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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Join Me in Welcoming Our New Editorial Board!

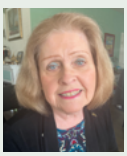
I am pleased to announce the appointment of a new Editorial Board. The Editorial Board plays a vital role in making *CareManagement* the leading journal in medical case management. The mission of *CareManagement* is to improve professional case management practice through education. Since our inception, you, the reader, have benefited from the direction of the Editorial Board in bringing you current knowledge to improve the professional practice of case management and ultimately patient outcomes.

Expectations of members of the Editorial Board include:

1. Advising the editorial staff about current trends, issues, and knowledge needed for case managers
2. Writing articles
3. Recruiting authors
4. Offering comments and feedback on published content
5. Making suggestions for the future direction of the journal

The Editorial Board represents a diverse group of case management leaders bringing different clinical experiences, backgrounds, and practice settings into our discussions. Each individual makes a unique contribution. These names may be familiar to you. Current positions are listed for information only and do not imply any endorsement. Drum roll, please.

CareManagement Editorial Board



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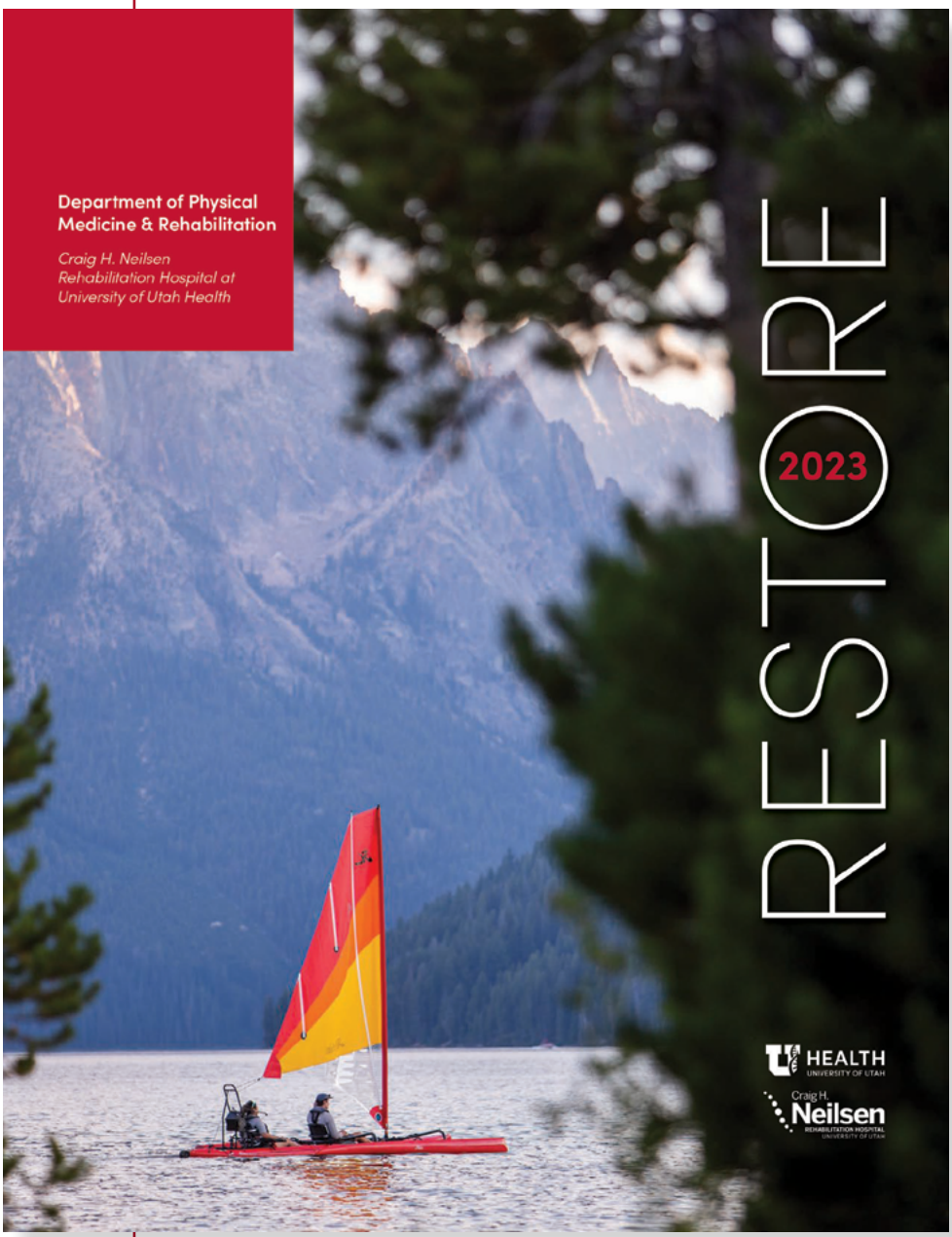
WHEN INSPIRED PATIENTS MEET INNOVATIVE CARE, AMAZING STORIES ARE WRITTEN.



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Catherine M. Mullahy

Case Managers: Embrace and Be Catalysts for Change

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

There's no question that health care in America is at a critical crossroad. The pandemic, coupled with persistent health care labor shortages and rising inflation, have had a major impact on health care providers (most notably those serving in hospitals) and patients. While providers grapple with maintaining financial stability as the costs of care continue to rise, case managers in various settings are playing a vital role in providing patient care in the context of today's value-based health care system. The challenges case managers face day-to-day as they care for their patients and perform more and more administrative, data entry, and documentation tasks, demand that they gain the support they need from providers. Achieving cost-conscious care requires greater insight and action on the part of both health care providers and case managers. Case managers will need to take a more proactive and an open-minded approach to new, transformational strategies.

To achieve these objectives, hospitals and other health care providers need to recognize the vital role of case managers and be open to their recommendations and new ways of doing things.

Hospitals are facing unprecedented workforce shortages along with rising contract labor, medical supply, and drug costs. This is happening at a time when inflation is at historic levels. According to the health care consulting firm Syntellis Performance Solutions, between 2019 and 2022 hospital expenses rose 17.5%. In fact, more than 50% of America's hospitals ended 2022 operating at a financial loss. One way hospitals can overcome some of their hurdles is with new government policies such as those that would help address their workforce challenges and prevent further Medicare or Medicaid payment cuts to hospitals. At the same time, the Centers for Medicare & Medicaid Services (CMS) must utilize its special exceptions authority to issue retrospective adjustments to address current market conditions.

For hospitals, other health care providers, and health care professionals—including case managers—transformation of strategies, policies, and programs is needed. All of these stakeholders want to ensure that patients receive high-quality, cost-effective care both conveniently and consistently; therefore, a team approach to solutions is imperative. To their credit and despite financial challenges, leading health systems are investing heavily in infrastructure to improve the coordination of care within the hospital environment and within other patient care settings. Case managers have always been at the center of patient care and relied on to coordinate, communicate, and share patient updates while also offering insights that can improve care and processes. But, case managers also have needs that must be met so they can ensure the best patient outcomes.

The role of case managers has continued to expand. In addition to assessing data relating to a patient's hospital stays, they now are required to interface with the providers involved in their patients' pre- and post-hospital care. Their transition of care plans must be comprehensive and address many goals, from reducing hospital readmissions and improving discharge processes, to ensuring that patients understand their medical condition and treatment plans, and reducing high-cost emergency department visits. On top of this, case managers have significant responsibilities in population health management and tracking of social determinants of health. They must also master myriad new technologies (eg, electronic health records, advanced telehealth platforms, artificial intelligence [AI]-driven software) along with utilization management, discharge planning, and care coordination. Today's case managers must be able to navigate complex and siloed health care systems. It is clearly a challenging role that requires flexibility and open-mindedness to embrace new ways of doing things without compromising their ethics, professional standing, best practices, and, most importantly, their commitment to providing the highest standards of patient

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Autonomy and Beneficence: Guardrails for Case Management Practice

Michelle Baker, BS, RN, CRRN, CCM

Professional case managers, particularly those who are board certified, are obliged to uphold several ethical principles as outlined in the Code of Professional Conduct for Case Managers, from the Commission for Case Manager Certification (CCMC). These principles include autonomy and beneficence, which I will address in this column.

Autonomy seeks to preserve and uphold a client's right to self-determination. This means individuals have the right to make informed decisions in support of their goals. Beneficence compels case managers to show compassion while taking action to promote the welfare of the client and their support system.

These two principles go together, like twin guardrails that help case managers navigate through the complexities of each case as they advocate for clients. As the Code states, Certified Case Managers (CCMs) "understand and commit to quality for clients, appropriate use of resources, and empowerment of clients in a manner that is supportive and objective."

These two principles [beneficence and autonomy] go together, like twin guardrails that help case managers navigate through the complexities of each case as they advocate for clients.

There are times, however, when a catastrophic injury or illness impacts how autonomy and beneficence can best be carried out by the case manager. While the client's choices and decisions still need to be respected and supported, the case manager is also ethically obligated to minimize unreasonable risks to the client. Risks might include potential injuries, such as burns or falls, that could occur if the client fails to realize or accept that their physical and/or cognitive abilities are impaired.

An example is a 21-year-old man who suffered a traumatic brain injury. As an adult, this individual had no legal guardian, and yet did not have the capacity to make informed decisions on his own behalf. The principle of autonomy precludes the case manager from stepping in and making decisions for the client. Instead, the case manager needed to identify someone in the client's support system to help him understand the circumstances, weigh the options, and make informed decisions, while guardianship or other legal appointments such as medical power of attorney could be arranged.

Information—But Not Undue Influence

Beneficence obligates case managers to do good for the client. This means ensuring that the welfare of the client and their support system is appropriate. One way beneficence is carried out is providing education and information to promote the client's self-care and support independence.

Case managers can engage other care providers—such as primary care physicians, internists, psychologists, rehabilitation counselors, dieticians, and others—to help educate the client. There is no guarantee, however, that the client will act on that information. Autonomy means the individual has the right to make their own choices, even when those decisions or actions are not what the case manager views as prudent or the "right thing" to do.

This sets up a challenge for case managers who typically come from helping professions such as nursing, social work, counseling, and similar backgrounds. Because of their education, training, and experience, case managers have a wealth of information to share. But their support and advice cannot cross the line into undue influence. Autonomy means the client and the support system have the final word

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Michelle Baker, BS, RN, CRRN, CCM, *is a Commissioner and a former chair of the CCMC, the first and largest nationally accredited organization that certifies case managers. She is also Director, Clinical Network Operations, for Paradigm. Her primary areas of focus include managing workers' compensation catastrophic nurse case managers and ensuring program development/implementation, and training the clinical network.*

It's a Wrap!

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

The 2023 CMSA National Conference just ended yesterday, and I am still processing the events of the week.

The kickoff preconference day was a showcase of workshops: leadership, writing, chapter management, MVD (military/Veterans Affairs/Department of Defense) Day, 2 bonus education sessions, and a first-time attendees meeting that was energetic and set the tone for the week! The Opening Night Reception demonstrated the value and importance of connecting with new people and reconnecting with cherished friends. The keynote speakers brought us purpose, encouragement, and new perspectives.

The days were jam-packed with educational opportunities and topics that ran the gamut of practice settings and included acute care, maternal/child health/pediatrics, mental/behavioral health, managed care/managed Medicare/managed Medicaid, ambulatory case management, older adult/geriatric care, postacute/community care, and, of course, military services/DoD/Veterans Affairs. Attendees enhanced their case management practice with subjects including communication techniques, value-based reimbursement, disease/condition-specific case management readmission prevention, transition management, technology, professional development, leadership, self-care, and legal/regulatory/ethical topics.

Studies have shown that professional organizations play a crucial role in the professional and personal development and advancement of people. These organizations, such as CMSA, provide platforms for individuals to connect, share knowledge, collaborate, and stay updated on the latest trends and developments in their respective fields.

As I sit on this plane and reflect on the past week, what really stands out to me is the community I experienced this week: reconnecting with people I have known for years, meeting new friends. The energy was palpable and reinvigorating. The vibe was awesome; as one would expect from over 1000 engaged, passionate case management professionals gathered in 1 place. Some of the highlights for me, of course, revolved around the professional networking experiences.

Studies have shown that professional organizations play a crucial role in the professional and personal development and advancement of people. These organizations, such as CMSA, provide platforms for individuals to connect, share knowledge, collaborate, and stay updated on the latest trends and developments in their respective fields. Networking refers to the process of building and maintaining professional relationships with individuals in your industry or related fields.

Networking offers several advantages, including:

1. Career opportunities: networking can help you discover job openings, career advancements, and business opportunities. Building a strong network can raise your professional profile, increase your visibility in the industry, and open doors to new opportunities. Many jobs are filled through referrals and personal connections. Case in point, professional networking helped me to obtain my current position. Working with my local CMSA chapter gave me greater visibility in the career marketplace. Greater visibility brings opportunities whether in the form of information (in my case) of available positions or actual offers.
2. Knowledge sharing: networking

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What Autonomy and Beneficence Look Like in Action

Ed Quick, MA, MBA, CDMS

Certified Disability Management Specialists (CDMS) must uphold ethical principles of practice as described in our Code of Conduct. Putting these values into action, however, can be complicated by a regulated environment, such as workers' compensation, which is governed by state statutes.

There is often a fine line between what the individual—in this case, the employee who has been injured on the job—may want and what the regulations allow. This is particularly challenging when addressing the ethical principles of autonomy, meaning respect for the individual's rights to make their own decisions, and beneficence, requiring the disability manager to "do good" for others.

Workers' compensation and other state-regulated programs require specific actions, such as treatment and rehabilitation being completed in a timely manner. If these time frames are not met, significant consequences can result, including loss of reimbursement or denial of the entire workers' compensation claim. That is why, in my own experience working for large companies, I tell employees who have been injured on the job that they can make their own decisions; however, they need to understand the consequences of those decisions.

However, if the underlying condition is a work-related injury, the health care insurer may reject the claim, thus making the employee responsible for the cost of care—and often without the benefit of negotiated rates or fee schedules that lower the cost.

For example, an employee with a workers' compensation claim may express the desire to be treated by their own health care provider. However, several states restrict injured workers from choosing their providers. Instead, regulations in those states allow employers or their insurers to "direct care"—meaning choosing the treatment providers. If an employer opts to direct care in a workers' compensation case, employees must understand the consequences of choosing to be treated by a provider other than the one identified by the employer. That decision could result in a lack of reimbursement for out-of-pocket expenses and even the employee being financially obligated for the total cost of care.

Sometimes employees will assume that their care can be covered by their regular health care benefits. However, if the underlying condition is a work-related injury, the health care insurer may reject the claim, thus making the employee responsible for the cost of care—and often without the benefit of negotiated rates or fee schedules that lower the cost.

When and How an Employee Returns to Work

Autonomy is not limited to decision-making around care and treatment. It also applies to the return-to-work (RTW) process following an injury or illness, particularly when a condition is work related.

All of us have rights in how we report to work each day, whether after a vacation, an extended leave to bond with a newborn, or an absence related to recovery from an injury or illness. In addition, the employer has rights around what to expect from employees when they do report to work.

When advocating for those who are off work due to injury or illness, the disability manager must educate themselves and the employee about the regulations that protect the rights of employees who have a disability. In addition, they also need to understand the essential functions of the work the employee performs and the

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Knocking on Strangers' Doors

Elizabeth E. Hogue, Esq.

On April 22, 2023, The Washington Post's Kim Bellware reported on risks to workers in an article entitled, "In an Armed and Tense Nation, Knocking on Doors Feels Risky for Workers." The article highlights a string of recent incidents across the country. In the past week, says Bellware; a 16-year-old boy in Kansas City, Missouri, was shot after going to the wrong address to pick up his brother; a 20-year-old woman in New York state was shot after pulling into the wrong driveway; and an 18-year-old high school cheerleader in Texas was shot after getting into the wrong car.

The article concludes that vigilance is simply a part of the job for people in lines of work that require them to visit strangers' homes. Home health care, hospice, and home medical equipment field staff members do exactly that every single day!

In view of news of ongoing violence, it's important to review practical aspects of threatened and actual violence included in *The Gift of Fear* by Gavin de Becker. The premise of Mr. de Becker's book is that there is never violence that comes without warning. In fact, if caregivers learn to listen to their intuition, there are warning signs that are likely to prevent injury. This point is not intended to blame caregivers by saying that violence is their fault because they did not listen to their "gut," but to encourage caregivers to pay attention to their instincts and to act upon them.

Caregivers need to use their "radar" to identify these indicators and to act upon them in order to avoid violence.

To illustrate this point, Mr. de Becker uses the example of a woman who was raped in her apartment. Her rapist said that he was going to the kitchen to get a drink of water and told her not to move. As he was leaving the bedroom, he closed an open window. The woman said that she knew instinctively at that moment that the rapist was going to kill her and wanted to minimize the sound of his crime. In what the woman describes as an "out-of-body" experience, she silently followed the rapist down the hall and slipped past him in the kitchen, out of the apartment door, and into the apartment across the hall. As she left the apartment, she could hear the rapist rummaging in kitchen drawers looking for a knife.

Mr. de Becker points out that many people who suffer violence say that it came "out of nowhere," "out of the blue," or that it was "random." After some thought, however, the victims of violence are often able to identify that they felt uneasy with the perpetrator or that the criminal seemed suspicious. "I just knew," many victims of violence say.

These intuitive feelings must be balanced against the overwhelming tendency to deny that violence is possible. As Mr. de Becker points out:

> It may be hard to accept its importance, because intuition is usually looked upon by us thoughtful Western beings with contempt. It is often described as emotional, unreasonable or inexplicable. Husbands chide their wives about "feminine intuition" and don't take it seriously. If intuition is used by a woman to explain some choice she made or a concern she can't let go of, men roll their eyes and write it off. We much prefer logic, the grounded, explainable, unemotional thought process that ends in a supportable conclusion. In fact, Americans worship logic, even when it's wrong, and deny intuition, even when it's right.

Mr. de Becker's point is that there are almost always "pre-incident" indicators, detectable factors that occur before violent acts. Caregivers need to use their "radar" to identify these indicators and to act upon them in order to avoid violence.

Managers and supervisors may be tempted to minimize and deny caregivers' concerns about potential violence, especially because they often do not have direct contact with patients and their families. Managers and supervisors should recognize that fearful caregivers have likely experienced some "pre-incident indicators" that are described in detail in Mr. de Becker's book. Managers and supervisors should help caregivers express their concerns,

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OSHA Increasingly Likely to Act Against Workplace Violence

Elizabeth E. Hogue, Esq.

Texas Children's Hospital has been cited by the US Department of Labor Occupational Safety and Health Administration (OSHA) for failing to protect employees from being physically assaulted by aggressive patients. In 2022, the hospital recorded 15 incidents in which aggressive patients attacked employees. The citation references an incident from November 10, 2022, for example, in which an aggressive patient "pulled a security officer to the ground by the hair and kicked them repeatedly in the chest and abdomen." The officer lost consciousness and was taken to the emergency department and hospitalized.

After an investigation, OSHA concluded that the hospital had inadequate policies and procedures to protect its employees from physical assault by patients. Nurses and aides were among the workers exposed to physical threats and assault. This citation involving violence follows another issued by OSHA against a homecare agency.

OSHA issued a $98,000 fine for an alleged willful violation of applicable requirements related to exposure to workplace violence, including physical and sexual assault. The citation was based on an investigation that began after a staff member was assaulted by a homecare client. In this case, a staff member who previously took care of the client had warned the agency about sexual assaults by the client. OSHA concluded that the agency failed to protect its staff from life-threatening hazards of workplace violence. According to OSHA, the agency also failed to provide an effective workplace violence prevention program.

Contributing to the vulnerability of home health, hospice, private duty, and home medical equipment staff is, of course, the fact that they work alone on territory that may be unfamiliar and over which they have little control.

Specifically, OSHA took issue with 2 types of conduct by the agency:

- Staff members were exposed to physical assault.
- There was no system in place for staff to use to report threats and instances of violence to the agency.

Contributing to the vulnerability of home health, hospice, private duty, and home medical equipment staff is, of course, the fact that they work alone on territory that may be unfamiliar and over which they have little control.

If OSHA's citations based on workplace violence are upheld, OSHA will likely require providers to pay a fine and to:

- Develop and implement a written, comprehensive program to prevent violence in the workplace
- Implement a hazard assessment of violence in the workplace
- Develop and implement measures to control violence in the workplace, such as an option to refuse to provide services to clients in hazardous situations
- Develop and implement a training program on violence in the workplace
- Develop procedures to follow in instances of violence, including making reports and conducting investigations of such instances
- Establish a system that allows staff to report all instances of violence, regardless of severity

Homecare staff provide increasingly important services under circumstances that can be difficult, to say the least. One of the highest obligations of all homecare providers is to protect their employees. Possible action by OSHA described above provides a "road map" for providers to follow as they continue to work to address the issue of violence against staff. Violence is not part of the job description! CM

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Recent OIG Study Shines Spotlight on Medicare Advantage Plans' Payment Practice

Elizabeth E. Hogue, Esq.

Enrollment in Medicare Advantage Plans (MAPs) recently exceeded the number of beneficiaries in the Medicare fee-for-service (FFS) program. The number of enrollees in MAPs will undoubtedly continue to increase. In April of 2022, the Office of Inspector General (OIG) of the US Department of Health and Human Services (HHS) issued Report OEI-09-18-00260, "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care," concerning the payment practices of MAPs.

First, the OIG confirmed that MAPs must cover the same services as FFS. According to the OIG, MAPs must follow Medicare coverage rules that specify what items and services are covered and under what circumstances. MAPs may not impose limitations that are not present in FFS Medicare. The OIG also pointed out that MAPs may impose additional requirements, such as using in-network providers for certain health care services and requiring prior authorization and referrals for specialty services.

Since MAPs are paid on a capitated basis, the OIG is concerned that payments create incentives for MAPs to deny access to services and payment in order to increase profits. The purpose of the report was to assess the extent to which denied requests for preauthorization and payment met Medicare rules and would likely have been approved in FFS Medicare.

Medicare Advantage Plans sometimes delayed or denied beneficiaries access to services even though the requests met Medicare coverage rules.

Based on this review, the OIG concluded that:

1. MAPs sometimes delayed or denied beneficiaries access to services even though the requests met Medicare coverage rules.
2. MAPs also denied payments to providers for some services that met both Medicare coverage rules and MAP billing rules.
3. Regarding prior authorization requests that MAPs denied, 13% met Medicare coverage rules and these services likely would have been approved for beneficiaries under FFS.
4. Common causes of denials of prior authorization requests included MAPs' use of clinical

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What Experienced and New Nurses Want to Say to Each Other

Elizabeth E. Hogue, Esq.

Becker's Hospital Review *recently reported about what new and experienced nurses/case managers would like to say to each other.*

Dear Experienced Nurses/Case Managers,
Here is what new nurses and case managers would like you to know:

- First, we are grateful. Thank you for answering question after question and all of the knowledge and experience you share with us.
- Technology now plays a very important role in our profession. All of us must continually adapt.
- Because of the pandemic, we often did not get the hands-on clinical experience with some skills. Please be patient with us.
- Treat us as individuals and help identify areas that need improvement for each of us.
- Remember that we are experiencing for the first time some of the things you have already seen, such as coping with the loss of a patient.
- We did not learn how to communicate and interact with patients and families in nursing school. Please help us.

Dear New Nurses/Case Managers,
Here is what experienced nurses and case managers would like you to know:

- We often have decades of experience and been there, done that, seen and heard it all.
- We are willing to share advice about

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The Case Manager as a Leader

Catherine M. Mullahy, RN, BSN, CRRN, FCM

Some leaders are born, but most have to develop leadership skills. This is true for case managers as well. John Calvin Maxwell, an American pastor, author, and speaker on many leadership topics, described leadership in this way: "A leader is one who knows the way, goes the way, and shows the way." (Maxwell 2014) It is a sound description of what it takes to be a leader in case management. There are many reasons why case managers, regardless of their positions, should aspire to be a leader. Leadership skills play an important role in all of a case manager's interactions with their patients, patients' family members, primary care physicians, specialists, social workers, hospital administrators, insurers, health plan sponsors, and other case managers. Gaining the knowledge and insight regarding critical leadership traits and skills that are most important for case managers and all they serve is a valuable endeavor for case managers who strive for professional excellence and optimum patient outcomes.

Character Traits of a Leader

There are many traits ascribed to leaders in government, business, education, and sports. Some of them are applicable to leaders in health care, but not all of them. After all, the health care environment is very different from other fields in its mission and high stakes that involve human lives. Some traits that apply to all fields include having a vision that considers the big picture but is equally focused on the details that facilitate that vision. Another characteristic that is universally applied is having both self-confidence and humility. Self-confidence is essential to making decisions, inspiring others, and meeting challenges head-on. Humility helps break down barriers, makes leaders more approachable and real, while it also helps to build trust. Perhaps the most important personal trait every leader should have is integrity. By leading with strong values of honesty and transparency, others recognize that you say what you mean and do what you say, and that one's words and actions are aligned with good values. This is important for gaining buy-in for the journey ahead that will affect the lives of patients, staff, and the case management department. (Mullahy 2017)

The aforementioned traits of a good leader are essential regardless of one's profession or field. There are, however, leadership traits that have special significance for case managers serving in health care. Chief among these is accountability. It is vital as a leader in case management to have a strong sense of responsibility both to the case manager's role and standards of practice, as well as to other members of the interdisciplinary health care team, employers, insurers and, of course, patients.

The fact that case management is a process and not a singular task demands accountability. Without it, the ripple effect on the entire continuity of care can jeopardize desired outcomes. During the pandemic, the significance of accountability held even greater weight. With health care demand up and resources down, each case manager had to give the best they could in addressing this unprecedented health care crisis. Not only did case management leaders have to be accountable in meeting their normal responsibilities, but they also had to allocate personnel in new and challenging ways and ensure that discharge planning and transitions of care activities were not compromised. (Tahan 2019)

Finally, all of these traits would not be possible without emotional intelligence. It is not enough to have a high IQ (intelligence quotient) and strong health care and case management knowledge without that being backed by emotional intelligence. In case management, having emotional intelligence or a high emotional quotient (EQ) enables a case manager to be astute regarding the personal feeling of others. It enhances one's ability to lead others, manage behavior, and engage team members and patients in a plan of care. (Hargett et al 2017)

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Essential Leadership Skills for Case Managers

In addition to having certain personal traits, there are leadership skills that are fundamental for case managers. Effective communication skills are essential. To lead, case managers must be able to communicate clearly, in a timely manner to keep all parties updated regarding important developments in a patient's status. Leaders must keep their team informed regarding the journey—where they are, where they are heading, and roadblocks they may encounter. (Mullahy 2017) Effective communication also depends on encouraging an open dialogue, building interactions that promote learning, and practicing active listening. (Marshall 2018)

There are other skills that are integral to sound leadership in case management such as critical thinking and the ability to problem solve. Leading in case management demands the ability to take initiative and think outside of the box to drive resolution in challenging situations. It is not enough to simply follow the status quo when the course of direction must be changed to mitigate risks and facilitate the best patient-centered care. Leaders know how to apply critical thinking to properly assess any given situation, and access the information and answers needed to arrive at the optimal decision.

In conjunction with critical thinking skills, leading in case management also requires innovation. To nurture growth among team members in the complex health care environment, being innovative and fostering innovation is vital. It also supports yet another essential skill for leading in case management, which is the ability to promote collaboration. (Mullahy C2017) Collaboration involves the teamwork of both case managers and other clinicians along with health care administrators. As a leader, it is important to encourage collaboration and also be an example of it, working closely with other practitioners in multiple disciplines. Through the ongoing exchange of ideas, new strategies and solutions develop that ultimately help to improve the quality of case management services and the health outcomes of patients.

While being able to foster collaboration can be an exhilarating experience for case management leaders, conflict resolution can be quite challenging. Even under the most astute leaders, conflicts arise and must be swiftly and conclusively resolved. A leader in case management must be able to promote compromise, effective negotiations, and communications among those involved to bring a conflict to a resolution. (MHA Health Administration 2021)

Time management is a particularly important leadership skill for case managers. Considering the fast pace of the health care environment, in which minutes of lost time can factor heavily when seriously ill patients with comorbidities are involved; being able to use one's time wisely is critical. Leadership in case management demands the ability to set clear priorities, delegate wisely, and continuously focus on ways to improve processes and make them more efficient. (AMN Healthcare 2018)

Advocacy is also a key leadership skill case managers require. Case managers are at the center of their patient's care. Caring for a patient, often those with complex and debilitating medical conditions, demands the ability to staunchly advocate for that patient. Sometimes the advocacy needs to be directed at patients and/or family members to motivate a change in a negative behavior that is compromising patients' health (eg, excessive drinking or eating, smoking, noncompliance with their treatment plans, etc.). In these cases, subtle leadership is needed to influence change. (Relias Media 2018) A good technique reflecting this is the use of questions to engage the patient and learn what may be causing the negative behavior and/or failure to follow the prescribed treatment plan. This form of advocacy through subtle leadership also serves to build trust between case managers and patients.

Another valuable leadership skill for case managers to develop is that of mentoring. The Commission for Case Manager Certification (CCMC) encourages mentoring, noting that after becoming a Certified Case Manager (CCM), the case manager "can extend [their] own professional development by becoming a mentor—by looking for individuals in [their] sphere of influence who show that spark for autonomy and have the qualities that would make a great case manager." (CCMC) This essential leadership skill not only raises the skill set of other team members but also encourages them to mentor others. All case managers should be committed to sharing their knowledge with new case managers through mentoring. This demonstrates leadership and not management.

Leadership Is Not Management

Many people equate leadership with management; however, they are not one and the same. Their characteristics

Leading in case management demands the ability to take initiative and think outside of the box to drive resolution in challenging situations.

are distinctly different. For example, leaders have followers whereas managers have subordinates. Leaders drive transformation. They have a vision of where they are and where they want to go and engage their team in charting the course forward for the future. They demonstrate the personal traits previously discussed such as vision, honesty and integrity, inspiration, and the ability to think outside of the box and challenge the status quo. By contrast, managers execute a vision by breaking it down into a road map that their team is expected to follow. In their day-to-day role, managers direct work efforts, monitor activities as needed, and anticipate problems. They set the work rules and processes to be used to achieve the defined objectives. (Mullahy 2017)

There are many definitions ascribed to the word *leadership*. This one is particularly applicable to leadership in case management. "Leadership is a set of behaviors used to help people align their collective direction, to execute strategic plans, and to continually renew an organization." (McKinsey & Company 2022) In contrast, management is defined as "The process of dealing with or controlling things or people." (Oxford English Dictionary 1989) By these definitions alone, it is evident that leadership, and not management, is what is needed in case management.

Like case management, leadership is a process that focuses on other people or groups. It requires the ability to influence and motivate others, whether that be patient, patient's family, other clinicians, administrators, insurers, health plan sponsors, etc. The goal of leadership is to accomplish goals. In case management, case manager leaders must be capable of assessing many variables pertaining to their patients, patients' family, the patient's disease/medical condition process, related treatment plan, insurance coverage, and other factors such as psychosocial considerations. (Powell et al 2019) Their very functions reflect the need for this goal-oriented form of leadership.

Case Management Leadership in a Crisis

During the COVID-19 pandemic, case management leadership was sharply tested. And, while case managers are accustomed to performing their duties in crisis situations, this crisis was like no other. It demanded the ability to lead effectively during a global pandemic that made their role even more complex. First, case managers had to learn about COVID-19, how it spreads, and how to prevent its transmission. They had to broaden their coaching skills with patients and families and guide them toward adopting new habits (ie, wearing face masks, adopting good hand hygiene, and monitoring symptoms). Additionally, they had to increase their knowledge and skills relating to remote communications and telehealth platforms. Further, discharge planning took on a heightened priority as bringing patients back to their homes and communities reduced the risk of COVID-19 transmission. (Staub 2023) In short, case managers had to step up, assume new responsibilities and yes, be the leaders their patients and health care colleagues needed them to be. If ever there was a time when effective communications, accountability, critical thinking, innovation, advocacy, and mentoring were needed, the pandemic was that time.

Leadership and Case Management Standards of Practice

As case managers know, the Case Management Society of America (CMSA) has established Standards of Practice for Case Management that delineate the standards case managers should adhere to in their practice. These standards provide both general guidelines and condition-specific recommendations within various clinical categories. Within the CMSA's Standards of Practice, there is Appendix 3-A—the Statement Regarding Ethical Case Management Practices. Along with the CMSA's guidance is the Commission for Case Manager Certification (CCMC) Code of Professional Conduct for Case Managers. Other professional organizations also publish documents to help guide the practice of case management. These include the Certification of Disability Management Specialists Commission (CDMS' Code of Professional Conduct), the American Nurses Association (ANA's Code of Ethics), American Association of Occupational Health Nurses (AAOHN's Standards of Occupational and Environmental Health Nursing and Code of Ethics), and the National Academy of Social Workers (NASW's Code of Ethics). While all of these guidelines are intended to support consistently high standards of care, leadership demands a level of discretion when applying them. Case managers acting as leaders should rely on their professional knowledge and experience when transforming guidelines into action. There are some guidelines that are restrictive, and some are potentially dangerous. (Mullahy 2017) This is where the leadership skills of critical thinking and advocacy are vital for making sure that guidelines are applied prudently.

To nurture growth among team members in the complex health care environment, being innovative and fostering innovation is vital.

The Goals of Leadership in Case Management

There are some primary goals that leadership in case management should prioritize. Managing challenging patients should take priority among these goals. In these instances when patients become noncompliant, noncommunicative, and possibly even combative, a case manager's communication, advocacy, collaboration, and critical thinking skills are essential. When communicating with challenging patients, asking questions in a nonthreatening way enables a case manager to better assess why the patient is being difficult. To identify the problem, case managers need to consider possible factors such as long waiting times for assistance, poor communication by other staff, language difficulties, unrealistic expectations relating to their condition and progress, limited resources and support, and being in pain. (The MDU 2023)

Conveying to that patient that their best interests are most important and demonstrating advocacy for that patient can help diffuse a challenging situation. Through collaboration with other members of the patient's care team and their family members, case managers can gain additional insights, drawing on the experience and expertise of others for new ideas and solutions. Finally, critical thinking also becomes essential to drill down into what are the root causes of the patient's behavior.

Driving needed change should also be a top goal of leadership in case management. This goal demands the application of all essential leadership skills and can have a significant impact across many strategic areas—from population health management, health literacy, and improving staffing ratios, to efficient application of technology in case management, reducing health care costs, and promoting increased health parity. For example, regarding population health management, which focuses on high-risk, high-cost patients and improving the delivery of care, containing health care costs, and improving the health of a given community/population, case managers play an important role. They are at the forefront in the application of health care informatics that help facilitate predictive modeling, which is central to population health management. Their collection of data demands that they understand how informatics can be used to facilitate care transitions for patients with complex, chronic medical conditions. (Mullahy 2017)

Future-Proofing Case Management and Its Leadership

Case managers, who are serious about becoming a leader, should consider how to build and continuously improve their leadership skills. Continuing education is paramount. Health care and, therefore, case management are continually evolving. There are new medical advancements, changes in technology, population demographics, and emerging trends, about which case managers need to remain informed. Additionally, case managers benefit from continuing education and its role in helping sharpen and refresh their leadership skills. There are numerous resources for continuing education from professional associations, independent case management educational consulting firms, professional journals, myriad case management textbooks.

Another valuable resource for ongoing case management leadership development is professional conferences. Not only do case managers benefit in learning from seminars and workshops presented by case management leadership experts and authors, but also they have an opportunity to network with peers. Through these networking opportunities, case managers can exchange ideas, share tips, and further enhance their leadership skills. Regardless of a case manager's practice setting (eg, hospital, physician's office, government agency, independent case management firm, etc.), being able to tap into the experiences of others, who too are committed to best practices in case management, is beneficial. By regularly enhancing their leadership skills through various educational channels, case managers can advance their own careers, while also driving positive change.

A recent survey conducted by the CCMC found that 86% of respondents report that certification has benefited their career. Respondents cited their median annual salaries have risen since 2019, ranging from $90,000 to $100,000. Certification is an essential element of case manager leadership. Certified case managers adhere to the CCMC's Code of Professional Conduct and participate in continuing education. They also are required to keep up their certification with continuing education to ensure that they are up-to-date on their fundamental case management skills. To ensure that its Certification exam reflects the latest developments in case management, the exam is updated on a timely basis. (CCMC 2023)

Maintaining one's own leadership skills is important, but so too is helping the next generation of case managers gain those skills as well. While not everyone has the personal traits to be a leader, there are many who do. Case managers need to be able to recognize those newer case managers who demonstrate strong communications, collaboration, critical

While the nursing shortages in America has been widely publicized, less attention has been focused on the shortages of skilled case management leaders and nurse case management professionals.

thinking, problem-solving, and decision-making that would enable them to become effective case management leaders. To nurture potential case management leaders, it is important to offer constructive feedback and mentoring, which facilitates learning and improvement. Feedback should be provided in a timely manner and be specific to the matter at hand. There should also be a sharing of the case manager leader's experiences and challenges. As part of this mentoring of the next generation of case manager leaders, delegating new responsibilities and empowering the mentees fosters trust and accountability and enables future case management leaders to make decisions, take actions, and gain knowledge from their outcomes. (LinkedIn)

While the nursing shortage in America has been widely publicized, less attention has been focused on the shortages of skilled case management leaders and nurse case management professionals. These labor shortages can lead to adverse effects in patient care, excessive hospital readmissions, and associated increased costs. Case managers unable to adhere to professional standards become frustrated with their increased workloads and inability to best serve their patients, impacting staff retention and even retention of current case managers who become frustrated by workloads that do not enable them to best serve their patients. To future-proof the field, resilient and effective case management leaders are crucial. In applying their leadership skills, they can be catalysts in helping to address myriad challenges, including labor shortages. CE1

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CE2 Approved for 1 hour of CCM, CDMS, and nursing education
Exam expires on February 15, 2024

Understanding the Background and Case Management Operations for the SNF 3-Day Rule

Tiffany Ferguson, LMSW, CMAC, ACM

The 3-day stay rule for Medicare patients is the expectation that patients must have an inpatient hospitalization of at least 3 days, not including the discharge day, to be transitioned to a skilled nursing facility (SNF) or swing bed. During the public health emergency (PHE) of COVID, the 3-day rule had been waived for Medicare authorization for skilled nursing placements. However, since the end of the PHE on May 11, 2023, the rule has returned despite best efforts to eliminate it by various advocacy groups. The 3-day rule for inpatient stay specifically applies to traditional Medicare patients. Although the rule impacts hospital case management workflows, the requirement is for the guaranteed reimbursement of SNF services. It is the case manager who is typically tasked with being the timekeeper to ensure the patient meets the rule before transfer or meets qualifying exceptions to solidify final acceptance for placement. The case manager also ensures that patients' rights are met by ensuring patient choice for post-acute care. Case managers also ensure a safe and timely transition. Monitoring the inpatient order against exclusionary factors for the 3-day SNF rule seems to be a diversion from the objectives of right time, right place, right setting.

History & Background

The Medicare Part A SNF benefit was enacted in 1965 as part of the Social Security Act, Section 1861(i) and 42 CFR 409.30, providing benefit for SNF extended care services if a patient has a qualifying inpatient stay of at least 3 consecutive days starting with the inpatient admission, but not counting the discharge day. The SNF requirement for a qualifying stay applies to hospitals and critical access hospitals (CAHs). (CMS MLN 2023) When the rule was enacted, Congress placed some restrictions on the SNF benefit such as limiting SNF coverage to 100 days per "spell of illness" and instituting a daily co-payment rate starting at day 21 in the SNF episode of care. (CRS Report 2016) Originally, beneficiaries were required to have a 3-day qualifying inpatient hospital day within the last 14 days before a SNF admission; however, this was later modified with The Omnibus Budget Reconciliation Act of 1980 to extend the required period to 30 days from a qualifying hospital inpatient admission. Interestingly, the 3-day stay was not unique to just a SNF stay. The same requirement had applied to home health benefits. However, this stipulation was later removed with the Omnibus Act to allow for greater access to home health services. (CRS Report 2016)

At the time of the Medicare enactment of the 3-day rule, the average length of stay in the hospital was more than 13 days, and thus there was no concern regarding patients meeting the 3-day requirement. (Edelman 2022) By 1972, the average inpatient stay was roughly 12 days, and by 2012 that had dropped to 5 days, largely as a result of the medical advancements, outpatient surgical and procedural services, and observation care in the hospital environment. (CRS Report 2016) The addition of outpatient status with observation services (OBS) has been perceived as the greatest limiting factor to the 3-day rule for patients to qualify for SNF placement. In 2013, the Department of Health and Human Services (DHHS) Office of the Inspector General (OIG) reported that, in 2012, Medicare beneficiaries had more than 600,000 hospital stays that had at least a 3-day length of stay; however, because of their OBS designation, they missed the qualification for SNF placement. CMS attempted to combat any confusion around OBS stays and subsequent limited transitions to SNFs with the "Two-Midnight Rule" released in August of 2013. This rule was intended to provide clarification in differentiating between OBS and inpatient hospitalization, with a medical necessity plus 2-midnight timeframe criteria; unfortunately, confusion continued. In August 2015, the NOTICE Act was signed into law to provide notification to Medicare beneficiaries, known as the Medicare Outpatient Observation Notice or MOON regarding their observation care and its implications regarding eligibility for SNF coverage. (CRS 2016) However, this notice has been perceived as only adding to Medicare beneficiaries' frustration with their hospital stay and covered

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Monitoring the inpatient order against exclusionary factors for the 3-day SNF rule seems to be a diversion from the objectives of right time, right place, right setting.

services. Moreover, it has not improved the designation for the 3-day qualifying stay to SNF placement.

Efforts to Eliminate or Work Around the Rule

The 3-day rule is well known as an unpopular and outdated policy by numerous case management, hospital, health care provider, and Medicare advocacy organizations. A prior attempt to repeal the 3-day ruling occurred on January 1, 1989, with the Medicare Catastrophic Coverage Act (MCCA). However, 1 year later the 3-day rule was reinstated when Medicare SNF placements increased by 16% that year, resulting in a spending increase from $964 million to $2.8 billion. This short-term experiment, prior to the PHE, was the first attempt to eliminate the 3-day rule, which was deemed a failure due to lack of administrative guardrails to prevent Medicare spend. (Mor 2023; CRS 2016)

The more recent attempts to work around the SNF 3-day ruling include 2 allowances. Medicare Part C, or Medicare Advantage (MA), plans have the discretion to not follow the SNF 3-day rule. It is estimated that more than 92% of MA plans do not follow the SNF 3-day rule and instead use prior authorization requirements for approval to SNFs. Since 2013, Accountable Care Organizations (ACOs) have also been given the opportunity to participate in the 3-day SNF Day Waiver program for Medicare Shared Saving Program (MSSP) participants. This waiver grants participating SNFs that hold a 3-star rating on CMS Care Compare to be excluded from the 3-day stay ruling. The waiver also exists for various value-based programs through the Center for Medicare & Medicaid Innovation (CMMI), such as bundled payment and joint replacement initiatives. (CMS 2023) It is estimated that between MA beneficiaries and MSSP participants, 60% of Medicare beneficiaries no longer require the 3-day ruling. The remaining 40% have left advocacy groups concerned that all Medicare beneficiaries no longer receive the same benefits, and they question health equity.

Since enactment of the PHE in March 2020, beneficiaries were awarded the equal opportunity to enter SNF placement without the requirements of the 3-day stay ruling. However, data seem to be unclear as many of the beneficiaries received SNF benefits "without using a PHE-related waiver, with a prior hospitalization, and without a COVID-19 diagnosis." (Edelman 2022) A surprisingly large movement during the PHE was found in existing nursing home residents who used SNF benefits without a corresponding hospital-based service. It's unclear if the SNF stay was deemed to avoid hospitalization during the height of the pandemic or if the SNF waiver was being inappropriately used by nursing home facilities. (Mor 2023) Without substantial data, it was concluded that the SNF waiver was not extended with the end of the PHE in May 2023.

In the public efforts to repeal the existing regulations, including the most recent letter from the CEO of American Case Management Association (Cunningham 2023), 2 approaches have been taken: a request to eliminate the ruling all together, and a request to consider observation services as part of the time equation. House and Senate bills have been proposed (although yet to be passed) to allow for time in OBS to be counted toward meeting the 3-day inpatient stay. The Medicare Payment Advisory Commission (MedPAC) has also recommended to Congress that up to 2 OBS days be counted toward meeting the 3-day stay requirement. (CRS 2016) Both provisions offer a compromise on the 3-day stay requirement while still ensuring some guardrails exist to manage Medicare spending.

Understanding the Requirements

While the 3-day inpatient stay before SNF placement primarily applies to traditional Medicare patients, some MA plans (although likely few) may follow this rule. MA plans have specifications in their contract with the hospital or provider manual that likely allow the transfer of patients to skilled placement regardless of the 3-day rule or even the requirement of inpatient admission through the pre-authorization process. Additionally, this requirement does not apply to Medicaid or commercial plans, which also follow a pre-authorization process for post-acute services. Case managers will want to check their hospital contracts and verify the payer requirements for their patients' skilled nursing authorization period to receive approval for SNF admission.

For traditional Medicare beneficiaries the following rules apply. The patient must have completed a 3-day inpatient stay at time of hospital transfer or within the previous 30 days of the expected SNF admission date. The stay must have extended through 3 midnights, beginning at the time of the physician inpatient order. Case managers must monitor the time of the order and not the patient's length of stay for

The addition of outpatient status with observation services (OBS) has been perceived as the greatest limiting factor to the 3-day rule for patients to qualify for SNF placement.

transfer because the patient may have been in OBS before being placed in inpatient level of care. For example, a patient was in the hospital under OBS for the first day, and then the order was placed on day 2 of the hospitalization. In this example, the patient would not be eligible for skilled nursing transfer, if deemed medically necessary, until day 4 of the hospitalization, after the third midnight was passed from time of inpatient order. This scenario validates the importance of case managers to navigate the balance between regulation and patient needs. Proactive involvement is key for educating the care team regarding these regulations, identifying patients that potentially require skilled nursing early in the hospitalization, and discussing the level of care status requirements with the care team.

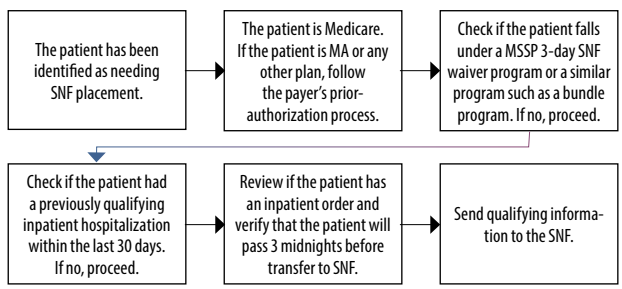
It is important to note that if the patient is initially meeting all requirements for medical necessity, then the continued days of the hospitalization for SNF placement are all medically necessary for SNF qualification because the patient would not have a safe discharge otherwise. There is no need for the utilization review team to provide daily clinical reviews on the subsequent days for the 3-day stay rule to qualify for skilled nursing as long as the initial order exists. However, case management teams will need to ensure the SNF receives verification of the qualifying stay because they are required to report the dates on their claim form under occurrence span code 70. Claims that do not have the 3 consecutive inpatient days or include at least 1 day that was overlapped from the inpatient hospital's claim service dates risk being rejected for reimbursement. (CMS MLN 2023)

As if the calendar clock was not confusing enough, the qualification of the 3-day stay also includes 2 calendar periods, the previously mentioned 30-day stay and the 60-day benefit period. The 30-day period states that if a patient has a break in skilled care that lasts more than 30 days, they will need a new 3-day hospital stay to qualify for additional SNF care. The new hospital stay doesn't need to be for the same condition that they were treated for during the previous stay. For patients that do not have a 30-day break in skilled care, then the 3-day stay rule does not apply. For example, a patient was inpatient on the index admission for 4 inpatient hospital days, the patient was then recommended for SNF, but the patient elected to go home with home health instead. The patient went home for 2 days and realized this was a terrible idea and returned to the hospital. The patient was readmitted as OBS and recommended again for SNF placement. The patient would still be eligible for SNF placement because they completed a qualifying inpatient hospitalization during their index admission, and it was within the 30-day period.

Patients that go to SNF must also have a 60-day break from utilization in order for their SNF benefits to renew. This means that a patient that was in the hospital and then spent 24 days in the SNF, then returned the next week to the hospital, and then needed to discharge to skilled again, would not renew their benefits. Instead, they would go straight into the continuation of the previous benefit period, which would be the patient's coinsurance days 21≠100. This could be up to $200/day unless the patient has secondary insurance to help cover the cost. (Medicare.gov 2023)

SAMPLE DECISION TREE

The case manager must consider the following when facilitating patient transfer to SNF:



SAMPLE MEDICARE 3 NIGHT SNF QUALIFICATION NOTE

The patient has met 3 consecutive Acute Inpatient Hospital Days

Patient's 1st Hospital Inpatient Date was on _____

Additional Acute Inpatient Dates were _____
and _____

Determination was made by:

_____ Utilization Review/ Case Management

_____ Physician Advisor or outsourced resource

Source: Phoenix Medical Management. Reprinted with permission.

Case Scenarios

Case 1

A traditional Medicare patient is admitted to the hospital under an inpatient-only procedure and is 1-day post-surgery. On day 2 the patient is determined to require SNF. The patient is evaluated by the care team, and during interdisciplinary rounds the care team learns that the patient will need to remain in the hospital until day 4 before transferring to skilled nursing placement. The case manager reviews the case because the patient is medically ready for transfer on hospital day 3 (second midnight) and finds that the patient is under an approved MSSP program that participates in the 3-day waiver program with the patient's first-preference facility. Under these terms, the patient is excluded from the 3-day ruling and eligible for transfer that day.

Case 2

A traditional Medicare patient is dropped off at the emergency department (ED) because her family is struggling to care for her at home due to their work demands and personal care needs that were exacerbated by a recent hospitalization. The family is applying for long-term benefits through the state to transition the patient into a nursing home; however, the patient has not been approved yet. The ED physician is unsure of what to do with the patient and calls the hospitalist service to review the patient for possible admission. The ED case manager sees the patient listed on the ED tracking board as "placement" and immediately gets involved. The ED case manager is familiar with this patient and starts connecting with the patient's family to develop a long-term strategy. The ED case manager talks with the ED physician and hospitalist and notes that the patient previously had a qualifying hospital stay within the last 30 days that would make the patient eligible for SNF placement. The ED case manager is able to coordinate with the patient, the family, and the SNF facility that the patient and family are hoping to transition to for SNF placement for admission. Although it takes most of the day, the ED case manager is able to avoid an unnecessary hospitalization and instead coordinates transfer to the SNF from the ED.

Case 3

A traditional Medicare patient is admitted to the hospital under an inpatient order directly from their family physician. During utilization review, it is unclear that the patient meets medical necessity for inpatient level of care. The case is escalated to the physician advisor who concurs, and the Condition Code 44 process is followed, changing the patient to OBS. The patient is evaluated by physical therapy, and SNF recommendation is documented. Case management is involved and discusses the case; the patient does not have a previous qualifying stay and because the patient has been changed to OBS, the patient no longer has an active inpatient order to meet the 3-day stay rule. The patient has no MSSP/ACO affiliation. The case manager discusses the case with the patient, saying that under this scenario the patient would only have Part B benefits for services, and thus, would have to pay out of pocket for SNF or discharge home with outpatient or home health services because the acuity of the patient's therapy needs does not qualify them for acute rehab.

Since the end of the PHE, the 3-day SNF stay has been an adjustment for the hospital case manager who may have not been working during the pre-COVID time when the 3-day stays were calculated into the SNF equation. And although the PHE has ended, advocacy groups are requesting the removal of the historical rule, first initiated in 1965. As health care moves towards a focus on health equity, CMS will need to consider how benefits for skilled care can be provided to all of their members equally. To navigate resources for patients, case managers will need a clear understanding of the 3-day rule and its exclusion opportunities, such as those under the 3-day SNF waiver in an MSSP or bundle, those who are MA members, and patients with a prior qualifying hospitalization. CE II

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CE3 Approved for 1 hour of CCM, CDMS, and nursing education credit
Exam expires on February 15, 2024

Demonstrating Better Outcomes for Children Through Care Coordination

Kimberly Conkol, RN, MSN, CCM, and Sandra Beer, CPA, MBA

PARTNERS FOR KIDS (PFK) is one of the nation's oldest pediatric accountable care organizations (ACOs), helping children who are most in need get the best care when they need it and where they need it. PFK was established in 1994 and has proven that it can facilitate high-quality care at a lower cost. It was formed as a joint venture—Physician Hospital Organization (PHO)—between Nationwide Children's Hospital (NCH), NCH-employed physicians, and contracted community physicians. Today, PFK is recognized as both a 501(c)3 and an intermediary organization that accepts full financial risk for its population. In September of 2020, PFK added Dayton Children's Hospital as an additional hospital partner, expanding the geographic reach to include a 47-county region.

PFK's mission is to improve the health of children through high-value, innovative care, and community partnerships. PFK's vision is to create a system of care that promotes best outcomes in child health. One of the ways PFK accomplishes this vision, is by providing care coordination services to children who need help navigating the health care system. Since the inception of the Care Navigation program, over 20,000 children have received care coordination from PFK.

The Care Navigation program provides long-term case management to children and their families. The program is based on the Case Management Society of America's (CMSA's) standard philosophy of case management practice (2022): "a collaborative process of assessment, planning, facilitation and advocacy for options and services to meet an individual's health needs through communication and available resources to promote quality cost-effective outcomes"; and the Agency for Healthcare Research and Quality definition of care coordination (2018): "Care coordination involves deliberately organizing patient care activities and sharing information among all of the participants concerned with a child's care to achieve safer and more effective care."

Care Navigation team members are trained in a structured program based on the American Academy of Ambulatory Care Nursing (AAACN) care coordination and transition management competencies. A 5-week orientation includes classroom and practical experience including simulation and role-play on topics such as motivational interviewing, health risk assessment, care planning, and promoting collaboration and self-management with families and their care team. Other topics include:

- Transitions of care, both between medical settings or foster placement locations, and to adulthood
- Disease-specific interventions, such as behavioral health and healthy development for the neonatal intensive care population
- Safety, including staff safety while in the community and reporting of childhood abuse and neglect concerns

Kimberly Conkol, RN, CCM, *is an experienced nurse leader with a clinical background in women and infants health and case management. Kimberly graduated from Drexel University with a Master's degree in innovation. She is a CCM. In 2012, she began the care coordination program at Partners for Kids, an accountable care organization affiliated with Nationwide Children's Hospital in Columbus, Ohio. She is the author of several articles on innovative programs focused on achieving the triple aim in pediatrics, including the use of telehealth. Currently, she is Vice President of care coordination and utilization management at Nationwide Children's Hospital and Partners for Kids and is responsible for enterprise-wide care coordination activities in the inpatient and outpatient settings for behavioral health and specialty and primary care.*

Sandra Beer, CPA, MBA, *is Business Director for care coordination, Partners For Kids and The Blue Jackets' Family Resource Center, Nationwide Children's Hospital, Ohio. Sandra has a strong background in international business and accounting. In 2013, Sandra completed her MBA at the University of Exeter, UK, with a specialization in sustainable business methods. While completing her MBA, she transitioned into the health and social care field, initially working as a program specialist for Project SEARCH. In her current role, she is responsible for all of the operational aspects of care coordination, ranging from patient intake and staff scheduling and payroll, to external partnership management, data analysis, and regulatory compliance.*

The Care Navigation program assists children and families with their health care in the same way a global positioning system (GPS) is used by a traveler.

The Care Navigation program assists children and families with their health care in the same way a global positioning system (GPS) is used by a traveler. Experienced pediatric nurses, social workers, and case management extenders collaborate with families and providers to determine a desired outcome, or final destination. Together, they determine next steps according to the individualized needs and preferences of the child, called the route. Along the way, the care navigation team will find resources and maximize benefits in both the health care system and community to ensure that no points of interest are missed and that the right care is provided in the most appropriate setting at the right time, and obstacles are avoided. Providers and families are encouraged to use the team for help with troubleshooting and when barriers are encountered, known as recalculating. Beginning In March 2022, the Care Navigation program was replicated at Dayton's Children's Hospital and utilizes the same roles, practices, and tools to provide care coordination to children in the west region of Ohio.

Children With Medical Complexity (CMC)

Children with medical complexity (CMC) are a subgroup of the pediatric population who have chronic conditions and functional limitations. These children experience high costs and significant burdens when interacting with the health care system. (Berry et al 2013; Cohen et al 2011) Their expenses account for more than one-third of all health care costs within pediatrics. (Cohen et al 2012) Despite high expenditures and frequent interaction with the health care system, CMC often do not experience improved health outcomes. They have higher rates of readmission, intensive care, gastrostomy and tracheostomy placement, and inpatient mortality. (O'Mahony et al 2013) Advances in medical care and technology, particularly in critical care and neonatology, have resulted in a growing number of children in this group (Cohen et al 2011), as children who would have historically died of their conditions are living longer, often into adulthood. Research documents that parents and caregivers of CMC self-report document a need for help with coordinating their care. (Golden & Nageswaran 2012; Toomey et al 2013)

The Care Navigation program prioritizes several populations of children to receive services including children with medical complexity, behavioral health conditions, who are in foster care, have a neonatal intensive care stay, or have chronic conditions like asthma, as well as those who utilize the emergency room frequently or whose total care is expensive when compared to the rest of the population. Outreach efforts focus on these populations, but referrals are accepted from many different sources including primary care and specialty physicians, schools, social service agencies, as well as parents and caregivers of children self-referring. As described here, the breadth of children served by the program is vast, ranging from young women giving birth to the babies they bring into the world.

Case Studies

A 17-year-old mother was delivering her first child 2 weeks after being released from the Juvenile Intervention Center (JIC). She needed health education, linkage to baby-care resources, and medical follow-up for herself and her infant. As part of the Care Navigation program, a care coordinator who was integrated in the clinic that serves children from within JIC was able to assist. This care coordinator was able to seamlessly work with the mom before and after her release from the JIC. The care coordinator successfully linked her with Nationwide Children's Nurse-Family Partnership before leaving the JIC. The care coordinator was also able to connect with the juvenile probation officer to help balance probation requirements with medical needs. The JIC care coordinator was able to do a warm handoff with the care coordinator who is integrated into the Nationwide Children's Teen and Pregnant clinic for ongoing follow-up. This warm handoff ensured that no additional gaps occurred as part of this mom's transition and helped to build rapport with the family and her new care team member.

A 5-year-old child was rescued by her father from a house fire, in which she sustained burns to 80% of her body and was hospitalized for 6 months. The care coordinator helped to transition the child back home to her family in rural Meigs County with comprehensive support to manage a trach, dialysis, wound care, and feeding tubes. The care coordinator also made sure she could complete follow-up with 11 different specialists and make weekly trips to Columbus for dressing changes. Currently, she is attending virtual kindergarten and receiving additional supports from Social

One of the key measures that PFK has used to assess success is what percent of cases close because the child and family have obtained an optimal level of health and established independence in navigating the health care system to meet their needs. This is referred to as goals met.

Security Income and the board of developmental disabilities, services that her care coordinator helped the family obtain.

A 4-year-old girl with cerebral palsy who had a feeding tube and trach was in a wagon when her care coordinator first met her and her family. While speaking with the family to assess current needs, barriers, and care gaps, the care coordinator inquired about the wagon. The parents noted that they had been unable to navigate the long and confusing process of getting a wheelchair. Through her training and experience, the care coordinator knew that there were many steps, including getting a therapist evaluation, physician order, insurance approval, and finding a vendor to fill the order to obtain a wheelchair. The care coordinator also knew that each of these steps has multiple built-in, smaller sub-steps, and that complications were likely along the process. The care coordinator was able to support the parents step-by-step through a 9-month process. The care coordinator led many care conferences with the care team (phone calls with the providers, insurance companies, and vendors) to ensure that the process was successful. The care coordinator's persistence paid off, and she was finally able to help deliver a custom wheelchair that will not only ensure the safety and comfort of the child, but also change the lives of her parents, who are now better able to support their child to explore the world around them.

Measuring Outcomes to Evaluate the Process of Care Coordination

The foundational standards of care coordination for children recommend that care coordination activities are assessed with outcome measures that evaluate the process of care coordination, as well as its impact on family experience and preventable health care utilization. Challenges to measuring care coordination can include lack of information caused by inadequate documentation tools, often compounded by gaps in availability or comprehensiveness of health care claim and payment information. Because care coordination interventions can span long ranges of time (potentially multiple years), it is difficult to control for other variables that may impact outcomes, including all the changes that come with routine child development. Lastly, care coordination activities often focus proactively on prevention, which involves the difficulty of measuring things that didn't happen. Recently, measurement has been further complicated by the COVID pandemic that dramatically changed utilization patterns and health care practices.

The PFK program is fortunate to have had the opportunity to find a sizable population of similar children for whom data are available and who received care coordination services, allowing us to assess some of the key outcomes. This was accomplished through careful planning and program development with measurement capabilities kept in mind, alongside clinical workflows and interventions. Care coordination activities are documented in an electronic medical record system that discretely captures key milestones in the care coordination process, including first outreach to the child and family, completion of the assessment, creation of a care plan, all visits with the care coordinator regardless of method (phone, in-person, at home, medical appointments, or video visit), and completion of child and family goals. The reasons for ending care coordination are also tracked for all children who receive services and can include outcomes such as goals met, unable to contact, lost eligibility, deceased, etc. To complement this process data, PFK also receives medical, pharmacy, and behavioral health claims for all care received by the children in the ACO, regardless of where care was received; therefore, utilization information is comprehensive. PFK membership is based on county of residence; as such, PFK can maintain longitudinal records even when families change insurance providers or move to a different county within the PFK region.

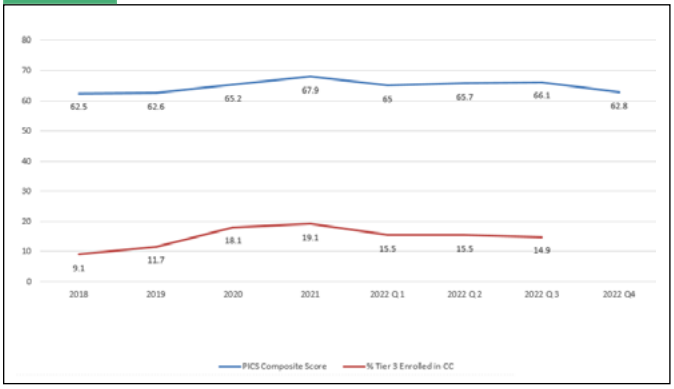
One of the key measures that PFK has used to assess success is what percent of cases close because the child and family have obtained an optimal level of health and established independence in navigating the health care system to meet their needs. This is referred to as goals met. The families receive a certificate of achievement when they reach this milestone, which is tracked as part of the case closure reasons and is known as goals met status. As of 2023, about 65% of children and their families' cases are closed as goals met.

Additionally, families who could qualify for care coordination services at Nationwide Children's Hospital, including those offered by PFK, are asked to complete the Pediatric Integrated Care Survey (PICS), which measures family experiences of care integration and is publicly available from Boston Children's Hospital. Respondents include both those who

have and have not received care coordination. Over a 5-year period, PFK noted that survey scores in the population correlated with the trend of the percent of the population that was receiving care coordination services. In other words, survey scores increased when a higher percentage of the population was enrolled in care coordination and started to decrease when less of the population was enrolled (Figure 1).

Having established that a majority of children and families (65%) were reaching their goals and successfully graduating from the Care Navigation program and that involvement seemed to have a positive impact on overall satisfaction with

FIGURE 1 PEDIATRIC INTEGRATED CARE SURVEY



the care they received as well as how connected it felt, we wanted to take our analysis to the next stage by looking at outcome measures for the population as a whole. It was great that families were reaching their goals, but did that process decrease their utilization and need for the health care system? This is important to establish, not only from the standpoint of the family—keeping them out of the hospital and emergency department (ED) as much as possible—but also from the perspective of reducing cost, and effectively using the limited resources of our health care system.

The analysis showed that there was a slight decrease in utilization of the ED, after just 90 days of care coordination intervention (Figure 2). Furthermore, there was an even greater decrease after a child and family had met their goals (Figure 3).

Recommendations

In our experience to date, the ability to measure the effectiveness of care management activities depends on building workflows and a documentation system that allows for efficient capture of the data needed, without increasing the administrative burden on the nurses, social workers, and other care management team members. It is a challenge to get this balance right. As a result of our 10 years of experience, we offer the following recommendations based on lessons learned.

FIGURE 2 ED VISITS DECREASED SLIGHTLY AFTER 90 DAYS OF CARE COORDINATION

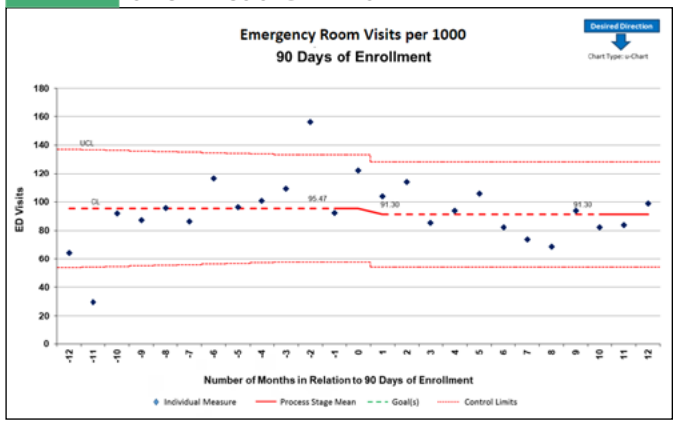
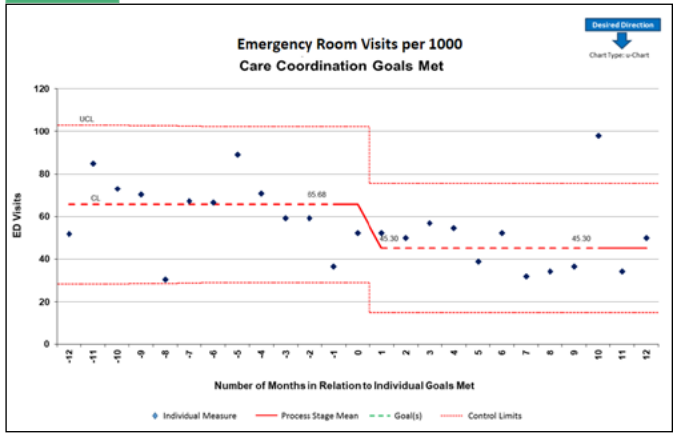


FIGURE 3 ED VISITS DECREASED AFTER PATIENTS AND FAMILIES MET CARE COORDINATION GOALS



1. **Milestones:** Determine distinct key milestones that can denote the progression of child and family engagement in the process of care management. Some examples of key milestones include identification for care management, assessment completion, care plan completion, visits with the care coordinator, completion of individual goals, and end of engagement with the care coordinator.
2. **Outcome Measurement:** Clearly distinguish between a process milestone and an outcome. For example, the end of the relationship with a care coordinator is a process milestone, but it can be measured as either a positive or a negative outcome. When the relationship ends as a result of the care coordinator and child and family jointly determining that all goals are met and they have developed the skills and obtained the resources to be successful in independently managing their health, it is considered a positive outcome. Other instances are considered negative outcomes, such as when the relationship ends because the care coordinator is unable to contact the child and family or they stop meeting the

In our experience to date, the ability to measure the effectiveness of care management activities depends on building workflows and a documentation system that allows for efficient capture of the data needed, without increasing the administrative burden on the nurses, social workers, and other care management team members.

eligibility requirements for a specific care coordination program. To accurately evaluate the effectiveness of the care management program, it is imperative to be able to separate out these different types of outcomes.

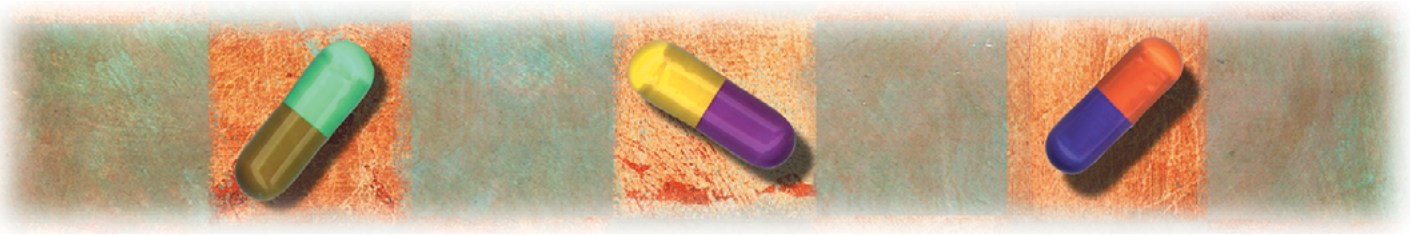
3. **Comprehensive Utilization Data:** Ensure access to continuous information on utilization that is comprehensive of all places where care is received. PFK is able to achieve this because of its design as a ACO that has full financial risk for all care received by the children who are members. Therefore, comprehensive claims data are available, giving a full picture of the child's utilization.
4. **Population Classification:** Establish a method to classify children who are similar to avoid drawing inaccurate conclusions while comparing populations that received care management to populations that didn't. At PFK, we have used a population-classification system provided by a vendor that uses inpatient and ambulatory diagnosis and procedure codes, pharmaceutical data, and functional health status to assign each individual to a single, severity-adjusted group. This classification system is applied to the entire population, which allows us to categorize children into groups, allowing for comparative analysis on groups of interest, such as those who have enrolled in care coordination or those who have successfully completed care coordination by meeting their goals.
5. **Longitudinal Data:** Patience is key in the process of proving the value of the intervention. The team will need to allow time for data to accumulate before making a comprehensive assessment. The amount of time needed can be determined by both the length of the intervention, and the amount of data collection wanted before and after the intervention point. For our most complex children, it is not unusual for care coordination engagement to last a year or longer. In our analysis, we found it most useful to compare 1 year of utilization before engagement in care coordination to 1 year of utilization after engagement ended.
6. **Population Size:** As outliers and extremes are inherently included in a high-risk population, it is important to have a large enough population to draw a reasonable conclusion. Our evaluation of pre- and postcare coordination impact described above includes data from 6000 children.
7. **Standardized Care Coordination Processes:** Lastly, it is important to have well-defined and consistent practice among the team doing the care coordination. While the unique needs of each child must be assessed and interventions catered to their circumstances, goals and abilities of each individual, ability to describe the key components of the program, and competencies of the staff are essential in understanding and measuring its effectiveness.

In the future, PFK desires to continue to use similar methods of data analysis to understand which specific interventions most efficiently assist the child and family to reach their goals. We also believe that care coordination supports impact factors beyond health care utilization, and we will be seeking access to data that will help us measure the impact on social and family functioning like school attendance and employment. Further analysis of the survey data on the child and family experience of the health care system will also allow us to understand how the provision of care coordination services affect these results. Mary Ellen Gervais (2023) indicates that care management programs can indirectly impact clinical outcomes like lab values through direct interventions of care managers that improve self-management skills, medication adherence, access, and participation. Recent advancements in the electronic documentation system used by PFK will allow for future evaluation of specific interventions to more clearly articulate the key components of the program that impact not only utilization and satisfaction measures but also clinical outcomes.

PFK created the Care Navigation program because we believed it would help to achieve our mission to improve the health of children through high value, innovative care, and community partnerships. With the full support of our executive and clinical teams the program was designed, redesigned, and adapted over the last 10 years. With each year, we increased our population sizes and were able to evaluate the work more accurately. We've been able to demonstrate that the Care Navigation program reduces utilization, meaning decreased cost for the ACO and increased time outside of the hospital for the children and families that enroll in our program. Our evolution continues as we strive to have an even greater impact on the children we serve and the communities that they live in. CM

Exam and References on page 37

PharmaFacts for Case Managers



LANTIDRA (donislecel-jujn) Allogeneic Pancreatic Islet Cellular Suspension for hepatic portal vein infusion

INDICATIONS AND USAGE

LANTIDRA is an allogeneic pancreatic islet cellular therapy indicated for the treatment of adults with Type 1 diabetes who are unable to approach target HbA1c because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education. Use LANTIDRA in conjunction with concomitant immunosuppression.

Limitations of Use

When considering the risks associated with the infusion procedure and long-term immunosuppression, there is no evidence to show a benefit of administration of LANTIDRA in patients whose diabetes is well- controlled with insulin therapy or patients with hypoglycemic unawareness who are able to prevent current repeated severe hypoglycemic events (neuroglycopenia requiring active intervention from a third party) using intensive diabetes management (including insulin, devices, and education).

Repeated intraportal islet infusions are not recommended in patients who have experienced prior portal thrombosis, unless the thrombosis was limited to second- or third-order portal vein branches.

There is no evidence to support the safe and effective use of LANTIDRA in patients with liver disease, renal failure, or who have received a renal transplant.

DOSAGE AND ADMINISTRATION

For infusion into the hepatic portal vein only.

Dose

The recommended minimum dose is 5,000 EIN/kg for initial infusion and 4,500 EIN/kg for subsequent infusion in the same recipient. The maximum dose per infusion is dictated by the estimated tissue volume, which should not exceed 10 cc per infusion, and the total EIN present in the infusion bag (up to a maximum of 1 x 10^6 EIN per bag).

A second infusion may be performed if the patient does not achieve independence from exogenous insulin within one year of infusion or within one year after losing independence from exogenous insulin after a previous infusion. A third infusion may be performed using the same criteria as for the second infusion.

There are no data regarding the effectiveness or safety for patients receiving more than three infusions.

Preprocedural medications

Provide preprocedural induction immunosuppression 30–360 minutes prior to LANTIDRA infusion. Include the following, at the discretion of the treating physician who is experienced with management of immunosuppression regimens for islet cell transplantation:

- Nondepleting monoclonal anti-interleukin-2 (anti-IL-2) receptor antibody 120 minutes prior to islet infusion
  - Note: In patients who are sensitized (hypersensitivity with a past history of anaphylactic reaction) to non-depleting monoclonal anti-interleukin-2 (anti-IL-2) receptor antibody therapies, a polyclonal, T-cell-depleting antibody should be used instead.
- Calcineurin inhibitor
- Mammalian target of rapamycin (mTOR) inhibitor
- Tumor necrosis factor (TNF) blocker
- Periprocedural antibiotic prophylaxis is recommended

Preparation

- Keep LANTIDRA in the insulated container at 15°C to 25°C no longer than 6 hours from time of product release (See carton label and certificate of analysis). Dispose of any product not used within 6 hours.
- Do not irradiate.
- Select and prepare units under the direction of a medical professional who is experienced in islet infusion (transplantation).
- Use LANTIDRA as supplied and without further dilution.

Administration

Failure to follow these directions may result in damage and decreased viability of the islets.

Do not administer with leukodepleting filters.

- To optimize viability, administer LANTIDRA as soon as possible after product release.
- Interventional radiologists and surgeons with expertise

in islet cell infusion may administer LANTIDRA in an interventional radiology suite or operating suite under controlled aseptic conditions.
- Perform all steps aseptically.
- Use a 5 or 6 French angiographic catheter indicated for the delivery of drugs or other therapeutic fluids for infusion of LANTIDRA.
  - Catheter length: 65 cm or less.
  - Internal diameter: 0.97mm (0.038 inches) or greater.
- Use only sheaths and introducers in combination with a catheter with the specified dimensions listed above to deliver LANTIDRA.

Pre-Infusion Patient Preparation

1. Confirm the identity of the patient for the specified unit of LANTIDRA.
2. Confirm that the patient has received appropriate premedication.
3. Confirm that appropriate medications and blood products are available to manage any potential emergencies, such as hemorrhage, portal vein thrombosis, allergic reactions, glycemic lability, bleeding, and pain.
4. Confirm that the patient is hydrated adequately prior to infusion.
5. If indicated, administer a saline/glucose infusion and administer insulin using an intravenous insulin pump during the periprocedural period.
6. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.
   a. LANTIDRA is a cellular suspension (light yellow liquid with the presence of visible cellular aggregates).
   b. The Rinse Bag contains transplant media (light yellow liquid only with no cellular aggregates present).
7. Inspect the LANTIDRA infusion bag and the Rinse Bag for leaks and breaches of container integrity.
8. Ensure the connector between the LANTIDRA infusion bag and the Rinse Bag is secure and closed.

Note: If there are any product irregularities present or if the container appears damaged or otherwise compromised, do not infuse product and immediately notify the transplant physician/team and CellTrans at 1-800-500-1617

9. Gently agitate the LANTIDRA infusion bag to ensure that the islets are suspended and to prevent clumping. Do not shake the bag, as this may damage the islets. Repeat gentle agitation periodically throughout the infusion process.
10. Remove the first drape bag and transfer the product to an infusion operator to remove the second drape bag.
11. Ensure that the intravenous tubing is closed, then connect the LANTIDRA infusion bag, fill the drip chamber, and open the roller clamp to fill the tubing and remove air.

LANTIDRA Infusion Procedure

12. Insert the catheter into the portal vein.
13. Once the catheter placement in the portal vein is confirmed, connect the intravenous tubing from the LANTIDRA infusion bag to the catheter using a Luer lock connector.
14. Infuse all infusion bags by gravity flow over approximately 30 minutes at rates ≤ 25 mL/kg/h.
15. Flush the infusion lines periodically to clear them.
16. Do not administer LANTIDRA (islet cell product and rinse bag) through intravenous lines that contain any other medications or infusates other than physiological saline.
17. Reduce infusion rate if the fluid load is not tolerated.
18. Discontinue the infusion in the event of an allergic reaction or if the patient develops a moderate to severe infusion reaction.
19. Once the islet infusion is complete, open the roller clamp on the Rinse Bag tubing to allow refilling and rinsing of the LANTIDRA infusion bag. Gently agitate the LANTIDRA infusion bag with small amounts of rinse solution to ensure that all cells have been administered. Repeat until the Rinse Bag is empty.
20. Withdraw the catheter tip from the main portal vein into the liver parenchyma until it lies within a few centimeters (cm) of the liver capsule. Before withdrawing the catheter completely, manage hemostasis in the catheter track using standard practices to reduce the risk of bleeding.

Monitoring during LANTIDRA Infusion

- Measure portal pressure during the infusion.
  - Pause infusion if portal pressure rises above 22 mm Hg and do not resume until it falls below 18 mm Hg.
  - Terminate infusion if portal pressure remains above 22 mm Hg for longer than 10 minutes.
- Monitor blood glucose levels every 15 minutes during the infusion and then every 30 minutes for the first 4 to 8 hours after infusion. Provide appropriate treatment if blood glucose levels fall below 70 mg/dL. Monitor blood glucose levels as needed once blood glucose levels have stabilized. After the acute period (first 4 to 8 hours following infusion), continue to monitor blood glucose (laboratory, capillary blood glucose, or continuous glucose monitor). Only use blood glucose meters and continuous glucose monitoring systems labelled for use in the hospital.
- Monitor the patient for portal vein branch thrombosis. Early diagnosis and prompt management with systemic heparinization may prevent clot propagation. However, anticoagulation therapy may lead to intra-abdominal hemorrhage requiring blood transfusion and surgical intervention.

Post-Infusion

- Monitor the patient in hospital for a minimum of 24 hours.
- Perform an abdominal ultrasound and Doppler examination of the liver after catheter removal to detect portal vein thrombosis and intra-abdominal bleeding. Repeat these examinations at least on days 1 and 7 post infusion procedure.
- Continue to monitor the patient for adverse reactions.
- Continue to monitor blood glucose levels following infusion and manage according to inpatient standard of care.

Post-Infusion Medications

- Anti-infective medications: Administer Pneumocystis jirovecii pneumonia (PCP) and cytomegalovirus (CMV) prophylaxis immediately following infusion of LANTIDRA and continue treatment as described in the prescribing information for the specific anti-infective medications.
- A non-depleting monoclonal anti-IL-2 receptor antibody: Administer at Week 2 after infusion for a total of two (2) doses, except in sensitized patients, who should instead be administered a polyclonal, T-cell- depleting antibody.
- Tumor necrosis factor (TNF) blocker: Administer on post-infusion Days 3, 7, and 10.

Long-term Medications

Immunosuppression: Continue immunosuppression permanently to prevent islet graft rejection. [See Warnings and Precautions (5.1)]. (See Section 5.1 for reasons to discontinue immunosuppression.)

Avoid systemic steroids. Use a combination of a calcineurin inhibitor and an mTOR inhibitor or appropriate alternatives, at the discretion of the physician. Monitor trough levels of maintenance immunosuppressant drugs, and adjust the dose to maintain appropriate blood levels.

DOSAGE FORMS AND STRENGTHS

LANTIDRA is a cellular suspension of allogeneic pancreatic islets (islets of Langerhans) in buffered transplant media containing sodium chloride, dextrose, minerals, amino acids, vitamins, and other compounds supplemented with HEPES (2-[4-(2-hydroxyethyl)piperazin-1-yl] ethanesulfonic acid; 10 mM final concentration) and human serum albumin (0.5% final concentration).

Each infusion uses one lot of LANTIDRA which consists of islets manufactured from the pancreas of a single deceased donor. Each dose of LANTIDRA is provided as two (2) infusion bags connected to each other via sterile connector. One bag contains LANTIDRA up to a maximum of 1 x 106 EIN in 400 mL of transplant media and the second bag (Rinse Bag) contains transplant media used to rinse the LANTIDRA bag and the infusion line.

The dosage strength is represented by the total EIN in a single preparation and varies between product batches. Dosage strength information for an individual batch is provided on the container label and in accompanying documentation,

WARNINGS AND PRECAUTIONS

Risks from Concomitant Immunosuppression

Concomitant use of immunosuppression is required to maintain islet cell viability. The use of immunosuppression in patients receiving LANTIDRA increases the risk of serious and potentially fatal adverse reactions

Patients receiving immunosuppressants are at increased risk of:

- Bacterial, viral, fungal, and parasitic infections, including opportunistic infections.
- Lymphomas and other malignancies, particularly of the skin.
- Severe anemia, sometimes requiring transfusion.

Before Treatment

- Vaccination: To mitigate the risk of infection, patients should receive recommended immunizations prior to treatment.

After Treatment

- Administer PCP and CMV prophylaxis following administration of LANTIDRA.
- Avoid live vaccination while receiving immunosuppression.
- Monitor for fever and other signs of infection; initiate appropriate treatment early.
- Clinically monitor for malignancy, including skin cancer.
- Monitor hemoglobin/hematocrit and give blood products as indicated.

Considerations for discontinuation of immunosuppression

- If a patient develops a life-threatening infection or cancer and treatment requires discontinuation of immunosuppression.
- If a patient has been dependent on exogenous insulin for two years after their last infusion, then immunosuppression should be discontinued. However, the treatment team may consider continuation of immunosuppression if they determine that the patient has achieved target HbA1c without recurrent severe hypoglycemia in the presence of clinically relevant C-peptide, that provides a potential ongoing benefit that outweighs the risks of severe and potentially life-threatening effects of immunosuppression.
- If a patient becomes pregnant.

Procedural Complications

Liver laceration, hemorrhage and intra-abdominal bleeding have occurred with portal administration of LANTIDRA. Manage hemostasis in the catheter track using standard prac-

tices following infusion of LANTIDRA to reduce the risk of bleeding. Monitor for bleeding clinically and with laboratory assessments. Blood transfusions have been required.

Elevation in portal blood pressure has occurred during and following intraportal islet infusion [Adverse Reactions (6.1)]. Monitor portal pressure; pause infusion if portal pressure rises above 22 mmHg and do not resume until it falls below 18 mmHg. Terminate infusion if portal pressure remains above 22 mmHg for longer than 10 minutes.

Portal vein branch thrombosis may occur following infusion of LANTIDRA. Repeated intraportal islet infusions are not recommended in patients who have experienced prior portal thrombosis unless the thrombosis was limited to second- or third-order portal vein branches. [Limitations of Use (2.1)]

Increased Risk of Islet Graft Rejection

Patients with a positive T- and B-cell crossmatch between recipient serum and donor lymphocytes may immediately reject the islet cells. The T- and B-cell crossmatch assay is binary. T- and B-cell both need to be negative.

Transmission of Donor-Derived Infections

There is a risk of communicable disease transmission from donor to recipient that exists for LANTIDRA. Monitor patients for signs of active infection following LANTIDRA infusion and treat appropriately if infection is suspected.

Panel Reactive Antibodies (PRA)

Product administration may elevate PRA and negatively impact candidacy for renal transplant. Consider benefit-risk of administering LANTIDRA to a patient who may require a renal transplant in the future.

ADVERSE REACTIONS

Ninety percent (90%) of subjects had at least one serious adverse reaction. The major causes were attributed to:

- Infusion procedure
  - liver laceration/hematoma, hemorrhage, and intra-abdominal bleeding (13%)
  - elevation of portal pressure (7%)
- Immunosuppression
  - Infection (87%)
  - Malignancy (37%)

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Pregnancy risk has not been assessed for LANTIDRA.

Females and Males of Reproductive Potential

Pregnancy Testing

Due to the risk of fetal malformations associated with required concomitant medications, including immunosuppressants, females of reproductive potential should have a confirmed negative pregnancy test prior to LANTIDRA infusion.

Female patients of reproductive potential should be counselled to contact their transplant team immediately if they become pregnant.

Contraception

Because long-term immunosuppression is required following LANTIDRA administration, women of childbearing potential should be informed of the potential risks that these medications pose during pregnancy and should be told to use effective contraception prior to initiation of immunosuppression and thereafter for as long as they retain reproductive potential.

Infertility

Male and female fertility may be compromised by certain medications used for maintenance immunosuppression following LANTIDRA administration.

Pediatric Use

The safety and effectiveness of LANTIDRA have not been established in pediatric patients with type 1 diabetes.

Geriatric Use

The safety and effectiveness of LANTIDRA have not been established in geriatric patients with type 1 diabetes and hypoglycemic unawareness. Clinical studies of LANTIDRA did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently than younger patients.

CLINICAL STUDIES

The effectiveness of LANTIDRA in subjects with type 1 diabetes and hypoglycemic unawareness was demonstrated in 2 clinical trials (Study 1, Study 2) involving a combined 30 subjects, all of whom received at least one islet infusion and a maximum of 3 infusions. Both trials were prospective, open-label, single-arm studies.

Subject demographics: median age 46.5 (range: 21 – 67) years, 80% female, 100% white, 97% non- Hispanic.

Subjects received a median islet number of 399,178 EIN (range 253,924 EIN to 858,856 EIN) per infusion. Subjects received a median islet dose of 6,570 EIN/kg (range 4,186 EIN/kg to 13,633 EIN/kg) per infusion. Thirty subjects participated in the combined Study 1 and Study 2, with 11 subjects receiving one infusion, 12 subjects receiving two infusions, and 7 subjects receiving three infusions. Of the 19 subjects who received a second infusion, 6 were insulin-independent at the time of their second infusion. Of the 11 subjects who did not receive a second infusion, 4 were insulin-independent, 3 did not have a donor, and 4 were intolerant to immunosuppression or withdrew from the study within 6 months. All 7 subjects who received a third infusion were insulin-dependent. One subject was not able to get a third infusion because of infection. No subject was unable to receive a third infusion because of lack of a donor or intolerance to immunosuppression.

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LitScan for Case Managers

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

AIDS. 2023 Jul 7. doi: 10.1097/QAD.0000000000003650. Online ahead of print.

Impact of ART intensification with CCR5 antagonist maraviroc on HIV-associated neurocognitive impairment

Cecilia M Shikuma, Valerie Wojna, Victor De Gruttola, et al.

OBJECTIVES: Chemokine-receptor CCR5 is the principal co-receptor for entry of M-tropic HIV virus into immune cells. It is expressed in the central nervous system and may contribute to neuroinflammation. The CCR5 antagonist maraviroc (MVC) has been suggested to improve HIV-associated neurocognitive impairment (NCI).

DESIGN: A double-blind, placebo-controlled, 48-week, randomized study of MVC vs placebo in people living with HIV (PLWH) on stable antiretroviral therapy (ART) >1 year in Hawaii and Puerto Rico with plasma HIV RNA <50 copies/mL and at least mild NCI defined as an overall or domain-specific neuropsychological (NP) Z score <-0.5.

METHODS: Study participants were randomized 2:1 to intensification of ART with MVC vs placebo. The primary endpoint was change in global and domain-specific NP Z scores (NPZ) modeled from study entry to week 48. Covariate adjusted treatment comparisons of average changes in cognitive outcome were performed using winsorized NPZ data. Monocyte subset frequencies and chemokine expression, as well as plasma biomarker levels, were assessed.

RESULTS: Forty-nine participants were enrolled with 32 individuals randomized to MVC intensification and 17 to placebo. At baseline, worse NPZ scores were seen in the MVC arm. Comparison of 48-week NPZ change by arm revealed no differences except for a modest improvement in the Learning and Memory domain in the MVC arm, which did not survive multiplicity correction. No significant changes between arms were seen in immunologic parameters.

CONCLUSIONS: This randomized controlled study found no definitive evidence in favor of MCV intensification among PLWH with mild cognitive difficulties.

Antiviral Res. 2023 Aug;216:105666.

Identification of alpha-linolenic acid as a broad-spectrum antiviral against zika, dengue, herpes simplex, influenza virus and SARS-CoV-2 infection

Yifei Feng, Yan Yang, Shuqi Qiu, et al.

Zika virus (ZIKV) has garnered global attention due to its association with severe congenital defects including microcephaly. However, there are no licensed vaccines or drugs against ZIKV infection. Pregnant women have the greatest need for treatment, making drug safety crucial. Alpha-linolenic acid (ALA), a polyunsaturated ω-3 fatty acid, has been used as a health care product and dietary supplement due to its potential medicinal properties. Here, we demonstrated that ALA inhibits ZIKV infection in cells without loss of cell viability. Time-of-addition assay revealed that ALA interrupts the binding, adsorption, and entry stages of ZIKV replication cycle. The mechanism is probably that ALA disrupts membrane integrity of the virions to release ZIKV RNA, inhibiting viral infectivity. Further examination revealed that ALA inhibited DENV-2, HSV-1, influenza virus, and SARS-CoV-2 infection dose-dependently. ALA is a promising broad-spectrum antiviral agent.

J Infect Dis. 2023 Jul 12;jiad263. doi: 10.1093/infdis/jiad263. Online ahead of print.

Evaluating clinic-based interventions to reduce racial differences in mortality among people with HIV in the United States

Lauren C Zalla, Stephen R Cole, Joseph J Eron, et al.

BACKGROUND: Mortality remains elevated among Black vs White adults receiving HIV care in the United States. We evaluated the effects of hypothetical clinic-based interventions on this mortality gap.

METHODS: We computed 3-year mortality under observed treatment patterns among >40,000 Black and >30,000 White adults entering HIV care in the United States from 1996-2019. We then used inverse probability weights to impose hypothetical

interventions, including immediate treatment and guideline-based follow-up. We considered 2 scenarios: "universal" delivery of interventions to all patients, and "focused" delivery of interventions to Black patients while White patients continued to follow observed treatment patterns.

RESULTS: Under observed treatment patterns, 3-year mortality was 8% among White patients and 9% among Black patients, for a difference of 1% (95% CI: 0.5, 1.4). The difference was reduced to 0.5% under universal immediate treatment (-0.4, 1.3), and to 0.2% under universal immediate treatment combined with guideline-based follow-up (-1.0, 1.4). Under the focused delivery of both interventions to Black patients, the Black-White difference in 3-year mortality was -1.4% (-2.3, -0.4).

CONCLUSIONS: Clinical interventions, particularly those focused on enhancing the care of Black patients, could have significantly reduced the mortality gap between Black and White patients entering HIV care from 1996-2019.

AIDS. 2023 Jun 28. doi: 10.1097/QAD.0000000000003635.Online ahead of print.

Physical activity is associated with adiposity in older adults with HIV in the modern HIV era

Allison R Webel, Christine Horvat Davey, Vitor Oliveira, et al.

OBJECTIVES: People with HIV (PWH) are aging and are experiencing higher rates of abdominal adiposity. Physical activity is an effective nonpharmacological strategy to reduce adiposity in the general aging population. Yet, the relationship between physical activity and adiposity in people with well-controlled HIV is unclear. Our OBJECTIVE was to describe the association between OBJECTIVEly measured physical activity and abdominal adiposity in PWH.

METHODS: As part of the multisite, observational PROSPER-HIV study, virologically suppressed adult PWH wore an Actigraph accelerometer for 7-10 days and completed duplicate waist and hip circumference measures. Demographic and medical characteristics were abstracted from the CFAR Network of Integrated Clinical Systems dataset. Descriptive statistics and multiple linear regressions were used to analyze the data.

RESULTS: On average, our 419 PWH were 58 years of age (IQR: 50, 64), male (77%), Black (54%), and currently taking an integrase inhibitor (78%). PWH completed a mean of 7.06 (±2.74) days of total actigraphy wear time. They took an average of 4905 (3233, 7140) steps per day and engaged in 5.4 hours of sedentary time per day. Controlling for age, sex, employment, and integrase inhibitor use, the number of steps taken per day was associated with reduced abdominal adiposity (F = 3.27; P< 0.001) and the hours of daily sedentary time was associated with increased abdominal adiposity (F = 3.24; P< 0.001).

CONCLUSIONS: Greater physical activity is associated with reduced abdominal adiposity in aging PWH. Future work should investigate how to tailor the amount, type, and intensity of physical activity needed to reduce adiposity in PWH taking contemporary HIV medication.

Am J Cardiol. 2023 Aug 1;200:50-56.

Risk stratification in patients who underwent percutaneous left atrial appendage occlusion

Matthew W Segar, Allan Zhang, Robert D Paisley, et al.

Left atrial appendage occlusion (LAAO) is effective in preventing thromboembolism. Risk stratification tools could help identify patients at risk for early mortality after LAAO. In this study, we validated and recalibrated a clinical risk score (CRS) to predict risk of all-cause mortality after LAAO. This study used data from patients who underwent LAAO in a single-center, tertiary hospital. A previously developed CRS using 5 variables (age, body mass index [BMI], diabetes, heart failure, and estimated glomerular filtration rate) was applied to each patient to assess risk of all-cause mortality at 1 and 2 years. The CRS was recalibrated to the present study cohort and compared with established atrial fibrillation-specific (CHA2DS2-VASc and HAS-BLED) and generalized (Walter index) risk scores. Cox proportional hazard models were used to assess the risk of mortality, and discrimination was assessed by Harrel C-index. Among 223 patients, the 1- and 2-year mortality rates were 6.7% and 11.2%, respectively. With the original CRS, only low BMI (<23 kg/m2) was a significant predictor of all-cause mortality (hazard ratio [HR] [95% CI] 2.76 [1.03 to 7.35]; P = 0.04). With recalibration, BMI <29 kg/m2 and estimated glomerular filtration rate <60 mL/min/1.73 m2 were significantly associated with an increased risk of death (HR [95% CI] 3.24 [1.29 to 8.13] and 2.48 [1.07 to 5.74], respectively), with a trend toward significance noted for history of heart failure (HR; 95% CI, 2.13; 0.97-4.67, P = 0.06). Recalibration improved the discriminative ability of the CRS from 0.65 to 0.70 and significantly outperformed established risk scores (CHA2DS2-VASc = 0.58, HAS-BLED = 0.55, Walter index = 0.62). In this single-center, observational study, the recalibrated CRS accurately risk stratified patients who underwent LAAO and significantly outperformed established atrial fibrillation-specific and generalized risk scores. In conclusion, clinical risk scores should be considered as an adjunct to standard of care when evaluating a patient's candidacy for LAAO.

J Viral Hepat. 2023 Jul 6. doi: 10.1111/jvh.13859. Online ahead of print.

Dynamic risk assessment for hepatocellular carcinoma in patients with chronic hepatitis C

Mei Lu, Reena Salgia, Jia Li, et al.

Chronic hepatitis C (HCV) is a primary cause of hepatocellular carcinoma (HCC). Although antiviral treatment reduces risk of HCC, few studies quantify the impact of treatment on long-term risk in the era of direct-acting antivirals (DAA). Using data from the Chronic Hepatitis Cohort Study, we evaluated the impact of treatment type (DAA, interferon-based [IFN], or none) and outcome (sustained virological response [SVR] or treatment failure [TF]) on risk of HCC. We then developed and validated a predictive risk model. 17186 HCV patients were followed until HCC, death or last follow-up. We used extended landmark modelling, with time-varying covariates and propensity score justification and generalized estimating equations with a link function for discrete time-to-event data. Death was considered a competing risk. We observed 586 HCC cases across 104,000 interval-years of follow-up. SVR from DAA or IFN-based treatment reduced risk of HCC (aHR 0.13; 95% CI, 0.08-0.20; and aHR 0.45; 95% CI, 0.31-0.65); DAA SVR reduced risk more than IFN SVR (aHR 0.29; 95% CI, 0.17-0.48). Independent of treatment, cirrhosis was the strongest risk factor for HCC (aHR 3.94; 95% CI, 3.17-4.89 vs no cirrhosis). Other risk factors included male sex, White race, and genotype 3. Our 6-variable predictive model had 'excellent' accuracy (AUROC 0.94) in independent validation. Our novel landmark interval-based model identified HCC risk factors across antiviral treatment status and interactions with cirrhosis. This model demonstrated excellent predictive accuracy in a large, racially diverse cohort of patients and could be adapted for 'real world' HCC monitoring.

Am J Cardiol. 2023 Jul 8;202:119-130. doi: 10.1016/j.amjcard.2023.06.066. Online ahead of print.

Meta-analysis of efficacy and safety of intravenous iron in patients with iron deficiency and heart failure with reduced ejection fraction

Mohammad Hamza, Yasar Sattar, Nouraldeen Manasrah, et al.

Iron deficiency is an independent risk factor for heart failure (HF) exacerbation. We aim to study the safety and efficacy of intravenous (IV) iron therapy in patients with HF with reduced ejection fraction (HFrEF). A literature search was conducted on MEDLINE (Embase and PubMed) using a systematic search strategy by PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) until October 2022. CRAN-R software (The R Foundation for Statistical Computing, Vienna, Austria) was used for statistical analysis. The quality assessment was performed using the Cochrane Risk of Bias and Newcastle–Ottawa Scale. We included 12 studies with a total of 4376 patients (IV iron n = 1985 [45.3%]; standard of care [SOC] n = 2391 [54.6%]). The mean age was 70.37 ± 8.14 years and 71.75 ± 7.01 years in the IV iron and SOC groups, respectively. There was no significant difference in all-cause mortality and cardiovascular mortality (risk ratio [RR] 0.88; 95% CI, 0.74-1.04, P <0.15). However, HF readmissions were significantly lower in the IV iron group (RR 0.73; 95% CI, 0.56-0.96, P = 0.026). Non-HF cardiac readmissions were not significantly different between the IV iron and SOC groups (RR 0.92; 95% CI, 0.82-1.02, P = 0.12). In terms of safety, there was a similar rate of infection-related adverse events in both arms (RR 0.86; 95% CI, 0.74-1, P = 0.05). IV iron therapy in patients with HFrEF is safe and shows a significant reduction in HF hospitalizations compared with SOC. There was no difference in the rate of infection-related adverse events. The changing landscape of HFrEF pharmacotherapy in the last decade may warrant a redemonstration of the benefit of IV iron with current SOC. The cost-effectiveness of IV iron use also needs further study.

Ann Thorac Surg. 2023 Jul 5;S0003-4975(23)00685-9. doi: 10.1016/j.athoracsur.2023.06.021. Online ahead of print.

Comparison of intra-aortic balloon pump and impella 5.5 as heart transplant bridging strategies

Amit Iyengar, David Rekhtman, Noah Weingarten, et al.

BACKGROUND: Temporary mechanical circulatory support is increasingly utilized as a bridge to heart transplantation. The Impella 5.5 has achieved anecdotal success as a bridge since receiving approval. The purpose of the current study was to compare waitlist and post-transplant outcomes of patients bridged with intra-aortic balloon pumps (IABP) to those receiving Impella 5.5 therapy.

METHODS: Patients listed for heart transplantation between Oct 2018 and Dec 2021 who received IABP or Impella 5.5 at any time during waitlist course were identified from the United Network for Organ Sharing (UNOS) database. Propensity-matched groups of recipients with each device were created. Competing-risks regression for mortality, transplantation, removal from waitlist for illness was performed according to the method of Fine and Gray. Post-transplant survival was censored at 2 y.

RESULTS: Overall, 2936 patients were identified, of whom 2484 (85%) were supported with IABP while 452 (15%) received Impella 5.5. Patients with Impella 5.5 support had more functional impairment, higher wedge pressures, higher rates of preoperative diabetes and dialysis, and more ventilator support (all P<0.05).

Waitlist mortality was significantly worsened in the Impella group and transplantation was less frequent (P<0.001). However, survival at 2 y following transplant was similar in both complete (90% vs 90%, P=0.693) and propensity-matched cohorts (88% vs 83%, P=0.874).

CONCLUSIONS: Patients bridged with Impella 5.5 were sicker than IABP-bridged patients and less frequently transplanted; however, post-transplant outcomes were similar in propensity-matched cohorts. The role of these bridging strategies in patients listed for heart transplantation should be continually assessed with future allocation system changes.

Ann Surg. 2023 Aug 1;278(2):e377-e381. doi: 10.1097/SLA.0000000000005699. Epub 2022 Sep 8.

The presence of a cost-volume relationship in robotic-assisted thoracoscopic lung resections

Arjun Verma, Joseph Hadaya, Shannon Richardson, et al.

OBJECTIVE: To characterize the relationship between institutional robotic-assisted pulmonary lobectomy volume and hospitalization costs.

BACKGROUND: The high cost of robotic-assisted thoracoscopic surgery (RATS) is among several drivers of hesitation among nonadopters. Studies examining the impact of institutional experience on costs of RATS lobectomy are lacking.

METHODS: Adults undergoing RATS lobectomy for primary lung cancers were identified from the 2016 to 2018 Nationwide Readmissions Database. A multivariable regression to model hospitalization costs was developed with the inclusion of hospital RATS lobectomy volume as restricted cubic splines. The volume corresponding to the inflection point of the spline was used to categorize hospitals as high- (HVH) or low-volume (LVH). We subsequently examined the association of HVH status with adverse events, length of stay, costs, and 30-day, nonelective readmissions.

RESULTS: An estimated 14,756 patients underwent RATS lobectomy during the study period, with median cost of $23,000. Upon adjustment for patient and operative characteristics, hospital RATS volume was inversely associated with costs. Although only 17.2% of centers were defined as HVH, 51.7% of patients were managed at these centers. Patients at HVH and LVH had similar age, sex, and distribution of comorbidities. Notably, patients at HVH had decreased risk-adjusted odds of adverse events (adjusted odds ratio: 0.62, P <0.001), as well as significantly reduced length of stay (-0.8 d, P <0.001) and costs (-$3900, P <0.001).

CONCLUSIONS: Increasing hospital RATS lobectomy volume was associated with reduced hospitalization costs. Our findings suggest the presence of streamlined care pathways at high-volume centers, which influence costs of care.

Am J Cardiol. 2023;15;201:328-334.

Virtual echocardiography screening tool identifies pulmonary arterial hypertension significantly than high-risk clinical diagnosis

Vedage NA, Forfia PR, Grafstrom A, Vaidya A.

Pulmonary arterial hypertension (PAH) is often a progressive, fatal disease. Because of nonspecificity of symptoms and limited awareness of PAH, patients are often diagnosed and referred late to accredited pulmonary hypertension (PH) centers, contributing to worsening survival and overall prognosis. The OBJECTIVE of the present study was to determine if the virtual echocardiography screening tool (VEST), a simple scoring system using routinely reported echocardiographic metrics, could capture earlier diagnoses of PAH before clinical recognition and referral to expert PH centers. This study is a retrospective analysis of 132 patients with PAH evaluated consecutively at 2 accredited referral PH centers. VEST scores and time to evaluation at PH center were quantified based on the first available echocardiogram before referral. Clinical risk assessment was calculated at initial evaluation by the PH center using the REVEAL (Registry to Evaluate Early and Long-term PAH Disease Management) 2.0 calculator. An overwhelming majority (93%) of the study participants had markedly abnormal VEST scores predictive of PAH before evaluation at a PH referral center. The median delay from VEST to evaluation was >6 months at 206 days (quartile 1, quartile 3: 55, 757). At initial evaluation, 72% were intermediate or high risk, based on REVEAL 2.0 risk assessment. In conclusion, we propose that VEST is a powerful yet simple scoring tool that can capture high-risk patients with PAH, prompting earlier diagnosis and referrals to accredited PH centers, and allowing for earlier expert implementation of PH medical therapies.

Ann Surg Oncol. 2023;30(8):4737-4743.

Duration of time CD4/CD8 ratio is below 0.5 is associated with progression to anal cancer in patients with HIV and high-grade dysplasia

Karim A, Freeman MJ, Yang Q, et al.

BACKGROUND: A CD4/CD8 ratio < 0.5 is associated with increased risk of advanced anal disease (AAD), but it is unknown if duration below 0.5 matters. The purpose of this study was to determine if duration of a CD4/CD8 ratio < 0.5 is associated with increased risk of invasive anal cancer (IC) in people living with HIV and high-grade dysplasia (HSIL).

METHODS: This single institution, retrospective study used the University of Wisconsin Hospital and Clinics Anal Dysplasia

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Autonomy and Beneficence: Guardrails for Case Management Practice *continued from page 5*

in making choices.

Here are some tips to help respect and uphold autonomy and beneficence, while striking a balance between the two.

- **Advocacy first.** Case managers must advocate for clients, providing access to the right care and treatment at the right time, in the right setting, and at the right cost. At the same time, there may be stipulations on what can be provided because of regulations, insurance coverage, and financial resources. When insurance or other financial means will not cover a particular resource, it may be possible to obtain it for the client within the community. However, there are limits, both in terms of availability and eligibility. Doing good does not mean meeting unnecessary or unreasonable demands from the client.
- **Documentation is crucial.** Documentation is part of the case management process, from assessment through care coordination, monitoring, and beyond. With complex cases in particular, case managers must show proof that they have done their best to provide information and education to help the client and the support system weigh their options, investigate alternatives, and make informed decisions.
- **Seek input and support.** We all have different beliefs and ideas, and the decisions made by the client may go against what we feel is "right" or what we might do for a loved one. This can create an ethical dilemma, making it hard for case managers to determine where their responsibility ends and the client's decision-making begins. When faced with a particularly difficult challenge, case managers should consult with a supervisor. Those who work for agencies or large institutions may also have the support of an ethics committee. If case management services are being contracted by an insurance company, make sure the insurer is in the loop.

Autonomy and beneficence speak to the best of case management practice—empowering, respecting, and supporting clients and their support systems. Understanding the scope and nuances of these ethical principles can help case managers uphold the highest standards. CM

Recent OIG Study Shines Spotlight on Medicare Advantage Plans' Payment Practice *continued from page 10*

criteria that are not included in Medicare coverage rules and MAP staff members who overlooked documentation that showed that the services were medically necessary.

5. The OIG also concluded that 18% of requests for payment denied by MAPs met Medicare coverage rules and MAP billing rules. Most of these denials were caused by human error during manual processing of claims such as overlooking documents and system processing errors such as using outdated programs.
6. Denials of both prior authorization and payment requests were often reversed when beneficiaries or providers disputed the denials.

What providers have long suspected has been confirmed by the OIG. Now fix it! CM

Knocking on Strangers' Doors *continued from page 8*

as opposed to denying them.

Referral sources for home health services of all kinds, including case managers and discharge planners, should also use their intuition about patients and their families. When their intuition tells them that violence is possible, they should not refer patients for home health services.

From a practical perspective, violence against providers may be minimized by encouraging staff to pay attention to their intuition about patients, their families, and others they encounter in the workplace. Mr. de Becker's book is surely a must-read for providers! CM

Reference

de Becker G. *The Gift of Fear.* Back Bay Books; 2021.

What Autonomy and Beneficence Look Like in Action
continued from page 7

environment in which those functions are carried out. Furthermore, understanding what modifications can be accommodated (eg, modified duties, shorter work schedules, or alternative duties) is very important.

Such baseline knowledge about the job is crucial for helping an employee return to work, especially when the individual's physical and/or mental capacity differs from when they were hired or were last on the job. This understanding can help determine whether job modifications are truly medically necessary or only reflect what the employee wants.

It can be very challenging to differentiate between medical necessity and an employee's desire—while also balancing job accommodations with what an employer feels is needed to preserve their work culture, product control, and creative processes. In such scenarios, the disability manager should understand all the nuances of the employer's rules and culture, and fully educate the employee about their options and what the results of choosing a particular option might be.

Finally, we address beneficence, which resonates with disability managers who want to "do good" as they advocate for ill/injured employees who need interventions to remain productive and on the job. Once again, it is often a balancing act.

Very early in my career I acknowledged that both employees and employers have agendas when dealing with work-related injuries or illnesses and RTW. Only by understanding those agendas or requirements could I be effective in supporting both the employee and employer—including how regulations and other rules could affect everyone involved.

Being informed and informing others are the best ways to practice beneficence while helping uphold the employee's right to autonomy and the employer's desire to preserve culture and productivity while reducing or avoiding risk. CM

It's a Wrap *continued from page 6*

provides a platform to exchange ideas, insights, and best practices with peers, which can enhance your professional knowledge and skills. Just reading the above synopsis of the CMSA National Conference should give you a bit of insight into the volume and caliber of the incredible knowledge sharing in action and the opportunities for you to share your knowledge as well. The networking roundtables were a significant highlight for me: seeing packed tables of case managers discussing the hot topics laid out at each table, problem sharing, and solving. That event will be back next year for sure!

3. Mentorship and guidance: by networking, you can find mentors and experienced professionals who can provide guidance, support, and advice in your career journey. Deanna Cooper gave a great presentation on the importance of mentorship, both as mentor and mentee. I enjoyed the perspective and examples she gave on the various types of mentorships and the roles and responsibilities. We all need mentorship throughout our careers and can be mentors as well.

Once you join a professional organization, make the most of networking opportunities by attending events (national, local, and even virtual events can help keep you connected), engaging online (social media, blogs, etc), and volunteering through local and national committee work, and leadership opportunities. Ten years ago, would I have ever thought I would be the President of this national organization? The answer is a resounding no. Ten years ago was the absolute low point of my life. I had lost my job through a restructuring, and my spouse abruptly ended our marriage through a text message. My professional organization supported me through all that. The relationships I made through CMSA and CMSA Chicago were some of the most important ones in navigating my recovery from these life-changing events. And I thank them every day for their presence in my life. It is very important to remember to follow up and maintain the critical relationships. After networking events, follow up with new contacts, stay in touch, and nurture professional relationships through regular communication and interaction. Remember that networking is a 2-way street, and it's essential to offer support, advice, and assistance to your network whenever possible. Active engagement and genuine connections can lead to a rewarding professional network and opportunities for career growth.

So, my professional advice is to definitely attend professional conferences—for the education, energy, and new ideas, but most of all, for the people and the networking. You can't go wrong! CM

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

Case Managers: Embrace and Be Catalysts for Change

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care. Case management leaders have the added task of building, motivating, and training strong case management teams who have the skillset, credentials (eg, CCM), and passion to provide best care for their patients. To achieve these objectives, hospitals and other health care providers need to recognize the vital role of case managers and be open to their recommendations and new ways of doing things.

Many new tools and strategies are being implemented, and we should welcome them. For example, hospital Z codes for hospital case managers are a tool for capturing data related to a patient's socioeconomic position—how it relates to social determinants of health and higher incidences of chronic diseases. The widespread use of this tool can lead to improved allocation of funds. The codes have proven effective when used, but many hospitals have been sluggish in capturing the data. CMS found that health care providers used Z codes for just 1.6% of Medicare fees for beneficiaries in 2019 even though using them provides a better view of a hospital's value-based programs and the risks associated with certain patient populations.

Another program that has shown great promise, but which focuses on nurses, can be a great source of inspiration for case managers. The American Nurses Foundation's "Reimagining Nursing Initiative" seeks to break down the barriers that prevent or inhibit nurses, including nurse case managers, from participating in decision-making intended to drive meaningful change. Using effective tools and engaging initiatives is how growth and change will take place to the benefit of patients, providers, and, yes, case managers.

I encourage all case managers—from case management leaders to those just entering the field—to reimagine what case management should look like in light of today's health care market challenges, and to be catalysts for much-needed change.

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Readers

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What Experienced and New Nurses Want to Say to Each Other

continued from page 10

what we wish new nurses knew.

- Invest in the best shoes you can.
- Never be afraid to ask us for help.
- Remember that we need your help sometimes, too.
- Find a mentor.
- Always do your best.
- Ask a million questions.
- Give of yourself freely.
- Care about the person behind the condition. Look at the person—it's a human experience.
- Advocate for your patients until you are blue in the face.
- Find your tribe and love them hard because nobody understands the life of nurses except your fellow nurses.
- You may be tired, but your heart will be full.
- Embrace a mindset of lifelong learning.
- Teamwork and communication will always be essential.
- It is important to remember your *why*. Nursing is a calling. Being a nurse is a commitment.
- One small word or caring touch could be a life-altering moment for someone. The feeling of being "well cared for" will last for a long time.

So, there you have it! CM

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A glucagon-like peptide-1 (GLP-1) agonist (e.g., exenatide 5 mcg subcutaneously within 60 minutes before infusion), was administered and was supposed to be continued (5 mcg BID), for up to 6 months after transplant. Exenatide was not given to the first 4 subjects in Study 1, and 11 of the remaining 26 subjects used exenatide less than the per protocol 6-months post-transplant because of adverse reactions. Because of the variability of exenatide use in the clinical studies, there are insufficient data to support exenatide use in patients receiving LANTIDRA.

Insulin independence, defined as not requiring exogenous insulin to achieve adequate glycemic control, was also determined. Results are summarized below.

ACHIEVEMENT AND MAINTENANCE OF GLYCEMIC CONTROL FOLLOWING LANTIDRA INFUSION (STUDIES STUDY 1 AND STUDY 2)

Total Duration Insulin Independent (years)	N	Mean	Std Dev	Min	Max
Study 1	10	5.1	4.2	0.2	12.8
Study 2	20	3.2	3.1	0	9.9

Five subjects had no days of insulin independence. For the 25 subjects who achieved insulin independence, 4 subjects (13.3%) were insulin independent for less than one year, 12 subjects (36.7%) for 1 to 5 years, and 9 subjects (33.3%) for greater than 5 years. Figure 1 shows the entire experience of the individual subjects.

HOW SUPPLIED/STORAGE AND HANDLING

LANTIDRA (NDC 73539-001-01) is supplied as purified allogeneic islets of Langerhans suspended in buffered transplant medium containing sodium chloride, dextrose, minerals, amino acids, vitamins, and other compounds supplemented with HEPES (2-[4-(2-hydroxyethyl)piperazin-1-yl] ethanesulfonic acid; 10 mM final concentration) and human serum albumin (0.5% final concentration)).

LANTIDRA is contained in one 1000 mL infusion bag filled with a supplied volume of 400 mL, containing not more than 10 cc of estimated packed islet tissue and not more than 1 x 106 EIN. The 1000 mL infusion bag is aseptically connected to a smaller 750 mL Rinse Bag (NDC 73539-002-01) containing 200 mL of supplied volume of transplant media for use in rinsing the 1000 mL bag containing LANTIDRA and infusion line following infusion to assure complete transfer of islets to the patient. Additional product information, including islet number, is included on the Final Islet Product Certificate of Analysis and the container label.

Cost

The anticipated average annual cost is over $300,000.

For full prescribing information, please see Product Insert.

LANTIDRA is manufactured by CellTrans, Inc.

CE2

Understanding the Background and Case Management Operations for the SNF 3-Day Rule

continued from page 19

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LITSCAN FOR CASE MANAGERS

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and Anal Cancer Database. Patients with IC versus HSIL alone were compared. Independent variables were mean and percentage of time the CD4/CD8 ratio was < 0.5. Multivariate logistic regression was performed to estimate the adjusted odds of anal cancer.

RESULTS: We identified 107 patients with HIV infection and AAD (87 with HSIL, 20 with IC). A history of smoking was significantly associated with the development of IC (95% in patients with IC vs 64% in patients with HSIL; P = 0.015). Mean time the CD4/CD8 ratio was < 0.5 was significantly longer in patients with IC compared with patients with HSIL (7.7 years vs 3.8 years; P = 0.002). Similarly, the mean percentage of time the CD4/CD8 ratio was < 0.5 was higher in those with IC versus those with HSIL (80% vs 55%; P = 0.009). On multivariate analysis, duration CD4/CD8 ratio was < 0.5 was associated with increased odds of developing IC (odds ratio 1.25; 95% CI, 1.02-1.53; P = 0.034).

CONCLUSIONS: In this retrospective, single-institution study of a cohort of people living with HIV and HSIL, increasing duration the CD4/CD8 ratio was < 0.5 was associated with increased odds of developing IC. Monitoring the number of years the CD4/CD8 ratio is < 0.5 could inform decision-making in patients with HIV infection and HSIL.

CE3

Demonstrating Better Outcomes for Children Through Care Coordination *continued from page 24*

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Join Me in Welcoming Our New Editorial Board! *continued from page 2*

Welcome to all of these uniquely qualified Editorial Board members. I look forward to working with them.

New Fellows in Case Management

The Case Management Society of America has announced the 2023 Fellows in Case Management:

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- Kathleen Moreo, RN, BC, BSN, BHSA, CCM, CDMS, FCM
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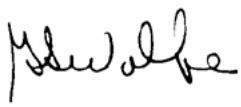
- Heaven Sims, MBA, DNP, RN, PHNA-BC, NE-BC, CCM, LNHA, CAHIMS, FCM

The Fellow in Case Management Program recognizes individuals who have made significant contributions to the professional practice of case management through leadership, practice, or research. Applicants submit a detailed application documenting their contributions and achievements. The application then receives a rigorous review before fellowship is awarded. Recipients can use the designation FCM after their name and credentials. It is an honor to be selected and recognized as a Fellow. Congratulations, and welcome to the Class of 2023.

It is near the end of the 2023 summer. We continue to face challenges, particularly this summer, with the climate: extreme heat, flooding, fires, and tornadoes. I trust you are safe. In these waning days of summer, be sure to take care of yourself. That might mean a few days doing something just for yourself or just letting your mind wander into a peaceful place for a while. Regardless, take care of yourself and remember you make a difference in the life of every patient and family you touch.



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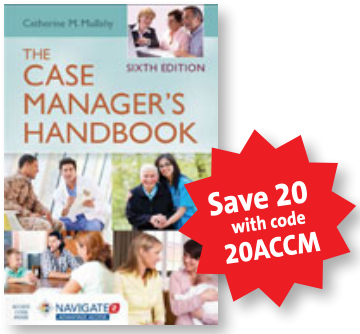

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