CareManagement

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

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Gary S. Wolfe

Health Care Themes to Be Addressed in 2023

The first issue of *CareManagement* in 2023 provides an opportunity to look ahead and identify trends that case managers must address. To provide a patient-centered health care system, we must look to the consumer to identify trends and to improve patient engagement:

- Ease of access to patient data
- The patient's digital experience
- Administrative efficiency
- Building in human connections
- Recognizing the importance of work culture

To provide a patient-centered health care system, we must look to the consumer to identify trends and expectations. Consumers expect speed, personalization, and convenience in their health care. Case managers must address patient engagement, health care inequalities, staffing/labor issues, technology, mental health, and value-based health care.

expectations. Consumers expect speed, personalization, and convenience in their health care. To meet those challenges, I identified 6 trends that case managers must address: patient engagement, health care inequalities, staffing/labor issues, technology, mental health, and value-based health care.

Patient Engagement

Patients want a proactive approach rather than a reactive approach, and thus patients must be engaged with providers. Patient engagement leads to better outcomes and improved quality of life. Each patient journey should be personalized and without barriers so that individuals can remain engaged in their health care. Technology, including wearables, educational resources, and mobile apps, will play an increasing role in patient engagement. If the patient experience is not reliable, transparent, and easy to navigate, the consumer will switch to a different provider. The following should be considered in order

Health Care Inequities

Social determinants of health (SDOH) contribute to health inequities. SDOH are environmental conditions where individuals are born, live, and worship and affect a broad range of health, quality-of-life outcomes, and medical-related risks. SDOH impact the well-being of individuals, especially those with limited access to safe and health options. Case managers can make a significant impact improving health inequities because we see the outcomes of these inequities. SDOH include education, food insecurity, transportation, working life conditions, social inclusion and nondiscrimination, housing, and basic amenities.

Staffing/Labor Issues

We need additional health care workers to meet the demand for health care. We currently don't have enough health care professionals, and the situation is getting worse. These challenges became more apparent during the COVID-19

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Catherine M. Mullahy

Another Opportunity…and an Invitation!

Each issue of this publication provides me with many opportunities to communicate with our readers. As Executive Editor, I reach out to authors to explore their interests, to learn what is resonating with them, and to gather new articles. As I review their manuscripts, there is often a recurring theme. Understandably, at the height of the COVID-19 pandemic, many of our authors felt a need to discuss the issues affecting their colleagues and their patients. There have been articles discussing those issues, and we continue to explore other COVID-19 topics that will meet the changing needs of our readers.

Some of our case management authors are highly experienced clinicians, social workers, counselors, and therapists who have shared their expertise through their manuscripts, whereas others are submitting their first article to *CareManagement*. We welcome all of these efforts! This publication and others fulfill an important need—the continuing education of our case management readers.

Various programs and evidenced-based initiatives in a wide variety of practice settings have been created by case management teams and departments all across the country. When these professionals decide to "tell their story," they provide valuable information. Often these articles serve as models of care and intervention that others might adopt. As the authors discuss the various components of those programs, the goals they hoped to achieve, the challenges they encountered, the research that was conducted, the case studies that illustrated their process, and the outcomes they achieved, they become the instructors in the laboratory of case management's real world. This information is increasingly valued and vital in these rapidly changing times.

> ***CareManagement* and other publications fulfill an important need—the continuing education of our case management readers.**

While some perceive their experiences in healthcare as learning opportunities and want to share those with others and contribute to the body of knowledge and the practice of case management, not everyone in case management responds the same way to the overwhelming environment that was their experience over the past several years.

Many case managers felt overwhelmed. There was (and still is) the burden of caring for too many patients, with increasing uncertainty and the lack of a roadmap to ensure that they were providing the best care possible. Many of our colleagues were dealing with the death of individuals who were not able to be comforted by their families. Understandably, many case managers felt overwhelmed because they were trying to determine the protocols while supporting each other, their patients, and their families. Without time to react to those feelings as they were occurring, those feelings eventually took their toll. We are just now seeing the aftermath of an unprecedented worldwide health crisis.

Some case managers wanted to deepen their understanding of the factors that were impacting their patients, including clinical, behavioral, and, of course, the growing importance and influence of the social determinants of health. To address these factors, case managers have returned to the classroom with the hope that they would be better prepared to meet the needs of the growing numbers of patients with complex care needs. For other case managers, their professional responsibilities, staffing shortages, and the increasing challenges to balance work and family schedules while also taking caring of themselves led them to evaluate their role and workplace setting. Some made the decision to leave the profession, and others decided they wanted to practice in another healthcare setting.

We are seeing articles and forums that explore "quiet resignation," hiring and retention of staff, issues of empathy, bullying in the workplace, and strategies to overcome or reduce burnout. Additionally, there has been a focus on developing a strategic approach to the disturbing increase in suicide among our colleagues. Although these situations are often difficult, they need to be addressed.

There certainly are more than enough issues that impact our

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Home Care Nurse Shot and Killed

Elizabeth Hogue, Esq.

Home care field staff members who provide services on behalf of private duty agencies, hospices, Medicare-certified home health agencies and home medical equipment (HME) companies are extremely vulnerable. Contributing to their vulnerability is the fact that they work alone on territory that may be unfamiliar and over which they have little control.

Home care field staff members who provide services on behalf of private duty agencies, hospices, Medicare-certified home health agencies and home medical equipment (HME) companies are extremely vulnerable. Contributing to their vulnerability is the fact that they work alone on territory that may be unfamiliar and over which they have little control. Staff members certainly need as much protection as possible.

Evidence of the danger that field staff members face is the December 1, 2022, shooting death of Douglas Brant, 56, a home care nurse in Spokane, Washington. Brant was shot and killed by his patient's grandson during a home care visit. Brant was visiting the home that his patient, her husband, and grandson shared. It was Brant's first visit to the home.

According to the police report, both the patient and her husband were in the living room with Brant while the patient's grandson was cooking in the kitchen. After talking for about an hour with Brant, the patient heard "three loud booms" and Brant said, "I've been shot." Brant put down his computer and tried to stand up, but fell to the ground. The patient's husband tried to help him and then went to the kitchen to get his grandson for help. At that point, the grandson walked into the living room from the kitchen and shot Brant again while standing over him.

Elizabeth Hogue, Esquire, *is an attorney who represents health care providers. She has published 11 books, hundreds of articles, and has spoken at conferences all over the country.*

From a practical point of view, it is important to ask what home care companies of all types can do to protect their employees from harm. The most important answer to this question is that managers must listen and act when staff members complain about safety hazards. One of the strengths of the home care industry has always been that staff members are often willing to go beyond the extra mile to care for patients.

The perception of many who know the industry well is that workers tend to put up with safety hazards that others would not hesitate to avoid. It becomes essential, therefore, for supervisors to listen carefully to staff members who complain about safety hazards. Assessments by most staff members that they regard situations as unsafe are usually valid since their natural inclination is often to continue to provide services to patients in unsafe situations.

It is also extremely important for managers to act in response to complaints by personnel. There is an old legal adage that "every dog is entitled to one bite." This means that, as soon as the dog has bitten one person, those responsible for the animal are on notice that the dog is dangerous. They must then take reasonable precautions to prevent further injury or damage. Consequently, once employees register even a single complaint regarding dangers associated with the care of certain patients, employers are likely on notice that further care may involve harm to workers. In view of this "first bite," so to speak, providers must take appropriate action or face possible liability for injuries to their personnel.

What kinds of actions are appropriate? The Centers for Medicare & Medicaid Services (CMS) issued guidance to state survey agency directors on November 28, 2022, entitled "Workplace Violence– Hospitals." Although the title of the guidance seems to focus on hospitals, language in the guidance focuses on other healthcare settings, such as patients' homes.

First, CMS points out that a Bureau of Labor Statistics Fact Sheet from April of 2020 states that healthcare workers accounted for 73% of all nonfatal workplace injuries and illnesses due to violence in 2018. The Fact Sheet also points out that the number of injuries and illnesses due to violence has been steadily increasing since tracking of these events began in 2011.

CMS goes on to assert that violence can be addressed with appropriate controls in place. According to CMS, appropriate controls applicable to care in patients'/clients' homes include:

• Adequate education training

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Fraud and Abuse Compliance for Marketing

Elizabeth Hogue, Esq.

Fraud and abuse compliance is more critical than ever for all providers. There may be nothing that destroys the value of businesses more quickly or significantly than a fraud and abuse compliance problem.

Fraud and abuse compliance is more critical than ever for all providers. There may be nothing that destroys the value of businesses more quickly or significantly than a fraud and abuse compliance problem.

The Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS), the primary enforcer of fraud and abuse prohibitions, has stated that there are two major types of fraud and abuse compliance that must be addressed through ongoing evaluation processes: (1) submission of claims, and (2) standards and procedures reviews.

There is no doubt that getting the submission of claims right is key to running a healthcare company that provides quality of care and makes money. Submission of claims requires providers to conduct prebilling reviews and postbilling retrospective audits. The process of these reviews is relatively straightforward, although providers take a regular beating on issues of whether care provided was reasonable and necessary, whether patients are homebound, whether patients are terminally ill, etc.

Some providers, however, seem to have the perception that as long as they have the requirements of submission of claims down pat, then they have done everything "fraud and abuse compliance-wise" that needs to be done.

These providers are missing the proverbial boat in a big way! There is a whole other area of fraud and abuse compliance that is equally important, according to the OIG. That is, do providers' standards and procedures measure up?

Here are some key areas related to standards and procedures that have been the focus of recent enforcement actions by the OIG and other fraud and abuse enforcers:

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The Premier Case Management Event of the Year Is for Everyone: 2023 CMSA Annual Conference and Expo

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

Make plans to join us for the 2023 CMSA Annual Conference and Expo titled "Discovering Solutions, Driving Change," which will be held June 27–30, 2023, in Las Vegas, Nevada. With a jam-packed schedule offering loads of CEs, this is the chance to spend 4 days with case manager peers, learn from experts in the field, find out about the latest advances in support and resources in the CMSA Exhibit Hall, and have a ton of fun!

Just a few of the Conference highlights in the works:

CMSA Military-VA-DoD Day

This special 1-day event, which is developed for case managers working in the military services, VA, and Department of Defense, focuses on hot topics to help them become better case managers and serve their patients. As a key membership segment of CMSA, we are committed to delivering education on top trends and innovations unique to MVD case managers.

Dr. Colleen Morley, DNP, RN, CCM, CMAC, CMCN, ACM-RN, FCM, *is the current President of the Case Management Society of America National Board of Directors and Associate Chief Clinical Operations–Continuum of Care at University of Illinois Hospital and Health Sciences System. Her current passion is in the area of improving health literacy. She has recently authored her 1st book, "A Practical Guide to Acute Care Case Management." Dr. Morley has over 20 years of nursing experience. Her clinical specialties include medical/surgical, oncology, and pediatric nursing.*

Opening Keynote: Kai Kight

"Compose Your World"

As a classical violinist turned innovative composer, Kai Kight uses music as a metaphor to inspire individuals and organizations across the world to compose paths of imagination and fulfillment. Kai is on a mission to spark a global mindset shift in which ingenuity is the norm and not the exception.

Day 2 Keynote: Bruce Berger, PhD

"Living With Your Eyes Open"

Professor Emeritus, Auburn University Harrison School of Pharmacy (AU HSP); President, Berger Consulting; Former Chair of the Department of Pharmacy, Care Systems at AU HSP; he is codeveloper of com-MIt (Comprehensive Motivational Interviewing Training).

Closing Keynote: Jean Watson, PhD, RN, AHN-BC, FAAN, LL (AAN)

Internationally renowned Jean Watson is an American nurse theorist and nursing professor who is best known for her theory of human caring. She is the author of numerous texts, including "Nursing: The Philosophy and Science of Caring." As I based my doctoral project on Dr. Watson's work, this is a dream come true for me!!

Plus Educational Sessions & Poster Presentations

The 2023 concurrent lineup will focus on the latest trends and updates in case management, which may include:

- Maternal/child health/pediatrics
- Mental/behavioral health
- Communication techniques
- Value-based reimbursement/ managed care/managed Medicare & Medicaid
- Disease/condition-specific case management
- Readmission prevention/transition management
- Ambulatory case management
- Technology
- Older adult/geriatric care
- Community care
- Professional development/leadership/ self-care
- Legal/regulatory/ethical
- Military services/DoD/Veterans Affairs

Each session will have the appropriate level represented as follows:

- NOVICE: New to case management practice, care coordination, and transition management culture, students or health care professionals not familiar with case management as a subspecialty.

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Seven Steps for Improving Equity in Health Care Delivery: A Roundtable Discussion

Ed Quick, MA, MBA, CDMS, Rebecca Fisco, CDMS, R. Keith Franklin, PhD, LPC, CEAP, LCDC, CCM, ACS, and Kendra Greene, MSN, MBA/HCM, RN, CCM

Note: The following article is based on a presentation by the authors at the Commission for Case Manager Certification (CCMC) Symposium held in October 2022.

When we think of equity in health care, one of the first things that often comes to mind is the concept of equal access. But equality is not synonymous with equity; in fact, they are distinct. One way to understand the difference is to view equality as beginning at the hospital entrance; every patient who arrives for care will receive treatment. Equity, however, looks at how—and if—a person can get to the door of the hospital. Financial, environmental, mobility, and other barriers can stand in the way, preventing access.

With this understanding, we see the close connection between equity and the social determinants of health (SDOH): the economic, environmental, and social factors that impact health and well-being. With the goal of improving equity, certified case managers (CCMs) and certified disability management specialists (CDMSs) can devise and implement care plans that bridge the gaps within the systems that influence the health of individuals and the population.

Pursuit of equity elevates advocacy within case management and disability management, ensuring that all clients (known as patients in some care settings) receive the right care and treatment at the right time, in the right setting, and of the same quality. Here are seven steps case managers and disability managers can take to ensure greater equity in health care access and delivery:

1. **Understand the difference between equity and equality:** Although these two terms are sometimes used interchangeably, they are not synonymous. As stated above, in health care, equality can be thought of ensuring everyone who comes to a hospital or other facility receives treatment. Equity, however, accounts for if and how people can access that treatment by considering financial, environmental, mobility, and other barriers.
2. **Screen for SDOH:** We cannot assume that poverty and financial insecurity affect only those who are unemployed, have no health insurance, or are undomiciled. Inflation and a higher cost of living are putting pressures on more individuals, including those who are employed. As part of intake and assessment, case managers and disability managers need to ask open-ended questions that can uncover the potential impact of SDOH. For example: Are you able to fill your prescriptions on time? How do you get to your doctor appointments? Do you have access to quality providers or ancillary services? What issues cause you stress

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Ed Quick, MA, MBA, CDMS, *is a Commissioner and Chair-elect of the Commission for Case Manager Certification (CCMC), the first and largest nationally accredited organization that certifies more than 50,000 professional case managers and disability management specialists. He has more than 30 years of experience in disability and workforce management with Fortune 100 companies and currently works as a global senior benefits manager.*

Rebecca Fisco, CDMS, *is a Commissioner of the CCMC and the Associate Director of Integrated Absence Management and Vocational Services for The Ohio State University.*

R. Keith Franklin, PhD, LPC, CEAP, LCDC, CCM, ACS, *is a Commissioner of the CCMC and an EAP psychologist with the U.S. Department of Defense's Employee Assistance Program (EAP), with more than 20 years of clinical experience.*

Kendra Greene, MSN, MBA/HCM, RN, CCM, *is a Commissioner of CCMC and a Sr. Consultant—Medical Management for Optum/UnitedHealth Care.*

Insights for Case Managers: The Need for Better Data Systems to Capture Impact

Megan Wilson, MS, AGNP-BC, Jodi Massey, BSW, Kristy Walker, BA, Lisa Macon Harrison, MPH, and Devon Noonan, PhD, MPH, FNP-BC

As part of an ongoing academic health department partnership between Granville Vance Public Health (GVPH) in North Carolina and Duke University School of Nursing, we partnered with GVPH case managers to tell their stories and provide insights for strategies to use data and advocacy to better capture the value of case management in rural communities.

Public health case management teams often go unrecognized and undervalued, given that systems to capture outcomes are currently based solely on contact and engagement with patients instead of a more holistic approach that captures the breadth of care provided. Case managers at GVPH often carry heavy caseloads comprised of high-risk Medicaid patients (ages 0-5 years) and pregnant and postpartum women. GVPH case managers are adept at building trusting, sustainable relationships with their clients, thus ensuring bidirectional communication that uncovers and addresses all their patients' needs. Excerpts from patient testimonials highlight that GVPH case managers help their patients navigate a complex healthcare system and overcome barriers related to social determinants of health (SDOH) (eg, lack of transportation, financial insecurity, and difficulty obtaining needed durable medical equipment such as breast pumps). Strong relationships focused on addressing the social needs of patients are fundamental not only to the longitudinal relationships that GVPH case managers sustain with their clients but also to health outcomes (although not easily measurable in the current infrastructure); this is particularly true for populations in rural areas served by GVPH, where lack of trusting provider patient relationships can lead to care delays (Spleen et al., 2014) and, ultimately, worse health outcomes.

Although case managers are adept at maximizing resources for clients in a resource-limited environment, lack of resources remains one of the greatest barriers to providing care in rural communities. Reliable public transport is often unavailable, so transportation resources are usually limited to taxi or cab vouchers. Housing resources are scarce; often by the time a patient reports an upcoming eviction, they have exhausted all available resources and case managers must use creative thinking to find assistance for them. The reporting metrics for capturing their efforts to address SDOH has improved with the introduction in North Carolina of NCCARE360, a closed loop system to connect patients to community resources that address SDOH, yet there is much room for

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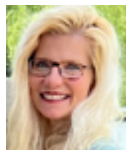
Megan Wilson, MS, AGNP-BC, *has a background in emergency nursing, Medicaid case management, and Medicare case management. She currently works as a nurse practitioner at Courtland Terrace, providing acute and primary care services to geriatric residents and short-term rehabilitation patients.*



Jodi Massey, BSW*, worked for over 25 years at the local health department as a social worker and care manager specializing in providing care management services to children birth to 5 years of age with special needs. She is currently the lead social worker/care manager in our CMARC—Care Management for At Risk Children—program.*

Kristy Walker, BA*, is an OB care manager who works with women during pregnancy and the postpartum period. She promotes healthy moms and pregnancy outcomes and provides support, guidance, referrals, and information.*

Lisa Macon Harrison, MPH, *has broad experience directing health programs, analyzing data, and fostering partnerships. She also has experience in public health leadership, quality improvement, advocacy, health equity, and community health assessment. She is currently the Health Director at Granville Vance Public Health.*

Devon Noonan, PhD, MPH, FNP-BC, *is a nurse scientist, certified addictions nurse, and an Associate Professor in the Duke School of Nursing. Dr. Noonan's research is focused on using community-engaged approaches to develop innovative health behavior change interventions, including digital interventions, with the goal of reducing risk for chronic diseases including cancer and cardiovascular disease.*

CE1 Approved for 1 hour of CCM, CDMS, and nursing education credit
Exam expires on August 16, 2023

Leveraging the Unique Role of Case Managers to Ensure Safe Opioid Use

Cheri Lattimer, RN, BSN

Case managers have a unique opportunity to raise awareness about the risks of prescription opioid misuse while helping their patients transition from one care setting to another. As health advocates focused on prioritizing well-being and autonomy, case managers connect patients to the appropriate service resources, providers, and facilities in a timely and cost-effective manner. The unique relationship between case managers and patients is centered around communication, education, and advocacy, which means that case managers have the vital opportunity and responsibility to help prevent opioid misuse in their patients.

At the height of the prescription opioid crisis in 2012, more than 255 million opioid prescriptions were written nationwide, which means that providers were issuing more than 81 prescriptions per 100 patients (CDC, 2021). Since then, the national opioid dispensing rate has dropped by 44%, reaching the lowest point in 15 years in 2020 (CDC, 2021). Despite this progress, it remains critical for all stakeholders, including case managers, to continue educating patients about the risks of prescription opioids to further drive down rates of prescription opioid misuse.

Case Managers are a Crucial Link in Preventing Prescription Opioid Misuse

Case managers develop unique relationships with their patients and can play a crucial role in informing their patients about the safe use of prescription opioids.

Research shows that a proactive and comprehensive approach is essential to counseling patients about the management of prescription opioids (Professional Case Management, 2018). By taking an advocacy-centered approach, case managers can help foster engagement and trust as well as open conversations with their patients. These conversations can occur when moving patients from primary care to specialty physicians, transferring patients from the emergency department to intensive care or surgery, or when patients are discharged from the hospital to the home, to assisted living arrangements, or to skilled nursing facilities.

Further, by speaking candidly with patients about the safe use and disposal of prescription opioids, case managers can fill the gaps that occur when patients are transitioning from one care setting to another.

About Allied Against Opioid Abuse and The National Transitions of Care Coalition

Founded in 2018, the mission of Allied Against Opioid Abuse (AAOA) is to contribute to solving the opioid crisis in a meaningful way by educating patients about the rights, risks, and responsibilities associated with prescription opioids. AAOA aims to focus on all aspects of health care to prevent opioid misuse and engages with diverse partners across the health care spectrum.

This year, AAOA celebrates its fifth anniversary of advancing this crucial mission, and the National Transitions of Care Coalition (NTOCC) is proud to serve as a critical partner in preventing prescription opioid misuse. By supplying tools and resources to health care professionals, patients, caregivers, and policymakers, NTOCC addresses the challenges patients face while transitioning between care settings. AAOA's and NTOCC's missions are aligned, with both coalitions dedicated to aiding health care professionals and caregivers in their effort to inform patients about the rights, risks, and responsibilities of prescription opioid use.

How NTOCC is Developing Resources for Pain Management

In the last 18 years, NTOCC has focused its efforts on improving transitions and care coordination for providers, patients, and family caregivers. Since 2018, NTOCC has

Cheri Lattimer, RN, BSN, *is Executive Director for the National Transitions of Care Coalition (NTOCC) and President/CEO of Integrity Advocacy & Management. She is affiliated with various professional organizations and maintains active roles on several national boards and committees including URAC's Health Standards Committee, CMS Caregiver Workgroup, CMS Advisory Committee for Education and Outreach, ACHIEVE, and ABQAURP CME Committee.*

The unique relationship between case managers and patients is centered around communication, education, and advocacy, which means that case managers have the vital opportunity and responsibility to help prevent opioid misuse in their patients.

been working to address the issues and concerns about prescribing opioids, their misuse and abuse, and the continued increase in opioid abuse—related deaths. Data from the CDC show that overdose deaths involving opioids increased from an estimated 70,029 in 2020 to 80,816 in 2021 (CDC, 2022). Overdose deaths from synthetic opioids (primarily fentanyl) and from psychostimulants such as methamphetamine and cocaine also increased from 2021 compared with 2020. Equally concerning is that approximately 44.9% of the people who misused prescription opioids obtained them from a friend or relative (SAMHSA 2020).

NTOCC has worked to ensure that health care professionals are given the resources they need to provide support and communication at point of transitions of care for patients and their family caregivers when opioids are prescribed. Patients and their caregivers need to be informed about the safe use of prescription opioids, have access to educational resources, be able to participate in shared decision making with their providers, and be informed about alternative pain management options. During this process of identifying the needs and resources relating to prescription opioid use, it became clear that alternative nonopioid pain management options often did not have associated insurance reimbursement. In other words, to access alternative care options, patients would need to pay out of pocket. This reinforced the need for NTOCC to address the current financial models related to pain management and increase the alternative options for nonopioid pain management.

Holding to its mission of raising "awareness about transitions of care among health care professionals, government leaders, patients and caregivers to increase the quality of care, reduce medication errors and enhance clinical outcomes," NTOCC began a quality improvement process defined by an integrated approach (NTOCC 2022):

1. Partner with aligned organizations to increase education and awareness regarding opioid use, misuse, and abuse to the health care industry;
2. Develop resources and provide them to the industry at no cost; and
3. Address policy issues that had negative impacts to changing the way pain medications are prescribed and reimbursed and were barriers to new models of pain management.

NTOCC Resources to Support Case Managers

Case managers have a significant role in supporting patients and their family caregivers in understanding the options and choices for nonopioid therapies. The 2022 CMSA Standards of Practice highlight the importance of the Advocacy Standard stating "the professional case manager will seek creative ways to advocate for client's best interests" (CMSA Standards of Practice, 2022). Through the case manager's client assessment, care needs identification, care planning, care coordination, and collaboration, the process of safe opioid use and options are a key component in improving care quality.

Another important intervention in this fight is the role of the pharmacist and their role in improving transitions of care. In 2022, NTOCC worked with a Transitions of Care Pharmacists Task Force to develop the Transitions of Care Pharmacists 10 Principles (NTOCC, Transitions of Care Pharmacists 10 Principles, 2022). The principles highlight key pharmacy concepts and interventions when it comes to transitions of care.

As emphasized in the Principles, NTOCC supports the practice of medication management services and pharmacists working within a collaborative health care team to support the education and advocacy for safe use of prescribed opioids. NTOCC also supports the integrative delivery of medication management services between pharmacists and case managers in providing the interventions needed to address the issues and concerns of the prescription opioid crisis.

NTOCC's Policy Engagement

In 2018, NTOCC began work with Voices for Non-Opioid Choices to provide recommendations, support changes to reimbursement for nonopioid therapies, and assess therapeutic services for pain management. While this coalition has helped facilitate the introduction of many bills over the years, in 2021 the Non-Opioids Prevent Addiction in the Nation (NOPAIN) Act (H.R. 3259/S. 586) was introduced with bipartisan support and was passed on December 23, 2022, as part of the end-of-year legislative package (Congress.gov. 2021-2022). The bill provides for access to nonopioid treatment for pain, including drug or biological products and medical devices. In the case of ambulatory

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surgical payment centers, the bill provides for a separate payment for nonopioid treatment as defined by the bill.

Furthermore, the bill instructs the secretary of the Department of Health and Human Services, acting through the administrator of the Centers for Medicare & Medicaid Services, to conduct an evaluation and submit a report to Congress no later than 1 year of enactment of the bill, which is scheduled for January 1, 2025. The evaluation should identify limitations, gaps, barriers to access, or deficits in Medicare coverage or reimbursement for restorative therapies as well as behavioral approaches and complementary and integrative health services identified in the Pain Management Best Practices Inter-Agency Task Force Report that have demonstrated the ability to replace or reduce opioid consumption.

Strengthening Quality of Care through Industry Collaboration

The power of working together with aligned organizations and health care professionals has provided a pathway to change and has implemented new models of care addressing pain management. Case managers will play a significant role in providing the education, coordination, and resources for patients and their family caregivers as they journey through the health care system in pain management as well as in informed decision making as a team member. The communication, advocacy, and support that case managers, pharmacists, and other health care professionals bring to the collaborative health care team is an essential element in transformational change. Being informed about resources and regulatory changes that improve access to and care of nonopioid choices, providing responsible safe use of prescription opioids including safe storage and disposal, and collaborating with patients and their family caregivers in support of shared decision making will improve patient quality of care and outcomes.

At the World Congress 3rd Annual Opioid & Pain Management Summit in 2020, NTOCC discussed taking a multimodal approach to pain management before a surgical intervention to support patients who did not want to use opioids for pain management:

- Clinicians talk with the patient and their family caregiver about the issues, facts, and options for pain management
- Patient and their family caregiver prepare for surgery being fully informed of their options after discussion with their provider
- Standard anesthesia protocol
- Use of nonopioid analgesics with an extended-release infiltration at the time of surgery
- Patients offered nonopioids such as nonsteroidal anti-inflammatory drugs postsurgery
- Hospitals and providers develop tailored clinical pathways that can be shared with patients and their family caregivers
- The health care community works together to support financial reimbursement for nonopioid therapies including medication, medical devices, services, and educational resources.
- Reimbursement for nonopioid therapy management is a "standard of care"

This discussion only reinforced the value of patient and caretaker education, and, accordingly, the partnership between AAOA and NTOCC, in supporting case managers across the country.

The Rights, Risks, and Responsibilities of Prescription Opioids

AAOA provides a range of educational resources that case managers can leverage in their role as patient advocates. The AAOA Pharmacy Toolkit helps case managers prompt difficult but important conversations between patients and pharmacists to help prevent opioid abuse and misuse. AAOA also offers an English-Spanish bilingual toolkit, created in partnership with the National Hispanic Medical Association, and a suite of resources designed to help educate women in their role as consumers, developed with HealthyWomen.

AAOA's Rights, Risks and Responsibilities fact sheet is an essential document for patients (or their caregivers) whose health care providers have recommended prescription opioids or who are currently taking prescription opioids. Particularly before or during transitions of care, case managers can leverage the fact sheet to help educate patients on how to safely use prescription opioids. For example, case managers can use the fact sheet to ensure patients know their rights related to pain management options and to

Data from the Centers for Disease Control and Prevention show that overdose deaths involving opioids increased from an estimated 70,029 in 2020 to 80,816 in 2021. Equally concerning is that approximately 44.9% of the people who misused prescription opioids obtained them from a friend or relative.

emphasize the importance of safe storage and disposal.

Further, NTOCC has developed a range of resources to help foster conversations between patients and providers about any concerns they may have regarding opioid use management, including a pain management questionnaire. These resources provide evidence that the key to effective pain treatment is to follow provider instructions, learn as much as possible about any medications a health care professional has prescribed, and talk to a pharmacist about any questions or concerns.

Through their partnership with AAOA, NTOCC has helped highlight information around the safe use and disposal of prescription opioids with case managers. Last year, NTOCC hosted a town hall with representatives from AAOA, Healthcare Distribution Alliance, National Community Pharmacists Association, and the PA Foundation. The town hall featured an insightful dialogue about the ongoing fight against the opioid epidemic and how stakeholders can aid in the prevention of prescription opioid misuse through transitions of care.

By collaborating with partners like NTOCC across the health care and public health space, AAOA is helping to foster important discussions that can help prevent prescription opioid misuse, especially during transitions of care.

Increasing Awareness with Partners

NTOCC's partnership with AAOA enabled both organizations to marshal resources and support the important work that both organizations perform. It expanded NTOCC's educational reach and opened the doors for many other organizations to participate. Health care providers, case managers, pharmacists, consumers, and others are encouraged to download the resources and put them into practice. It takes a village to accomplish worthwhile change, and at NTOCC we believe it takes a nation to build that movement.

To learn more about NTOCC and AAOA's work on preventing opioid misuse through education and awareness, visit www.ntocc.org and againstopioidabuse.org. CE1

The National Transitions of Care Coalition would like to thank their partner, Allied Against Opioid Abuse, for their contribution of content and resources to this article.

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How Case Managers Can Help Patients Achieve Health Literacy

Catherine M. Mullahy, RN, BSN, CRRN, CCM, FCM, and Jeanne Boling, RN, MSN, CRRN, CDMS, CCM, FCM

The problem of health literacy in the United States and abroad is pervasive. Data collected by the U.S. National Assessment of Health Literacy and reported by the University Libraries of the University of Toledo found that approximately 50% of American adults have low health literacy skills and therefore have difficulty understanding and following through on health information provided to them. Additionally, the data show that 26% of Americans have difficulty performing tasks such as adhering to their prescription medications and medical appointments, and only 12% of American have the proficiency to make informed decisions based on complex information regarding the management of their diseases (University Libraries of the University of Toledo, 2021).

Many of Americans' health literacy problems are associated with socioeconomic factors, an individual's age, reading deficits, fear and confusion about a medical condition, lack of ability to access health information due to mental or physical limitations, cultural and/or language barriers, and the overall complexities associated with medical information and clinical terms. Other factors related to health literary that are noted by MedlinePlus in its Health Literacy document include a lack of knowledge of medical words, a lack of understanding how our health system works, and an inability to effectively communicate with health care providers (Medline Plus, 2023). Addressing Americans' low health literacy is essential because there is a strong correlation between low health literacy and rising health care costs. Health literacy also affects patient outcomes and preventable hospital admissions and readmissions.

Patients with poor health literacy can pose serious challenges for case managers. Every case manager should strive to understand the state of health literacy in the United States (US), and it is critical that case managers adopt best practices relating to the assessment of their patients' health literacy and take direct measures to help raise their patients' health literacy IQs.

State of Health Literacy in America Today

What exactly is health literacy? The U.S. Department of Health and Human Services (HHS) defines health literacy as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions." (Health Literacy: MedlinePlus). There are wide variations in health literacy among residents of the 50 US states. Health IQ developed a Health Literacy Quiz and daily health quiz app in 2014 and compiled the results of over 10.2 million quizzes taken in states across the United States. The quizzes asked questions relating to nutrition, exercise, and medical subjects. Its findings confirmed the connections between health literacy, healthcare costs, and patient health. For example, Tennessee had a Health IQ score of 134 and among the highest Medicare prescription costs (per capita 65+ years) at $3,911, potentially because of the impact of the opioid epidemic. Compare this with North Dakota, which had a Health IQ score of 153 and among the lowest Medicare prescription costs (per capita 65+ years) at $1,412. Other states with low Health IQ scores (eg, Alabama with 114, Louisiana with 114, and Mississippi with 110) showed a close correlation between low Health IQs and the highest rates of high blood pressure, which led to these states being within the nation's so-called "stroke belt," where the highest incidence of stroke and stroke-related deaths prevail. Other data from Health

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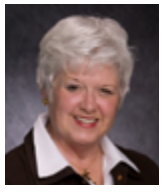

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Data collected by the U.S. National Assessment of Health Literacy and reported by the University Libraries of the University of Toledo found that approximately 50% of American adults have low health literacy skills and therefore have difficulty understanding and following through on health information provided to them.

IQ's Health Literacy Quiz data found that higher Health IQs correlate with lower obesity rates and lower diabetes rates. (Health IQ: Health Literacy in the 50 States)

Government Initiatives to Improve Health Literacy

Across the country, federal, state, and local government entities are taking steps to improve Americans' health literacy. In the broadest sense, government and health care providers working in concert should be striving to achieve certain foundational objectives. In its "Understanding Health Literacy," the Centers for Disease Control and Prevention recommends measures such as providing information that is aligned with a person's health literacy, working with health educators and others to help people gain greater familiarity with health information and health services, having health care professionals become better communicators, building health literate organizations, considering cultural and linguistic norms, and using translators and interpreters able to support the intended audience (ie, patient and patient family members to support better health literacy skills). Beyond these measures, other initiatives to improve health literacy are underway by various agencies (Centers for Disease Control and Prevention, 2022).

The Agency for Healthcare Research and Quality (AHRQ) reported on the Healthy People 2030 program. It establishes national goals to improve health, encompassing the overarching objective of "attaining health literacy to improve the health and well-being of all." AHRQ is also providing leadership on health literacy through other channels such as developing improvement tools, designing professional training and education, and funding health literacy research. (AHRQ 2022).

In another example of government health literacy initiatives, the HHS created a compilation of health literacy resources from various government entities such as the National Institutes of Health, Centers for Disease Control and Prevention, Health Resources and Services Administration, National Library of Medicine, U.S. Food and Drug Administration, Office of Minority Health, and Centers for Medicare & Medicaid Services. These can be found in the AHRQ's "About Health Literacy" at the HHS (AHRQ, 2022). It reflects the HSS' support of the Plain Writing Act in its HHS National Action Plan to Improve Health Literacy. The plan outlines practical goals including having health professionals use plain language to communicate with lay persons and provides a "blueprint for efforts to improve health literacy across all sectors." (AHRQ 2022).

The goals of the HHS also include the following:

- Develop and disseminate health and safety information that is accurate, accessible, and actionable
- Promote changes in the health care delivery system that improve health information, communication, informed decision-making, and access to health services
- Incorporate accurate, standards-based, and developmentally appropriate health and science information and curricula in childcare and education through the university level
- Support and expand local efforts to improve adult education, English-language instruction, and culturally and linguistically appropriate health information services in the community
- Build partnerships, develop guidance, and change policies
- Increase basic research and development, implementation, and evaluation of practices and interventions to improve health literacy
- Increase the dissemination and use of evidence-based health literacy practices and interventions

There have also been other federal initiatives that increased health literacy. Within the Affordable Care Act, there are sections that consider the different needs of health care providers and consumers and the diverse levels of health literacy in the nation. The Plain Writing Act of 2010 requires federal agencies to use easily understood plain language in its health care communication publications. Additionally, there is federal legislation mandating health and physical education at the K-12 education level as noted in the "Every Student Succeeds Act" of 2015, as well as in National Health Education Standards and the Whole School, Whole Community, whole Child Model. Seniors over the age of 60, 70% of whom have difficulty with printed health information, 80% of whom are challenged by charts, forms, and e-tools, and 68% of whom have low numeracy skills, are also getting support from the government. This support is being driven by the Centers for Disease Control and Prevention and by the efforts of an expert panel on "Improving Health Literacy for Older Adults." (Milken Institute).

Health Literacy Care Models

To help care managers and health care providers support health literacy goals, efforts have been made to create a standard Health Literate Care Model. One of these models is the "Health Literate Care Model–A Universal Precautions Approach." (Health Affairs). It encompasses six components: community partners; health literate systems; strategies for health literate organizations; productive interactions; informed, health literate, activated patient and family; and prepared, proactive, health literate health care team. Within the Health Literate Systems component was the directive that health care organizations provide a delivery system design, health information systems, self-management support, and shared decision making. The following directives are under the Strategies for Health Literate Organizations component (Health Affairs):

- Apply improvement methods
- Improve verbal interaction
- Improve written communication
- Link to supportive systems
- Engage patients as partners in care

This care model was designed with the goal of improving patient outcomes.

The Role of Case Managers in Health Literacy

Given the role of the case manager in supporting patients' improved outcomes, their direct role in facilitating higher health literacy levels in their patients and their patients' family members is vital. As patient educators and advocates, being effective requires identifying and assessing your patients' health literacy levels. How do you identify a low health literacy level? The Center for Health Care Strategies has developed a list of informal patient assessments. Some of the red flags that could identify a patient with a low health literacy level are as follows: frequently missing medical appointments, failure to complete medical forms, unable to list their medications and the role of each, identifying a pill by how it looks rather than by reading the label, being unable to provide a clear and sequential medical history, demonstrating a lack of follow through on their tests of referrals, and statements such as "I forgot my reading glasses," or "I'll read this when I get home." (Center for Health Care Strategies, Inc., 2013).

More formal patient assessment tools include the REAL M/D (Rapid Assessment of Adult Literacy in Medicine/Dentistry), which assesses ability to read common medical terms, the SAHLSA (Short Assessment of Health Literacy for Spanish-Speaking Adults), and TOFHLA (Test of Functional Health Literacy in Adults), which measures reading and numeracy levels using ordinary medical scenarios and materials. Case managers should use both informal and formal assessment tools to identify low health literacy levels in their patients.

Case managers can take courses in health literacy. For example, the Commission for Case Manager Certification (CCMC) has a course titled, "Case Management: Health Literacy." The course, which provides 1 Continuing Education (CE) credit, has the following learning objectives: being able to explain the difference between health literacy and general literacy, being able to summarize the impact of low health literacy, and being able to identify factors that can impact a patient's or family member's ability to use health-related information (CCMC, 2023).

Case Managers as Patient Educators and Advocates

Because case managers are directly involved in educating their patients so that they better understand their medical conditions and treatment plans and the importance of adhering to their prescribed treatments and medical schedules, they can achieve several goals. Case managers can improve their patients' confidence by ensuring that their patients know more about their medical conditions, which may be complex and involve comorbidities. They can help a patient and his/her family members gain a stronger voice when communicating with other members of their health care team (e.g., primary care physicians, specialists, pharmacists). Case managers can help their patients make better, more-informed health care decisions relating to various medical procedures such as tests and medications and ensure that their patients fully understand these decisions in terms of goals, risks, and projected outcomes.

Improving Patients' Understanding of Printed Health Information

Case managers can help educate and advocate for patients who receive health information in different formats. When sharing printed health information with patients, it is important that this information be presented in plain and clear language using common words that assumes minimal health knowledge. Health information conveyed in short sentences is always preferable to longer sentences, as is a simple presentation of numbers that does not require a calculator to grasp what is being conveyed. The information should be organized in a logical progression with headings and content grouped appropriately. Summaries are always helpful in reinforcing what is being shared in the simplest way. Even the design and layout of the printed materials should be considered. Ideally, printed health information should include a lot of white space and heavy use of bullets, frequently asked questions, and large and easy-to-read fonts. If a health care provider's printed communication does not reflect these features, it might be worth pointing that out to the provider and suggesting that materials be modified before their next print run (Centers for Health Care Strategies).

Addressing Americans' low health literacy is essential because there is a strong correlation between low health literacy and rising health care costs. Health literacy also affects patient outcomes and preventable hospital admissions and readmissions.

Helping Patients Use Digital Tools

Case managers can also play an important role in helping their patients improve their digital health literacy. While some older adults and/or those within certain ethnic or racial minority groups may find using electronic devices to access health information challenging, if these individuals have access to computers or smartphones and/or have relatives or friends who can help them learn how to use these devices, they may discover that online access can be convenient (Relias Media).

Within the Healthy People 2030 initiative, there is a proposal to "increase the proportion of persons who use health information technology to track healthcare data or communicate with providers." (Relias Media).

Digital solutions can be used to teach the basics using the teach-back method. Case managers can assist in improving their patients' health literacy by showing them how to use digital tools to gain greater health knowledge and raise their health literacy. Telehealth, for example, is a great way for a patient to access a nurse case manager or other health care professional and ask questions about a symptom they are experiencing, about a procedure that a doctor recommended, or about a new medication they have been prescribed. The case manager can answer the question and also guide them with digital solutions that can further provide basic information.

Case managers should be proactive in encouraging patients to use easier technologies rather than, for instance, phone apps, which may more difficult for some individuals. They can play an important role in identifying those individuals who need the most support, which are likely to be those with low health literacy levels. Specifically, these individuals need support in using digital interventions, and case managers can provide the initial training in this area when a patient is discharged from the hospital. They may need help setting up a mobile device provided by a health care agency that is providing a nurse case manager and other nurses to visit and monitor the patient. The patient will be asked to take his/her blood pressure, oxygen level, and weight on a daily basis using the computer/digital device, blood pressure machine, oximeter, and digital scale provided. This equipment automatically records and saves the data on the computer/digital device, which can be readily accessed by the health care provider and acted upon when necessary.

In more sophisticated applications of digital technology, case managers can teach their patients how to use Bluetooth technology and biometric sensor devices that act in concert with scales, blood pressure cuffs, and various wearable devices to monitor, record, and store vital patient data. Finally, case managers can help patients understand how to conduct a telehealth/virtual appointment with their physician or other health care provider. Some patients with developmentally disabilities may have difficulty both with using the digital tools provided and/or conducting a virtual visit. Case managers can be advocates for them by providing solutions to address these challenges such as a simple link to access a video visit.

One caveat to be mindful of regarding digital tools. While telehealth became a necessity during the pandemic when in-person doctor visits were not an option during certain lockdown periods in various regions, the shift toward eHealth was not always advantageous for individuals who were not digitally literate and thus this shift added to the existing inequities in our health caresystem. For that reason, the AHRQ and HHS recommend adhering to the sixth-grade reading level for online health-related content.

The Teach-Back Method and Other Strategies for Achieving Health Literacy Goals

Many case managers are familiar with the teach-back method, which has a valuable role in supporting improved health literacy. By having patients repeat what was explained to them in their own words, case managers can assess their patients' understanding of what was said to them. Other strategies for achieving health literacy goals are to gain greater understanding of your patient's personal concerns and needs by taking time to listen closely to what they are saying in order to identify misconceptions in their thinking. Explain their medications (ie, their purpose and how they should be taken), help patients prepare information to bring to their doctor appointments, and help interpret information patients receive from other health care professionals. Avoid using medical terms and instead speak in simple language that can be understood by your patients. Finally, be mindful of a patient's facial expressions to assess their understanding or potential confusion regarding information that is being conveyed (Heath Literacy: MedlinePlus).

Given the role of the case manager in supporting patients' improved outcomes, their direct role in facilitating higher health literacy levels in their patients and their patients' family members is vital. As patient educators and advocates, being effective requires identifying and assessing your patients' health literacy levels.

How Case Managers Can Help with a Patient's Low Disease-Specific Health Literacy

When a patient is diagnosed with a serious illness, the case manager's role in supporting a patient's health literacy can be especially important. Take the example of a patient who had just received a cancer diagnosis (Professional Case Management, LWW). Real-time decisions were needed with lasting consequences, yet the individual was, understandably, in a state of anxiety, stress, and fear. This same patient had already lost her mother, father, and sister to cancer, making her situation even more difficult. Her breast cancer diagnosis also left her concerned with how others would perceive her body image and how it would change, and her strong religious beliefs causing her to question surgery that would change a part of her body that God created.

The case manager, who was a friend of the patient, considered herself to be informed about human anatomy, the disease process, patients' responses to treatments, postoperative care, case management, and insurance plans and benefits as well as the area's health care community and resources. What also had to be taken into account were cultural considerations, which have a strong impact on health literacy, and how best to support this patient's health literacy in the context of cultural considerations (ie, body image, religious beliefs, and her personal family history). To be able to address a patient's health literacy needs, a case manager must assess the patient's social determinants of health. This case manager helped this patient by, for example, preparing questions pertaining to the tumor's location and nodal aspects, drains, and blood transfusions that the patient could ask her health care team during the postoperative period. The case manager also helped with a pharmacy store clerk's request for a detailed description of the patient's surgery, a pain score, and if there was a prior prescription for the same surgery to determine if the prescription was necessary (a requirement because of a street epidemic in the sale of pills and presumably because the prescription was for a controlled substance).

Some of other challenges this patient faced including those related to her financial situation. The patient was living with family members but still incurring costs for shared rent, home childcare, food, and home maintenance; these financial challenges were more difficult for the case manager to address but still influenced the patient's health literacy. What this case manager realized, and is important for other case managers to understand, is that case managers, as change agents, must consider how social determinants of health affect health literacy. Within this context, case managers can and should strive to promote the concept that cultural and social determinants of health must be brought into an expanded understanding of health literacy to improve health literacy and health outcomes.

The Serious Consequences of Poor Patient Health Literacy

Clearly, the most serious consequence of a patient's poor health literacy can be death. Patients who do not fully understand, for example, their medical condition, related diet restrictions, environmental triggers, and medication schedules, can suffer life-threatening consequences. Patients with low health literacy levels are especially at risk for negative consequences, particularly if they have health conditions such as congestive heart disease, diabetes, asthma, or other chronic conditions (JAMA Network).

As far back as 1999, an Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs of the American Medical Association was convened (American Medical Association, JAMA). It found that patients with inadequate health literacy and communication difficulties have worse health status and an increased risk of hospitalization. This group advocates for more research focused on optimizing methods for screening patients for low health literacy, providing more effective health education techniques, determining outcomes and costs associated with poor health literacy, and determining how "the causal pathway of how poor health literacy influences health."

Improving Health Literacy—A Catalyst for Better Health Outcomes, Lower Readmissions, and Increased Cost Savings

Case managers have a tremendous opportunity to support and advocate for health literacy, not just for their patients but for the entire American population. By improving health literacy, it is estimated that nearly 1,000,000 hospital visits

could be prevented at a cost savings of $25 billion a year (UnitedHealth Group). The data supports this. For example, Medicare beneficiaries in US counties with the highest health literacy levels experience better health outcomes. This is evidenced in data that found these individuals, on average, have received 31% more flu shots; have had 26% fewer avoidable hospitalizations, 9% fewer hospital readmissions, and 18% fewer emergency department visits; and have 13% lower costs per beneficiary. A commitment by case managers and other health care professionals to communicate with patients at all levels of health literacy can greatly improve patient satisfaction and health outcomes. CE II

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Intertrigo—Helping Case Managers Iron Out Skin Fold Challenges

Michelle Christiansen, MS, PA, CN-E, CCDS

Preventing harm within health care environments is a big challenge, yet it is also an expectation for case managers, their patients and their families. As the largest organ in the human body, our skin is vulnerable to a multitude of threats. Protecting patients from skin damage is a critical part of providing care, but as conditions become more complex, it's more challenging than ever to keep skin safe and healthy.

The harmful effects of water on the skin have long been known. Several causes of skin breakdown, seen in clinical practice, are related to the overexposure of the skin to moisture. The term moisture-associated skin damage (MASD) is used to describe the spectrum of damage that occurs as a result of prolonged exposure of a patient's skin to various sources of moisture, including urine or stool, perspiration, wound exudate, mucus, or saliva (1). However, MASD is a general umbrella term and is made up of four commonly encountered separate conditions, which often coexist. These conditions are incontinence-associated dermatitis (IAD), intertriginous dermatitis, commonly referred to as "intertrigo," periwound moisture–associated dermatitis, and peristomal moisture–associated dermatitis.

Normal skin barrier and control of moisture

One of the major functions of healthy skin is the maintenance of a physical protective barrier against the external forces that can be detrimental to the body, such as mechanical trauma, noxious irritants, excessive fluids, and infectious pathogens. This is achieved by the uppermost layer of the skin, the epidermis, and in particular the outermost part of the epidermis, the stratum corneum. The stratum corneum is composed of tightly packed, flattened, protein-rich cells called corneocytes, which are held together by a lipid-rich matrix. The stratum corneum (horny layer) also contains a mix of substances that actively attract and hold water in the corneocytes, collectively termed natural moisturizing factor (NMF). NMF acts by absorbing water from the atmosphere and deeper layers of the skin and enables the outermost layers of the skin to remain hydrated, despite the drying action of the environment (2).

This delicate balance is one of the most important factors in maintaining the flexibility and elasticity of the skin and an effective barrier against the external environment (3). Disruption of this balance leads to either excessive skin dryness or prolonged exposure to various sources of moisture such as urine or stool, perspiration, wound exudate, and secretions including mucus and saliva. Overexposure to moisture disrupts the intricate lipid-rich matrix of the outermost layer of the skin, the stratum corneum, as well as the intercellular connections between the corneocytes, which compose the stratum corneum (4, 5). Furthermore, wet skin has a high coefficient of friction, which makes it susceptible to damage from both friction and shearing forces (5).

Moisture-Associated Skin Damage

Disruption of the skin barrier increases its permeability to irritants, leading to inflammation or dermatitis (5). The spectrum of conditions characterized by inflammation and erosion of the skin resulting from continued exposure to moisture are described by the umbrella term "MASD." MASD includes four distinct clinical entities: (1) IAD, (2) intertrigo, (3) peristomal dermatitis or peristomal MASD (PMASD), and (4) periwound moisture–associated dermatitis or periwound skin damage (4,5).

Intertrigo is a form of MASD that affects opposing skin folds of the body and often coexists with IAD (4). The prevalence of intertrigo ranges from 2%–6% in hospital patients to 6%–17% in nursing home patients and to 9%–20% in home care patients. Large skin folds of the body such as the axillary, inguinal, and intergluteal areas as well as the inframammary areas in females are commonly affected by intertrigo.

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Abdominal and pubic panniculi may be affected in individuals with obesity. However, other sites of the body like neck creases, antecubital, popliteal, umbilical, perianal, and interdigital areas as well as the folds of eyelids and retroauricular areas may also be involved (4, 6, 7, 8).

Intertrigo

Intertrigo is a common dermatological condition that occurs in skin folds as a result of moisture becoming trapped due to poor air circulation. The major underlying causes of intertrigo are perspiration and lack of air circulation within the skin folds; this leads to skin-on-skin friction and eventually results in skin inflammation and maceration. Bacterial infections are a common complication associated with intertrigo. Intertrigo is primarily caused by trapped moisture in skin folds that causes the skin to "stick" together, thereby increasing friction. This can occur in any areas of the body where there are two skin surfaces in close contact with each other, such as between the toes or fingers, but is more common in the natural large skin folds of the body (axillary and inguinal areas) as well as under the breasts in females (9). Babies are particularly prone to developing intertrigo in the neck folds because they have short necks, flexed postures, and drool (10).

Several factors increase the likelihood of intertrigo developing in obese individuals. First, the skin folds are more pronounced, and intertrigo commonly occurs under the abdominal or pubic panniculi. Second, the associated problems of increased sweating and reduced dexterity can make it difficult to ensure these areas are kept clean and dry. Initially intertrigo presents as mild erythema in the skin folds, but it may progress to more severe inflammation with erosion, oozing, exudation, maceration, and secondary infection (11). This combination of warm, moist, and damaged skin provides ideal conditions for microorganisms to breed. Fungal infections are common, including those due to *Candida* species and dermatophytes such as *Trichophyton* often complicate interdigital intertrigo. Numerous bacterial species often coexist, such as *Staphylococcus, Streptococcus, Pseudomonas,* and *Proteus,* and include antibiotic-resistant strains (methicillin-resistant *Staphylococcus aureus* [MRSA] and vancomycin-resistant *Staphylococcus aureus* [VRSA]) (10). A particular variation of secondary infection seen in intertrigo is caused by an organism called *Corynebacterium minutissimum.* This bacterial infection leads to a condition known as erythrasma, in which red/brown skin discoloration occurs in the intertriginous areas. If not effectively dealt with, any initial secondary infection can easily progress into more serious soft tissue infection, such as cellulitis or even systemic sepsis (9).

The Role of the Case Manager for Patients with Intertrigo and Related Conditions

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Patients who may have intertrigo are typically not referred for case management intervention because of this diagnosis but rather because of a concomitant diagnosis such as hyperhidrosis, diabetes, and obesity as well as other conditions that render patients compromised physically and either mostly immobile or bedridden. Intertrigo can be a challenging disorder to manage for both the patient and for the health care team. The initial and most important step in the case management process is screening and assessing patients at the earliest opportunity. Knowing the risk factors that can contribute to this often-debilitating condition is important; the case manager should be aware of the medical conditions mentioned in this article and should also carefully assess the patient's social determinants of health and behavioral health factors.

Individuals who have health literacy issues, who live in underserved areas, who lack family support, and who are coping with transportation and financial barriers will need to have their care carefully coordinated and to have ongoing collaboration with the health care professionals and service providers that will be involved in their care.

Addressing the very real and significant psychosocial factors that impact so many patients with intertrigo is an extremely significant role for the case manager because patients who develop intertrigo and related conditions are frequently embarrassed and delay obtaining treatment in a timely manner, which of course only serves to complicate the situation and to increase the costs of care. Because some patients with intertrigo often have an unpleasant appearance and an objectionable odor, members of the patient's health care team might have an aversion to caring for these individuals. Case managers can make an invaluable contribution by serving as the patient's advocate and providing education and support to hands-on providers.

Because intertrigo may be a lifelong chronic condition with recurrent exacerbations and costly complications, the case manager will likely need to provide ongoing education and support for the patient and the patient's family.

Outcomes can be determined by objectively assessing the results obtained from case management intervention. While cost savings obtained from case management interventions for intertrigo and related conditions are not widely available, the goal of case managers is to reduce their patients' complications and to provide education and resources for their patients.

Intertriginous dermatitis, or intertrigo, is a form of moisture-associated skin damage that affects opposing skin folds of the body and often coexists with incontinence-associated dermatitis. The prevalence of intertrigo ranges from 2%–6% in hospital patients to 6%–17% in nursing home patients and to 9%–20% in home care patients.

Important Risk Factors

Bedridden and elderly individuals as well as infants are commonly affected by intertrigo because of reduced immunity, immobility, and incontinence (7). Infants are also prone to develop intertrigo because of drooling, short neck structure with prominent skin folds, and a flexed position (4, 6, 12). Obesity and hyperhidrosis are important risk factors for intertrigo. Predisposing factors for intertrigo include diabetes, urinary or fecal incontinence, poor personal hygiene, malnutrition, immunosuppression, occlusive clothing, and a hot and humid climate.

People of size may also develop additional skin folds, including lateral folds above the waist, folds across the back just below the scapulae, abdominal folds, pannus, and folds in the legs and arms. "Angel wings" develop both in overweight individuals, even with a body mass index <30 kg/m^2, and in the elderly who have lost height. In patients with a body mass index >40 kg/m^2, skin also folds over at the waist laterally and then centrally as weight increases. Pannus is graded from 1 to 5, with a grade 1 pannus apron reaching the hairline and mons pubis but not the genitals and a grade 5 pannus apron reaching to the knees. The most prevalent locations for problems were the groin, limbs, beneath the breasts, and the abdomen.

Moisture barrier function is also impaired in obese individuals, with increased sweating after overheating among obese compared with lean individuals. These individuals are less efficient than lean comparators in regulating body temperature by sweating. This inefficiency increases the duration of sweating and the exposure of the skin to moisture. Sweating is most pronounced in skin folds, where moisture is prevented from evaporating. Obese individuals also have more alkaline skin pH than lean individuals.

Etiology

The main factor in the development of intertrigo is occurrence of mechanical skin-to-skin friction. Lack of air circulation in the skin folds traps moisture in the form of sweat, leading to overhydration and maceration of the skin. Feces, urine, wound exudate, and vaginal discharge may aggravate intertrigo. Maceration enhances friction between opposing skin surfaces and initially appears as minimal erythema of the skin folds (4). Intertrigo has an insidious onset, with symptoms such as itching, pain, burning, prickling, or stinging sensations at the site of the skin folds. Although intertrigo presents initially as mild erythematous patches mirrored on both sides of the skin fold, the lesions may progress quickly to exudative erosions, fissures, macerations, or crusts (13). Worsening erythema, pustules, or vesicles and malodor may suggest development of a secondary cutaneous infection (6, 7, 14).

Complications

A variety of microorganisms including different gram-positive or gram-negative bacteria or fungi (including yeasts, molds, and dermatophytes) can complicate intertrigo. Warm, moist, macerated skin, may become inflamed and denuded and can provide ideal conditions for these pathogens to breed. Bacterial species found in the affected areas include staphylococci such as *Staphylococcus aureus* (including antibiotic-resistant strains), group A β-hemolytic *Streptococcus, Pseudomonas, Proteus mirabilis, Proteus vulgaris,* enterococci, and vancomycin-resistant enterococci (13). The bacterium *C. minutissimum* causes a particular variation of secondary infection seen in intertrigo called erythrasma (4). An infected intertrigo lesion may result in serious cellulitis, especially in patients with diabetes. Additionally, skin fissuring and ulceration can occur within the deep skin folds in individuals with obesity leading to pain, disability, and, potentially, sepsis. Among fungi, *Candida albicans* is most commonly associated with secondary infection in individuals with intertrigo (6, 12). However, complications resulting from fungal infection in intertrigo-affected areas are beyond the scope of this paper.

Physical examination

The appearance of intertrigo is dependent on the skin area involved and the duration of inflammation. Intertrigo initially presents as mild erythematous patches on both sides of the skinfold. The erythematous lesions may progress to weeping, erosions, fissures, maceration, or crusting. Worsening erythema or inflammation could suggest the development of a secondary cutaneous infection (1, 15).

Pustules or vesicles may herald infection. In the perineum, depths of the skin folds are involved, whereas with purely

Intertrigo is a common dermatological condition that occurs in skin folds as a result of moisture becoming trapped due to poor air circulation. The major underlying causes of intertrigo are perspiration and lack of air circulation within the skin folds; this leads to skin-on-skin friction and eventually results in skin inflammation and maceration.

irritant diaper dermatitis, only convex surfaces are involved. Bluish-green staining of the diaper or underclothing may indicate pseudomonal intertrigo, which can be treated with vinegar soaks (6, 16). Intertrigo infected by *Candida* species often presents with satellite lesions. Any skin fold may be involved with intertrigo.

Treatment

Treatment of intertrigo aims at reducing symptoms and minimizing the risk for complications related to secondary infection. Management practices generally focus on removal of predisposing factors, including minimizing moisture and friction in the involved areas. These are followed by appropriate use of topical or systemic antimicrobial (antibacterial or antifungal) agents as well as low-potency corticosteroids, if required (6, 14). Preventive measures are important because they may help with management of current intertrigo and may also help avoid occurrence of future episodes (14, 16). The following are measures to prevent intertrigo:

1. An interventional skin care program that removes irritants from the skin, maximizes its intrinsic moisture barrier function, and protects the skin from further exposure to irritants
2. Use of devices or products that wick moisture away from affected or at-risk skin
3. Use of a moisture-wicking textile with hydrogen peroxide between affected skin folds.
4. Continue treatment until intertrigo has been controlled
5. Treat secondary infection with appropriate systemic and topical agents
6. Revisit the diagnosis in cases that do not respond to usual therapy
7. Initiate a prevention program that can include weight loss, a skin-fold hygiene program, and early detection and treatment of recurrence

Prevention

As the common causative agent in MASD is overexposure of the skin to moisture, the main preventative measure is avoiding excessive contact of the skin with moisture. During patient instruction, emphasize topics such as weight loss (in patients of size), glucose control (in patients with diabetes), good hygiene, and the need for daily skin care and monitoring. These are:

1. Minimize skin-on-skin contact and friction
2. Remove irritants from the skin and protect the skin from additional exposure to irritants
3. Wick moisture away from affected and at-risk skin
4. Consider using a moisture-wicking textile with hydrogen peroxide between skin folds
5. Educate patient about proper skin fold hygiene

Skin folds should be kept as clean and dry as possible to minimize friction. Gentle cleansing with a pH-balanced no-rinse cleanser is recommended. Irritated skin folds should be patted dry rather than wiped or rubbed (13). Loose-fitting lightweight clothing made of natural fabrics or athletic clothing that wicks moisture away from the skin are good choices. Open-toed shoes may be beneficial in preventing toe-web intertrigo (6). However, closed-toe shoes would be recommended for patients with diabetes, and a moisture-wicking textile with hydrogen peroxide could be woven between the toes to help translocate moisture.

Moisture-wicking textile with hydrogen peroxide

Various standard treatments for intertrigo, such as drying agents, barrier creams, topical antifungals, and absorptive materials, may be ineffective in some patients. Moisture-wicking textile with hydrogen peroxide is a medical device that helps to wick moisture away from the skin folds. The textile is effective for signs and symptoms of intertrigo, such as maceration, denudement, inflammation, pruritus, erythema, and satellite lesions.

This textile is a soft, thin, smooth, polyurethane-coated polyester fabric that helps with management of moisture and provides comfort and odor control; the softness of the textile provides a friction-reducing surface that reduces the risk of skin tears. The moisture from the skin fold is translocated towards the end of the fabric hanging outside the skinfold. Additionally, hydrogen peroxide is encapsulated in a binder, leading to its slow release over time when exposed to moisture. Hydrogen peroxide is a known germicidal agent that prevents the growth of bacteria in the fabric throughout the duration of use. Hydrogen peroxide shows activity against a wide variety of microorganisms, including bacteria, yeast,

As the common causative agent in moisture-associated skin damage is overexposure of the skin to moisture, the main preventative measure is avoiding excessive contact of the skin with moisture. During patient instruction, emphasize topics such as weight loss (in patients of size), glucose control (in patients with diabetes), good hygiene, and the need for daily skin care and monitoring.

fungi, viruses, and spores. Hydrogen peroxide produces destructive hydroxyl free radicals that can attack membrane lipids, DNA, and other essential cell components.

For patients who experience incontinence, good continence care is central to success after each major incontinence episode, particularly if feces are present. Ideally the skin care provided for patients with any form of MASD should be based on a structured regimen and involve the use of a skin cleanser and a protectant. The use of ordinary soap and water should be avoided, as in most cases the pH of the soap is too alkaline and may contribute to the skin irritation (17).

After cleansing, the skin needs to be protected against subsequent contact with moisture by using a skin protectant or barrier product. These are designed to repel moisture and protect the skin from the harmful effects of incontinence. Basic barrier preparations consist of a lipid/water emulsion base with the addition of metal oxides (eg, zinc or titanium) that form a thin layer on the surface of the skin to repel potential irritants. The more sophisticated preparations often contain a water-repellent, silicone-based ingredient. Unfortunately, some of these ingredients may cause irritation in sensitive individuals, which should always be kept in mind, particularly if the skin irritation appears to worsen when using any preparation.

Many cleansing products combine a cleanser with a protectant and moisturizer and are pH balanced to help maintain the normal slightly acidic skin pH range of 5.5-5.9, making it easier for patients to adhere to a skin care protocol (18). Similar products should be used for individuals whose skin has already broken down. The problem should be reassessed and the likely cause should be identified. In severe excoriation of the skin, more active measures may need to be taken to contain either urine or feces to protect the skin and to reduce the area of skin exposed to stool or urine. For individuals with an ostomy, changes to the pouch system being used and the introduction of a silicone-based protectant can help. These actions need to be combined with the initiation of a structured skin care regimen.

If assessment of the skin breakdown suggests a fungal infection is present, an antifungal cream will be needed. If bacterial infection is suspected, the use of topical or systemic antimicrobials may be indicated, ideally following sensitivity results and in accordance with local antimicrobial prescribing policy. In the case of intertrigo, care has to be taken to ensure all the skin folds are carefully examined and efforts made to improve air circulation. The use of excessive talcum powder, gauze, towels, or coffee filters between the skin folds should be avoided as these practices may increase the risk of fungal infection and increase moisture trapping (9). The management of periwound dermatitis is based on the same principles as already outlined but is often more of a balancing act in trying to control excessive moisture without causing excessive drying of the skin (19). Most guidelines for the management of heavily exudating wounds advocate using highly absorbent dressings, more frequent dressing changes, and the use of a skin protectant on the periwound skin; in addition, the use of a collecting device should be considered (20).

Learning points

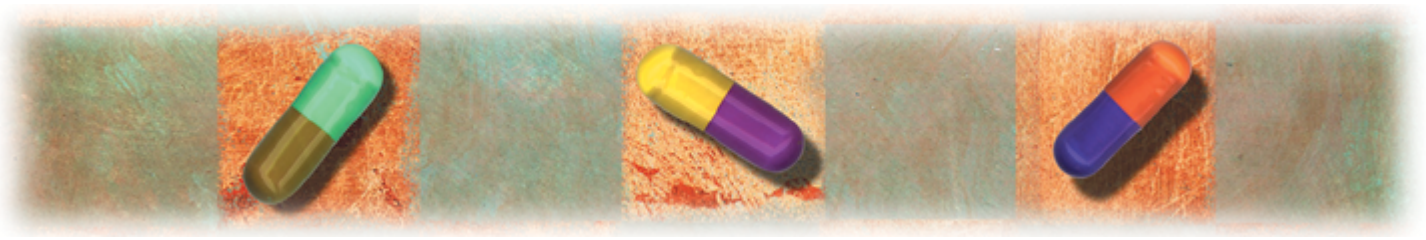
- MASD is an umbrella term for skin breakdown caused by a range of factors in which the skin is exposed to excessive moisture
- Intertrigo is one type of MASD and is an inflammatory condition of skin folds, induced or aggravated by heat, moisture, maceration, friction, and lack of air circulation.
- Intertrigo commonly affects the axilla, perineum, inframammary creases, and abdominal folds. Uncommonly, it can also affect the neck creases and interdigital areas.
- Prevention and treatment require regular assessment, with an appropriate skin care regimen that protects the skin from excessive wetness, controls the source of the excessive moisture, and treats secondary infection.

Conclusion

MASD is a common problem encountered in many patient groups. It is generally accepted that MASD consists of four main separate conditions, each having slightly different etiologies. These are IAD, intertrigo, periwound moisture–associated dermatitis, and peristomal moisture–associated dermatitis. Whatever the cause of the excessive moisture, effective interventions should consist of adopting a structured skin care regimen to cleanse and protect the skin, using methods to keep the skin dry by wicking away excessive

continues on page 39

PharmaFacts for Case Managers



Leqembi™ (lecanemab-irmb) injection, for intravenous use Initial

INDICATIONS AND USAGE

Leqembi is indicated for the treatment of Alzheimer's disease. Treatment with Leqembi should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with Leqembi. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial.

DOSAGE AND ADMINISTRATION

Patient Selection

Confirm the presence of amyloid beta pathology before initiating treatment.

Dosing Instructions

The recommended dosage of Leqembi is 10 mg/kg that must be diluted then administered as an intravenous infusion over approximately 1 hour, once every 2 weeks.

If an infusion is missed, administer the next dose as soon as possible.

Monitoring and Dosing Interruption for Amyloid Related Imaging Abnormalities

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

Monitoring for ARIA

Obtain a recent (within 1 year) brain magnetic resonance imaging (MRI) before initiating treatment with Leqembi. Obtain an MRI before the 5th, 7th, and 14th infusions.

Recommendations for Dosing Interruptions in Patients with ARIA

ARIA-E

The recommendations for dosing interruptions for patients with ARIA-E are provided in Table 1.

TABLE 1 DOSING RECOMMENDATIONS FOR PATIENTS WITH ARIA-E1

Clinical Symptom Severity[1]	ARIA-E Severity on MRI		
	Mild	**Moderate**	**Severe**
Asymptomatic	May continue dosing	Suspend dosing[2]	Suspend dosing[2]
Mild	May continue dosing based on clinical judgment	Suspend dosing[2]	
Moderate or Severe	Suspend dosing[2]		

1 ***Mild***: discomfort noticed, but no disruption of normal daily activity.
Moderate: discomfort sufficient to reduce or affect normal daily activity.
Severe: incapacitating, with inability to work or to perform normal daily activity.

2. Suspend until MRI demonstrates radiographic resolution and symptoms, if present, resolve; consider a follow-up MRI to assess for resolution 2 to 4 months after initial identification. Resumption of dosing should be guided by clinical judgment.

ARIA-H

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

TABLE 2 DOSING RECOMMENDATIONS FOR PATIENTS WITH ARIA-H1

Clinical Symptom Severity	ARIA-H Severity on MRI		
	Mild	**Moderate**	**Severe**
Asymptomatic	May continue dosing	Suspend dosing[1]	Suspend dosing[2]
Symptomatic	Suspend dosing[1]	Suspend dosing[2]	

1 Suspend until MRI demonstrates radiographic stabilization and symptoms, if present, resolve; resumption of dosing should be guided by clinical judgment; consider a follow-up MRI to assess for stabilization 2 to 4 months after initial identification.

2 Suspend until MRI demonstrates radiographic stabilization and symptoms, if present, resolve; use clinical judgment in considering whether to continue treatment or permanently discontinue Leqembi.

In patients who develop intracerebral hemorrhage greater than 1 cm in diameter during treatment with Leqembi, suspend dosing until MRI demonstrates radiographic stabilization and symptoms, if present, resolve. Use clinical judgement in considering whether to continue treatment after radiographic stabilization and resolution of symptoms or permanently discontinue Leqembi.

DOSAGE FORMS AND STRENGTHS

Leqembi is a clear to opalescent and colorless to pale yellow solution, available as:

- Injection: 500 mg/5 mL (100 mg/mL) in a single-dose vial
- Injection: 200 mg/2 mL (100 mg/mL) in a single-dose vial

CONTRAINDICATIONS

None.

Amyloid-Related Imaging Abnormalities

Monoclonal antibodies directed against aggregated forms of beta amyloid, including Leqembi, can cause ARIA, characterized as ARIA with edema (ARIA-E), which can be observed on MRI as brain edema or sulcal effusions, and ARIA with hemosiderin deposition (ARIA-H), which includes microhemorrhage and superficial siderosis. ARIA-H can occur spontaneously in patients with Alzheimer's disease. ARIA-H associated with monoclonal antibodies directed against aggregated forms of beta amyloid generally occurs in association with an occurrence of ARIA-E. ARIA-H of any cause and ARIA-E can occur together. ARIA is usually asymptomatic, although serious and life-threatening events, including seizure and status epilepticus, rarely can occur. When present, reported symptoms associated with ARIA may include headache, confusion, visual changes, dizziness, nausea, and gait difficulty. Focal neurologic deficits may also occur. Symptoms associated with ARIA usually resolve over time.

Incidence of ARIA

Symptomatic ARIA occurred in 3% (5/161) of patients treated with Leqembi in Study 1. Clinical symptoms associated with ARIA resolved in 80% of patients during the period of observation.

Including asymptomatic radiographic events, ARIA was observed in 12% (20/161) of patients treated with Leqembi, compared to 5% (13/245) of patients on placebo in Study 1. ARIA-E was observed in 10% (16/161) of patients treated with Leqembi compared with 1% (2/245) of patients on placebo. ARIA-H was observed in 6% (10/161) of patients treated with Leqembi compared with 5% (12/245) of patients on placebo. There was no increase in isolated ARIA-H (i.e., ARIA-H in patients who did not also experience ARIA-E) for Leqembi compared to placebo.

Intracerebral hemorrhage greater than 1 cm in diameter was reported in one patient in Study 1 after treatment with Leqembi compared to none on placebo. Events of intracerebral hemorrhage, including fatal events, in patients taking Leqembi have also been reported in other studies.

ApoE ε4 Carrier Status and Risk of ARIA

In Study 1, 6% (10/161) of patients in the Leqembi group were apolipoprotein E ε4 (ApoE ε4) homozygotes, 24% (39/161) were heterozygotes, and 70% (112/161) were noncarriers. The incidence of ARIA was higher in ApoE ε4 homozygotes than in heterozygotes and noncarriers among patients treated with Leqembi. Of the 5 patients treated with Leqembi who had symptomatic ARIA, 4 were ApoE ε4 homozygotes, 2 of whom experienced severe symptoms. In addition, an increased incidence of symptomatic and overall ARIA in ApoE ε4 homozygotes compared to heterozygotes and noncarriers in patients taking Leqembi has been reported in other studies. The recommendations on management of ARIA do not differ between ApoE ε4 carriers and noncarriers. Consider testing for ApoE ε4 status to inform the risk of developing ARIA when deciding to initiate treatment with Leqembi.

Radiographic Findings

The radiographic severity of ARIA associated with Leqembi was classified by the criteria shown in Table 3.

Most ARIA-E radiographic events occurred early in treat-

TABLE 3 ARIA MRI CLASSIFICATION CRITERIA

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

ment (within the first 7 doses), although ARIA can occur at any time and patients can have more than 1 episode. The maximum radiographic severity of ARIA-E in patients treated with Leqembi was mild in 4% (7/161) of patients, moderate in 4% (7/161) of patients, and severe in 1% (2/161) of patients. Resolution on MRI occurred in 62% of ARIA-E patients by 12 weeks, 81% by 21 weeks, and 94% overall after detection. The maximum radiographic severity of ARIA-H microhemorrhage in patients treated with Leqembi was mild in 4% (7/161) of patients and severe in 1% (2/161) of patients; 1 of the 10 patients with ARIA-H had mild superficial siderosis.

Concomitant Antithrombotic Medication and Other Risk Factors for Intracerebral Hemorrhage

Patients were excluded from enrollment in Study 1 for baseline use of anticoagulant medications. Antiplatelet medications such as aspirin and clopidogrel were allowed. During the study, if anticoagulant medication was used because of intercurrent medical events that required treatment for 4 weeks or less, treatment with Leqembi was to be temporarily suspended. Patients who received Leqembi and an antithrombotic medication (aspirin, other antiplatelets, or anticoagulants) did not have an increased risk of ARIA-H compared to patients who received placebo and an antithrombotic medication. The majority of exposures to antithrombotic medications were to aspirin; few patients were exposed to other antiplatelet drugs or anticoagulants, limiting any meaningful conclusions about the risk of ARIA or intracerebral hemorrhage in patients taking other antiplatelet drugs or anticoagulants. Because intracerebral hemorrhages greater than 1 cm in diameter have been observed in patients taking Leqembi, additional caution should be exercised when considering the administration of antithrombotics or a thrombolytic agent (e.g., tissue plasminogen activator) to a patient already being treated with Leqembi.

Additionally, patients were excluded from enrollment in Study 1 for the following risk factors for intracerebral hemorrhage: prior cerebral hemorrhage greater than 1 cm in greatest diameter, more than 4 microhemorrhages, superficial siderosis, evidence of vasogenic edema, evidence of cerebral contusion, aneurysm, vascular malformation, infective lesions, multiple lacunar infarcts or stroke involving a major vascular territory, and severe small vessel or white matter disease. Caution should be exercised when considering the use of Leqembi in patients with these risk factors.

Monitoring and Dose Management Guidelines

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

Baseline brain MRI and periodic monitoring with MRI are recommended. Enhanced clinical vigilance for ARIA is recommended during the first 14 weeks of treatment with Leqembi. If a patient experiences symptom suggestive of ARIA, clinical evaluation should be performed, including MRI if indicated. If ARIA is observed on MRI, careful clinical evaluation should be performed before continuing treatment.

There is no experience in patients who continued dosing through symptomatic ARIA-E or through asymptomatic, but radiographically severe, ARIA-E. There is limited experience in patients who continued dosing through asymptomatic but radiographically mild to moderate ARIA-E. There are limited data in dosing patients who experienced recurrent ARIA-E.

The Alzheimer's Network for Treatment and Diagnostics (ALZ-NET) is a voluntary provider-enrolled patient registry that collects information on treatments for Alzheimer's disease, including Leqembi. Providers may obtain information about the registry at www.alz-net.org or contact alz-net@acr.org.

Infusion-Related Reactions

In Study 1, infusion-related reactions were observed in 20% (32/161) of patients treated with Leqembi compared to 3% (8/245) of patients on placebo; and the majority (88%, 28/32) occurred with the first infusion. Infusion-related reactions were mild (56%) or moderate (44%) in severity. Infusion-related reactions resulted in discontinuations in 2% (4/161) of patients treated with Leqembi. Symptoms of infusion-related reactions include fever and flu-like symptoms (chills, generalized aches, feeling shaky, and joint pain), nausea, vomiting, hypotension, hypertension, and oxygen desaturation.

After the first infusion, 38% of patients treated with Leqembi had transient decreased lymphocyte counts to less than 0.9 x109/L compared to 2% in patients on placebo, and 22% of patients treated with Leqembi had transient increased neutrophil counts to greater 7.9 x109/L compared to 1% of patients on placebo.

In the event of an infusion-related reaction, the infusion rate may be reduced, or the infusion may be discontinued, and appropriate therapy initiated as clinically indicated. Prophylactic treatment with antihistamines, acetaminophen, nonsteroidal anti-inflammatory drugs, or corticosteroids before future infusions may be considered

ADVERSE REACTIONS

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

- Amyloid-Related Imaging Abnormalities
- Infusion-Related Reactions

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

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

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

Lactation

Risk Summary

There are no data on the presence of lecanemab-irmb in human milk, the effects on the breastfed infant, or the effects of the drug on milk production. Published data from other monoclonal antibodies generally indicate low passage of monoclonal antibodies into human milk and limited systemic exposure in the breastfed infant. The effects of this limited exposure are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Leqembi and any potential adverse effects on the breastfed infant from Leqembi or from the underlying maternal condition.

Pediatric Use

Safety and effectiveness of Leqembi in pediatric patients have not been established.

Geriatric Use

In Study 1, the age of patients exposed to Leqembi 10 mg/kg every two weeks ranged from 51 to 88 years, with a mean age of 73 years; 62% were 65 to 80 years, and 21% were 80 years and older. Age-related findings about clinical efficacy and safety are limited by the small numbers of patients less than 65 years of age and 80 years of age and older in clinical studies of Leqembi.

CLINICAL STUDIES

The efficacy of Leqembi was evaluated in a double-blind, placebo-controlled, parallel-group, dose finding study (Study 1, NCT01767311) in patients with Alzheimer's disease (patients with confirmed presence of amyloid pathology and mild cognitive impairment [64% of patients] or mild dementia stage of disease [36% of patients], consistent with Stage 3 and Stage 4 Alzheimer's disease). Study 1 had a 79-week double-blind, placebo-controlled period, followed by an open-label extension period for up to 260 weeks, which was initiated after a gap period (range 9 to 59 months; mean 24 months) off treatment.

In Study 1, 856 patients were randomized to receive one of 5 doses (161 of which were randomized to the recommended dosing regimen of 10 mg/kg every two weeks) of Leqembi or placebo (n=247). Of the total number of patients randomized, 71.4% were ApoE ε4 carriers and 28.6% were ApoE ε4 non-carriers. During the study the protocol was amended to no longer randomize ApoE ε4 carriers to the 10 mg/kg every two weeks dose arm. ApoE ε4 carriers who had been receiving Leqembi 10 mg/kg every two weeks for 6 months or less were discontinued from study drug. As a result, in the Leqembi 10 mg/kg every two weeks arm, 30.3% of patients were ApoE ε4 carriers and 69.7% were ApoE ε4 non-carriers. At baseline, the mean age of randomized patients was 71 years, with a range of 50 to 90 years. Fifty percent of patients were male and 90% were White.

Patients were enrolled with a Clinical Dementia Rating (CDR) global score of 0.5 or 1.0 and a Memory Box score of 0.5 or greater. All patients had a Mini-Mental State Examination (MMSE) score of ≥22, had objective impairment in episodic memory as indicated by at least 1 standard deviation below age-adjusted mean in the Wechsler-Memory Scale-IV Logical Memory II (subscale) (WMS-IV LMII). Patients were enrolled with or without concomitant approved therapies (cholinesterase inhibitors and the N-methyl-D-aspartate antagonist memantine) for Alzheimer's disease.

In Study 1, a subgroup of 315 patients were enrolled in the amyloid PET substudy; of these, 277 were evaluated at week 79. Results from the amyloid beta PET substudy are described in Figure 1 and Table 4.

The primary endpoint was change from baseline on a weighted composite score consisting of selected items from the CDR-SB, MMSE, and ADAS-Cog 14 at Week 53. Leqembi had a 64% likelihood of 25% or greater slowing of progression on the primary endpoint relative to placebo at Week 53, which did not meet the prespecified success criterion of 80%.

Key secondary efficacy endpoints included the change from baseline in amyloid PET SUVR composite at Week 79 and change from baseline in the CDR-SB and ADAS-Cog14 at Week 79. Results for clinical assessments showed less change from baseline in CDR-SB and ADAS-Cog 14 scores at Week 79 in the Leqembi group than in patients on placebo (CDR-SB: -0.40 [26%], 90% CI [-0.82, 0.03]; ADAS-Cog 14: -2.31 [47%], 90% CI [-3.91, -0.72].

HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

Leqembi (lecanemab-irmb) injection is a preservative-free, sterile, clear to opalescent, and colorless to pale yellow solution. Leqembi is supplied one vial per carton as follows: 500 mg/5 mL (100 mg/mL) single-dose vial (with white flip cap) – NDC 62856-215-01 200 mg/2 mL (100 mg/mL) single-dose vial (with dark grey flip cap)

Storage and Handling

Unopened Vial

- Store in a refrigerator at 2°C to 8°C (36°F to 46°F).
- Store in the original carton to protect from light.
- Do not freeze or shake.

Cost

Leqembi will cost about $26,500 a year.

For full prescribing information, please see Product Insert.

Leqembi is manufactured by Eisai, Inc.

FIGURE 1: **REDUCTION IN BRAIN AMYLOID BETA PLAQUE (ADJUSTED MEAN CHANGE FROM BASELINE IN AMYLOID BETA PET COMPOSITE, SUVR AND CENTILOIDS) IN STUDY 1**

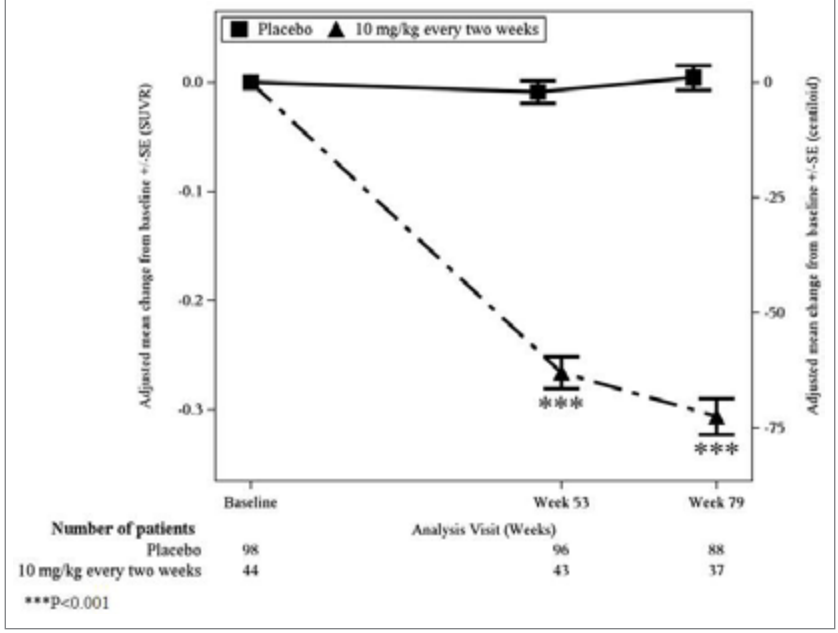


TABLE 4 BIOMARKER RESULTS OF LEQEMBI IN STUDY 1

Biomarker Endpoints[1]	**Leqembi 10 mg/kg every two weeks**	**Placebo**
Amyloid Beta PET Composite SUVR	N=44	N=98
Mean baseline	1.373	1.402
Adjusted mean change from baseline at Week 79 Difference from placebo	-0.306 -0.310 (p<0.001)	0.004
Amyloid Beta PET Centiloid	N=44	N=98
Mean baseline	78.0	84.8
Adjusted mean change from baseline at Week 79 Difference from placebo	-72.5 -73.5 (p<0.001)	1.0
Plasma Aβ42/40[2]	N=43	N=88
Mean baseline	0.0842	0.0855
Adjusted mean change from baseline at Week 79 Difference from placebo	0.0075 0.0054 (p=0.0036)	0.0021
Plasma p-tau181 (pg/mL)[2]	N=84	N=179
Mean baseline	4.6474	4.435
Adjusted mean change from baseline at Week 79 Difference from placebo	-1.1127 -1.1960 (p<0.0001)	0.0832

N is the number of patients with baseline value.

[1]P values were not statistically controlled for multiple comparisons.

[2]Plasma Aβ42/40 and plasma p-tau181 results should be interpreted with caution due to uncertainties in bioanalysis.

LitScan for Case Managers

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

Eur J Heart Fail. 2023 Jan 4. doi: 10.1002/ejhf.2762. Online ahead of print.

Bridging strategies and cardiac replacement outcomes in patients with acute decompensated heart failure-related cardiogenic shock

Varshney AS, Berg DD, Zhou G, et al.

AIMS: To describe outcomes associated with bridging strategies in patients with acute decompensated heart failure-related cardiogenic shock (ADHF-CS) bridged to durable left ventricular assist device (LVAD) or heart transplant (HTx).

METHODS AND RESULTS: Durable LVAD or HTx recipients from 2014 to 2019 with pre-operative ADHF-CS were identified in the Society of Thoracic Surgeons Adult Cardiac Surgery Database and stratified by bridging strategy. The primary outcome was operative or 30-day post-operative mortality. Secondary outcomes included post-operative major bleeding. Exploratory comparisons between bridging strategies and outcomes were performed using overlap weighting with and without covariate adjustment. Among 9783 patients with pre-operative CS, 8777 (89.7%) had ADHF-CS. Medical therapy (N = 5013) was the most common bridging strategy, followed by intra-aortic balloon pump (IABP; N = 2816), catheter-based temporary mechanical circulatory support (TMCS; N = 417), and veno-arterial extracorporeal membrane oxygenation (VA-ECMO; N = 465). Mortality was highest in patients bridged with VA-ECMO (22%), followed by catheter-based TMCS (10%), IABP (9%), and medical therapy (7%). Adverse post-operative outcomes were more frequent in LVAD recipients compared with HTx recipients.

CONCLUSION: Among patients with ADHF-CS bridged to HTx or durable LVAD, the highest rates of death and adverse events during index hospitalization were observed in those bridged with VA-ECMO, followed by catheter-based TMCS, IABP, and medical therapy. Patients who received durable LVAD had higher rates of post-operative complications compared with HTx recipients. Prospective trials are needed to define optimal bridging strategies in patients with ADHF-CS.

JAMA. 2023 Jan 3;329(1):52-62.doi: 10.1001/jama.2022.23617.

Association of race and ethnicity with initial prescription of antiretroviral therapy among people with HIV in the US

Zalla LC, Cole SR, Eron JJ, et al.

IMPORTANCE: Integrase strand transfer inhibitor (INSTI)-containing antiretroviral therapy (ART) is currently the guideline-recommended first-line treatment for HIV. Delayed prescription of INSTI-containing ART may amplify differences and inequities in health outcomes.

OBJECTIVES: To estimate racial and ethnic differences in the prescription of INSTI-containing ART among adults newly entering HIV care in the US and to examine variation in these differences over time in relation to changes in treatment guidelines.

DESIGN, SETTING, AND PARTICIPANTS: Retrospective observational study of 42 841 adults entering HIV care from October 12, 2007, when the first INSTI was approved by the US Food and Drug Administration, to April 30, 2019, at more than 200 clinical sites contributing to the North American AIDS Cohort Collaboration on Research and Design.

EXPOSURES: Combined race and ethnicity as reported in patient medical records.

MAIN OUTCOMES AND MEASURES: Probability of initial prescription of ART within 1 month of care entry and probability of being prescribed INSTI-containing ART. Differences among non-Hispanic Black and Hispanic patients compared with non-Hispanic White patients were estimated by calendar year and time period in relation to changes in national guidelines on the timing of treatment initiation and recommended initial treatment regimens.

RESULTS: Of 41 263 patients with information on race and ethnicity, 19 378 (47%) as non-Hispanic Black, 6798 (16%) identified as Hispanic, and 13 539 (33%) as non-Hispanic White; 36 394 patients (85%) were male, and the median age was 42 years (IQR, 30 to 51). From 2007-2015, when guidelines recommended treatment initiation based on CD4+ cell count, the probability of ART initiation within 1 month of care entry was 45% among

White patients, 45% among Black patients (difference, 0% [95% CI, -1% to 1%]), and 51% among Hispanic patients (difference, 5% [95% CI, 4% to 7%]). From 2016-2019, when guidelines strongly recommended treating all patients regardless of CD4+ cell count, this probability increased to 66% among White patients, 68% among Black patients (difference, 2% [95% CI, -1% to 5%]), and 71% among Hispanic patients (difference, 5% [95% CI, 1% to 9%]). INSTIs were prescribed to 22% of White patients and only 17% of Black patients (difference, -5% [95% CI, -7% to -4%]) and 17% of Hispanic patients (difference, -5% [95% CI, -7% to -3%]) from 2009-2014, when INSTIs were approved as initial therapy but were not yet guideline recommended. Significant differences persisted for Black patients (difference, -6% [95% CI, -8% to -4%]) but not for Hispanic patients (difference, -1% [95% CI, -4% to 2%]) compared with White patients from 2014-2017, when INSTI-containing ART was a guideline-recommended option for initial therapy; differences by race and ethnicity were not statistically significant from 2017-2019, when INSTI-containing ART was the single recommended initial therapy for most people with HIV.

CONCLUSIONS AND RELEVANCE: Among adults entering HIV care within a large US research consortium from 2007-2019, the 1-month probability of ART prescription was not significantly different across most races and ethnicities, although Black and Hispanic patients were significantly less likely than White patients to receive INSTI-containing ART in earlier time periods but not after INSTIs became guideline-recommended initial therapy for most people with HIV. Additional research is needed to understand the underlying racial and ethnic differences and whether the differences in prescribing were associated with clinical outcomes.

J Med Virol. 2022 Dec 30.doi: 10.1002/jmv.28445. Online ahead of print.

The salivary and nasopharyngeal microbiomes are associated with SARS-CoV-2 infection and disease severity

Kim JG, Zhang A, Rauseo AM, et al.

BACKGROUND: Emerging evidence suggests the oral and upper respiratory microbiota may play important roles in modulating host immune responses to viral infection. As the host microbiome may be involved in the pathophysiology of COVID-19, we investigated associations between the oral and nasopharyngeal microbiome and COVID-19 severity.

METHODS: We collected saliva (n = 78) and nasopharyngeal swab (n = 66) samples from a COVID-19 cohort and characterized the microbiomes using 16S ribosomal RNA gene sequencing. We also examined associations between the salivary and nasopharyngeal microbiome and age, COVID-19 symptoms, and blood cytokines.

RESULTS: SARS-CoV-2 infection status, but not COVID-19 severity, was associated with community-level differences in the oral and nasopharyngeal microbiomes. Salivary and nasopharyngeal microbiome alpha diversity negatively correlated with age and were associated with fever and diarrhea. Oral Bifidobacterium, Lactobacillus, and Solobacterium were depleted in patients with severe COVID-19. Nasopharyngeal Paracoccus was depleted while nasopharyngeal Proteus, Cupravidus, and Lactobacillus were increased in patients with severe COVID-19. Further analysis revealed that the abundance of oral Bifidobacterium was negatively associated with plasma concentrations of known COVID-19 biomarkers interleukin 17F (IL-17F) and monocyte chemoattractant protein-1 (MCP-1).

CONCLUSION: Our results suggest COVID-19 disease severity is associated with the relative abundance of certain bacterial taxa.

Heart. 2023 Jan 2;heartjnl-2022-321799.doi: 10.1136/heartjnl-2022-321799. Online ahead of print.

Prospective study of sleep duration, snoring and risk of heart failure

Zhuang S, Huang S, Huang Z, et al.

OBJECTIVE: To investigate whether nighttime sleep duration and snoring status were associated with incident heart failure (HF).

METHODS: A prospective study was conducted based on Kailuan cohort including 93 613 adults free of pre-existing cardiovascular diseases. Sleep duration and snoring status were assessed by self-reported questionnaire. Incident HF cases were ascertained by medical records. Cox proportional hazards model was applied to calculate the HR and 95% CI of risk of developing HF. Mediation analysis was used to understand whether hypertension and diabetes mediated the association between sleep duration, snoring and HF. Data analysis was performed from 1 June 2021 to 1 June 2022.

RESULTS: During a median follow-up of 8.8 years, we documented 1343 incident HF cases. Relative to sleep duration of 7.0-7.9 hour/night, short sleep duration was associated with higher risk of developing HF: adjusted HR was 1.24 (95% CI 1.01 to 1.55) for <6 hours/night and 1.29 (95% CI 1.06 to 1.57) for 6.0-6.9 hours/night, after adjustment for potential confounders such as age, sex, smoking, hypertension and diabetes. A similar 20%-30% higher risk of incident HF was found in individuals reporting occasional or frequent snoring relative to never/rare snorers: adjusted HR was 1.32 for occasional snoring (95% CI 1.14 to 1.52) and 1.24 (95% CI 1.06 to 1.46) for frequent snoring. Presence of diabetes significantly mediated the association between both short sleep duration and snoring and HF risk and hypertension significantly mediated the snoring-HF relationship.

CONCLUSION: Short sleep duration and snoring were associated with high risk of HF.

ASAIO J. 2023 Jan 1;69(1):43-49.doi: 10.1097/MAT.0000000000001801. Epub 2022 Sep 8.

Effects of body mass index on presentation and outcomes of COVID-19 among heart transplant and left ventricular assist device patients: a multi-institutional study

Iyengar A, Cohen W, Han J, et al.

The coronavirus disease 2019 (COVID-19) pandemic continues to pose a significant threat to patients receiving advanced heart failure therapies. The current study was undertaken to better understand the relationship between obesity and outcomes of SARS-CoV-2 infection in patients with a left ventricular assist device (LVAD) or heart transplant. We performed a retrospective review of patients with a heart transplant or LVAD who presented to one of the participating 11 institutions between April 1 and November 30, 2020. Patients were grouped by body mass index (BMI) into obese (BMI ≥ 30 k/m2) and nonobese cohorts (BMI < 30 kg/m2). Multivariable logistic regression models were used to estimate effects of obesity on outcomes of interest. Across all centers, 162 heart transplant and 81 LVAD patients were identified; 54 (33%) and 38 (47%) were obese, respectively. Obese patients tended to have more symptoms at presentation. No differences in rates of hospitalization or ICU admission were noted. Obese patients with LVADs were more likely to require mechanical ventilation (39% vs. 8%, $p < 0.05$). No differences in renal failure or secondary infection were noted. Mortality was similar among heart transplant patients (11% [obese] vs. 16% [nonobese], $p = 0.628$) and LVAD patients (12% vs. 15%, $p = 1.0$). BMI was not associated with increased adjusted odds of mortality, ICU admission, or mechanical ventilation (all $p > 0.10$). In summary, acute presentations of SARS-CoV-2 among heart transplant and LVAD recipients carry a significantly higher mortality than the general population, although BMI does not appear to impact this. Further studies on the longer-term effects of COVID-19 on this population are warranted.

Hypertension. 2023 Jan 5. doi: 10.1161/HYPERTENSIONAHA.122.20081. Online ahead of print.

Continuous positive airway pressure for the treatment of supine hypertension and orthostatic hypotension in autonomic failure

Okamoto LE, Celedonio JE, Smith EC, et al.

BACKGROUND: Supine hypertension affects most patients with orthostatic hypotension (OH) due to autonomic failure, but it is often untreated for fear of worsening OH. We hypothesized that increasing intrathoracic pressure with continuous positive airway pressure (CPAP) had a Valsalva-like blood-pressure-lowering effect that could be used to treat nocturnal supine hypertension in these patients, while reducing nocturnal pressure diuresis and improving daytime OH.

METHODS: In Protocol 1, we determined the acute hemodynamic effects of increasing levels of CPAP (0, 4, 8, 12, and 16 cm H2O, 3 minutes each) in 26 patients with autonomic failure and supine hypertension studied while awake and supine. In Protocol 2 (n=11), we compared the effects of overnight therapy with CPAP (8-12 cm H2O for 8 hours) versus placebo on nocturnal supine hypertension, nocturnal diuresis and daytime OH in a 2-night crossover study.

RESULTS: In Protocol 1, acute CPAP (4-16 cm H2O) decreased systolic blood pressure in a dose-dependent manner (maximal drop 22±4 mmHg with CPAP 16) due to reductions in stroke volume (-16+3%) and cardiac output (-14±3%). Systemic vascular resistance and heart rate remained unchanged. In Protocol 2, overnight CPAP lowered nighttime systolic blood pressure (maximal change -23±5 versus placebo -1±7 mmHg; P=0.023) and was associated with lower nighttime diuresis (609±84 versus placebo 1004±160 mL; P=0.004) and improved morning orthostatic tolerance (AUC upright SBP 642±121 versus placebo 410±109 mmHg*min; P=0.014).

CONCLUSIONS: CPAP is a novel nonpharmacologic approach to treat the supine hypertension of autonomic failure while improving nocturia and daytime OH.

Cancer Epidemiol Biomarkers Prev. 2022 Dec 28;EPI-22-0873. doi: 10.1158/1055-9965.EPI-22-0873. Online ahead of print.

Machine learning and real-world data to predict lung cancer risk in routine care

Chandran U, Reps J, Yang R, et al.

BACKGROUND: This study used machine learning to develop a 3-year lung cancer risk prediction model with large real-world data in a mostly younger population.

METHODS: Over 4.7 million individuals, aged 45-65 years with no history of any cancer or lung cancer screening, diagnostic, or treatment procedures, with an outpatient visit in 2013 were identified in the Optum® Deidentified Electronic Health Record (EHR) Dataset. A Least Absolute Shrinkage and Selection Operator model was fit using all available data in the 365 days prior. Temporal validation was assessed with recent data. External validation was assessed with data from Mercy Health Systems EHR and Optum® De-Identified Clinformatics Data Mart. Racial inequities in model discrimination were assessed with xAUCs.

RESULTS: The model AUC was 0.76. Top predictors included age, smoking, race, ethnicity, and diagnosis of chronic obstructive pulmonary disease. The model identified a high-risk group with lung cancer incidence 9 times the average cohort incidence, representing

10% of lung cancer patients. Model performed well temporally and externally, while performance was reduced for Asians and Hispanics.

CONCLUSIONS: A high-dimensional model trained using big data identified a subset of patients with high lung cancer risk. The model demonstrated transportability to EHR and claims data, while underscoring the need to assess racial disparities when using machine learning methods.

IMPACT: This internally and externally validated real-world data-based lung cancer prediction model is available on an open-source platform for broad sharing and application. Model integration into an EHR system could minimize physician burden by automating identification of high-risk patients.

Diabetes Obes Metab. 2023 Feb;25(2):596-601.doi: 10.1111/dom.14906. Epub 2022 Dec 1.

Continuous glucose monitoring metrics (mean glucose, time above range and time in range) are superior to glycated haemoglobin for assessment of therapeutic efficacy

David Rodbard

AIM: To evaluate continuous glucose monitoring (CGM) metrics for use as alternatives to glycated haemoglobin (HbA1c) to evaluate therapeutic efficacy.

METHODS: We reanalysed correlations among CGM metrics from studies involving 545 people with type 1 diabetes (T1D), 5910 people with type 2 diabetes (T2D) and 98 people with T1D during pregnancy and the postpartum period.

RESULTS: Three CGM metrics, interstitial fluid Mean Glucose level, proportion of time above range (%TAR) and proportion of time in range (%TIR), were correlated with HbA1c and provided metrics that can be used to evaluate therapeutic efficacy. Mean Glucose showed the highest correlation with %TAR (r = 0.98 in T1D, 0.97 in T2D) but weaker correlations with %TIR (r = -0.92 in T1D, -0.83 in T2D) or with HbA1c (r = 0.78 in T1D). %TAR and %TIR were highly correlated (r = -0.96 in T1D, -0.91 in T2D). After 6 months of use of real-time CGM by people with T1D, changes in Mean Glucose level were more highly correlated with changes in %TAR (r = 0.95) than with changes in %TIR (r = -0.85) or with changes in HbA1c level (r = 0.52). These metrics can be combined with metrics of hypoglycaemia and/or glycaemic variability to provide a more comprehensive assessment of overall quality of glycaemic control.

CONCLUSION: The CGM metrics %TAR and %TIR show much higher correlations with Mean Glucose than with HbA1c and provide sensitive indicators of efficacy. Mean glucose may be the best metric and shows consistently higher correlations with %TAR than with %TIR.

Am J Surg. 2022 Dec 23;S0002-9610(22)00794-2. doi: 10.1016/j.amjsurg.2022.12.012. Online ahead of print.

The impact of race and socioeconomic status on stage IV colorectal cancer survival

Cheong JY, Vu JV, Connelly TM, et al.

BACKGROUND: The aims of this study were to determine the impact of race and socioeconomics on survival in patients with stage IV colorectal cancer.

METHODS: A prospective database of stage IV colorectal cancer patients treated at a multi-hospital health system from 2015 to 2019 was retrospectively analyzed. Univariate and multivariate survival analysis using log-rank Mantel-Cox test and Cox proportional hazard model were performed to determine the impact of race, socioeconomic factors, presentation, and treatment on overall survival.

RESULTS: 4012 patients were diagnosed with colorectal cancer, of which 803 patients were stage IV. There were 677 (84.3%) White, and 108 (13.4%) Black patients. Black patients have worse 5-year overall survival than white patients (HR 1.43 (1.09-1.87)). Patients who received chemotherapy had significantly better survival than patients who did not receive chemotherapy (HR 0.58 (0.47-0.71)). Black patients have significantly lower rates of receiving chemotherapy as compared to white patients (61.1% vs 75.37%, p = 0.0018).

CONCLUSION: Patients with Stage IV colorectal cancer have worse survival if they are black, older age, and did not receive chemotherapy.

Osteoporos Int. 2023 Jan 4.doi: 10.1007/s00198-022-06659-6. Online ahead of print.

The effectiveness and cost-effectiveness of clinical fracture-risk assessment tools in reducing future osteoporotic fractures among older adults: a structured scoping review

Auais M, Angermann H, Grubb M, et al.

This scoping review described the use, effectiveness, and cost-effectiveness of clinical fracture-risk assessment tools to prevent future osteoporotic fractures among older adults. Results show that the screening was not superior in preventing all osteoporosis-related fractures to usual care. However, it positively influenced participants' perspectives on osteoporosis, may have reduced hip fractures, and seemed cost-effective.

PURPOSE: We aim to provide a synopsis of the evidence about the use of clinical fracture-risk assessment tools to influence health outcomes, including reducing future osteoporotic fractures and their cost-effectiveness.

METHODS: We followed the guidelines of Arksey and O'Malley and their modifications. A comprehensive search strategy

was created to search CINAHL, Medline, and Embase databases until June 29, 2021, with no restrictions. We critically appraised the quality of all included studies.

RESULTS: Fourteen studies were included in the review after screening 2484 titles and 68 full-text articles. Four randomized controlled trials investigated the effectiveness of clinical fracture-risk assessment tools in reducing all fractures among older women. Using those assessment tools did not show a statistically significant reduction in osteoporotic fracture risk compared to usual care; however, additional analyses of two of these trials showed a trend toward reducing hip fractures, and the results might be clinically significant. Four studies tested the impact of screening programs on other health outcomes, and participants reported positive results. Eight simulation studies estimated the cost-effectiveness of using these tools to screen for fractures, with the majority showing significant potential savings.

CONCLUSION: According to the available evidence to date, using clinical fracture-risk assessment screening tools was not more effective than usual care in preventing all osteoporosis-related fractures. However, using those screening tools positively influenced women's perspectives on osteoporosis, may have reduced hip fracture risk, and could potentially be cost-effective. This is a relatively new research area where additional studies are needed.

Fraud and Abuse Compliance for Marketing

continued from page 5

- Are you giving referral sources anything of value for free or at a price that is below fair market value? An example of such a practice is the provision of free discharge planning services to referral sources.
- Do agreements with referring physicians who also render services to providers for which they are paid comply with the federal anti-kickback statute, the federal Stark laws, and all applicable state requirements or so-called "mini-Stark laws?"
- What are marketing staff giving to referral sources?
- Are you swapping patients with referral sources? An example of this practice may occur when therapy companies agree to refer patients to home health agencies who need therapy so long as the therapy company provides the therapy to all patients referred under contracts with providers.
- Are you providing preop/coordination visits consistent with applicable requirements, as reflected in internal policies and procedures?
- Are you providing free care transition services to patients and/or referral sources?

You get the drift! Fraud and abuse compliance isn't just about submission of claims that meet all applicable requirements. It's not enough to be compliant with requirements for submission of claims while ignoring other aspects of fraud and abuse compliance. Providers must cast a wider net when it comes to fraud and abuse compliance in order to safeguard their financial viability and, in some instances, their very existence. You know what to do! CM

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Health Care Themes to Be Addressed in 2023

continued from page 2

pandemic, when an estimated 1 in 5 health care workers left the workforce. To address staffing shortages, we should offer flexibility in clinical workflow and caregiver leave, adopt innovations in the digital care space, provide a friendly environment, and establish new health care roles. Balanced recruitment and retention strategies are needed so that health care workers can provide patients with the highest quality of care.

Technology

Technology continues to change the way we live and work and will continue to do so. New technologies include expanded telehealth, wearables, and various mobile apps. During the COVID-19 pandemic, telehealth became more standard in many practice settings because it was safe and convenient and addressed a multitude of administrative issues. Telehealth will continue to expand and grow.

Patient wearables is gaining momentum because of innovations in technology. As individuals take their health into their own hands, wearables enable personalized data-driven care where the clinician and patients take a "proactive" rather than a "reactive" approach. Patients are demanding wearable technology. Wearables are, for example, currently used for exercise, cardiovascular health, mental health, and diabetes care. Patient wearables lead to better patient engagement and clinical outcomes. Case managers will need to understand how to incorporate these technologies into their practice.

Artificial intelligence (AI) is another area of technology that will be used in health care. AI is the ability of a computer or computer-controlled robot to perform tasks associated with an intelligent person. Although controversial partly because of privacy issues, AI can improve tasks by doing tasks quicker, easier, and more efficiently than humans. AI has been used in projecting health trajectories in patients, guiding care, monitoring patients, automating laborious tasks, and optimizing operational processes, and it has also been used in various educational models.

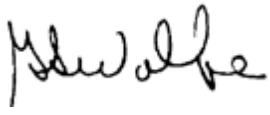
Mental Health

Improving patient's mental health continues to be a priority in health care, and there is a significantly increased demand for mental health services. According to the World Health Organization, mental health services were severely disrupted during the COVID-19 pandemic while anxiety and depression increased 25%. Another area of mental health that needs attention is the mental health of health care workers. Again, this demand has been exacerbated by the COVID-19 pandemic. Health care worker burnout is increasing; health care workers are leaving the workforce and transitioning to less stressful work. Digital mental health solutions are on the rise. Investments in digital mental health solutions will continue. Technological platforms enable more access to mental health services and connect patients with mental health providers.

Value-Based Health Care

Value-based health care is a health care delivery model in which providers, including hospitals, physicians, and other providers, are paid based on patient health outcomes. Under value-based care agreements, providers are rewarded for helping patients improve their health, for reducing the effects and incidence of chronic disease, and for helping patients live healthier lives in an evidenced-based way. Value-based care is different from a fee-for-service or capitated approach where providers are paid based on the amount of health care services delivered. The "value" in value-based health care is derived from measuring health outcomes against the cost of delivering the outcomes. Care models have started to shift toward value-based care, and this trend will continue.

As we look ahead, health care is becoming more complex, fragmented, and confusing for the consumer. The latest developments in health care point in the direction of an increasing demand for case managers. The six trends I have identified above impact case managers. In every organization, case managers advocate for patients to make sure that the health care model of the future is efficient, personal, and convenient for all.



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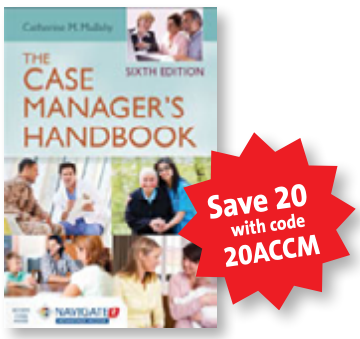

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Seven Steps for Improving Equity in Health Care Delivery: A Roundtable Discussion *continued from page 7*

and anxiety? Such questions invite clients to share information about economic insecurity, transportation challenges, or other issues that pose barriers to gaining access to care delivery.

3. **Know the resources for addressing SDOH:** Improving equity requires us to broaden our perspective around advocacy. It is not enough to inform clients about resources; we also need to do what we can to help improve access to those resources and assure their quality. The help that people need may exist in the community. For example, what organizations in the community are focused on providing food (eg, a food bank)? Are there volunteer networks that help provide transportation? A goal for case managers and disability managers is to know our community within a 5- to 10-mile circumference, taking into account clinics and public health resources, emergency care, telehealth, nonprofits, community organizations, and more. By learning more about these resources and their quality, case managers can share that information with colleagues and clients to help provide solutions to eliminate barriers and improve quality.
4. **Identify and overcome our own biases**. When we standardize our processes for providing access, it helps to control bias but won't eliminate it. To do that, we must look within ourselves to identify and overcome biases and assumptions that prevent us from seeing others and their circumstances. As uncomfortable as it may be to admit, everyone has biases, but they are often unconscious. Many organizations have bias training tools and programs. If not available, ask for such resources to be made part of personal and team development. As we increase our own understanding, we need to be cognizant that others may not be as aware or informed. If we see evidence of bias, we need to speak up with the intention of correcting the situation.
5. **Assume "unconditional positive intent."** Closely aligned with overcoming biases and suspending judgment is an attitude of assuming "unconditional positive intent." This is most easily expressed as giving others the benefit of the doubt. For example, starting with the assumption that the client who misses follow-up appointments is not being noncompliant but rather has difficulty (financial, transportation, family obligations) getting there. Similarly, the colleague on the interprofessional team who seems rushed and unwilling to listen may be facing other pressures. Keeping an open mind allows us to listen, see, and support others.
6. **Increase diversity in hiring**. Case management and disability management teams and organizations can do more to ensure that they are representative of the populations they serve. Within larger organizations, this can be facilitated by requesting that a member of the diversity committee/department sit in on interviews and debriefings. As case managers and disability managers, we need to advocate for greater diversity in all forms—gender identity, racial, ethnic, religious, cultural, sexual orientation, and professional discipline—to elevate our professions. The clients served deserve to engage with case managers and disability managers who are relatable and understand them.
7. **Amplify the voice of advocacy.** As professionals, particularly those who are board-certified, we have both the opportunity and the obligation to amplify the voice of advocacy within communities, our organizations, and society. One way is to look for ways to become involved in policy (for example, the Robert Wood Johnson Health Policy Fellowship: https://healthpolicyfellows.org/). Serve on committees and boards to become more educated about problems and solutions and bring that information back to our colleagues and communities.

Pursuit of equity elevates advocacy within case management and disability management, ensuring that all clients (known as patients in some care settings) receive the right care and treatment at the right time, in the right setting, and of the same quality.

Increasing equity in health care requires both a micro and a macro approach—among individuals and organizations and across populations. The goal is to identify and eliminate barriers that prevent people from pursuing their goals for health, healing, and wellness. Ensuring that health care access and quality are both equal and equitable will take all of us, working together. CM

Insights for Case Managers: The Need for Better Data Systems to Capture Impact *continued from page 8*

growth in integrating this data into the larger quality matrix used to determine the value of public health case management programs.

Our team provides two insights for better conceptualizing value in public health case management. First, case management programs should move toward demonstrating value based on more holistic outcomes including integration of social, health, and quality measures. Without a consistent model of care and electronic medical record/reporting systems designed to capture holistic measures such as SDOH interventions and outcomes, demonstrating positive healthcare results from the full scope of case management can be a daunting task. The integration of local data systems, such as NCCARE360, on health and quality outcomes in case management patient panels is currently lacking, and thus there is an opportunity for better integration of data to support the value of public health case management.

Our second insight is the need for increased advocacy to support more resources and infrastructure that allow case managers to address SDOH barriers identified by patients in rural communities. Although GVPH case managers have done a tremendous job addressing their patients' social and health needs in limited-resource settings, an infusion of resources to address pressing social needs would not only affect patient care positively but decrease the challenges that case managers face in providing care when resources are lacking. Investment in data systems that capture the impact of addressing social needs can ground advocacy for funding and infrastructure support to bolster resources that address SDOH in rural communities. However, it is critical to understand that there are people in the last mile of data entry and data analysis. Even with more modern technology (eg, NCCARE360 in North Carolina), centering people and building local relationships with those providing resources to address the social needs of patients is key. Continued investment to address transportation barriers, housing scarcity, and food insecurity in rural communities will continue to be essential to improving health and health care outcomes in rural communities.

Our team provides two insights for better conceptualizing value in public health case management. First, case management programs should move toward demonstrating value based on more holistic outcomes including integration of social, health, and quality measures. Second, there is the need for increased advocacy to support more resources and infrastructure that allow case managers to address social determinants of health barriers identified by patients in rural communities.

Public health case managers provide critical support to the health of rural communities despite many barriers. Expanding advocacy efforts and holistic data integration according to our insights could amplify the value of public health case management and facilitate advocacy for increased resources to improve health and healthcare in rural communities. CM

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Not Just One Week A Year!
Case Management Appreciation
continued from page 6

- INTERMEDIATE: Those with some case management practice experience and familiarity with the culture. The individual may not yet be certified.
- ADVANCED: Those who are very familiar with case management practice and culture. The individual may be in a leadership position or is seeking leadership skills.

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Being a leader can be rewarding but can also be challenging, especially with the current turbulence and uncertainty in health care. The most appreciated leaders create a sense of purpose, generate trust and optimism, and tap into the passion and talent of their staff, resulting in success for their organization and those served by the organization. Experienced CMSA thought leaders will inspire leaders at all stages of their careers while providing tangible steps to mastering employee engagement and recruitment, building a healthy case management department/environment, and training and managing your staff.

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Find the full schedule of events and register at cmsa.societyconference.com. CM

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Home Care Nurse Shot and Killed
continued from page 4

- Development and implementation of appropriate policies and procedures
- Ongoing assessment of patients/clients for aggressive behavior and possible indicators of such behaviors
- Appropriate adaptions of interventions and environment

For all types of providers of services in homes, termination of services to patients/clients is certainly an appropriate response to concerns regarding the safety of home care staff members. Termination of services must, of course, be consistent with applicable requirements to avoid liability for abandonment.

The use of so-called "escorts;" including armed, off-duty police officers; may also be appropriate. Some home care personnel, however, object to use of escorts. The basis for their concern may be that the presence of escorts interferes with their relationships with patients. They point out that there is an essential inconsistency between the caring and nurturing relationships they wish to foster with patients and their families and the use of escorts. Providers may, therefore, decide to establish and implement a policy that staff may not reject escorts when management deems that their use is appropriate. Refusal of escorts should be defined as insubordination in such policies and procedures, and appropriate disciplinary action, including termination of employment, may be taken in response to this type of insubordination.

Home care personnel knock on the doors of thousands of patients each day, unaware of what may be inside their homes. They regularly encounter unfamiliar terrain and unknown risks. These risks are likely to become even greater as the use of home care services continues to expand. Managers and field staff must be prepared to deal with the constant potential for compromised safety. CM

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Intertrigo—Helping Case Managers Iron Out Skin Fold Challenges *continued from page 23*

moisture, controlling the source of the excessive moisture, and treating any secondary infection. CM

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Another Opportunity…and an Invitation! *continued from page 3*

physical and behavioral well-being. Perhaps, we can and need to view these as opportunities for growth and reflection and then boldly choose an optimistic path forward.

As you read this column, if you are interested in "telling your story" and want to take the first step to see your name as an author, consider this your personal invitation and contact me at cmullahy@academyccm.org.

We can make a difference…one patient at a time!
– Catherine

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