CareManagement

OFFICIAL JOURNAL OF THE ACADEMY OF CERTIFIED CASE MANAGERS AND COMMISSION FOR CASE MANAGER CERTIFICATION

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Gary S. Wolfe

Alzheimer's Disease: A Case Management Challenge

Alzheimer's disease is an irreversible progressive brain disorder that slowly destroys memory and thinking skills, and, eventually, the ability to carry out the simplest tasks. With no known cure, Alzheimer's disease has a devastating disease progression that affects patients, families, loved ones, and caregivers.

In most patients with Alzheimer's disease, symptoms first appear in their mid-60s, but early-onset disease in people under the age of 60 is not unusual. It is estimated that some 5 million people in the United States are living with Alzheimer's disease or a related dementia, although not all our diagnosed. In addition, it is believed that over 200,000 of those people have early-onset Alzheimer's disease. Alzheimer's disease is ranked as the sixth leading cause of death in the United States, but according to recent estimates the disease may rank third (just behind heart disease and cancer) as a cause of death for older people. According to the Centers for Disease Control and Prevention, the rate of people dying from Alzheimer's disease rose by 55% over a 15-year period. The number of those patients dying at home also rose from 14% to 25%.

Although Alzheimer's disease is not part of normal aging, the likelihood of developing Alzheimer's increases with age. Thirteen percent of individuals over age 65 have Alzheimer's or another form of dementia, while almost 50% of individuals over the age of 85 have Alzheimer's or another form of dementia. The demographic group with the highest percentage of Alzheimer's disease is Caucasian females, perhaps because they have the highest life expectancy; approximately two-thirds of Americans with Alzheimer's disease are female. Other risk factors for Alzheimer's disease in addition to age include:

- A family history of Alzheimer's disease
- Genetic susceptibility
- Longstanding hypertension
- Head trauma
- Neuronal injury
- Medical conditions such as heart disease, diabetes, stroke, and hypercholesterolemia

Early warning signs of Alzheimer's disease may be different in every case. The following are typical symptoms that gradually increase and become more persistent:

- Memory loss, especially recent events, names, and placements of objects
- Confusion about time and place
- Struggling to complete familiar actions, such as brushing teeth or getting dressed
- Trouble finding appropriate words, completing sentences, or following conversations
- Poor judgment when making decisions
- Changes in mood and personality
- Difficulty with complex mental assignments, especially tasks involving numbers

Because there is no cure for Alzheimer's disease, the chief goals of treatment include:

- Maintain quality of life
- Maximize function of daily activities
- Enhance cognition, mood, and behavior
- Foster a safe environment
- Promote social engagement as appropriate

Once the clinical diagnosis of Alzheimer's disease has been made, a care management plan must be

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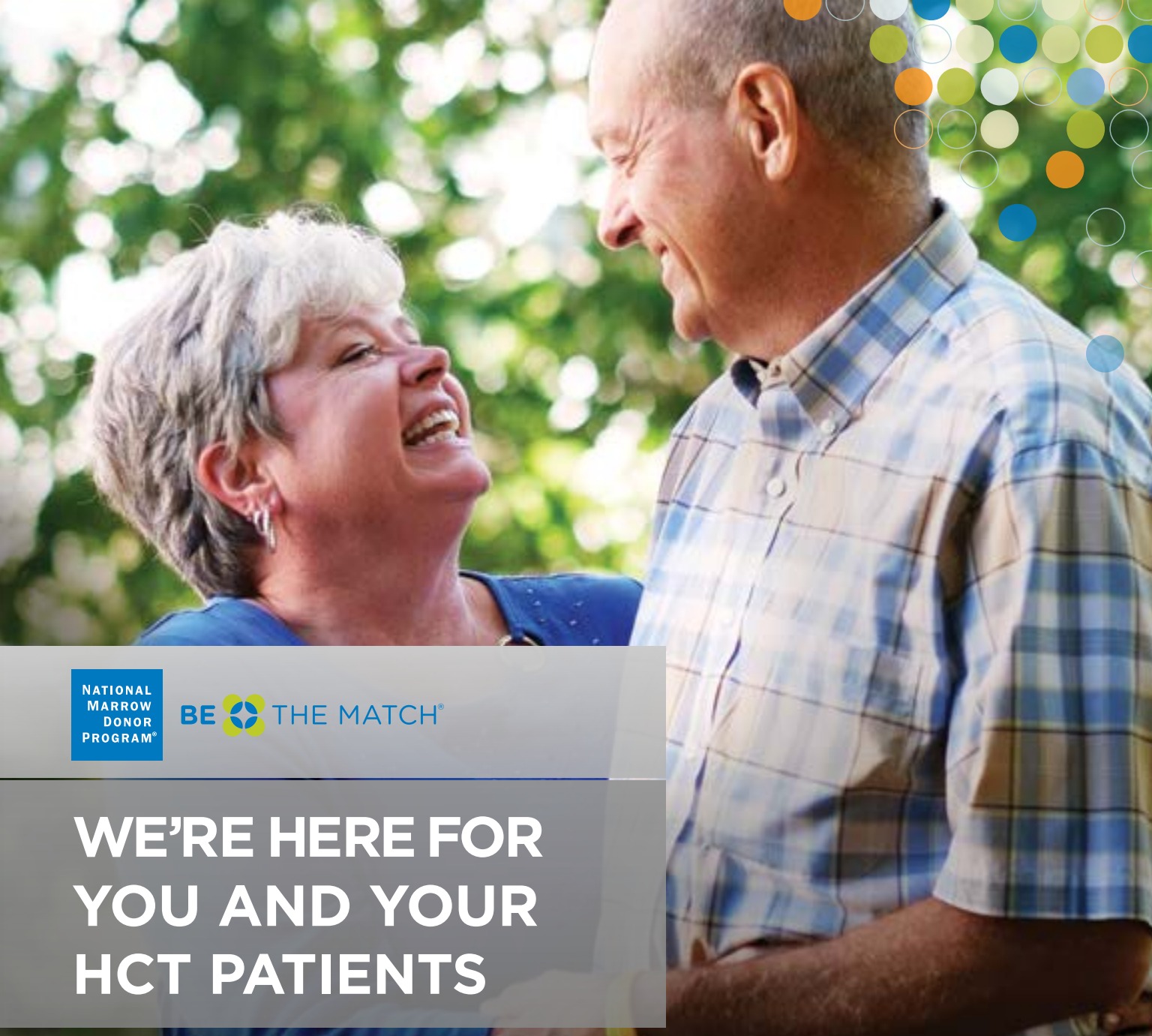

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CCMC Survey: Higher Salaries, More Specialties among CCMs

By MaryBeth Kurland, CAE, *CEO, Commission for Case Manager Certification*

Rapid changes in healthcare are demanding more from case managers than ever before, from greater emphasis on care coordination to more specialty training, according to a recent survey of Certified Case Managers (CCMs) conducted by the Commission for Case Manager Certification (CCMC).

The findings illustrate how CCMs, many with specialty training, are positioned to add significant organizational value. This is reflected in their salaries, which affirm a solid career path. Forty-six percent of CCMs report salaries above $80,000, while half of those in executive positions earn in excess of $100,000.

The median salary for board-certified case managers varies based on position, with consultants, staff, and educators earning on average between $75,000 and $80,000, and management earning on average between $90,000 and $95,000. These salaries for CCMs attest to the growing need for professional excellence as health and human services become more complex.

The median annual salary for CCMs varies based on specialty training. A CCM who specializes in care transitions, hospital, military, or orthopedics earns on average $80,000 to $85,000, while those who specialize in renal disease earn on average $85,000 to $90,000.

In addition, CCMs who are registered nurses (RNs) enjoy a median salary that is on average $7,500 to $12,500 above the average for RNs. CCMs with a background in social work earned on average between $19,000 and $24,000 above the national average for social workers.

Meanwhile, when asked about their work experience, 67% of CCMs surveyed reported being in case management for more than 10 years; 28% have advanced degrees and 32% work in accountable care settings. Women account for most of the practice, as 96% of CCMs are women. About one quarter (26%) of CCMs hold management or executive positions.

Most CCMs (89%) are RNs, although the percentages for other disciplines have been growing, with social workers accounting for 7%. The number of other disciplines represented in case management is based on a larger population of CCMs, with more than 42,000 board-certified case managers in practice today. Since 1992, more than 60,000 case managers have earned the CCM credential.

Nearly 9 of 10 respondents (86%) have specialty training, with the most popular specialty being managed care/insurance (35%). Although only 6% of CCMs have licensure/certification in workers' compensation, 25% of CCMs have specialty training in this area. Other specialties include chronic disease management, 21%; hospital case management, 18%; and care transitions, 15%.

Case managers are also valued members of healthcare teams and are often responsible for tracking and evaluating outcomes for the entire team. Among survey respondents, 92% said their organization evaluates and measures care coordination, which continues to be a key component of the case management process.

As organizations track care coordination, the most common means is measuring patient satisfaction (61%); however, half of the respondents says their organizations also track readmission rates (50%) and 37% assess cost savings and meeting patient self-management goals.

Among recent developments, the Centers for Medicare & Medicaid Services recognizes the value of better coordinated care. Beginning in 2017, payments for care coordination for complex chronic care management are more generous and can be billed more often. Case managers are often the hub of care coordination efforts for hospitals, physician practices, and other entities.

Healthcare providers and payers are exploring new ways to improve health outcomes and lower costs. Trends include alternative payment models that emphasize care coordination; integrating systems that address the social determinants of health; and reforms that improve the health of communities and control costs. These trends put CCMs at the forefront of healthcare delivery today and in the discussion of how it might evolve in the future.

As the evolution continues, CCMC will continue to survey the practice to identify changing and emerging trends. CM

MaryBeth Kurland, CAE, *is the CEO of the Commission for Case Manager Certification (CCMC), the first and largest nationally accredited organization that certifies case managers. (For information about CCM certification, please see https://ccmcertification.org/)*

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Part 5: Case Management Society of America Issues Revised Standards of Practice

Components of the Case Management Process

By Elizabeth Hogue, Esq.

The Case Management Society of America (CMSA) recently issued revised Standards of Practice for Case Management. The Standards were first published in 1995 and were revised in 2002 and 2010. The general purpose of the Standards is to identify important knowledge and skills for case managers, regardless of practice setting. CMSA decided to revise the Standards again this year in order to emphasize the professional nature of the practice and role of case managers as an integral and necessary component of the health care delivery system. These standards likely apply to all case managers, regardless of practice setting or whether they are certified case managers.

Recently revised standards describe the components of the case management process that generally include client identification, selection, and engagement in professional case management; assessment and opportunity identification; development of care management plans of care; and implementation and coordination of care management plans of care.

Recently revised standards describe the components of the case management process that generally include:

- Client identification, selection, and engagement in professional case management
- Assessment and opportunity identification
- Development of care management plans of care
- Implementation and coordination of care management plans of care
- Monitoring and evaluation of case management plans of care
- Closure of professional case management services

Client identification, selection and engagement includes:

- Screening clients to determine appropriateness for and benefits from services
- Engagement of clients and families and other caregivers in the case management process
- Obtaining consent to case management services as part of the process of initiation of services

Intermittent assessment and opportunity identification regarding behavioral health, substance use and abuse, and social determinants of health, including:

- Data gathering, analysis and synthesis of information in order to develop client-centric case management plans of care
- Use of effective communication skills to help establish relationships with patients and patients' readiness to engage in their own health and well-being
- Identification of care needs, including needs, barriers, and/or gaps in care

Development of the case management plan of care includes:

- Identification of care needs, barriers and opportunities for collaboration with clients, families and/or other caregivers and members of the interprofessional care team to provide effective integrated care
- Prioritization of goals and outcomes
- Interventions or actions needed to reach the goals of plans

Implementation and coordination of case management plans of care includes:

- Facilitating coordination of care, services, resources and health education specified in plans of care
- Ongoing communication with clients, their families, other caregivers, providers and the entire interprofessional health care team

Monitoring and evaluating case management plans of care includes:

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

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Aging Population Needs CCM and CDMS Expertise

By Ed Quick, MA, MBA, CDMS, CRC

The aging of the U.S. population presents challenges for how best to serve this growing demographic to achieve health, wellness, and productivity goals. The numbers tell a compelling story: According to the Population Reference Bureau, today there are more than 46 million Americans who are 65 years of age and older—a demographic that is projected to more than double to over 98 million by 2060. In addition, older adults are working longer: As of 2014, 23% of men and about 15% of women aged 65 and older were in the labor force; by 2022, these percentages are projected to grow to 27% of men and 20% of women.

This aging population, particularly those who want to work past the traditional retirement age, will require the expertise of both Certified Case Managers (CCMs) and Certified Disability Management Specialists (CDMSs). These two disciplines share the common ground of advocacy, helping ensure that people have access to the care and resources they need to achieve their goals. Mature individuals with multiple health challenges who want to remain in the workforce may need support to do the work differently, and collaboration between CCMs and CDMSs can identify and secure an array of available resources.

The ability to collaborate starts with a better understanding of each discipline. For example, case managers need to know that many CDMSs today take an integrated approach to disability management, beyond the traditional focus on workplace-related illnesses and injuries covered by state-mandated workers' compensation programs. With an integrated approach, CDMSs address return-to-work and stay-at-work for cases involving both occupational and nonoccupational injuries, illnesses, and disabilities, with a keen understanding of the employer environment.

Today there are more than 46 million Americans who are 65 years of age and older—a demographic that is projected to more than double to over 98 million by 2060.

On the nonoccupational side, a CDMS who is providing workplace support for an employee following a catastrophic illness or injury may work closely with a CCM who is managing the clinical side. With the employee's authorization, a CDMS may have access to appropriate health information to better understand the individual's needs. Together, the CCM and the CDMS seek to provide resources that further the individual's health, wellness, and productivity goals, while supporting human capital needs of the employer.

For CCMs, greater awareness of disability management and the expertise of a CDMS increase the resources they can incorporate into a case management plan. For example, a patient who is employed may be able to access a variety of workplace programs and benefits solutions. Many large employers provide Employee Assistance Programs (EAPs), which include personal, financial, eldercare, childcare, and some counseling services.

Consider the example of "Donna," a divorced woman with two children in high school and an elderly mother. During her treatment for a cancer recurrence, Donna tried to balance her health concerns with staying on the job as much as possible. A flexible work arrangement allowed Donna to work from home on the days immediately following chemotherapy treatments. In addition, when Donna mentioned concerns about her elderly mother who could no longer live independently, she was referred to the company's EAP, which helped her find assisted living facilities in the area.

Too often people are not fully aware of their employer's workplace programs and whether the company culture is conducive to flexible arrangements. In some organizational cultures, employers may be more apt to adapt workplace programs to a variety of needs: for example, the same kinds of job-sharing arrangements

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Ed Quick, MA, MBA, CDMS, CRC, is a Commissioner with the Commission for Case Manager Certification (CCMC), which manages and governs CDMS certification. He has more than 15 years of experience in disability and workforce management with Fortune 100 companies and currently works as a global senior benefits manager.

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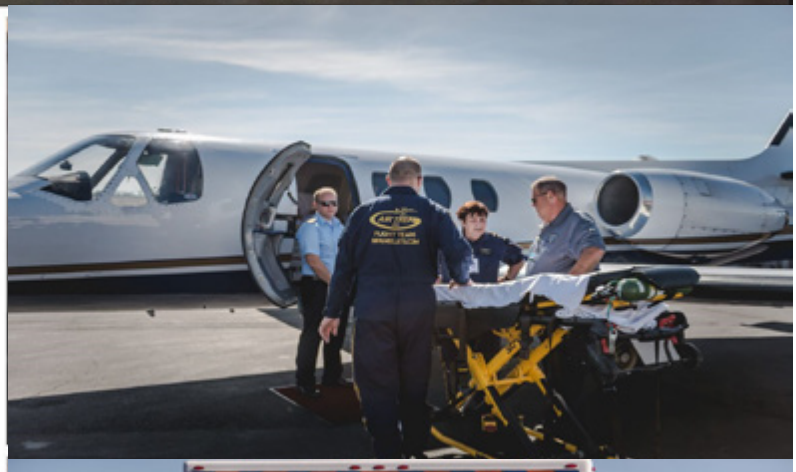

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CE 1

Case Management in Patients with Early-Onset Alzheimer's Disease

By Jennifer Voorlas, MSG, CMC

Introduction

One of the most difficult challenges facing case managers may be providing case management for individuals with early-onset Alzheimer's disease. Although some patients who are over age 65 may have some form of dementia (eg, memory loss, confusion, and difficulty with performing daily tasks), helping younger patients with early-onset Alzheimer's disease requires using a much wider lens to view our clients, their family support systems, and ultimately the resources and interventions that we will use.

Early-onset dementia is used to describe any form of dementia that is diagnosed before age 65, but the symptoms can begin affecting individuals in their 30s, 40s, and 50s. It is estimated that approximately 200,000 people in the United States have early-onset Alzheimer's disease, an illness that affects employment and intimate relationships, impairs judgment, and ultimately makes it difficult to take care of oneself.[1] Although early-onset Alzheimer's disease is thought to be rare, the number of cases is increasing every year as more accurate diagnostic tools are being developed and used. Thus, a case manager who works in a multitude of settings will undoubtedly come into contact with a patient with early-onset Alzheimer's disease who may not yet have been diagnosed or is in the early, middle, or end stages of the disease.

Impact of Cultural Stigma

The assumption that Alzheimer's disease is an illness that occurs exclusively in individuals over age 65 is a myth due to the lack of education about early-onset disease as well as cultural denial about who may be diagnosed with the disease. Case managers must be especially aware of how negative cultural attitudes impact individuals with early-onset Alzheimer's disease in terms of how individuals perceive their ability to fit into society and their ability to use available resources. Moreover, growing bodies of research suggest that cultural stigmatization promotes social exclusion and the reluctance to seek help.[2] This is a challenge for the case manager because resources for individuals with early-onset Alzheimer's disease are still somewhat limited with regard to financial help, social opportunities, and appropriate housing.

Because of diminished functioning, many individuals with early-onset Alzheimer's disease who become unemployed experience changes in their social support system, which may breed isolation. It may also be challenging for an individual with early-onset Alzheimer's disease to establish new relationships because of the age gap of the new pool of available "peers". Most social service programs and assisted living and residential care facilities that cater to individuals with dementia are primarily occupied by patients who are well over age 65. If an individual with early-onset Alzheimer's disease is still able to live at home but needs care, it can be isolating if ample support systems and outlets for social, recreational, and mental stimulation are not provided.

Problems with Diagnosis

Another challenge for case managers is that symptoms of early-onset Alzheimer's disease are typically difficult to detect. If the disease is not detected, opportunities for treatment intervention may be lost as the disease progresses. Early-onset Alzheimer's disease may be misdiagnosed because some physicians may overlook the warning signs in young patients who don't present with medical issues. In fact, many patients with early-onset Alzheimer's disease undergo multiple evaluations and delays before a formal diagnosis is made. Research suggests these delays may in part be due to the fact that patients with early-onset Alzheimer's disease before age 60 have atypical symptoms: they present with more behavioral, vision, or language problems rather than with memory problems.[3]

Because of these particular challenges, the case manager must strive to:

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One of the most difficult challenges facing case managers may be providing case management for individuals with early-onset Alzheimer's disease.

- Emphasize the importance of a good diagnostic work up: a baseline assessment is essential to providing a treatment plan and advanced planning for care
- Steer family members to competent specialists with knowledge, expertise, and interest in dementia
- Refer the patient to a well-respected neurologist if memory problems are suspected
- Support each family member in the way that makes sense. What is each member's role in the family system? What is their relationship to the individual with early-onset Alzheimer's disease? For example, support and resources will be different for a teenager than for a spouse.
- Locate top-rated university-based facilities devoted to research and treatment of early-onset Alzheimer's disease
- Advocate for proper medical care, including access to resources to pay for medical services.

Denial and Difficulty in the Family System

One of the most important things in working within a complex family system is that each family member's personal expression of grief is different. Some family members may be in disbelief, some members may be angry about their loved one's diagnosis, and other members may be accepting of the diagnosis and willing to be active in care planning. In addition, individuals with early-onset Alzheimer's disease may be aware of their diagnosis (especially in the beginning stages) but in denial about their capabilities. This may present challenges for case managers such as:

- Spouses with caregiver burden may still be in their 40s and 50s
- Grieving children who have a sick parent need support and education about Alzheimer's disease in language that they can understand
- Intense caregiver burden. The healthy spouse tries to care for everyone: the spouse with early-onset Alzheimer's disease, children, elderly parents, and in-laws.
- Minimization or refusal of home care services. This can range from the individual with early-onset Alzheimer's disease denying the need for help to feeling afraid about giving up control to concerns about cost of care.
- Minimization or refusing community resources, placement in a nursing home or institution, and or psychological support
- Intense grief/distress of family members
- Increased depression/agitation of the individual with early-onset Alzheimer's disease due to diagnosis and progression of the disease.
- Support groups for early-onset Alzheimer's disease may be difficult to locate, especially in rural areas
- Medicare may not cover medical benefits or social support programs for individuals with Alzheimer's disease who are under the age of 65

Comprehensive Planning

Although each patient with early-onset Alzheimer's disease is unique, the case manager's plan must be comprehensive enough to address immediate and possible future interventions but fluid enough to account for sudden changes in medical and or cognitive status. The case manager not only plays an integral role in assessing the independence level of the individual with early-onset Alzheimer's disease but also educates family members about next steps in care and advanced planning. It is important for the case manager to coordinate the patient's care with an array of professionals who can help complete the key pieces of the puzzle to develop an effective care plan.

If the individual with early-onset Alzheimer's disease still has mental capacity and is capable of making his or her own health care decisions, the case manager must walk a fine line by balancing the patient's safety versus his or her autonomy needs.

The case manager must use their skill set in the following areas:

- Help the healthy spouse adapt to his/her role of "decision-maker"
- Assess home and personal safety: Can the individual live at home? Are they a flight risk?
- Facilitate the preparation of legal documents such as advanced directives for medical treatment

A case manager who works in a multitude of settings will undoubtedly come into contact with a patient with early-onset Alzheimer's disease who may not yet have been diagnosed or is in the early, middle, or end stages of the disease.

- Implement a legal care plan and provide referrals for legal and financial issues (eg, incapacity, power of attorney)
- Early detection of financial abuse: This is especially important when considering capacity issues and diminished executive functioning abilities. Conservatorships are often established because of financial abuse by family, friends, or healthcare providers.
  - Help the patient apply for disability benefits (eg, a patient may lose income due to unemployment or have reduced income due to cognitive impairment). Applications for disability are often denied and reapplications are necessary.
  - Manage behavioral issues: Progression of disease is often associated with behavioral issues. It is essential to know when to set up a referral to a neuropsychologist or geriatric psychiatrist.
  - Advocate and educate for using a "team" approach (eg, geriatric care manager, family, friends, and legal/medical professionals) to manage care
  - Empathize with and validate each family member's unique role in the family system. Provide structure for grief as well as hope.
  - Encourage the development of support systems by providing referrals to caregiver support groups and or individual counseling to bridge isolation
  - Disease management: Encourage medication adherence and changes in diet and exercise as well as a reduction in stress levels
  - Locate well-qualified caregivers who have been properly trained for dementia care
  - Encourage volunteering and mentoring roles to foster a sense of self-mastery and to enhance self-esteem
  - Provide educational resources on Alzheimer's disease that support community education as well as volunteer opportunities (eg, organizations/universities with healthy aging outreach programs such as the Alzheimer's Association)
  - Designate a residence or appropriate placement in the event of incapacitation, which may be challenging given the age gap between individuals with early-onset Alzheimer's and late-onset Alzheimer's disease in residential care facilities.

Conclusion

Although there is considerable research and information about early-onset Alzheimer's disease, there is still a lot that we don't know. Progression of disease occurs at a different rate in each individual with early-onset Alzheimer's disease, and individual cope with their disability differently. One person with early-onset Alzheimer's disease might decline rapidly and end up institutionalized whereas another person with the disease may be able to serve in a leadership role.

Regardless of the breadth of the case manager's role and the amount of time they spend managing a case, case managers working in different settings have a unique opportunity to serve patients with early-onset Alzheimer's disease by being their advocate and inspiration. Although the outcome for each individual with early-onset Alzheimer's disease is different, the case manager's involvement is of tremendous value in helping the individual assess a plan of action to meet the individual's needs and to thus support the individual's independence for as long as possible. CE 1

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CE II

Coming Full Circle: Multidirectional Communication
Medical and Behavioral Health Services and the Patient

By Madeleine Y. Gómez, PhD; Mark Johns, PsyD; Eric Sanchez Gomez, BS; and Mitch Hall, PhD

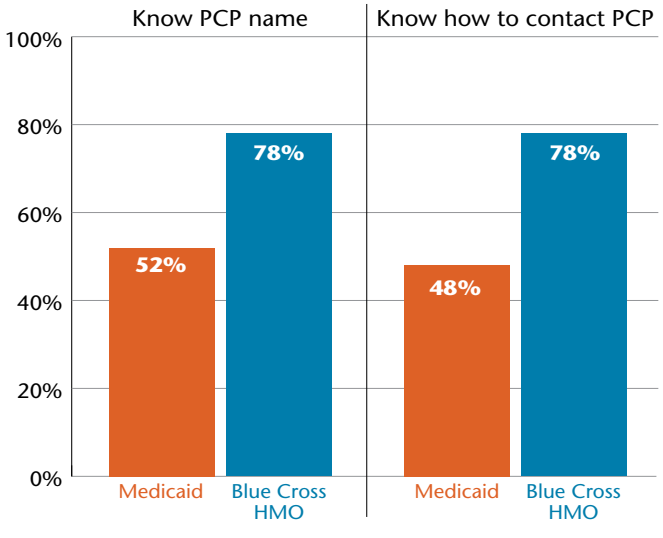
Introduction

The current care coordination and healthcare delivery systems continue efforts to integrate medical with behavioral health services. The field recognizes that behavioral health comprises a major component in the patient's overall health and wellness. Similarly, it is recognized that operational silos that isolate behavioral health services from medical treatment negatively impact quality of care and neglect to treat the patient as a whole person. The focus, however, has been on referrals from the medical system to behavioral health services. Conversely, there are individuals who enter the healthcare system by accessing behavioral health services independent of a primary care referral. This may occur with the complex care patients who, by definition, have more than one diagnosis.

Based on the probability that complex care patients will have had adverse childhood experiences (ACEs) as well as the stigma of a behavioral health diagnosis, these patients (who may enter the behavioral health system even before they have an appointment with a primary care physician [PCP]) will likely need medical services. Despite that need, such individuals may not have had a recent physical examination or even know how to access their PCP, as is shown in Figure 1. Figure 1 shows the percentage of patients with both Medicaid and commercial healthcare plans who know the name and contact information of their PCP.[1]

Despite the push to integrate behavioral health services with medical services via medical referrals to behavioral health coupled with Healthcare Effectiveness Data and Information Set (HEDIS) measures that are firmly rooted in the medical and data-oriented camps, the full circle of this model has yet to be realized. Behavioral health providers working within the confines of Health Insurance Portability and Accountability Act (HIPAA) and confidentiality laws are more likely to interface with care coordinators than with other treating providers regarding their cases.[2] Unless medical and/or behavioral health care coordinators ensure communication of data to PCPs and work to empower patients to engage in communication and medical follow-up as well as their behavioral health services, missed opportunities to support health and wellness will likely result in poorer health outcomes.

FIGURE 1 PATIENT AWARENESS OF THEIR PRIMARY CARE PHYSICIAN



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The Reality of ACEs: Their Impacts on Medical and Behavioral Health

The use of screenings continues to increase in both medical and behavioral health services as per accreditation standards.[3] Evidence from screening research about the health consequences of ACEs reinforces the importance of a thorough assessment, history, and holistic approach to health.[4] Physical and behavioral health issues are interrelated. The quality of care and level of security we experience in our early environments translates into a lifelong impact on our physical and behavioral health.

Let's consider the evidence.

The findings on ACEs are statistically significant. In graded fashion, the more ACEs found in a person's childhood, the greater the risk for substance abuse and aggression as well as dysfunctions in self-regulation of emotion and mood, physical health, and sexuality.[5] Most recently and long overdue, the case for adding corporal punishment as a de facto ACE has been made in the literature.[6]

Exposure to each ACE category is counted as one ACE point. Compared with having an ACE score of zero, having four or more ACEs leads to the following increased risks (Table 1).

Screenings and test results as well as medical, psychological, and medication complaints must be noted and shared between the services. Care coordinators are best positioned to ensure these processes, which can be cumbersome and take time even in the age of electronic records. Similarly, care coordinators are on the front lines of patient barriers and stigma.

Stigma and Barriers Impacting Complex Care and Patient Treatment

Henderson et al.[7] focused on mental-health stigma that have impacted both health care and mental health care settings. In their review, they employed a framework to consider "stigma as operating on three interrelated levels: structural, interpersonal, and intrapersonal." These same levels can be found in the Substance Abuse and Mental Health Services Administration (SAMHSA) most recent working definition of recovery.[8]

Historically, systemic stigma impacted behavioral health treatment parity. Mental health parity was first introduced to legislators in 1992, and the first version passed in 1996. The most recent "final" version of the bill was signed into law in October 2008. It has taken over 20 years to agree and put into law the requirement that "treatment limitations and financial requirements on mental health coverage are the same as those for coverage of physical illnesses."[9]

Equally important for medical and behavioral services are the barriers encountered on the front lines of service provision that impact patient navigation and engagement in their care plan. Table 2 identifies challenges to accessing appropriate medical and behavioral health services. Although this list is large, it is likely nonexhaustive and each barrier could warrant a subsection far beyond the scope of this paper.

Care Coordination Integrating Healthcare: Towards Treating the Whole Person with the Whole Team

The Substance Abuse and Mental Health Services Administration conservatively estimated that approximately 1 in 5 adults in the United States, or 43.8 million persons, experiences mental illness in a given year.[8] That same report estimated that 1 in 25 adults in the United States, or 10 million persons, experiences a serious mental illness that interferes with or limits one or more major life activities. Conditions of mental health and substance abuse have been shown to frequently co-occur with heart disease, diabetes, cancer, and neurological disorders.[10]

TABLE 1 INCREASED RISK ASSOCIATED WITH ADVERSE CHILDHOOD EXPERIENCES

Ischemic heart disease	**220%**
Diabetes	**160%**
Chronic bronchitis or emphysema	**390%**
Past-year depression	**460%**
Ever attempting suicide	**1,220%**
Currently smoking	**220%**
Ever using illegal drugs	**470%**
Becoming an alcoholic	**740%**
Injecting illegal drugs	**1,030%**

TABLE 2 IDENTIFIED BARRIERS TO MEDICAL AND BEHAVIORAL HEALTH SERVICES

1. Mobility (wheelchair, scooter, cane, walker assistive needs, body limitations, architectural barriers)
2. Transportation
3. Limited education, intellectual or developmental disorders
4. Inability to read, health literacy/comprehension
5. Hearing impairments, need for Certified Deaf Interpreter or American Sign Language interpreter, relay phone access
6. Sensory issues such as depth perception, ability to be in crowded rooms, acute or severely restricted abilities to smell, taste, or feel
7. Visual impairment, need for Braille, large print or audio materials, animal assistance
8. Limited functional strength (to open medication tops, doors, drawers), balance issues/vestibular (dizziness, vertigo)
9. Ability to speak, verbal communication, speaks other language
10. Environmental, abuse and violence including corporal punishment in home, unsafe community or violence in community
11. Lack of social/family supports, family not supportive of treatment
12. History of nonadherence, lack of prior healthcare, lack of prior healthcare coverage
13. Psychosis
14. Unable to care for self
15. Idiosyncratic responses to medication
16. Respiratory issues, oxygen, medical lines, tethers, catheter devices
17. Incontinence
18. Medical comorbidities—acute symptoms
19. Behavioral health—violent, homicidal, suicidal, paranoia, history of abuse/violence, psychosis
20. Substance use, medication effects
21. Cultural approaches or misconceptions regarding health, healing, and healthcare
22. Limited finances, hierarchy, or needs, homeless, no food, etc.
23. Medication side effects/interactions, idiosyncratic response to medications
24. Stigma
25. Privacy, patient may not want to share information
26. Deceit, lying, lack of trust, fear of retribution including job loss, incarceration, deportation, judgment/rejections by team, family, and/or friends
27. Prejudices/discrimination/disparities within the medical field
28. Lack of information or understanding of care coordination, healthcare, treating team need for information for quality of care
29. Hospice and related hospice issues including hospice "philosophy"
30. Inaccurate contact data including phone, email, addresses, emergency contacts

These outcomes are even more alarming in light of meta-analyses that indicate that although behavioral health conditions may certainly be a contributing factor to physical disease, those identified with a serious mental illness die sooner due to a poorly treated, undertreated, or untreated medical condition.[11,12] Despite such well-established findings, experience from the frontlines of care coordination suggests that many patients with mental health issues continue to have their medical needs overlooked or summarily dismissed.[2] In addition, mental health may be used as a "dumping ground" for difficult multineed medical and/or challenging behavioral health cases with coexisting disorders including substance use.

For over a decade, the call for integrated care coordination between physical and behavioral health services, in both private and public sectors, has become increasingly clear. The Affordable Care Act (ACA) underscored the deficits of fragmented systems of care. Regardless of the current status of the ACA, motivators are being established to ostensibly improve care while significantly reducing costs. Across states, focus is shifting from the quantity of services being offered to the quality of services delivered and demonstrated outcomes. To reach positive outcomes, health professionals, professional societies, managed care organizations, managed care purchasers, and public policy makers agree that care should be integrated.[13] Nardone et al.[14] noted that two themes tend to emerge from their review of attempts to assimilate physical and behavioral healthcare: 1) identifying all of a patient's healthcare needs regardless of precipitants or point of entry, and 2) person-centered care achieved via

For over a decade, the call for integrated care coordination between physical and behavioral health services, in both private and public sectors, has become increasingly clear.

successful care coordination.

Given these findings, effective care coordination necessitates multidirectional communication between medical providers, behavioral health providers, and patients. Ideally, per the recovery-oriented model, integrated treatment considers and incorporates all aspects of the patient's treatment and support systems, with emphasis on recipients of healthcare services as co-collaborators at the heart of their treatment plans. However, although many healthcare systems might espouse the philosophy of recovery-oriented care coordination, evidence gleaned from patient reports shows that we have yet to fully implement those ideals into practice.[2]

Failure to treat the whole person may even be more pronounced in patients with severe mental illness due to continued stigmatization of this population. To coordinate care effectively, patients need to feel worthy of care and not further fragmented by the systems that are supposed to heal. Care coordination allows all providers and practitioners with patients to "bridge" the gaps that continue to persist among the healthcare silos.[15]

An integrated whole-person recovery model and multi–directional practice of communication must become the standard in clinical care integration to ensure quality outcomes for patients. Ideally, not-at-risk patients requesting routine behavioral health outpatient services would be seen only after a PCP examination clearing them of medical hypotheses for their symptoms; diet and exercise would be reviewed, routine blood work would be performed, thyroid imbalances would be ruled out, and the patient would be screened for heavy metals and/or other environmental toxicities. Team communications that include the patient take enormous work and energy but are essential to achieve optimal engagement of all parties as well as the best quality. The care coordinator is uniquely positioned to lead the multidirectional team communications and serve as a repository for the data streams. Nonetheless, each person on the team must assume responsibility for communication regarding pieces of their treatment as well as factors from other service providers that impact that care in addition to the care of the whole person.

In this age of ever increasing speed and volume of information, miscommunications, missed communications, or poorly orchestrated transmission of information, care coordination must ensue as multidirectional within the team, a team that must include the patient because all aspects impact treatment planning, referrals, and progress. It would not be an overstatement to note that to provide a lesser standard of care may invite disaster.

Recommendations

The following are recommendations for care coordination and multidirectional ongoing communication between the services within a patient recovery model:

1. Special flagging of individuals whose point of entry in the healthcare system takes place via behavioral health services. Routing, reporting, and connecting with primary care medicine must ensue within the patient-centered recovery model.
2. Behavioral health treatment plans must not be developed in the absence of medical data and routine rule outs, such as thyroid issues and heavy metal and/or other environmental toxicities.
3. Behavioral health providers are on the front lines of hearing symptoms and complaints. These should not go unrecognized and should be coordinated with the appropriate treating team. These include communication regarding physical symptoms as well as medication side effects.
4. Appointments for follow-up with a PCP should be set within 30 days for patients with psychiatric admissions.
5. The patient's words should always have meaning to us. We may not agree with them or find evidence to support them, but compassion for their story and their right to share their perspective must always be respected.
6. The demands of the field continue to increase, stretching resources and people. Ensure documentation of a good history. Read the chart.
7. Multidirectional communications will best serve to integrate and treat the whole person. Mind, body, and spirit are one person. Medical health is part and parcel of behavioral health and vice versa.
8. Although technology continues to improve, medical tests will not always pick up medical issues. This can be acknowledged with patients rather than shutting them down. It is ok to say "at this time, the medical tests have not found an explanation."

An integrated whole-person recovery model and multidirectional practice of communication must become the standard in clinical care integration to ensure quality outcomes for patients.

9. Use of technology to maximize time and communications remains essential. Virtual staffings are possible, although the throwback to in-person team rounds has ensued. Fewer cases can be reviewed with the latter.
10. Continued evolution in care coordination means that multidirectional communication between the medical and behavioral health teams must exist, expand, and become a monitored industry standard.
11. Behavioral health can become a dumping ground for those high-need, resource-using patients with many physical complaints that are not easily explained. Multidirectional care coordination can reduce this possibility.
12. Complex care patients without behavioral health diagnoses/symptoms do not automatically have a need for behavioral health services. Rule out normal responses to certain situations that should not be pathologized.
13. Patient physical complaints should be accepted and taken seriously and integrated into the medical and/or behavioral health care plans.
14. Involve patients in team discussions and the care plan.
15. Practitioners and providers should develop increased sensitivity to patients with substance abuse diagnoses.
16. Consider that patients who do not adhere to medical regimens do not de facto have a mental health diagnosis.
17. Maintain a mindful and self-aware approach to facilitate helpful treatment alliance and the likelihood of patient adherence to treatment plans. Patients with behavioral health comorbidity may be tiring, frustrating, and draining to the professional team. This can negatively impact compassion, listening, and a clear clinical approach.
18. Patient recovery practices promote the best multidirectional communication between care coordinators, the treating team, and the patient.
19. Multidirectional care coordination is a holistic model that must grow in the field. Each provider on the team as well as the patient must work to communicate, share data, plan, and review. Although the care coordinator may take the lead, all must be invested and responsive. Use of technology for efficient communications remains key. Time- consuming phone tag should be avoided at all costs.
20. The ACE studies are 20 years old. The time to incorporate education, insight, and human rights, coupled with policies and practices for prevention of ACEs, into the entire health care field is overdue. Behavioral health providers should make assessment of ACEs standard practice and relay these scores to the medical team/PCP.
21. Continuous education and use of the following three tools provide a framework for effective implementation of the integrated person-centered recovery care coordination model: motivational interviewing, recovery language, and cultural competency.
22. The ACE studies demonstrate the impact of trauma and violence on health and wellness. The treating team must work with the patient to ensure safety and nonviolence, without which optimal health should not be expected.

CE II

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continues on page 33

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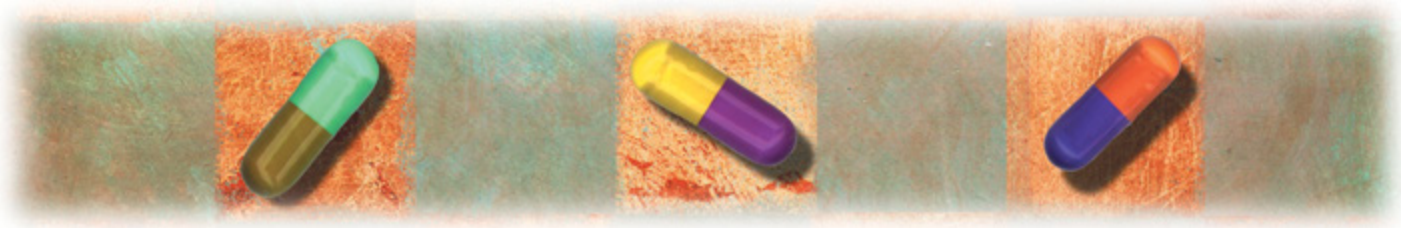

Radicava(edaravone injection), for intravenous use

INDICATIONS AND USAGE

Radicava is indicated for the treatment of amyotrophic lateral sclerosis (ALS).

DOSAGE AND ADMINISTRATION

Dosage Information

The recommended dosage of Radicava is an intravenous infusion of 60 mg administered over a 60-minute period according to the following schedule:

- An initial treatment cycle with daily dosing for 14 days, followed by a 14-day drug-free period
- Subsequent treatment cycles with daily dosing for 10 days out of 14-day periods, followed by 14-day drug-free periods.

Preparation and Administration Information

Radicava is for intravenous infusion only.

Preparation

Do not use if the oxygen indicator has turned blue or purple before opening the package. Once the overwrap package is opened, use within 24 hours.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Administration

Administer each 60 mg dose of Radicava injection as two consecutive 30 mg intravenous infusion bags over a total of 60 minutes (infusion rate approximately 1 mg per minute [3.33 mL per minute]).

Promptly discontinue the infusion upon the first observation of any signs or symptoms consistent with a hypersensitivity reaction.

Other medications should not be injected into the infusion bag or mixed with Radicava.

DOSAGE FORMS AND STRENGTHS

Radicava is supplied for intravenous infusion in a single-dose polypropylene bag containing 30 mg of edaravone in 100 mL of clear, colorless aqueous solution.

CONTRAINDICATIONS

Radicava is contraindicated in patients with a history of hypersensitivity to edaravone or any of the inactive ingredients of this product. Hypersensitivity reactions and anaphylactic reactions have occurred.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions (redness, wheals, and erythema multiforme) and cases of anaphylaxis (urticaria, decreased blood pressure, and dyspnea) have been reported in spontaneous postmarketing reports with Radicava.

Patients should be monitored carefully for hypersensitivity reactions. If hypersensitivity reactions occur, discontinue Radicava, treat per standard of care, and monitor until the condition resolve.

Sulfite Allergic Reactions

Radicava contains sodium bisulfite, a sulfite that may cause allergic type reactions, including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown. Sulfite sensitivity occurs more frequently in asthmatic people.

ADVERSE REACTIONS

Clinical Trials Experience

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

In randomized, placebo-controlled trials, 184 ALS patients were administered Radicava 60 mg in treatment cycles for 6 months. The population consisted of Japanese patients who had a median age of 60 years (range 29-75) and were 59% male. Most (93%) of these patients were living independently at the time of screening.

Most Common Adverse Reactions Observed During Clinical Studies

Table 1 lists the adverse reactions that occurred in ≥ 2% of patients in the RADICAVA-treated group and that occurred at least 2% more frequently than in the placebo-treated group in randomized placebo-controlled ALS trials. The most common adverse reactions

TABLE 1

Adverse Reactions from Pooled Placebo-Controlled Trials[a] that Occurred in ≥ 2% of RADICAVA-Treated Patients and ≥ 2% More Frequently than in Placebo Patients

Adverse Reaction	RADICAVA[b] (N=184)	Placebo (N=184)
Contusions	15	9
Gait disturbance	13	9
Headache	10	6
Dermatitis	8	5
Eczema	7	4
Respiratory failure, respiratory disorder, hypoxia	6	4
Glycosuria	4	
Tinea infection	4	2

a Pooled placebo-controlled studies include two additional studies with 231 additional patients, all using the same treatment regimen.

that occurred in ≥10% of RADICAVA-treated patients were contusion, gait disturbance, and headache.

CLINICAL STUDIES

The efficacy of Radicava for the treatment of ALS was established in a 6-month, randomized, placebo-controlled, double-blind study conducted in Japanese patients with ALS who were living independently and met the following criteria at screening:

1. Functionality retained most activities of daily living (defined as scores of 2 points or better on each individual item of the ALS Functional Rating Scale—Revised [ALSFRS-R; described below])
2. Normal respiratory function (defined as percent-predicted forced vital capacity values of [%FVC] ≥80%)
3. Definite or Probable ALS based on El Escorial revised criteria
4. Disease duration of 2 years or less

The study enrolled 69 patients in the Radicava arm and 68 in the placebo arm. Baseline characteristics were similar between these groups, with over 90% of patients in each group being treated with riluzole.

Radicava was administered as an intravenous infusion of 60 mg given over a 60 minute period according to the following schedule: An initial treatment cycle with daily dosing for 14 days, followed by a 14-day drug-free period (Cycle 1)

Subsequent treatment cycles with daily dosing for 10 days out of 14-day periods, followed by 14-day drug-free periods (Cycles 2–6).

The primary efficacy endpoint was a comparison of the change between treatment arms in the ALSFRS-R total scores from baseline to Week 24. The ALSFRS-R scale consists of 12 questions that evaluate the fine motor, gross motor, bulbar, and respiratory function of patients with ALS (speech, salivation, swallowing, handwriting, cutting food, dressing/hygiene, turning in bed, walking, climbing stairs, dyspnea, orthopnea, and respiratory insufficiency). Each item is scored from 0-4, with higher scores representing greater functional ability. The decline in ALSFRS-R scores from baseline was significantly less in the Radicava-treated patients as compared to placebo. For the group taking 60 mg of Radicava , the change from baseline LS mean ± SE (95% CI) was –5.01±0.64. For the placebo group, change from baseline LS mean ± SE (95% CI) was –7.50±0.66. The treatment difference (Radicava-placebo [95% CI]) was 2.49 (0.99, 3.98) and the P value was 0.0013.

HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

Radicava injection is supplied as a 30 mg/100 mL (0.3 mg/mL) clear, colorless, sterile solution for intravenous infusion in single-dose polypropylene bags, each overwrapped with polyvinyl alcohol (PVA) secondary packaging containing an oxygen absorber and oxygen indicator, which should be pink to reflect appropriate oxygen levels. These are supplied in cartons as listed below.

Storage and Handling

Store at up to 25°C (77°F). Excursions permitted from 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. Protect from light. Store in overwrapped package to protect from oxygen degradation until time of use. The oxygen indicator will turn blue or purple if the oxygen has exceeded acceptable levels. Once the overwrap package is opened, use within 24 hours.

Radicava is distributed by MT Pharma America.

TYMLOS™ (abaloparatide) injection, for subcutaneous use

INDICATIONS AND USAGE

Tymlos is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Tymlos reduces the risk of vertebral fractures and nonvertebral fractures.

Limitations of Use

Because of the unknown relevance of the rodent osteosarcoma findings to humans, cumulative use of Tymlos and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended.

DOSAGE AND ADMINISTRATION

Recommended Dosage

- The recommended dosage of Tymlos is 80 mcg subcutaneously once daily.

- Cumulative use of Tymlos and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended.
- Patients should receive supplemental calcium and vitamin D if dietary intake is inadequate.

Administration Instructions

- Administer Tymlos as a subcutaneous injection into the periumbilical region of the abdomen. Rotate the site of the injection every day and administer at approximately the same time every day. Do not administer intravenously or intramuscularly.
- Administer the first several doses where the patient can sit or lie down if necessary, in case symptoms of orthostatic hypotension occur.
- Tymlos is a clear and colorless solution. Visually inspect Tymlos for particulate matter and discoloration prior to administration. Do not use if solid particles appear or if the solution is cloudy or colored.
- Provide appropriate training and instruction to patients and caregivers on the proper use of the Tymlos pen.

DOSAGE FORMS AND STRENGTHS

Injection: 3120 mcg/1.56 mL (2000 mcg/mL) in a single-patient-use prefilled pen. The prefilled pen delivers 30 doses of Tymlos, each containing 80 mcg of abaloparatide in 40 mcL of a sterile, clear, colorless solution.

WARNINGS AND PRECAUTIONS

NOTE: This warning and three bullets should be in a black box.

WARNING: RISK OF OSTEOSARCOMA

- Abaloparatide caused a dose-dependent increase in the incidence of osteosarcoma (a malignant bone tumor) in male and female rats. The effect was observed at systemic exposures to abaloparatide ranging from 4 to 28 times the exposure in humans receiving the 80 mcg dose. It is unknown if Tymlos will cause osteosarcoma in humans.
- The use of Tymlos is not recommended in patients at increased risk of osteosarcoma including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, open epiphyses, bone metastases or skeletal malignancies, hereditary disorders predisposing to osteosarcoma, or prior external beam or implant radiation therapy involving the skeleton.
- Cumulative use of Tymlos and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended.

Risk of Osteosarcoma

Abaloparatide caused a dose-dependent increase in the incidence of osteosarcoma in male and female rats after subcutaneous administration at exposures 4 to 28 times the human exposure at the clinical dose of 80 mcg. It is unknown whether Tymlos will cause osteosarcoma in humans.

The use of Tymlos is not recommended in patients at increased risk of osteosarcoma including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, open epiphyses, bone metastases or skeletal malignancies, hereditary disorders predisposing to osteosarcoma, or prior external beam or implant radiation therapy involving the skeleton.

Cumulative use of Tymlos and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended.

Orthostatic Hypotension

Orthostatic hypotension may occur with Tymlos, typically within 4 hours of injection. Associated symptoms may include dizziness, palpitations, tachycardia or nausea, and may resolve by having the patient lie down. For the first several doses, TYMLOS should be administered where the patient can sit or lie down if necessary.

Hypercalcemia

Tymlos may cause hypercalcemia. Tymlos is not recommended in patients with preexisting hypercalcemia or in patients who have an underlying hypercalcemic disorder, such as primary hyperparathyroidism, because of the possibility of exacerbating hypercalcemia.

Hypercalciuria and Urolithiasis

Tymlos may cause hypercalciuria. It is unknown whether Tymlos may exacerbate urolithiasis in patients with active or a history of urolithiasis. If active urolithiasis or pre-existing hypercalciuria is suspected, measurement of urinary calcium excretion should be considered.

ADVERSE REACTIONS

Clinical Trials Experience

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

Postmenopausal Women with Osteoporosis

The safety of Tymlos was evaluated in a randomized, multicenter, double-blind, placebo-controlled clinical trial in postmenopausal women with osteoporosis aged 49 to 86 years (mean age 69 years) who were randomized to receive 80 mcg of Tymlos (N = 824) or placebo (N = 821), given subcutaneously once daily for 18 months.

In this study, the incidence of all-cause mortality was 0.4% in the Tymlos group and 0.6% in the placebo group. The incidence of serious adverse events was 10% in the Tymlos group and 11% in the placebo group. The percentage of patients who discontinued study drug due to adverse events was 10% in the Tymlos group and 6% in the placebo group. The most common adverse reactions leading to study drug discontinuation in the Tymlos group were nausea (2%),

dizziness (1%), headache (1%), and palpitations (1%).

The most common adverse reactions in the trial were hypercalciuria, dizziness, nausea, headache, palpitations, fatigue, upper abdominal pain, and vertigo. These adverse reactions were generally not present at baseline, occurred more commonly with Tymlos than with placebo, and occurred in at least 2% of the patients treated with Tymlos.

DRUG INTERACTIONS

No specific drug-drug interaction studies have been performed.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Tymlos is not indicated for use in females of reproductive potential. There are no human data with Tymlos use in pregnant women to inform any drug associated risks. Animal reproduction studies with abaloparatide have not been conducted.

Lactation

Risk Summary

Tymlos is not indicated for use in females of reproductive potential. There is no information on the presence of abaloparatide in human milk, the effects on the breastfed infant, or the effects on milk production.

Pediatric Use

Safety and effectiveness of Tymlos have not been established in pediatric patients. Tymlos is not recommended for use in pediatric patients with open epiphyses or hereditary disorders predisposing to osteosarcoma because of an increased baseline risk of osteosarcoma.

Geriatric Use

Of the total number of patients in the postmenopausal osteoporosis clinical studies of Tymlos, 82% were age 65 years and over, and 19% were age 75 years and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, but greater sensitivity of some older individuals cannot be ruled out.

Renal Impairment

No dosage adjustment is required for patients with mild, moderate, or severe renal impairment. A study of a single dose of Tymlos 80 mcg given subcutaneously was conducted in subjects with normal renal function or mild, moderate, or severe renal impairment. The maximal concentration (Cmax) and area under the concentration-time curve (AUC) of abaloparatide increased 1.4- and 2.1-fold, respectively, in subjects with severe renal impairment, compared to subjects with normal renal function. Patients with severe renal impairment may have increased abaloparatide exposure that may increase the risk of adverse reactions; therefore, monitor for adverse reactions.

CLINICAL STUDIES

Efficacy Study in Women with Postmenopausal Osteoporosis

The efficacy of Tymlos for the treatment of postmenopausal osteoporosis was evaluated in Study 003 (NCT 01343004), an 18-month, randomized, multicenter, double-blind, placebo-controlled clinical trial in postmenopausal women aged 49 to 86 years (mean age of 69) who were randomized to receive Tymlos 80 mcg (N = 824) or placebo (N = 821) given subcutaneously once daily. Approximately 80% of patients were Caucasian, 16% were Asian, and 3% were Black; 24% were Hispanic. At baseline, the mean T-scores were -2.9 at the lumbar spine, -2.1 at the femoral neck, and -1.9 at the total hip. At baseline, 24% of patients had at least one prevalent vertebral fracture and 48% had at least one prior nonvertebral fracture. Patients took daily supplemental calcium (500 to 1000 mg) and vitamin D (400 to 800 IU).

The efficacy study was extended as Study 005 (NCT 01657162), an open-label study where patients were no longer receiving Tymlos or placebo but were maintained in their original randomized treatment group and received 70 mg alendronate weekly, with calcium and vitamin D supplements for 6 months. Study 005 enrolled 1139 patients, representing 92% of patients who completed Study 003. This included 558 patients who had previously received Tymlos and 581 patients who had previously received placebo. The cumulative 25-month efficacy dataset included 18 months of exposure to Tymlos or placebo in Study 003, 1 month of no treatment, followed by 6 months of alendronate therapy in Study 005.

Effect on New Vertebral Fractures

The primary endpoint was the incidence of new vertebral fractures in patients treated with Tymlos compared to placebo. Tymlos resulted in a significant reduction in the incidence of new vertebral fractures compared to placebo at 18 months (0.6% Tymlos compared to 4.2% placebo, $p < 0.0001$). The absolute risk reduction in new vertebral fractures was 3.6% at 18 months and the relative risk reduction was 86% for Tymlos compared to placebo.

The incidence of new vertebral fractures at 25 months was 0.6% in patients treated with Tymlos then alendronate, compared to 4.4% in patients treated with placebo then alendronate ($p < 0.0001$). The relative risk reduction in new vertebral fractures at 25 months was 87% for patients treated with Tymlos then alendronate, compared to patients treated with placebo then alendronate, and the absolute risk reduction was 3.9%.

Effect on Nonvertebral Fractures

Tymlos resulted in a significant reduction in the incidence of nonvertebral fractures at the end of the 18 months of treatment plus 1 month follow-up where no drug was administered (2.7% for Tymlos-treated patients compared to 4.7% for placebo-treated patients). The relative risk reduction in nonvertebral fractures for

continues on page 32

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. 2017 Jun 1;31(9):1313-1321. doi: 10.1097/QAD.0000000000001473.

Long-term alcohol use patterns and HIV disease severity.

Marshall BDL, Tate JP, McGinnis KA, Bryant KJ, Cook RL, Edelman EJ, Gaither JR, Kahler CW, Operario D, Fiellin DA, Justice AC.

OBJECTIVE: We examined the relationship between alcohol use trajectories and HIV disease severity among men and women participating in the Veterans Aging Cohort Study (VACS). DESIGN: Prospective cohort of HIV-infected persons in care at eight US Veterans Health Administration sites. METHODS: Between 2002 and 2010, we assessed alcohol consumption annually using the alcohol use disorders identification test-consumption (AUDIT-C). HIV disease severity was ascertained using the VACS index, a validated measure of morbidity and all-cause mortality. We examined the relationship between alcohol use and HIV disease severity patterns using joint trajectory modeling. Alcohol use trajectories were validated using phosphatidylethanol - a biomarker of alcohol consumption - measured between 2005 and 2006 among a subset of participants. We examined associations between membership in alcohol use and VACS index trajectories using multinomial regression. RESULTS: Among eligible participants, we identified four alcohol consumption trajectories: abstainers (24% of the sample), lower risk (44%), moderate risk (24%), and higher risk drinkers (8%). Alcohol use trajectories were highly correlated with phosphatidylethanol (Cramér's V=0.465, P<0.001): mean concentrations were 4.4, 17.8, 57.7, and 167.6ng/ml in the abstainer, lower risk, moderate risk, and higher risk groups, respectively. Four VACS index trajectories were identified: low (2%), moderate (46%), high (36%), and extreme (16%). Higher risk drinkers were most common in the extreme VACS index group, and were absent in the low index group. In multivariable analysis, the association between alcohol use and VACS index trajectory membership remained significant (P=0.002). CONCLUSION: Alcohol use trajectories characterized by persistent unhealthy drinking are associated with more advanced HIV disease severity among HIV-infected veterans in the United States.

BMJ. 2017 May 9;357:j1794. doi: 10.1136/bmj.j1794.

The Dietary Approaches to Stop Hypertension (DASH) diet, Western diet, and risk of gout in men: prospective cohort study.

Rai SK, Fung TT, Lu N, Keller SF, Curhan GC, Choi HK.

OBJECTIVE: To prospectively examine the relation between the Dietary Approaches to Stop Hypertension (DASH) and Western diets and risk of gout (ie, the clinical endpoint of hyperuricemia) in men. DESIGN: Prospective cohort study. SETTING: The Health Professionals Follow-up Study. PARTICIPANTS: 44444 men with no history of gout at baseline. Using validated food frequency questionnaires, each participant was assigned a DASH dietary pattern score (based on high intake of fruits, vegetables, nuts and legumes, low fat dairy products, and whole grains, and low intake of sodium, sweetened beverages, and red and processed meats) and a Western dietary pattern score (based on high intake of red and processed meats, French fries, refined grains, sweets, and desserts).MAIN OUTCOME MEASURE: Risk of incident gout meeting the preliminary American College of Rheumatology survey criteria for gout, adjusting for potential confounders, including age, body mass index, hypertension, diuretic use, and alcohol intake. RESULTS: During 26 years of follow-up, 1731 confirmed cases of incident gout were documented. A higher DASH dietary pattern score was associated with a lower risk for gout (adjusted relative risk for extreme fifths 0.68, 95% confidence interval 0.57 to 0.80, P value for trend <0.001). In contrast, a higher Western dietary pattern score was associated with an increased risk for gout (1.42, 1.16 to 1.74, P=0.005). CONCLUSION: The DASH diet is associated with a lower risk of gout, suggesting that its effect of lowering uric acid levels in individuals with hyperuricemia translates to a lower risk of gout. Conversely, the Western diet is associated with a higher risk of gout. The DASH diet may provide an attractive preventive dietary approach for men at risk of gout.

Pediatr Nephrol. 2017 May 8. doi: 10.1007/s00467-017-3683-7. [Epub ahead of print]

The association between creatinine versus cystatin C-based eGFR and cardiovascular risk in children with chronic kidney disease using a modified PDAY risk score.

Sharma S, Denburg MR, Furth SL.

BACKGROUND: Children with chronic kidney disease (CKD) have a high prevalence of cardiovascular disease (CVD) risk factors which may contribute to the development of cardiovascular events in adulthood. Among adults with CKD, cystatin C-based estimates of glomerular filtration rate (eGFR) demonstrate a stronger predictive value for cardiovascular events than creatinine-based eGFR. The PDAY (Pathobiological Determinants of Atherosclerosis in Youth) risk score is a validated tool used to estimate the probability of advanced coronary atherosclerotic lesions in young adults. OBJECTIVE: To assess the association between cystatin C-based versus creatinine-based eGFR (eGFR cystatin C and eGFR creatinine, respectively) and cardiovascular risk using a modified PDAY risk score as a proxy for CVD in children and young adults. METHODS: We performed a cross-sectional study of 71 participants with CKD [median age 15.5 years; inter-quartile range (IQR) 13, 17], and 33 healthy controls (median age 15.1 years; IQR 13, 17). eGFR was calculated using age-appropriate creatinine- and cystatin C-based formulas. Median eGFR creatinine and eGFR cystatin C for CKD participants were 50 (IQR 30, 75) and 53 (32, 74) mL/min/1.73 m2, respectively. For the healthy controls, median eGFR creatinine and eGFR cystatin were 112 (IQR 85, 128) and 106 mL/min/1.73m2 (95, 123) mL/min/1.73 m2, respectively. A modified PDAY risk score was calculated based on sex, age, serum lipoprotein concentrations, obesity, smoking status, hypertension, and hyperglycemia. RESULTS: Modified PDAY scores ranged from -2 to 20. The Spearman's correlations of eGFR creatinine and eGFR cystatin C with coronary artery PDAY scores were -0.23 ($p = 0.02$) and -0.28 ($p = 0.004$), respectively. Ordinal logistic regression also showed a similar association of higher eGFR creatinine and higher eGFR cystatin C with lower PDAY scores. When stratified by age <18 or ≥18 years, the correlations of eGFR creatinine and eGFR cystatin C with PDAY score were modest and similar in children [-0.29 ($p = 0.008$) vs. -0.32 ($p = 0.004$), respectively]. Despite a smaller sample size, the correlation in adults was stronger for eGFR cystatin C (-0.57; $p = 0.006$) than for eGFR creatinine (-0.40; $p = 0.07$). CONCLUSIONS: Overall, the correlation between cystatin C- or creatinine-based eGFR with PDAY risk score was similar in children. Further studies in children with CKD should explore the association between cystatin C and cardiovascular risk.

Am J Cardiol. 2017 Apr 12. pii: S0002-9149(17)30620-3. doi: 10.1016/j.amjcard.2017.03.249. [Epub ahead of print]

Trajectory of congestion metrics by ejection fraction in patients with acute heart failure (from the Heart Failure Network).

Ambrosy AP, Bhatt AS, Gallup D, Anstrom KJ, Butler J, DeVore AD, Felker GM, Fudim M, Greene SJ, Hernandez AF, Kelly JP, Samsky MD,Mentz RJ.

Differences in the clinical course of congestion by underlying ejection fraction (EF) have not been well-characterized in acute heart failure (AHF). A post hoc analysis was performed using pooled data from the Diuretic Optimization Strategies Evaluation in Acute Heart Failure, Cardiorenal Rescue Study in Acute Decompensated Heart Failure, and Renal Optimization Strategies Evaluation in Acute Heart Failure trials. All patients were admitted for a primary diagnosis of AHF. Patients were grouped as reduced EF ≤40%, borderline 40% < EF < 50%, or preserved EF ≥50%. Multivariable Cox regression analysis was used to assess the association among measures of congestion and the composite of unscheduled outpatient visits, rehospitalization, or death. Mean age was 68 ± 13 years and 74% were male. Patients with a preserved EF were older, more likely to be female, less likely to have an ischemic etiology of HF, and had a higher prevalence of atrial fibrillation/flutter and chronic obstructive pulmonary disease. Compared with patients with a reduced EF, preserved EF patients had lower amino-terminal pro-b-type natriuretic peptide levels at baseline (i.e., reduced: 5,998 pg/ml [3,009 to 11,414] vs borderline: 4,420 pg/ml [1,740 to 8,057] vs preserved: 3,272 pg/ml [1,687 to 6,536]) and experienced smaller changes during hospitalization. In general, there were few differences between EF groups in the clinical course of congestion as measured by signs and symptoms of HF, body weight change, and net fluid loss. After adjusting for potential confounders, a greater improvement in global visual analog scale was associated with lower risk of unscheduled outpatient visits, rehospitalization, or death at day 60 (hazard ratio 0.94 per 10 mm increase, 95% confidence interval 0.89 to 0.995). This relation did not differ by EF ($p = 0.54$). In conclusion, among patients hospitalized for AHF, there were few differences in the in-hospital trajectory or prognostic value of routine markers of congestion by EF.

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Chest. 2017 Jan;151(1):139-148. doi: 10.1016/j.chest.2016.08.1457. Epub 2016 Sep 8.

Cardiac sarcoidosis: the impact of age and implanted devices on survival.

Zhou Y, Lower EE, Li HP, Costea A, Attari M, Baughman RP.

OBJECTIVE: To assess the clinical characteristics, diagnosis, and outcome of cardiac sarcoidosis in a single institution sarcoidosis clinic. METHODS: Patients with cardiac sarcoidosis were identified using refined World Association of Sarcoidosis and Other Granulomatous Diseases (WASOG) criteria of highly probable and probable. Patient demographics, local and systemic treatments, and clinical outcome were collected. RESULTS: Of the 1,815 patients evaluated over a 6-year period, 73 patients met the WASOG criteria for cardiac sarcoidosis. The median age at diagnosis was 46 years, with a median follow-up of 8.8 years. Reduced left ventricular ejection fraction (LVEF) was the most common manifestation (54.8%). Patients with arrhythmias experienced ventricular tachycardia or severe heart block, (35.6% and 19.2%, respectively) with or without reduced LVEF. A total of 45 (61.6%) patients underwent cardiac PET scan and/or MRI, with 41 (91.1%) having a positive study. During follow-up, 10 patients (13.7%) either underwent transplant (n = 3) or died (n = 7) from sarcoidosis. Kaplan-Meier survival curves revealed 5- and 10-year survival rates of 95.5% and 93.4%, respectively. Univariate factors of age at diagnosis < 46 years, implantation of pacemaker or defibrillator, mycophenolate treatment, or LVEF > 40% were associated with improved survival. Cox regression analysis demonstrated that age ≥ 46 years and lack of an implanted pacemaker or defibrillator were the only independent predictors of mortality. CONCLUSIONS: The new WASOG criteria were able to characterize cardiac involvement in our sarcoidosis clinic. Age and lack of pacemaker or defibrillator were the significant predictors of mortality for cardiac sarcoidosis, and reduced LVEF < 40% was associated with worse prognosis.

AIDS. 2017 May 5. doi: 10.1097/QAD.0000000000001535. [Epub ahead of print]

Elective cesarean section for women living with HIV: a systematic review of risks and benefits.

Kennedy CE, Yeh PT, Pandey S, Betran AP, Narasimhan M.

OBJECTIVE AND DESIGN: To inform World Health Organization guidelines, we conducted a systematic review and meta-analysis to assess maternal and perinatal outcomes comparing cesarean section before labor and rupture of membranes (elective C-section/ECS) with other modes of delivery for women living with HIV. METHODS: We searched PUBMED, CINAHL, Embase, CENTRAL, and previous reviews to identify published trials and observational studies through October 2015. Results were synthesized using random-effects meta-analysis, stratifying for combination antiretroviral therapy (cART), CD4/viral load (VL), delivery at term, and low-/middle-income countries (LMICs). RESULTS: From 2567 citations identified, 36 articles met inclusion criteria. The single randomized trial, published in 1999, reported minimal maternal morbidity and significantly fewer infant HIV infections with ECS (OR:0.2, 95% CI:0.0-0.5). Across observational studies, ECS was associated with increased maternal morbidity compared with vaginal delivery (OR:3.12, 95% CI:2.21-4.41). ECS was also associated with decreased infant HIV infection overall (OR:0.43, 95% CI:0.30-0.63) and in LMICs (OR:0.27, 95% CI:0.16-0.45), but not among women on cART (OR:0.82, 95% CI:0.47-1.43) or with CD4>200/VL<400/term delivery (OR:0.59, 95% CI:0.21-1.63). Infant morbidity moderately increased with ECS. CONCLUSIONS: While ECS may reduce infant HIV infection, this effect was not statistically significant in the context of cART and viral suppression. As ECS poses other risks, routine ECS for all women living with HIV may not be appropriate. Risks and benefits will differ across settings, depending on underlying risks of ECS complications and vertical transmission during delivery. Understanding individual client risks and benefits and respecting women's autonomy remain important.

Ann Intern Med. 2017 May 9. doi: 10.7326/M16-2350. [Epub ahead of print]

Hepatitis C virus infection among reproductive-aged women and children in the United States, 2006 to 2014.

Ly KN, Jiles RB, Teshale EH, Foster MA, Pesano RL, Holmberg SD.

BACKGROUND: In the United States, hepatitis C virus (HCV) infection has increased among young persons who inject drugs, but the extent of this epidemic among reproductive-aged women and their children is unknown. OBJECTIVE: To estimate numbers and describe characteristics of reproductive-aged women with HCV infection and of their offspring. DESIGN: Analysis of the National Notifiable Diseases Surveillance System

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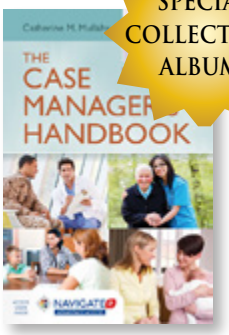

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(NNDSS) from 2006 to 2014 and the Quest Diagnostics Health Trends national database from 2011 to 2014. SETTING: United States. PARTICIPANTS: 171 801 women (aged 15 to 44 years) and 1859 children (aged 2 and 13 years) with HCV infection reported to the NNDSS; 2.1 million reproductive-aged women and 56 684 children who had HCV testing by Quest Diagnostics. MEASUREMENTS: NNDSS HCV case reports and Quest laboratory data regarding unique reproductive-aged women and children who were tested for HCV infection. RESULTS: The number of reproductive-aged women with acute and past or present HCV infection in the NNDSS doubled, from 15 550 in 2006 to 31 039 in 2014. Of 581 255 pregnant women tested by Quest from 2011 to 2014, 4232 (0.73% [95% CI, 0.71% to 0.75%]) had HCV infection. Of children tested by Quest, 0.76% (CI, 0.69% to 0.83%) had HCV infection, but the percentage was 3.2-fold higher among children aged 2 to 3 years (1.62% [CI, 1.34% to 1.96%]) than those aged 12 to 13 years (0.50% [CI, 0.41% to 0.62%]). Applying the Quest HCV infection rate to annual live births from 2011 to 2014 resulted in an estimated average of 29 000 women (CI, 27 400 to 30 900 women) with HCV infection, who gave birth to 1700 infants (CI, 1200 to 2200 infants) with the infection each year. LIMITATIONS: Only a fraction of HCV infections is detected and reported to the NNDSS. Quest data are potentially biased, because women who are asymptomatic, do not access health care, or have unreported risks may be less likely to be tested for HCV infection. CONCLUSION: These data suggest a recent increase in HCV infection among reproductive-aged women and may inform deliberations regarding a role for routine HCV screening during pregnancy.

Clin Transplant. 2017 May 6. doi: 10.1111/ctr.12997. [Epub ahead of print]

Effect of diltiazem on exercise capacity after heart transplantation.

Varnado S, Peled-Potashnik Y, Huntsberry A, Lowes BD, Zolty R, Burdorf A, Lyden ER, Moulton MJ, Um JY, Raichlin E.

BACKGROUND: Sinus tachycardia (ST) is common after heart transplantation (HTx). The aim of the study was to evaluate the effect of Diltiazem treatment during the first year after HTx on heart rate (HR), cardiac allograft function and exercise capacity. METHODS: From the total cohort, 25 HTx recipients started Diltiazem treatment 4±2 weeks after HTx and continued it for at least 1 year (Diltiazem group). Each study case was matched to a control. All patients underwent hemodynamic assessment and cardiopulmonary exercise test (CPET) at one year after HTx. RESULTS: HR decreased in the Diltiazem group from 99±11 bpm to 94±7 bpm (p=0.03) and did not change in the controls (98±11 bpm vs. 100±13 bpm, p=0.14). The difference between the groups at 1 year after HTx was significant (p=0.04). In the Diltiazem group left ventricular (LV) stroke volume and ejection fraction increased (48 ± 16 vs. 55± 17 ml, p=0.02, and 60% ± 10% vs. 62% ± 12% p=0.03 respectively) but did not differ from controls. E/E' decreased (10.7 ± 2.7 vs. 7.3 ± 1.9, p=0.003) while cardiac index was higher (3.5 ± 0.8 vs. 3.1 ± 0.5; p=0.05) in the Diltiazem group at 1 year follow up. The absolute peak VO2 (21 ± 4 vs. 18 ± 6 ml/kg/min; p=0.05) and normalized peak VO2 (73% ± 17% vs. 58% ± 14%; p=0.004) were significantly higher in the Diltiazem group. CONCLUSIONS: This study showed that Diltiazem treatment reduces ST, may improve cardiac allograft function and exercise tolerance during the first year after HTx.

Am J Kidney Dis. 2017 May 9. pii: S0272-6386(17)30610-8. doi: 10.1053/j.ajkd.2017.03.015. [Epub ahead of print]

Fractures and osteomalacia in a patient treated with frequent home hemodialysis.

Hanudel MR, Froch L, Gales B, Jüppner H, Salusky IB.

Bone deformities and fractures are common consequences of renal osteodystrophy in the dialysis population. Persistent hypophosphatemia may be observed with more frequent home hemodialysis regimens, but the specific effects on the skeleton are unknown. We present a patient with end-stage renal disease treated with frequent home hemodialysis who developed severe bone pain and multiple fractures, including a hip fracture and a tibia-fibula fracture complicated by nonunion, rendering her nonambulatory and wheelchair bound for more than a year. A bone biopsy revealed severe osteomalacia, likely secondary to chronic hypophosphatemia and hypocalcemia. Treatment changes included the addition of phosphate to the dialysate, a higher dialysate calcium concentration, and increased calcitriol dose. Several months later, the patient no longer required a wheelchair and was able to ambulate without pain. Repeat bone biopsy revealed marked improvements in bone mineralization and turnover parameters. Also, with increased dialysate phosphate and calcium concentrations, as well as increased calcitriol, circulating fibroblast growth factor 23 levels increased.

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FOR CASE MANAGERS

Cancer. 2017 May 11. doi: 10.1002/cncr.30765. [Epub ahead of print]

Contribution of patient, physician, and environmental factors to demographic and health variation in colonoscopy follow-up for abnormal colorectal cancer screening test results.

Partin MR, Gravely AA, Burgess JF Jr, Haggstrom DA, Lillie SE, Nelson DB, Nugent SM, Shaukat A, Sultan S, Walter LC, Burgess DJ.

BACKGROUND: Patient, physician, and environmental factors were identified, and the authors examined the contribution of these factors to demographic and health variation in colonoscopy follow-up after a positive fecal occult blood test/fecal immunochemical test (FOBT/FIT) screening. METHODS: In total, 76,243 FOBT/FIT-positive patients were identified from 120 Veterans Health Administration (VHA) facilities between August 16, 2009 and March 20, 2011 and were followed for 6 months. Patient demographic (race/ethnicity, sex, age, marital status) and health characteristics (comorbidities), physician characteristics (training level, whether primary care provider) and behaviors (inappropriate FOBT/FIT screening), and environmental factors (geographic access, facility type) were identified from VHA administrative records. Patient behaviors (refusal, private sector colonoscopy use) were estimated with statistical text mining conducted on clinic notes, and follow-up predictors and adjusted rates were estimated using hierarchical logistic regression RESULTS: Roughly 50% of individuals completed a colonoscopy at a VHA facility within 6 months. Age and comorbidity score were negatively associated with follow-up. Blacks were more likely to receive follow-up than whites. Environmental factors attenuated but did not fully account for these differences. Patient behaviors (refusal, private sector colonoscopy use) and physician behaviors (inappropriate screening) fully accounted for the small reverse race disparity and attenuated variation by age and comorbidity score. Patient behaviors (refusal and private sector colonoscopy use) contributed more to variation in follow-up rates than physician behaviors (inappropriate screening). CONCLUSIONS: In the VHA, blacks are more likely to receive colonoscopy follow-up for positive FOBT/FIT results than whites, and follow-up rates markedly decline with advancing age and comorbidity burden. Patient and physician behaviors explain race variation in follow-up rates and contribute to variation by age and comorbidity burden.

Arthritis Res Ther. 2017 May 12;19(1):90. doi: 10.1186/s13075-017-1299-8.

Comprehensive analysis of treatment response phenotypes in rheumatoid arthritis for pharmacogenetic studies.

Standish KA, Huang CC, Curran ME, Schork NJ.

BACKGROUND: An individual patient's response to a particular drug is influenced by multiple factors, which may include genetic predisposition. Pharmacogenetic studies attempt to discover and estimate the contributions of genetic variants to the variability in response to a drug treatment. The task of identifying the genetic contribution is often complicated by response phenotypes that are based on imprecise or subjective clinical observations. Because the success of a pharmacogenetic study depends on the analysis of a heritable phenotype, it is important to identify phenotypes with a significant heritable component to ensure reliable and reproducible results in subsequent genetic association studies. METHODS: We retrospectively analyzed data collected from 436 rheumatoid arthritis patients treated with golimumab during the phase III GO-FURTHER study. We investigated the reliability of several potential response outcomes after golimumab treatment. Using whole-genome sequencing of the clinical trial cohort, we estimated the heritability of each potential outcome measure. We further performed a longitudinal analysis of the clinical data to estimate variability of outcome measures over time and the degree to which each response metric could be confounded by placebo response. RESULTS: We determined that the high degree of within-patient variation over time makes a single follow-up visit insufficient to assess an individual patient's response to golimumab treatment. We found that different potential response outcomes had varying degrees of heritability and that averaging across multiple follow-up visits yielded higher heritability estimates than single follow-up estimates. Importantly, we found that the change in swollen and tender joint counts were the most heritable outcome metrics we tested; however, we showed that they are also more likely to be confounded by a placebo response than objective phenotypes like the change in C-reactive protein levels. CONCLUSIONS: Our rigorous approach to finding robust and heritable response phenotypes could be beneficial to all pharmacogenetic studies and may lead to more reliable and reproducible results.

Dramatic Rise in Hepatitis C Cures While Number of Cases Increases Sharply

Data from the Veterans Affairs show that cures for hepatitis C are occurring at an increased rate with new antiviral drugs. The cure rate rose from a low of 19.2% in 1999 to 36% in 2010 to 90.5% in 2015. Unfortunately, the rate of infection has tripled from 2010 to 2015, according to the Centers for Disease Control and Prevention (CDC). The highest rates of infection are among 20- to 29-year-olds who inject drugs. The current opioid crisis is fueling this rise in hepatitis C infection rates. The areas hardest hit are parts of Appalachia and rural areas of the Midwest and New England. Indiana, Kentucky, Maine, Massachusetts, New Mexico, Tennessee, and West Virginia have rates twice the national rate. ■

Helping the Hearts of Patients With Type 2 Diabetes

Curtis Triplitt, PharmD, associate professor of medicine at the University of Texas Health Science Center, presented during a symposium at the AMCP Annual Meeting 2017. The topic was cardiovascular risks in patients with type 2 diabetes. He presented information to support patient-centered strategies in minimizing cardiovascular risks in patients in a managed care setting. Included in his talk were the components of patient-centered care, including diabetes self-management education, team-based care, case management, and cardiologists and endocrinologists who function as part of the team. For more, check Managed Health Care Connect. ■

Drug Addiction Treatment at Home

Forty percent to 60% of people with drug addictions relapse, according to the National Institutes of Health. One problem with current treatment is that addiction is treated as an acute problem instead of a chronic problem that needs ongoing treatment. Aware Recovery Care is a Connecticut-based in-home drug treatment program with results that are about twice the sobriety rate of inpatient treatment. Currently, the program is only available to private-pay clients or those covered by Anthem insurance. ■

Palliative Nursing Summit

In May 2017, the American Nurses Association joined members of 25 other nursing organizations at the Palliative Nursing Summit. Recommendations from the Summit are available from the ANA. ■

BETTER CARE FOR PATIENTS WITH IBD

At Digestive Disease Week 2017, researchers Juan Nicolas Peña-Sánchez, MD, MPH, PhD, clinical assistant professor at the University of Saskatchewan, and colleagues presented an integrated care model for management of inflammatory bowel diseases (IBD) like Crohn's disease and ulcerative colitis.

These IBD care models include multidisciplinary teams of gastroenterologists, IBD nurses, psychologists, and dietitians to ensure diagnosis, care, management, and follow-up. Read more about their presentation at Managed Health Care Connect. ■

Easing Loneliness in Seniors

A study on loneliness among seniors by Louise Hawkley, a senior research scientist at the National Opinion Research Center (NORC) at the University of Chicago, points out that only 30% of seniors feel lonely, and that the state is usually transient, not permanent. It is usually more severe among the oldest old. The best way to help alleviate loneliness is to enable the senior to interact with other people and to help eliminate discord and disturbances in family relationships. ■

PPIS AND CKD CONNECTION

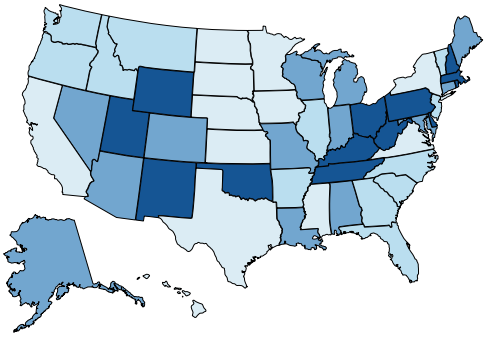
Research is suggesting a correlation between the long-term use of proton pump inhibitors (PPIs) and chronic kidney disease (CKD). The risk increases 50% in people who have taken the drugs versus those who have not. Furthermore, studies have shown that PPIs are overprescribed by 66%. Many patients take these drugs for months or years. For more information see the JAMA study and the study reported in the *Journal of the American Society of Nephrology*. ■

Keeping Up With Diabetes Care

The 2017 Standards of Medical Care in Diabetes emphasize psychological health, access to care, expanded and personalized treatment, and hypoglycemia tracking. New in this year's standards is a report titled "Differentiation of Diabetes by Pathophysiology, Natural History and Prognosis." ■

THE OPIOID EPIDEMIC BY THE NUMBERS

Drug overdose death rates, United States, 2014*



Drug overdose deaths per 100,000 population

6.3–11.7	11.9–14.4	15.1–18.4	19–35.5

*Age-adjusted death rate per 100,000 population

Source: CDC National Vital Statistics System

On an average day in the U.S.:

- More than 650,000 opioid prescriptions dispensed[1]
- 3,900 people initiate nonmedical use of prescription opioids[2]
- 580 people initiate heroin use[2]
- 78 people die from an opioid-related overdose**[3]

**Opioid-related overdoses include those involving prescription opioids and illicit opioids such as heroin

1. IMS Health National Prescription Audit
2. SAMHSA National Survey on Drug Use and Health
3. CDC National Vital Statistics System

TBI and Aggression

People who have traumatic brain injury (TBI) and show aggression and new-onset depression within 3 months of injury are more likely to continuing experiencing post-TBI aggression for a year or more. Researchers whose study was published in the *Journal of Neuropsychiatry and Clinical Neurosciences* note that evaluation of psychosocial and psychiatric disease burden in early TBI may help to prevent aggressive behavior in the future. Most of the aggression was verbal, but physical aggression toward self, others, or objects was also observed. Overall rates of aggression were 34.3% at 3 months, 41.1% at 6 months, and 38% at 12 months. Poor social functioning at 3 months had a close association with aggression at 12 months. Researchers call for effective and early screening for new-onset depression among those with TBI. ■

What Is Disaster Case Management?

The US Office of Human Services Emergency Preparedness and Response has developed a Disaster Case Management Program (DCM). The time-limited process involves a partnership between a case manager and a disaster survivor to design and implement a Disaster Recovery Plan. More information can be found from the U.S. Department of Health & Human Services. ■

Is There a Connection Between Antidepressant Use and Decreased Mortality?

A large study from Israel encompassing 53% of the nation's population and published in the *Journal of Clinical Psychiatry* suggests that people who regularly take prescribed antidepressants are less likely to die of any cause in a 4-year period. ■

Teens at Risk for Depression

The National Institute of Mental Health (NIMH) says up to 1 in 12 American teenagers suffers from depression, and 3 times as many will experience depression by age 18. Depression is twice as common in teen girls as it is in teen boys and often coincides with behavioral, attention, and learning disorders. These depressed teans go on to become depressed college students who drop out and/or later develop major depression, anxiety disorders, and eating disorders. They are more likely to smoke, self-medicate with alcohol and drugs, and engage in other risky behaviors. Risks are elevated among those with a family history of depression, who have faced difficult life events (loss, divorce, academic/social pressures, health problems, chronic or significant stress), or who have low self-esteem or a pessimistic outlook on life. ■

continued from page 23

Tymlos compared to placebo was 43% (logrank test p = 0.049) and the absolute risk reduction was 2.0%.

Following 6 months of alendronate treatment in Study 005, the cumulative incidence of nonvertebral fractures at 25 months was 2.7% for women in the prior Tymlos group compared to 5.6% for women in the prior placebo group. At 25 months, the relative risk reduction in nonvertebral fractures was 52% (logrank test p = 0.017) and the absolute risk reduction was 2.9%.

Tymlos demonstrated consistent reductions in the risk of vertebral and nonvertebral fractures regardless of age, years since menopause, presence or absence of prior fracture (vertebral, nonvertebral) and BMD at baseline.

Effect on Bone Mineral Density (BMD)

Treatment with Tymlos for 18 months in Study 003 resulted in significant increases in BMD compared to placebo at the lumbar spine, total hip and femoral neck, each with p<0.0001. Similar findings were seen following 6 months of alendronate treatment in Study 005. Tymlos demonstrated consistent increases in BMD regardless of age, years since menopause, race, ethnicity, geographic region, presence or absence of prior fracture (vertebral, nonvertebral), and BMD at baseline.

Effect on Bone Histology

Bone biopsy specimens were obtained from 71 patients with osteoporosis after 1–18 months of treatment (36 in the Tymlos group and 35 in the placebo group). Of the biopsies obtained, 55 were adequate for quantitative histomorphometry assessment (27 in the Tymlos group and 28 in the placebo group). Qualitative and quantitative histology assessment showed normal bone architecture and no evidence of woven bone, marrow fibrosis, or mineralization defects.

HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

Tymlos injection is supplied as a pre-assembled single-patient-use disposable pen packaged in a cardboard carton with the Instructions for Use and Medication Guide. Each disposable pen embodies a glass cartridge that contains 3120mcg of abaloparatide in 1.56 mL (2000 mcg/mL) of sterilized, clear, colorless fluid. Each pen provides a 30-day supply for once daily injection of 80 mcg

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Alzheimer's Disease: A Case Management Challenge

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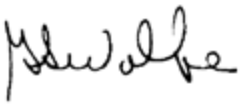
developed. The plan may include: 1) drug therapy: cholinesterase inhibitors and/or N-methyl D-aspartate antagonists to improve thought processes and slow the rate of cognitive decline; 2) management of comorbid conditions; 3) treatment of behavioral symptoms and mood disorders; 4) support and resources for patient and caregivers; 5) durable power of attorney for healthcare; 6) planning for changing care needs over the course of the disease; 7) preferences for end-of-life care.

Current Alzheimer's disease medications and management strategies may temporarily decrease symptoms and may help people with the disease maximize function and maintain independence for a little longer. Because there is no cure for Alzheimer's disease, it is important to seek supportive services as early as possible.

Having a case manager assigned to a patient with Alzheimer's disease early in the course of the disease can ensure that the patient receives the best care management plan possible. It is important to have a care management plan in place early and to work with the patient and the patient's caregivers to develop a plan, to educate and provide resources, to have support in place when needed, and to work with the patient and family to achieve their wishes.

Although Alzheimer's disease is devastating, having a care management plan in place can help patients manage this disease and maximize their care.



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ACCM: Improving Case Management Practice through Education

Aging Population Needs CCM and CDMS Expertise

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offered after maternity leave might be applicable to an older worker who needs to address health concerns or who can no longer handle full-time job stresses. At the same time, part of advocacy means helping employees to set reasonable expectations and avoid projecting a sense of entitlement. Not every work environment is the same, and state-mandated benefits vary.

Together, case management and disability management services offer a roadmap of solutions for the employer and the employee. By becoming more familiar with the cross-discipline expertise available, CCMs and CDMSs can work together to support people's health and wellness; they can help them pursue their goals of remaining in the workforce while ensuring that their employer stays compliant with all applicable federal, state, and local regulations and maintains a productive workforce. CM

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abaloparatide in 40 mcL.

Sterile needles are not included.

Storage and Handling

- Before first use, store Tymlos in a refrigerator between 2°C to 8°C (36°F to 46°F).
- After first use, store for up to 30 days at 20°C to 25°C (68°F to 77°F).
- Do not freeze or subject to heat.

Tymlos pen can be used for up to 30 days, and after the 30-day use period, to discard the Tymlos pen, even if it still contains unused solution.

Tymlos is distributed by Radius Health, Inc.

CE II Coming Full Circle: Multidirectional Communication Medical and Behavioral Health Services and the Patient

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Part 5: Case Management Society of America Issues Revised Standards of Practice: Components of the Case Management Process

continued from page 6

- Ongoing follow-up with clients, their families and other caregivers, and evaluation of clients' status, goals, and outcomes
- Monitoring activities, such as assessing clients' progress with planned interventions
- Evaluating care goals and interventions to help ensure that they remain appropriate, relevant, and realistic
- Determining if any revisions or modifications are needed to case management plans of care

Closure of professional case management services includes:

- Mutually agreeable closure to client-case manager relationships and engagement in case management
- Helping to ensure that case closure occurs when clients have attained the highest level of functioning and recovery, the best possible outcomes or when the needs and desires of clients have changed

In short, it's a tall order to meet these standards! But the role of case managers is so crucial for patients and providers that the demands of the discipline are definitely warranted. CM

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