative approach ensures clients receive the most suitable seating system tailored to their needs.

Technological Advancements

Technological advancements in wheelchair design and cushion technology have revolutionized how individuals with mobility impairments experience daily life. Modern wheelchairs are now equipped with enhanced features such as adjustable seat angles, multimodal ways to drive or control wheelchairs (brain-computer interface, eye-gaze systems, touchscreen control, sip-and-puff, smart watches, etc.), advanced suspension systems, seat elevation, and motorized options that provide greater independence and comfort. Wheelchair cushions have seen significant innovations to improve pressure distribution, comfort, and durability.

Advanced materials such as viscoelastic foams, gels, and air cells have been incorporated into cushion designs to offer superior support and pressure relief. Additionally, the advent of pressure mapping technology allows for precise assessment and customization of seating solutions, ensuring that high-risk areas are adequately protected. These technological improvements not only enhance the overall user experience but also contribute to the prevention of pressure sores and other medical complications, making it easier for case managers to recommend the most suitable options for their clients. Looking ahead, continued advancements in smart technology and materials science promise further enhancements in wheelchair and cushion design. Innovations such as sensors for real-time pressure monitoring, AI-driven customization, and the development of new, adaptive materials will likely offer even greater support and comfort, ensuring clients receive the most effective and personalized care possible.

Conclusion

In summary, helping to identify, select, and obtain appropriate wheelchair seating options is a critical responsibility for case managers, significantly impacting the comfort, health, and overall well-being of individuals with mobility impairments. At a minimum, case managers can ensure clients are aware of their options and receive support from healthcare professionals specializing in wheelchair seating and mobility. Collaborating with occupational and physical therapists and professionals with ATP and SMS credentials guarantees clients receive optimal seating solutions tailored to their unique needs. Proper wheelchair seating can prevent severe health complications such as pressure sores and postural deformities, enhance function, and promote active participation in daily activities. Understanding the various types of cushions, their benefits, and the importance of a comprehensive assessment are key to making informed decisions that support the client's functional abilities and lifestyle. By prioritizing these considerations, case managers can play an essential role in enhancing the quality of life for individuals who rely on wheelchairs for functional mobility.

Resources: RESNA (Rehabilitation Engineering & Assistive Technology Society of North America;

continues on page 33

PharmaFacts for Case Managers



ITOVEBI (inavolisib) tablets, for oral use

INDICATIONS AND USAGE

ITOVEBI, in combination with palbociclib and fulvestrant, is indicated for the treatment of adults with endocrine-resistant, PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer, as detected by an FDA-approved test, following recurrence on or after completing adjuvant endocrine therapy.

DOSAGE AND ADMINISTRATION Patient Selection

Select patients for the treatment of HR-positive, HER2-negative, locally advanced or metastatic breast cancer with ITOVEBI based on the presence of one or more PIK3CA mutations in plasma specimens .

Recommended Evaluation Before Initiating ITOVEBI

Evaluate fasting plasma glucose (FPG)/blood glucose (FBG) and hemoglobin A1C (HbA1C) and optimize blood glucose prior to starting ITOVEBI and at regular intervals during treatment.

Recommended Dosage

The recommended dosage of ITOVEBI is 9 mg taken orally once daily, with or without food, until disease progression or unacceptable toxicity.

Advise patients to take ITOVEBI at approximately the same time each day. Swallow ITOVEBI tablet(s) whole. Do not chew, crush, or split prior to swallowing.

If a patient misses a dose, instruct the patient to take the missed dose as soon as possible within 9 hours. After more than 9 hours, instruct the patient to skip the dose and take the next dose at the scheduled time.

If a patient vomits a dose, instruct patients not to take an additional dose on that day and resume the usual dosing schedule the next day.

Administer ITOVEBI in combination with palbociclib and fulvestrant. The recommended dosage of palbociclib is 125 mg taken orally once daily for 21 consecutive days followed by 7 days off treatment to comprise a cycle of 28 days. Refer to the Full Prescribing Information for palbociclib and fulvestrant for dosing information.

For premenopausal and perimenopausal women, administer a luteinizing hormone-releasing hormone (LHRH) agonist in accordance with local clinical practice.

For men, consider administering an LHRH agonist in accordance with local clinical practice.

Dosage Modifications for Adverse Reactions

The recommended dose reduction levels of ITOVEBI for adverse reactions are listed in Table 1. Permanently discontinue ITOVEBI if patients are unable to tolerate the second dose reduction.

TABLE 1	DOSE REDUCTION FOR ADVERSE REACTIONS		
Dose Level		Dose and Schedule	
Recommended starting dose		9 mg daily	
First dose reduction		6 mg daily	
Second dose reduction		3 mg daily	

The recommended dosage modifications of ITOVEBI for adverse reactions are summarized in Table 2.

Dosage Modification for Moderate Renal Impairment

The recommended starting dosage of ITOVEBI for patients with moderate renal impairment (eGFR 30 to < 60 mL/min based on CKD-EPI) is 6 mg orally once daily [see Use in Specific Populations (8.6) and Clinical Pharmacology (12.3)].

DOSAGE FORMS AND STRENGTHS

Tablets

- 3 mg: red and round convex-shaped with an "INA 3" debossing on one side.
- 9 mg: pink and oval-shaped with an "INA 9" debossing on one side.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Hyperglycemia

Severe hyperglycemia can occur in patients treated with ITOVEBI.

Increased fasting glucose occurred in 85% of patients treated with ITOVEBI, including 22% of patients with Grade 2 (FPG >



TABLE 2 RECOMMENDED DOSAGE MODIFICATIONS FOR ADVERSE REACTIONS

Adverse Reaction	Severity	Dosage Modification	
Hyperglycemia ^a [see Warnings and Precautions (5.1)]	Fasting glucose levels (FPG or FBG) > ULN to 160 mg/dL (> ULN – 8.9 mmol/L)	 No adjustment of ITOVEBI required. Consider dietary modifications and ensure adequate hydration. Initiate or intensify oral anti-hyperglycemic medications for patients with risk factors for hyperglycemia. 	
	Fasting glucose levels > 160 to 250 mg/dL (> 8.9 – 13.9 mmol/L)	 Withhold ITOVEBI until FPG or FBG ≤ 160 mg/dL (≤ 8.9 mmol/L). Initiate or intensify anti-hyperglycemic medications. Resume ITOVEBI at the same dose level. If FPG or FBG persists > 200 – 250 mg/dL (> 11.1 – 13.9 mmol/L) for 7 days under appropriate anti-hyperglycemic treatment, consider consultation with a healthcare professional experienced in the treatment of hyperglycemia. 	
Fasting glucose levels > 250 to 500 mg/dL (> 13.9 – 27.8 mmol/L)		 Withhold ITOVEBI. Initiate or intensify anti-hyperglycemic medications. Administer appropriate hydration if required. If FPG or FBG decreases to ≤ 160 mg/dL (≤ 8.9 mmol/L) within 7 days, resume ITOVEBI at the same dose level. If FPG or FBG decreases to ≤ 160 mg/dL (≤ 8.9 mmol/L) in ≥ 8 days, resume ITOVEBI at one lower dose level. If FPG or FBG > 250 to 500 mg/dL (> 13.9 – 27.8 mmol/L) recurs within 30 days, withhold ITOVEBI until FPG or FBG decreases to ≤ 160 mg/dL (≤ 8.9 mmol/L). Resume ITOVEBI at one lower dose level. 	
	Fasting glucose levels > 500 mg/dL (> 27.8 mmol/L)	 Withhold ITOVEBI. Initiate or intensify anti-hyperglycemic medications. Assess for volume depletion and ketosis and administer appropriate hydration. If FPG or FBG decreases to ≤ 160 mg/dL (≤ 8.9 mmol/L), resume ITOVEBI at one lower dose level. If FPG or FBG > 500 mg/dL (> 27.8 mmol/L) recurs within 30 days, permanently discontinue ITOVEBI. 	
Stomatitis Grade 1b [see Warnings and Precautions (5.2)]		 No adjustment of ITOVEBI required. Initiate or intensify appropriate medical therapy (e.g., corticosteroid-containing mouthwash) as clinically indicated. 	
	Grade 2 ^b	 Withhold ITOVEBI until recovery to Grade < 1. Initiate or intensify appropriate medical therapy. Resume ITOVEBI at the same dose level. For recurrent Grade 2 stomatitis, withhold ITOVEBI until recovery to Grade < 1, then resume ITOVEBI at one lower dose level. 	
	Grade 3 ^b	 Withhold ITOVEBI until recovery to Grade < 1. Initiate or intensify appropriate medical therapy. Resume ITOVEBI at one lower dose level. 	
	Grade 4 ^b	Permanently discontinue ITOVEBI.	

TABLE 2 (continued) RECOMMENDED DOSAGE MODIFICATIONS FOR ADVERSE REACTIONS

Adverse Reaction	Severity	Dosage Modification	
Diarrhea	Grade 1 ^b	No adjustment of ITOVEBI required.	
[see Warnings and Precautions (5.3)]		Initiate appropriate medical therapy and monitor as clinically indicated.	
Trecautions (5.5)	Grade 2 ^b	Withhold ITOVEBI until recovery to Grade \leq 1, then resume ITOVEBI at the same dose level.	
		Initiate or intensify appropriate medical therapy and monitor as clinically indicated.	
		For recurrent Grade 2 diarrhea, withhold ITOVEBI until recovery to Grade \leq 1, then resume ITOVEBI at one lower dose level.	
	Grade 3 ^b	Withhold ITOVEBI until recovery to Grade \leq 1, then resume ITOVEBI at one lower dose level.	
		Initiate or intensify appropriate medical therapy and monitor as clinically indicated.	
	Grade 4 ^b	Permanently discontinue ITOVEBI.	
Hematologic Toxicities	Grade 1, 2, or 3 ^b	No adjustment of ITOVEBI required.	
[see Adverse Reactions (6.1)]		Monitor complete blood count and for signs or symptoms of hematologic toxicities as clinically indicated.	
	Grade 4 ^b	Withhold ITOVEBI until recovery to Grade \leq 2.	
		Resume ITOVEBI at the same dose level or reduce to one lower dose level as clinically indicated.	
Other Adverse Reactions	Grade 1 ^b	No adjustment of ITOVEBI required.	
[see Adverse Reactions (6.1)]	Grade 2 ^b	Consider withholding ITOVEBI, if clinically indicated, until recovery to Grade ≤ 1.	
		Resume ITOVEBI at the same dose level.	
	Grade 3 (first event)b	Withhold ITOVEBI until recovery to Grade ≤ 1.	
		Resume ITOVEBI at the same dose level or one lower dose level based on clinical evaluation.	
	Grade 3 (recurrent)b	Withhold ITOVEBI until recovery to Grade ≤ 1.	
		Resume ITOVEBI at one lower dose level.	
	Grade 4 ^b	Permanently discontinue ITOVEBI.	

^a Before initiating treatment with ITOVEBI, test FPG or FBG, and HbA1C levels, and optimize plasma/blood glucose levels in all patients. After initiating treatment with ITOVEBI, monitor FPG or FBG levels based on the recommended schedule, and as clinically indicated [see Warnings and Precautions (5.1)].

160 to 250 mg/dL), 12% with Grade 3 (FPG > 250 to 500 mg/dL), and 0.6% with Grade 4 (FPG > 500 mg/dL) events.

In INAVO120, 46% (74/162) of patients who received ITOVEBI were treated with oral anti-hyperglycemic medications and 7% (11/162) were treated with insulin to manage increased fasting glucose. In patients who experienced increased fasting glucose of > 160 mg/dL, 96% (52/54) had an improvement in fasting glucose of at least one grade level with a median time to improvement from the first event of 8 days (range: 2 to 43 days).

Among patients with hyperglycemia, the median time to first onset was 7 days (range: 2 to 955 days). Hyperglycemia led to dose interruption in 28%, to dose reduction in 2.5%, and to discontinuation of ITOVEBI in 1.2% of patients.

The safety of ITOVEBI in patients with Type 1 diabetes

mellitus, or Type 2 diabetes mellitus requiring ongoing anti-hyperglycemic treatment have not been studied.

Before initiating treatment with ITOVEBI, test fasting glucose levels (FPG or FBG), HbA1C levels, and optimize fasting glucose.

After initiating treatment with ITOVEBI, or in patients who experience hyperglycemia after initiating treatment with ITOVEBI, monitor or self-monitor fasting glucose levels once every 3 days for the first week (Day 1 to 7), then once every week for the next 3 weeks (Day 8 to 28), then once every 2 weeks for the next 8 weeks, then once every 4 weeks thereafter, and as clinically indicated. Monitor HbA_{1C} every 3 months and as clinically indicated.

Manage hyperglycemia with anti-hyperglycemic medications as clinically indicated. During treatment with anti-hypergly-

^b Based on CTCAE version 5.0.

cemic medication, continue monitoring fasting glucose levels. Patients with a history of well-controlled Type 2 diabetes mellitus may require intensified anti-hyperglycemic treatment and close monitoring of fasting glucose levels.

Consider consultation with a healthcare professional experienced in the treatment of hyperglycemia, and initiation of fasting glucose monitoring at home for patients who have risk factors for hyperglycemia or who experience hyperglycemia. Advise patients of the signs and symptoms of hyperglycemia and counsel patients on lifestyle changes.

Based on the severity of the hyperglycemia, ITOVEBI may require dose interruption, reduction, or discontinuation.

Stomatitis

Severe stomatitis can occur in patients treated with ITOVEBI. Stomatitis occurred in 51% of patients treated with ITOVEBI in combination with palbociclib and fulvestrant, including Grade 3 events in 6% of patients. The median time to first onset was 13 days (range: 1 to 610 days).

Stomatitis led to interruption of ITOVEBI in 10%, to dose reduction in 3.7%, and to discontinuation of ITOVEBI in 0.6% of patients.

In patients who received ITOVEBI in combination with palbociclib and fulvestrant, 38% used a mouthwash containing corticosteroid for management or prophylaxis of stomatitis.

Monitor patients for signs and symptoms of stomatitis. Withhold, reduce dose, or permanently discontinue ITOVEBI based on severity].

Diarrhea

Severe diarrhea, including dehydration and acute kidney injury, can occur in patients treated with ITOVEBI.

Diarrhea occurred in 48% of patients treated with ITOVEBI in combination with palbociclib and fulvestrant, including Grade 3 events in 3.7% of patients. The median time to first onset was 15 days (range: 2 to 602 days). Anti-diarrheal medicines were used in 28% (46/162) of patients who received ITOVEBI in combination with palbociclib and fulvestrant to manage symptoms. Dose interruptions were required in 7% of patients, and dose reductions occurred in 1.2% of patients.

Monitor patients for signs and symptoms of diarrhea. Advise patients to increase oral fluids and start anti- diarrheal treatment at the first sign of diarrhea while taking ITOVEBI. Withhold, reduce dose, or permanently discontinue ITOVEBI based on severity.

Embryo-Fetal Toxicity

Based on findings in animals and its mechanism of action, ITOVEBI can cause fetal harm when administered to a pregnant woman . In an animal reproduction study, oral administration of inavolisib to pregnant rats during the period of organogenesis caused adverse developmental outcomes, including embryo-fetal mortality, structural abnormalities, and alter-

ations to growth at maternal exposures approximately equivalent to the human exposure at the recommended dose of 9 mg/day 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 non-hormonal contraception during treatment with ITOVEBI and for 1 week after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with ITOVEBI and for 1 week after the last dose.

ITOVEBI is used in combination with palbociclib and fulvestrant. Refer to the Full Prescribing Information of palbociclib and fulvestrant for pregnancy and contraception information.

ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the label:

- · Hyperglycemia
- Stomatitis
- Diarrhea

Patient reported symptoms in the clinical trials are reported in Table 3.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

ITOVEBI is used in combination with palbociclib and fulvestrant. Refer to the Full Prescribing Information of palbociclib and fulvestrant for pregnancy information.

Based on animal data and its mechanism of action, ITOVEBI can cause fetal harm when administered to a pregnant woman. There are no available data on the use of ITOVEBI in pregnant women to inform a drug-associated risk. In an animal reproduction study, oral administration of inavolisib to pregnant rats during the period of organogenesis caused adverse developmental outcomes, including embryo-fetal mortality, structural abnormalities, and alterations to growth at maternal exposures approximately equivalent to the human exposure at the recommended dose of 9 mg/day 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 U.S. general population, the estimated background risk of major birth defects is 2% to 4% and of miscarriage is 15% to 20% of clinically recognized pregnancies in the U.S. general population.

Lactation

Risk Summary

ITOVEBI is used in combination with palbociclib and fulvestrant. Refer to the Full Prescribing Information of palbociclib and fulvestrant for lactation information.

There are no data on the presence of inavolisib or its

PATIENT-REPORTED SYMPTOMS ASSESSED BY PRO-CTCAE IN INAVO120

Symptom (Attribute) ^a	Any Symptom Before Treatment (%)b		Any Worsening on Treatment (%) ^c		Worsening to Score 3 or 4 (%) ^d	
	ITOVEBI + P + F (N=148)e	Placebo + P + F (N=152) ^e	ITOVEBI + P + F (N=148)e	Placebo + P + F (N=152) ^e	ITOVEBI + P + F (N=148) ^e	Placebo + P + F (N=152)e
Diarrhea (frequency), %	23	15	78	49	32	8
Nausea (frequency), %	21	21	59	50	20	11
Vomiting (frequency), %	9	6	35	26	6	3.3
Fatigue (severity), %	72	69	72	58	32	22
Mouth sores (severity), %	11	14	74	52	30	9
Decreased appetite (severity), %	38	28	78	55	26	12

Symptom	Baseline Presence		Post-baseline Presence		
(Attribute)	ITOVEBI + P + F (N=148)	Placebo + P + F (N=152)	ITOVEBI + P + F (N=148)	Placebo + P + F (N=152)	
Rash (yes), %	5	5	50	38	

ITOVEBI+P+F = ITOVEBI with palbociclib and fulvestrant arm; Placebo+P+F = placebo with palbociclib and fulvestrant arm.

metabolites in human milk, its effects on milk production or a breastfed child. Because of the potential for serious adverse reactions in a breastfed child, advise lactating women to not breastfeed during treatment with ITOVEBI and for 1 week after the last dose.

Females and Males of Reproductive Potential

ITOVEBI is used in combination with palbociclib and fulvestrant. Refer to the Full Prescribing Information of palbociclib and fulvestrant for contraception and infertility information.

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

Pregnancy Testing

Verify pregnancy status in females of reproductive potential prior to initiating treatment with ITOVEBI.

Contraception

Females

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

Infertility

Based on animal studies, ITOVEBI may impair fertility in females and males of reproductive potential.

Pediatric Use

The safety and efficacy of ITOVEBI in pediatric patients have not been established.

Geriatric Use

Of the 162 patients who received ITOVEBI in INAVO120, 15% were \geq 65 years of age, and 3% were \geq 75 years of age.

Dosage modifications or interruptions of ITOVEBI due to adverse reactions occurred at a higher incidence for patients ≥ 65 years of age compared to younger patients (79% versus 68%, respectively).

Clinical studies of ITOVEBI did not include sufficient numbers of patients \geq 65 years of age to determine whether they respond differently from younger patients.

^a The symptom attribute scoring is defined by amount/frequency/severity with a score of 0 = 'not at all'/'never'/'none'; 1 = 'a little bit'/'rarely'/'mild'; 2 = 'somewhat'/ 'occasionally'/'moderate'; 3 = 'quite a bit'/'frequently'/'severe'; 4 = 'very much'/'almost constantly'/'very severe'.

^b The percentage of patients whose symptom score before treatment was 1-4.

^c The percentage of patients whose symptom score increased during treatment, with respect to their score before treatment.

d The percentage of patients whose symptom score increased to 3 or 4 during treatment, with respect to their score before treatment.

e The number of patients who provided a score before treatment and at least one on-treatment score.

Renal Impairment

Reduce the dosage in patients with moderate renal impairment (eGFR 30 to < 60 mL/min based on CKD-EPI) [see Dosage and Administration (2.5)]. No dosage modification is recommended in patients with mild renal impairment (eGFR 60 to < 90 mL/min). ITOVEBI has not been evaluated in patients with severe renal impairment (eGFR < 30 mL/min).

CLINICAL STUDIES

Locally Advanced or Metastatic Breast Cancer INAVO120

INAVO120 (NCT04191499) was a randomized (1:1), double-blind, placebo-controlled trial evaluating the efficacy of ITOVEBI in combination with palbociclib and fulvestrant in adult patients with endocrine-resistant PIK3CA-mutated, HR-positive, HER2-negative (defined as IHC 0 or 1+, or IHC 2+/ISH-), locally advanced or metastatic breast cancer whose disease progressed during or within 12 months of completing adjuvant endocrine therapy and who have not received prior systemic therapy for locally advanced or metastatic disease.

Randomization was stratified by presence of visceral disease (yes or no), endocrine resistance (primary or secondary), and geographic region (North America/Western Europe, Asia, other).

Primary endocrine resistance was defined as relapse while on the first 2 years of adjuvant endocrine therapy (ET) and secondary endocrine resistance was defined as relapse while on adjuvant ET after at least 2 years or relapse within 12 months of completing adjuvant ET.

Patients were required to have HbA1C < 6% and fasting blood glucose < 126 mg/dL. The study excluded patients with Type 1 diabetes mellitus or Type 2 diabetes mellitus requiring ongoing anti-hyperglycemic treatment at the start of study treatment.

PIK3CA mutation status was prospectively determined in a central laboratory using the FoundationOne® Liquid CDx assay on plasma-derived circulating tumor DNA (ctDNA) or in local laboratories using various validated polymerase chain reaction (PCR) or next-generation sequencing (NGS) assays on tumor tissue or plasma. All patients were required to provide both a freshly collected pre-treatment blood sample and a tumor tissue sample for central evaluation and determination of PIK3CA mutation(s) status.

Patients received either ITOVEBI 9 mg (n=161) or placebo (n=164) orally once daily, in combination with palbociclib 125 mg orally once daily for 21 consecutive days followed by 7 days off treatment to comprise a cycle of 28 days, and fulvestrant 500 mg administered intramuscularly on Cycle 1, Days 1 and 15, and then on Day 1 of every 28-day cycle. Patients received treatment until disease progression or unacceptable toxicity. In addition, all pre/perimenopausal women and men received an LHRH agonist throughout therapy.

The baseline demographic and disease characteristics were:

median age 54 years (range: 27 to 79 years); 98% female, of which 39% were pre/perimenopausal; 59% White, 38% Asian, 2.5% unknown, 0.6% Black or African American; 6% Hispanic or Latino; and Eastern Cooperative Oncology Group (ECOG) performance status of 0 (63%) or 1 (36%). Tamoxifen (57%) and aromatase inhibitors (50%) were the most commonly used adjuvant endocrine therapies. Sixty-four percent of patients were considered to have secondary endocrine resistance. Eighty-three percent of patients had received prior chemotherapy (in the neo/adjuvant setting) and 1.2% of patients had been treated with a CDK4/6 inhibitor.

The major efficacy outcome measure was investigator (INV)-assessed progression-free survival (PFS) per Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1. Additional efficacy outcome measures included overall survival (OS), INV-assessed objective response rate (ORR), and INV-assessed duration of response (DOR).

Efficacy results are summarized in Table below INV-assessed PFS results were supported by consistent results from a blinded independent central review (BICR) assessment. At the time of the PFS analysis, OS data were not mature with 30% deaths in the overall population.

TABLE 4

EFFICACY RESULTS IN PATIENTS WITH LOCALLY ADVANCED OR METASTATIC BREAST CANCER IN INAVO120

111/11/01/20		
Efficacy Endpoint	ITOVEBI + Palbociclib + Fulvestrant N=161	Placebo + Palbociclib + Fulvestrant N=164
Progression-Free Survival ^{a,b}		
Patients with event, n (%)	82 (51)	113 (69)
Median, months (95% CI)	15.0 (11.3, 20.5)	7.3 (5.6, 9.3)
Hazard ratio (95% CI)	0.43 (0.32, 0.59)	
p-value < 0.0001		
Objective Response Ratea,b,c		
Patients with CR or PR, n (%)	94 (58)	41 (25)
95% CI	(50, 66)	(19, 32)
Duration of Responseb		
Median DOR, months (95% CI)	18.4 (10.4, 22.2)	9.6 (7.4, 16.6)
CI - confidence interval CB - compl	oto rosponso, DOR — o	luration of rospons

CI = confidence interval; CR = complete response; DOR = duration of response; PR = partial response

HOW SUPPLIED/STORAGE AND HANDLING

ITOVEBI is supplied in the following strengths and package configurations:

continues on page 35

^a Per RECIST version 1.1.

 $^{^{\}it b}$ Based on investigator assessment.

^c Based on confirmed ORR.



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

Clin Infect Dis. 2024 Nov 4:ciae540. doi: 10.1093/cid/ciae540. Online ahead of print.

Switch To Integrase Strand Transfer Inhibitors
During the Menopausal Transition Is Associated
With Accelerated Body Composition Change In
Women With HIV

Abelman RA, Ma Y, Mehta CC, et al.

BACKGROUND: Integrase strand transfer inhibitors (INSTIs) and the menopausal transition have separately been associated with body composition changes in women with HIV (WWH), but their interaction is unknown.

METHODS: From 2006-2019, 1131 non-pregnant WWH with viral suppression [(419 who switched to INSTI (INSTI+); 712 who did not switch (INSTI-)] and 887 women without HIV (WWOH) from the Women's Interagency HIV Study were included. Mixed effect models were used to evaluate change in waist circumference (WC) and BMI by menopausal phase defined using anti-Müllerian hormone, a biomarker of ovarian reserve.

RESULTS: During premenopause, WWH had increases in WC (INSTI+: 0.01cm per 6 month (mo); 95%CI:-0.29,0.32 and INSTI-: 0.22cm per 6mo;95%CI:-0.01,0.44) that were not statistically significantly different from WWOH; there was also little difference by INSTI status. In late perimenopause, INSTI+ had faster increases in WC (0.37cm per 6mo;95%CI:0.15,0.60) while INSTI- had smaller increases (0.14cm per 6mo;95%CI:-0.06,0.34) compared to WWOH. In menopause, INSTI+ had faster increases (0.14cm per 6mo;95%CI:-0.02,0.30). Compared to INSTI-, in late perimenopause, INSTI+ had 0.26 cm per 6mo (95%CI:0.02,0.50) faster linear increases in WC and in menopause, INSTI+ was associated with faster increases peaking at 41mo. BMI trajectories were similar to WC in late peri- and menopausal women.

CONCLUSIONS: Switching to an INSTI-based regimen during late peri- and menopause is associated with faster increases in WC and BMI when compared to women who did not switch. Menopausal status should be considered when switching to an INSTI.

HIV Med. 2024 Nov 7. doi: 10.1111/hiv.13730. Online ahead of print.

Burden of Liver Steatosis and Liver Fibrosis in a

Large Cohort of People Living With HIV

Laguno M, de Lazzari E, Berrocal L, et al.

BACKGROUND: Liver steatosis (LS) and liver fibrosis (LF) can increase the risk of cardiovascular disease in people with HIV, but their prevalence and associated factors are poorly understood. This study aimed to assess the prevalence of and factors associated with LS and LF in a large cohort of people with HIV.

METHODS: We conducted a cross-sectional study of consecutive people with HIV attending the Clinic of Barcelona from September 2022 to September 2023, excluding those with chronic B or/and C hepatitis virus coinfection. LS was assessed using the Hepatic Steatosis Index (HSI) and Fatty Liver Index (FLI), and LF was assessed using the Non-Alcoholic Fatty Liver Disease Fibrosis Score (NFS), Fibrosis-4 score (FIB-4), and the European AIDS Clinical Society (EACS) algorithm in both the whole cohort (cohort 1) and in a specific cohort more susceptible to liver disease (cohort 2). We identified independent variables associated with LS and LF using logistic regression.

RESULTS: Cohort 1 included 4664 people with HIV; 76% and 37% of them had available HSI and FLI data, LS was present in 28% and 19%, respectively. LF risk was present in 1%, 2%, and 1% of people with HIV according to NFS, FIB-4, and EACS algorithm scores, respectively. Cohort 2 included 1345 people with HIV; 60% and 30% of them had available HSI and FLI data, LS affected 55% and 43% and LF 2%, 5%, or 3%, respectively. Factors associated with LS included current CD4 cell count, diabetes, and hypertension, whereas LF was associated with previous exposure to dideoxynucleoside drugs and current CD4 to LF. Current integrase strand transfer inhibitor (INSTI) therapy appeared protective for LF in cohort 1.

CONCLUSIONS: In this study, one in four people with HIV had LS, and the prevalence rose to one in two in those with cardio-vascular risk factors. The prevalence of LF was low, but it should be considered in older people with HIV with low CD4 counts or high aspartate transaminase levels. A possible protective effect from INSTIs deserves further investigation.



J Viral Hepat. 2024 Nov 6. doi: 10.1111/jvh.14033. Online ahead of print.

Long-Term Follow-Up of Neuropsychiatric
Symptoms After Sustained Virological Response
to Interferon-Free and Interferon-Based
Hepatitis C Virus Treatment

Dirks M, Hennemann A-K, Grosse GM, et al.

Chronic hepatitis C virus (HCV) infection can be associated with neuropsychiatric symptoms like fatigue and cognitive impairment, independent of the liver status. The present study aims to assess changes in the pattern and extent of neuropsychological symptoms after successful treatment with interferon (IFN)-based and IFN-free therapy. HCV-infected patients who underwent neuropsychological assessment in previous studies were invited to a follow-up examination. Patients were grouped according to the treatment status: Sustained virological response (SVR) after IFN treatment (IFN SVR, n = 14) or after therapy with direct acting antivirals (DAA SVR, n = 28) or ongoing HCV infection (HCV RNA+, n = 11). A group of 33 healthy controls served as reference. Patients completed self-report questionnaires addressing health-related quality of life (HRQoL), mood and sleep quality and a neuropsychological test battery including tests of memory and attention (Luria's list of words, PSE test, cancelling "d" test, Word-Figure-Memory Test and computer-based test battery for the assessment of attention [TAP]). At baseline, all three patient groups had worse fatigue, depression, anxiety and HRQoL scores compared to healthy controls. Longitudinal analysis revealed that fatigue and mood slightly improved in all patient groups over time, while HRQoL improved in SVR patients but not in HCV RNA+ patients. Memory test results improved significantly in all patient groups, irrespective of their virological status. In contrast, the attention test results showed no clear change from baseline to follow-up. Our data can be considered as a hint that HCV eradication-independent of therapy regimen-does not substantially ameliorate neuropsychiatric symptoms in HCV-afflicted patients.

Eur J Heart Fail. 2024 Nov 5. doi: 10.1002/ejhf.3499. Online ahead of print.

<u>Long-term Clinical Outcomes and Healthcare</u>
<u>Resource Utilization in Male and Female Patients</u>
Following Hospitalization for Heart Failure

Averbuch T, Lee SF, Zagorski B, et al.

AIMS: Heart failure (HF) is a leading cause of hospitalization, and sex differences in care have been described. We assessed sex-specific clinical outcomes and healthcare resource utilization following

hospitalization for HF.

METHODS AND RESULTS: This was an exploratory analysis of patients hospitalized for HF across 10 Canadian hospitals in the Patient-Centered Care Transitions in HF (PACT-HF) cluster-randomized trial. The primary outcome was all-cause mortality. Secondary outcomes included all-cause readmissions, HF readmissions, emergency department (ED) visits, and healthcare resource utilization. Outcomes were obtained via linkages with administrative datasets. Among 4441 patients discharged alive, 50.7% were female. By 5 years, 63.6% and 65.5% of male and female patients, respectively, had died (p = 0.19); 85.4% and 84.4%, respectively, were readmitted (p = 0.35); and 72.2% and 70.9%, respectively, received ED care without hospitalization (p = 0.34). There were no sex differences in mean [SD] number of all-cause readmissions (males, 2.8 [7.8] and females, 3.0 [8.4], p = 0.54), HF readmissions (males, 0.9 [3.6] and females, 0.9 [4.5], p = 0.80), or ED visits (males, 1.8 [11.3] and females, 1.5 [6.0], p = 0.24) per person. There were no sex differences in mean [SD] annual direct healthcare cost per patient (males, \$80 334 [116 762] versus females, \$81 010 [112 625], p = 0.90), but males received more specialist, multidisciplinary HF clinic, haemodialysis, and day surgical care, and females received more home visits, continuing/convalescent care, and long-term care. Annualized clinical events were highest in first year following index discharge in both males and females.

CONCLUSIONS: Among people discharged alive after hospitalization for HF, there were no sex differences in total and annual deaths, readmissions, and ED visits, or in total direct healthcare costs. Despite similar risk profiles, males received relatively more specialist care and day surgical procedures, and females received more supportive care.

Ann Thorac Surg. 2024 Nov;118(5):1088-1096. doi: 10.1016/j. athoracsur.2024.05.046. Epub 2024 Jun 29.

Adult Congenital Heart Disease Transplantation:

Does Univentricle Physiology Impact Early

Mortality?

Stephens EH, Dearani JA, et al.

BACKGROUND: With patients with congenital heart disease increasingly living into adulthood, there is a growing population of patients with adult congenital heart disease (ACHD) who have heart failure. Limited data exist on evaluating heart transplantation in this population.

METHODS: A retrospective review was performed of patients with ACHD who underwent heart transplantation from November 1990 to January 2023. Kaplan-Meier, cumulative incidence accounting for competing risk of death, and subgroup analyses



comparing those patients with biventricular (BiV) and univentricular (UniV) physiology were performed. Data are presented as median (interquartile range [IQR]) or counts (%).

RESULTS: A total of 77 patients with a median age of 36 years (IQR, 27-45 years) were identified, including 57 (74%) BiV and 20 (26%) UniV patients. Preoperatively, UniV patients were more likely to have cirrhosis (9 of 20 [45.0%] vs 4 of 57 [7.0%]; P < .001) and protein losing enteropathy (4 of 20 [20.0%] vs 1 of 57 [1.8%]; P = .015). Multiorgan transplantation was performed in 23 patients (30%) and more frequently in UniV patients (10 [50%] vs 13 [23%]; P = .04). Operative mortality was 6.5%, 2 of 20 (10%) among UniV patients and 2 of 57 (4%) among BiV patients (P = .276). Median clinical follow-up was 6.0 years (IQR, 1.4-13.1 years). Survival tended to be lower among UniV patients compared with BiV patients, particularly within the first year (P = .09), but it was similar for survivors beyond 1 year. At 5 years, the incidence of rejection was 28% (IQR, 17%-38%) and that of coronary allograft vasculopathy was 16% (IQR, 7%-24%).

CONCLUSIONS: Underlying liver disease and the need for heart-liver transplantation were significantly higher among UniV patients. Survival tended to be lower among UniV patients, particularly within the first year, but it was similar for survivors beyond 1 year.

J Am Coll Cardiol. 2024 Nov 2:S0735-1097(24)09771-7. doi: 10.1016/j.jacc.2024.06.049. Online ahead of print.

Hypertensive Disorders of Pregnancy Increase the Risk for Myocardial Infarction: A Population-Based Study

Vaughan LE, Kanaji Y, Suvakov S, et al.

BACKGROUND: Angiographic evidence of the anatomy of coronary arteries and the type of coronary artery lesions in women with a history of hypertensive disorders of pregnancy (HDP) are poorly documented.

OBJECTIVES: This study sought to determine the role of a history of HDP as a unique risk factor for early coronary artery disease (CAD) and type of acute coronary syndrome (ACS) (ie, atherosclerotic vs myocardial infarction with nonobstructive coronary arteries [MINOCA]) in women who underwent coronary angiography.

METHODS: This study used a population-based cohort of parous female patients with incident CAD who underwent coronary angiography and age-matched control subjects. The SYNTAX (Synergy between PCI [percutaneous coronary intervention] with TAXUS [Boston Scientific] and Cardiac Surgery) score was assessed to determine the complexity and degree of CAD; MINOCA was

diagnosed in the presence of clinical acute myocardial infarction in the absence of obstructive coronary disease.

RESULTS: A total of 506 parous female Olmsted County, Minnesota (USA) residents had incident CAD and angiographic data from November 7, 2002 to December 31, 2016. Women with HDP were younger than normotensive women at the time of the event (median: 64.8 years vs 71.8 years; P = 0.030). There was a strong association between HDP and ACS (unadjusted P = 0.018). Women with HDP compared with women with normotensive pregnancies were more likely to have a higher SYNTAX score (OR: 2.28; 95% CI: 1.02-5.12; P = 0.046), and MINOCA (OR: 2.08; 95% CI: 1.02-4.25; P = 0.044).

CONCLUSIONS: A history of HDP is associated with CAD earlier in life and with a future risk for myocardial infarction with both obstructive and nonobstructive coronary arteries. This study underscores the need for timely detection and treatment of nonobstructive disease, in addition to traditional risk factors.

Am J Clin Oncol. 2024 Nov 5. doi: 10.1097/ COC.0000000000001155. Online ahead of print.

Complications, Costs, and Health Care Resource Use with Tissue Biopsy Followed by Liquid Biopsy Versus Tissue Re-biopsy in Patients With Newly Diagnosed Metastatic Nonsmall-cell Lung Cancer

Shah A, Apple J, Aslam S, Engel-Nitz NM, Le L, Terpenning M

OBJECTIVES: We compared complications, costs, and health care resource utilization (HCRU) of patients with newly diagnosed metastatic nonsmall-cell lung cancer (mNSCLC) who had a tissue biopsy followed by either liquid biopsy (TFLB) (identified with a novel algorithm) or tissue re-biopsy (TRB).

METHODS: This claims-based retrospective analysis included commercial and Medicare Advantage members in the Optum Research Database with mNSCLC (January 2017 to June 2021) and ≥2 tissue biopsy claims (7 to 90 d apart) (TRB) or ≥1 tissue and ≥1 liquid biopsy claim within 90 days (TFLB). Patients in the TFLB group were matched 1:1 to patients in the TRB group using propensity score matching. Surgical biopsy-related complications and complication-related and all-cause medical costs and HCRU during the 6-month follow-up were compared.

RESULTS: Both groups had 235 patients post-match. During the follow-up, the surgical biopsy-related complication rate was lower in the TFLB group than the TRB group (65.1% [153/235] vs. 84.7% [199/235], P<0.001). Mean complication-related medical costs were significantly lower with TFLB (\$8494 vs. \$19,741, P<0.001) during the follow-up; mean (SD) duration of complica-



tion-related inpatient stays was significantly lower with TFLB (3.5 [7.0] vs. 6.6 [13.3] d, P=0.002). Mean all-cause medical costs were not significantly different between the groups; the TFLB group had fewer all-cause inpatient stays, inpatient days, and outpatient visits.

CONCLUSIONS: Multiple tissue biopsy procedures may be associated with significantly higher biopsy complication rates, higher complication-related medical costs, and longer complication-related inpatient stays than TFLB. All-cause medical costs were similar between groups.

Clin Lung Cancer. 2024 Oct 1:S1525-7304(24)00203-1. doi: 10.1016/j.cllc.2024.09.008. Online ahead of print.

Implementation and Retrospective Examination of a Lung Cancer Survivorship Clinic in a Comprehensive Cancer Center

Price SN, Willis AR, Hensley A, et al.

PURPOSE: The number of early-stage lung cancer survivors (LCS) is increasing, yet few survivorship programs address their specific needs. We developed a workflow to transition early-stage LCS to dedicated lung survivorship care and comprehensively identify and address their needs using electronic patient-reported outcomes (ePROs).

METHODS: A lung cancer multidisciplinary team developed a workflow (eg, referrals, survivorship care plan delivery, documentation, orders, tracking, ePROs, and surveillance) for a survivorship clinic staffed by Advanced Practice Providers (APPs). ePROs included the NCCN Distress Thermometer, PROMIS-29, and investigator-developed patient satisfaction items. Patient characteristics, ePROs, and referrals are described; chi-square and t-tests examined ePRO completion by patient characteristics and compared PROMIS-29 domains by treatment modality and to a national sample.

RESULTS: From January 2020-March 2023, 315 early-stage LCS completed a survivorship orientation visit. Patient satisfaction was high; 75% completed ePROs. Females were overall less likely to complete ePROs than males; male, age 65+, Black or other race, and rural patients were more likely to complete ePROs in clinic versus online. Patients reported lower symptom burden compared to a general population of early-stage LCS in the United States; scores were similar regardless of treatment modality. Rates of moderate-severe symptoms ranged from 6% (depression) to 42% (poor physical function); ≤ 20% had a referral placed.

CONCLUSIONS: A referral-based, APP-staffed survivorship clinic model for early-stage LCS which includes ePROs to identify specific needs is acceptable to patients. Future work should include outreach to female LCS and increasing supportive care referrals and acceptability to further address early-stage LCS reported needs.

J Natl Cancer Inst. 2024 Oct 28:djae270. doi: 10.1093/jnci/djae270. Online ahead of print.

Novel Metabolomic Predictors of Incident Colorectal Cancer in Men and Women

Downie JM, Joshi AD, Geraghty CM, et al

BACKGROUND: Metabolomic profiles may influence colorectal cancer (CRC) development. Few studies have performed prediagnostic metabolome-wide analyses with CRC risk. Methods: We conducted a nested case-control study among women (Nurses' Health Study (NHS)) and men (Health Professionals Follow-up Study (HPFS)) who provided blood between 1989 and 1995. Over 22.9 years, 684 (409 NHS, 275 HPFS) incident CRC cases occurred and were matched 1:1 to controls. Liquid chromatography-mass spectrometry (LC-MS) identified 255 plasma metabolites after quality control. Cohort-specific and combined metabolite association analyses were performed using conditional logistic regression. Metabolite set enrichment analysis (MSEA) was used to identify differential abundance in metabolite classes. Weighted Correlation Network Analysis (WGCNA) provided modules of covarying metabolites, which were tested for CRC association.

RESULTS: MSEA identified specific acylcarnitines associated with higher CRC risk and triacylglycerols with lower CRC risk among women and men. Further, phosphatidylcholines were associated with a higher risk of CRC among men. In an analysis restricted to CRC cases diagnosed two years after blood draw, myristoleic acid (OR = 1.37; 95%CI = 1.15-1.62; FDR = 0.072) and C60:12 triacylglycerol (OR = 0.75; 95%CI = 0.64-0.88; FDR = 0.072 were associated with CRC risk in women. WGCNA identified amino acids associated with CRC in men, fatty acid esters (carnitines) with distal CRC in men, and triradylcglycerols inversely associated with CRC in women.

CONCLUSIONS: We identified pre-diagnostic CRC-associated metabolites with distinct sex-specific profiles. These results provide insight into CRC etiopathogenesis and have implications for risk prediction strategies.

J Hum Hypertens. 2024 Nov 4. doi: 10.1038/s41371-024-00971-w. Online ahead of print.

Sleep Quality and Hypertension in an Indigenous African Population: A Cross-Sectional Investigation From the COMBAT-CVDS Study

Aremu OG, Asowata OJ, Danladi DK, Okekunle AP, Akpa OM

Hypertension is a major risk factor for cardiovascular events worldwide, and little is known about its association with sleep



quality (SQ) among Africans. We evaluated the association of SQ with hypertension among adults in Ibadan, Nigeria. In Ibadan and its suburbs, we identified 3635 participants in the door-todoor Community-based Investigation of the Risk Factors for Cardiovascular Diseases (COMBAT-CVDs) study. SQ was selfreported, and SQ scores were classified by the tertile distribution in this sample as good (<9), moderate (10-18), and poor (≥19), and hypertension was defined as one of the following conditions: systolic blood pressure ≥140 mmHg or diastolic blood pressure ≥90 mmHg or prior diagnosis by a certified health professional or current use of blood pressure-lowering drugs. Using good SQ as a reference, logistic regression models were used to estimate the multivariable-adjusted odds ratio and 95% confidence interval (CI) for odds of hypertension by tertiles of SQ scores in a two-sided test at p < 0.05. In all, 1182 (32.5%) had poor SQ, 903 (24.8%) had hypertension, and the mean(±SD) age was 35.3 ± 15.2 years in this sample. The multivariable-adjusted odds of hypertension by tertiles of SQ scores (using good SQ as reference) were OR: 1.13 (95% CI: 0.92, 1.38) for moderate SQ, and OR: 1.29 (95% CI: 1.05, 1.59) for poor SQ; P for trend = 0.06 after adjusting for relevant covariates. Poor SQ is associated with higher odds of hypertension in this sample. The imperative of culturally sensitive interventions to improve SQ would be promising in managing poor sleep-associated hypertension burden in this population.

Gynecol Oncol. 2024 Nov 2:191:292-298. doi: 10.1016/j. ygyno.2024.10.017. Online ahead of print.

<u>Disparities In Ovarian Cancer Survival Among</u> <u>Ethnic Asian American Populations, 2006-2020</u>

Lee AW, Poynor V, Siddiqui S

BACKGROUND: Asian Americans have the highest ovarian cancer survival across the major racial groups although it is unclear whether this survival advantage is observed when each Asian ethnic subgroup is examined separately. Disaggregated survival analyses of this heterogeneous population is needed to ensure ethnic-specific disparities are not overlooked.

METHODS: Data on ovarian cancer cases diagnosed from 2006 through 2020 from the Surveillance, Epidemiology, and End Results (SEER) Program were analyzed. Age-standardized five-year cause-specific survival was calculated for Non-Hispanic Whites and seven Asian ethnic subgroups in the U.S. (Asian Indian/Pakistani, Chinese, Filipino, Hawaiian/Pacific Islander, Japanese, Korean, Vietnamese) by stage and histotype. Multivariable Cox regression analyses using a weighted approach were conducted to calculate average hazard ratios (AHRs) and 95 % confidence intervals (CIs) to quantify the risk of ovarian cancer death comparing each Asian

ethnic subgroup to Non-Hispanic Whites.

RESULTS: Hawaiian/Pacific Islanders were the only Asian subgroup to show lower five-year cause-specific survival than Non-Hispanic Whites (44.99 % versus 47.90 %, respectively); Asian Indian/Pakistanis showed the highest survival (56.12 %). After adjusting for sociodemographic, tumor, and treatment characteristics, Asian Indian/Pakistani ovarian cancer patients were 17 % less likely to die from their disease whereas Hawaiian/Pacific Islander patients were 28 % more likely to die when compared to Non-Hispanic Whites (AHR = 0.83, 95 % CI 0.75-0.92 and AHR = 1.28, 95 % CI 1.07-1.53, respectively).

CONCLUSIONS: There are clear ethnic-specific survival disparities among Asian American ovarian cancer patients that are missed when the population is examined as a single group, further highlighting the need for data disaggregation in future ovarian cancer research.

CE₃

Wheelchair Seating Options: A Guide for Case Managers continued from page 22

http://www.resna.org) is the premier professional organization for assistive technology, including wheelchairs and seating options. They offer ATP and SMS certifications and have many resources for healthcare professionals and the public, including position papers, current research, guidelines, and continuing education. CE3

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

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Advocating for Clients With Chronic Health Issues and Disabilities Into Retirement and Other Career Transitions

continued from page 5

companies do not provide short-term disability benefits. Also, when individuals are responsible for family members, these leave benefits can continue their income.

Seeing the Whole Person

As board-certified case managers and disability managers, we understand the importance of seeing the whole person. In clinical terms, a whole-person approach means looking beyond a single incident, such as the onset of an illness or injury, to view the person's ongoing health and wellness

needs, their earnings capacity and socioeconomic status, and their overall life goals. The same holistic thinking becomes more critical to individuals who, due to chronic illness or injury, wish to explore retirement or other career transitions. Decisions must be weighed in the context of their resources and financial stability, as well as paid leave and other benefits that can help bridge the gap between what they have available and what they need to sustain their standard of living.

With greater awareness and understanding, case managers and disability managers can assist people in making informed decisions as they pursue their goals toward retirement and put in place important financial safety nets for the future.

Legal Updates continued from page 8

and caregivers to help ensure that caregivers are receiving the respect they deserve. Follow-up activities and on-going monitoring should also be specifically documented.

A representative of the EEOC said, "Employers cannot make job assignment decisions based on a client's preference for a worker of a particular race or national origin. It is imperative for employers to have policies in training their employment decisions."

Caregivers are a scarce commodity. Providers cannot afford to lose or alienate a single caregiver based on discrimination or inappropriate behavior by patients/clients.

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Passion in Case Management: An **Essential Connection**

continued from page 3

setting affords opportunities to coordinate and integrate services and is one of the more satisfying aspects of the interventions case managers provide. The passionate case manager looks forward to those opportunities.

I hope this column provides opportunities to reignite the passion you have for the important interventions we provide and to look forward to the New Year and a commitment to make a difference...one patient at a time!

Wishing each of you an enjoyable holiday season, some time to spend with family and friends, and some much-needed time to rest and renew your passion!

Patherine M. Mullahy

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

Spirituality, Faith, Religion and **Health** continued from page 2

include spirituality in that assessment and plan.

There are many studies that demonstrate improved health outcomes when spirituality is addressed.

- At least 18 prospective studies have shown that spiritually involved people live longer.
- Studies have found that spiritual involvement is associated with lower blood pressure and less hypertension.
- Spirituality is associated with less death anxiety and more accepting
- Spirituality involvement has been shown to be associated with less
- Spiritual people coped with illness better than those who were not
- According to a study from Harvard T.N. Chan School of Public Health, spirituality is associated with healthier lives, including greater longevity, less depression and suicide, and less substance use.

The association between spirituality and better health outcomes seems valid.

The case manager should address spirituality with each patient during the assessment process. It could start

with a simple question: Are you religious or spiritual? The answer will then lead to further questions like: How does that play out in your life? It goes further than just checking a box about what church do you go to. Case managers have an ethical obligation under the CCMC Code of Conduct and Ethics to respect the rights and dignity of all clients including their spirituality.

The case manager asking questions about spirituality must also be secure in their own beliefs about spirituality and be able to engage the patient in a discussion that brings meaning to the patient. Patients have many different beliefs so be mindful of your implicit

Again, it is the holiday season and regardless of your beliefs, I hope you take time to joyfully celebrate and reflect on how you are meeting the spirituality needs of your patients.

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

ACCM: Improving Case Management Practice through Education



PharmaFacts for Case Managers

continued from page 28

Package Configuration	Tablet Strength	NDC	Tablet Description
Bottle of 28 tablets	3 mg	50242-084-08	Red and round convex-shaped with an "INA 3" debossing on one side
Bottle of 28 tablets	9 mg	50242-079-08	Pink and oval-shaped with an "INA 9" debossing on one side

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F) [see USP Controlled Room Temperature].

The estimated AWP of ITOVEBI is \$22,867 for a 28-day cycle.

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experience, leadership and success in case management. These CMSA Lifetime Achievement Award Winners and veterans who helped develop case management standards and codes of conducts have created "Best in Class" tools to address your career needs and goals.

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A: Online exams are processed instantly. Mailed exams are normally processed within 4 to 6 weeks.

Q: Do CE programs expire?

A: Continuing education programs expire approximately 6 months from date of issue. Continuing education programs that offer ethics CE credit expire in 1 year.

Q: Is your Website secure for dues payment?

A: ACCM uses the services of PayPal, the nation's premier payment processing organization. No financial information is ever transmitted to ACCM.

application on next page

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