CareManagement

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

Vol. 24, No. 3 June/July 2018

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By Stacey Rice, BSN, RN, CRRN, CCM

The right home health care provider can be your eyes and ears, partnering with you to closely monitor your client's progress, track measurable outcomes, communicate updates, and implement requests from you, your client's doctors, and their family. This article is an insider's glimpse into the world of home health care services that is intended to help you more quickly and easily navigate available resources and their processes to find the best solutions for your clients.

17 Independent Case Managers—Why Are They Necessary? CE

By Michelle Greene Rhodes, MHS, RN, CCM, CMCN

In a health care network that is vast and complex, the independent case manager helps facilitate conversations. This includes the initial conversations that take place with doctors and caregivers as well as the follow-up conversations with family members about the next steps and the best options for the long run. Independent case managers are also essential when it comes to coordinating with the health care team.

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Gary S. Wolfe

Working with Home Health Care Agencies

Home health care can play a vital role in a case management plan. It is important for the case manager to know how and when to utilize home health care to achieve the desired outcomes. Home health care provides a variety of medical services in a patient's home for individuals who are recovering from an illness or injury, who are living with a chronic disease or disability, or who are in declining health because of aging. Typically home health care is intermittent and has a time limit.

Home health care can bring many benefits to a patient and family. Some of these benefits include:

- Shortened length of hospital stay
- Reduced stress caused by hospitalization
- Reduced rehospitalizations
- Contagious infections less likely to spread
- More affordable than inpatient care
- Increased personal freedom and independence
- More patient accessibility to family and friends

Important considerations for working with a home health care agency include safety, credentialing, monitoring, quality, and outcomes. The first issue to consider when determining whether home health care is a patient's best option is safety. Is the patient safe to be home? Is the care needed safe to be provided in the home? If the answer to either of these questions is no, home health care is not indicated for this patient. But if the answer to both questions is yes, then selecting the home health care agency is the next step.

Although a health plan may specify which home health care agencies are available for a patient, ultimately the choice is up to the patient. Patients use various home health care agencies for many reasons: they have used a particular home health care agency in the past; the agency is recommended by their physician, the hospital, the discharge planner, or the case manager; the agency is in-network for their health plan; or they know an employee at the home health care agency. Once any agency has been selected, it is important that the case manager review the agency's credentials.

Even if the home health care agency is in-network for the health plan and has been selected by the patient, it is the case manager's responsibility to make sure this particular home health care agency is appropriate for this patient's needs. Some basic questions should be asked:

- Is the agency licensed and accredited? Most states require licensing.
- Is the agency certified by Medicare? (Even if your patient is not a Medicare recipient, Medicare certification is a good benchmark.)
- What services are provided?
- How are employees hired, trained, and supervised?
- What is the staff turnover rate?
- Does the agency have an effective quality improvement/program improvement program?
- How are patient complaints handled?
- Is someone available 24/7 for patient issues?

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Vol. 24, No. 3, June/July 2018. *CareManagement* (ISSN #1531-037X) is published electronically six times a year, February, April, June, August, October, and December, and its contents are copyrighted by Academy of Certified Case Managers, 2740 SW Martin Downs Blvd. #330, Palm City, FL 34990; Tel: 203-454-1333; Fax: 203-547-7273.

Subscription rates: $120 per year for ACCM members; $150 for institutions.

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CareManagement is indexed in the CINAHL® Database and Cumulative Index to Nursing & Allied Health Literature™ Print Index and in RNdex.™

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Informed Advocacy:

Empowering Knowledge For Case Managers and Those They Serve

By Chikita B. Mann, MSN, RN, CCM, *Commissioner, Commission for Case Manager Certification*

Advocacy is the heart of case management practice. The Code of Professional Conduct for Case Managers from the Commission for Case Manager Certification (CCMC's Code) states that "case management is a means for improving client health, wellness and autonomy through advocacy, communication, education, identification of service resources, and service facilitation." Board-certified case managers are obliged to adhere to the rules and standards of the Code as they provide access to the right care and treatment at the right time, in support of goals set by the individuals they serve.

Advocacy is most effective when case managers have full knowledge of the regulations, laws, and guidelines that impact their practice.

Advocacy is most effective, of course, when case managers have full knowledge of the regulations, laws, and guidelines that impact their practice. This is what I've come think of as "informed advocacy." With informed advocacy, knowledgeable case managers can empower themselves with evidence-based best practices as they also empower their clients (known in some practice settings as "patients") and their support systems/families.

My specialization of workers' compensation case management is impacted by regulations that differ from state to state; therefore, as an informed advocate, I must stay up-to-date with regulatory changes that affect workers' compensation cases. Similarly, disability case managers and certified disability management specialists (CDMSs) must know workplace laws and regulations (both federal and state) such as the Family Medical and Leave Act (FMLA) and the Americans with Disabilities Act (ADA). (CDMSs are also governed by their own Code.) Case managers in acute care, primary care, and other settings need to be well versed in Medicaid and Medicare rules, such as those impacting reimbursement.

For all case managers across the health and human services spectrum, there are rules and standards for professional and ethical practice: CCMC's Code and the Standards of Practice for Case Management from the Case Management Society of America (CMSA's Standards). In addition, each of our professional disciplines, such as nursing, social work, and vocational rehabilitation, have codes of ethics and practice standards. Combined, these standards and rules allow us to practice at the top of our certification and licensure to advocate for and protect consumers of case management services.

Informed Advocacy in Action

Here are five ways informed advocacy can help elevate case management practice:

1. **Advocate for what the law (or coverage) allows:** Workers' compensation provides an excellent illustration of informed advocacy in action. State regulations stipulate eligibility for certain types of services and interventions and under what circumstances or conditions. For example, if a person is unable to return to his or her job because of a permanent disability resulting from a work-related injury or illness, state law may allow that individual to receive vocational training. With this information, case managers can help open more possibilities for a

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Chikita Mann, MSN, RN, CCM, is a commissioner of the Commission for Case Manager Certification (CCMC), the first and largest nationally accredited organization that certifies case managers, and chair of the CCMC Ethics Committee & Professional Conduct Committee. She is also a disability RN case manager for GENEX Services Inc., for the State of Georgia, and she is responsible for workers' compensation, short- and long-term disability, and legal nurse consulting. She is a member of the Honor Society of Nursing, Sigma Theta Tau International. Her areas of expertise are cultural competency, workers' compensation case management, medication reconciliation, and virtual case management. She has a blog called "Case Management 411" that explores issues that directly and indirectly affect care coordination.

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Informed Advocacy: Empowering Knowledge For Case Managers and Those They Serve *continued from page 4*

person who is adjusting to a life-altering illness or injury. Accessing vocational services can expand a person's skills, improve employability, and increase self-esteem. Similarly, a disability case manager can investigate what resources might be available through the employer's Employee Assistance Program (EAP). Certified disability management specialists explore return-to-work and stay-at-work options to help ill/injured employees, pending medical approval, remain productive as they heal. Case managers in acute care, primary care, or similar settings can identify treatment options that are covered by the individual's health plan as well as community-based resources. Across the health and human services spectrum, informed advocacy is grounded in the knowledge of what the regulations and/or insurance coverage allow.

2. **Understand regulatory and insurance coverage limitations.** There are times, however, when the individual cannot access a certain resource or provider. With a workers' compensation case, it may be a state law limitation. For nonoccupational illnesses and injuries, the person's health insurance plan may not cover a particular treatment option, or a provider may be out of network, which poses a financial burden beyond the person's means. While these limitations may feel like restrictions, they can actually empower the case manager's advocacy by channeling efforts into what is allowed. The case manager can present the options available to empower the individual and his/her support system in making informed decisions in support of their goals.
3. **Keep ethics and standards top of mind**. CCMC's Code and CMSA's Standards should be reviewed regularly—not just when a problem or dilemma arises. I suggest my staff do so about every 3 months. Case managers should also review the standards and ethics of their professional discipline, such as nursing, social work, vocational rehabilitation, or other fields. Keeping these standards fresh in one's mind improves knowledge and instills confidence when interacting with other health and human services professionals as part of interdisciplinary teams.
4. **Ask questions, seek clarifications.** When confronted with an ethical dilemma or managing a complex case in which there may be conflict among the stakeholders, case managers should never feel as if they are going it alone. Help is available. For example, a case manager who was new to workers' compensation practice was asked by an insurance carrier if she could deliver a recording of surveillance activity of an injured employee to the attending physician. The case manager was asked because she had regular face-to-face contact with the physician. The case manager was not comfortable with the request and came to me, as her supervisor, for clarification. I explained that the workers' compensation board in our state prohibits any rehabilitation supplier (ie, case manager) from participating in surveillance activity of any type or from delivering or viewing any surveillance footage. In addition, our company policies prohibit case managers from participating in any type of surveillance activity. This clear-cut information supported the case manager and provided clear language on how to respond to the insurance company's request.

   As this example shows, in the midst of an ethical dilemma or complex situation, case managers should reach out to a supervisor, a more experienced peer, and/or the ethics panel at their workplace. Consult CCMC's Code, CMSA's Standards, and the case management employer's company policies. If all other resources have been exhausted, an advisory opinion can be requested from CCMC's Ethics Committee.
5. **See rules and laws as informative, not punitive.** Rules do not restrict, they protect. Like the guardrails on a highway, they show the way to go and avoid danger or difficulty. State laws and regulations, the Code and Standards for case management practice, and professional discipline guidelines exist to protect the practitioner and those they serve. To be an informed advocate, case managers must regularly revisit these resources as helpful guides to support ethical practice.

Advocacy reminds all case managers why we practice: to serve those who benefit most from case management services. It is up to each individual case manager to stay informed of the rules and regulations governing case management practice and their particular specialization. By knowing the parameters of eligibility for services under state law or insurance coverage, and where and how to "make the case" for our clients, we are more effective as informed advocates and uphold the integrity of our practice. CM

Here are five ways informed advocacy can help elevate case management practice:

- Advocate for what the law (or coverage) allows
- Understand regulatory and insurance coverage limitations
- Keep ethics and standards top of mind
- Ask questions, seek clarifications
- See rules and laws as informative, not punitive

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Listen to Patients and Their Families: Dead People Don't Move or Do They?

By Elizabeth Hogue, Esq.

On January 31, 2018, The *Washington Post* reported on the case of Michael Cleveland in an article entitled "'Dead People Don't Move: Buffalo Doctor Pronounced a Living Man Dead, Says Family'" by Kyle Swenson.

For 2 hours and 40 minutes after Mr. Cleveland was pronounced dead in the emergency room (ER) at a hospital in Buffalo on October 10, 2014, his grieving family saw signs of life in the body of the 46-year-old man. His tongue tried to push out an endotracheal tube inserted down his throat. His chest continued to rise and fall. His knees bent and then straightened again.

Cleveland's wife and other family members repeatedly asked an ER physician to recheck the patient and he repeatedly refused.

Finally, the coroner arrived to collect the body and was completely "unnerved" by Cleveland's condition. "Dead people don't move," the coroner protested to the doctors and nurses at the hospital as he urged them to check the patient's pulse.

Finally, a family member drew a doctor's attention to a vein throbbing in Cleveland's neck and pointed out that it was a pulse.

The doctor checked the patient's pulse and said, "Oh my God. He's alive." The patient's wife responded as follows: "No s____. I have been telling you that for hours."

Unfortunately, Cleveland passed away hours later after transfer to another hospital.

Regardless of practice setting, practitioners must listen intently to patients/clients and their caregivers in order to provide quality of care and manage risks.

Cleveland's family sued. No surprise there! The case is still pending.

But here's what is especially important for all practitioners to hear: The physician made at least 5 visits to the patient's cubicle in the ER and brushed off the family's assertions that the patient was still alive each time. The family said that the doctor seemed "irritated."

"He didn't take the time for me at all," Cleveland's wife said. "He just told me that my husband passed. He couldn't just come in there and show that he was dead. He couldn't take a second and put a stethoscope on him and prove to me that he wasn't breathing. I don't understand that. Why wouldn't you do that to appease a grieving widow at that time, instead of walking in there nonchalant and give me your two cents acting like I was crazy?"

The crucial point for practitioners illustrated by this case is that they must listen carefully to everything patients/clients and their caregivers say. They may not express themselves in clinical language! They may be dead wrong! They may be irritating! But practitioners need to listen anyway because it will likely assist them to provide better care for patients.

In her book entitled "Every Patient Tells a Story: Medical Mysteries and the Art of Diagnosis," Dr. Lisa Sanders makes the point that practitioners must listen to what patients say because paying attention often leads to accurate diagnosis and/or better quality care. Mr. Cleveland and his family would certainly agree!

So, regardless of practice setting, practitioners must listen intently to patients/clients and their caregivers in order to provide quality of care and manage risks. CM

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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We Are Case Management in Chicago

By Kathleen Fraser, RN-BC, MSN, MHA, CCM, CRRN, CMSA Executive Director

Our beloved CMSA Annual Conference & Expo is upon us again, and in our 28th year we are headed to vibrant and energetic Chicago! This conference is where I always find myself inspired by our ever-growing community, and I am also impressed watching the progress of capable and highly educated case managers over the course of their careers. Between packed educational days and networking events, it's a time to unwind, reconnect, and remember the reasons why we became case managers.

On June 19–23, 2018, we pack an educational punch with concurrent blocks, keynote presenters, and preconference opportunities, offering up to 37.5 CEs in total. Eight concurrent session tracks feature leadership, acute care, long-term care, workers' compensation, disease-specific, legal, managed care, and population health case management.

While our educational offerings are enough reason to attend, we are honored to welcome back over 250 exhibitors and dozens of sponsors to the Expo Hall. From hospitals to hospice and everything in between, our 3-day expo offers new knowledge, connections, and hundreds of fabulous giveaways for case managers in every practice setting and career stage. If you're planning to attend, please be sure to participate in our expo hall hours and to talk to our exhibitors and thank them for supporting this conference year after year. Without them, this event would not be possible.

Our beloved CMSA Annual Conference & Expo is upon us again, and in our 28th year we are headed to vibrant and energetic Chicago!

CMSA is bringing an exciting and inspiring group of keynote speakers to Chicago. This year's lineup includes Dr. Travis Stork, who kicks off our keynote series on Thursday. Dr. Stork will share personal stories about his upbringing in the Midwest, his fascinating work as an emergency room physician, and his unique perspective as host of the Emmy Award-winning daytime hit *The Doctors*.

In addition, decorated Army officer and distinguished neurosurgeon, Dr. Allan Hamilton, will join us on Friday to discuss the underlying causes of the changes happening in healthcare and the transformative forces most likely to affect healthcare. He will share how we, as case managers, can negotiate these forces to help create a more empathetic healthcare delivery system that not only improves the quality of patients' lives but also of the healthcare professionals who work in the system.

And last but certainly not last is the award-winning journalist, Dr. Rick Rigsby, who closes out our 2018 keynote series on Saturday with an inspiring presentation on how to make an impact, not just an impression, in a career. Dr. Rigsby argues that for many organizations, appearance—or what he refers to as impression—has become the new corporate wardrobe. Attendees will consider what is really important and meaningful—not only in one's professional career but in one's personal life as well.

We're presenting some unique new opportunities this year, such as a peer-to-peer networking session where you can connect with fellow case managers from your state, practice setting, or discipline over coffee. And as always, our signature opening night event will not disappoint, presenting a "taste of Chicago" for dinner and camaraderie that cannot be replicated elsewhere in our industry.

If you're reading this before June 19, there's still time to register,

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Kathleen Fraser, RN-BC, MSN, MHA, CCM, CRRN, *is the Executive Director of the Case Management Society of America.*

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CE I

Simplifying Continuity of Care: The Home Health Care/Case Manager Partnership

By Stacey Rice, BSN, RN, CRRN, CCM

When it's time for your client to be discharged from acute care to home, there are a lot of moving parts that will predict successful outcomes—including medications, medical or assistive equipment, transportation, doctor appointments, home modifications and other safety precautions, staffing for clinical or assistive care, monitoring, and recordkeeping for any changes in condition.

It's a lot of keep track of, and as a case manager, you can't always be there with eyes and ears on the ground. However, the right home health care provider can be your eyes and ears, partnering with you to closely monitor your client's progress, track measurable outcomes, communicate updates, and implement requests from you, your client's doctors, and their family. The following is an insider's glimpse into the world of home health care services that is intended to help you more quickly and easily navigate available resources and their processes to find the best solutions for your clients.

Engaging Home Health Care Services

Transitional Care Managers

Transitional care managers (TCMs) simplify the continuity of care by serving as one point of contact for the case manager, family, and local home health care service office. Most hospitals now have TCMs onsite, and they are a terrific resource to help identify patients being discharged who will need home health care services and to help coordinate their smooth and safe transition back home. A good TCM can be a case manager's best friend, taking on mutually important tasks like getting medical authorizations and communicating with commercial and workers' compensation insurance carriers.

As part of my role as a director of transitional care and case management for a leading home health care company, I help train, develop, and support onsite TCMs for adult patients in most major health care systems in New Jersey, Pennsylvania, and North Carolina. In my experience, I've found that many case managers are not aware of the large number of home care options. Most case managers don't realize that most care plans—including high-tech plans of care—can be implemented in the comfort of home or that we can provide the same levels of quality physical, occupational, and speech therapies available in rehabilitation facilities. As a unique benefit, one-on-one attention and care coordination in the home ensures that your client receives the right care from the right provider at the right time, without duplication.

> **The right home health care provider can be your eyes and ears, partnering with you to closely monitor your client's progress, track measurable outcomes, communicate updates, and implement requests from you, your client's doctors, and their family.**

If you have a question about whether your client is a good candidate for home health care, ask a TCM. They can determine if an individual can be served safely at home or if they should be in a hospital or other facility. For example, a TCM will recognize red flags like invasive monitoring or certain cardiac medications and can ensure that the home environment is clean and safe enough for staff and family to provide care.

Transition

Based on my organization's best practices and processes, I can illustrate how a partnership with a high-quality home health care company ideally should work. To initiate a referral, contact your onsite TCM or home care agency's customer care center. They will ask for

Stacey Rice, BSN, RN, CRRN, CCM is the Southeast regional director of adult transitional care and case management at BAYADA Home Health Care (www.bayada.com). She has more than 20 years of nursing experience and specializes in complex case management as a Certified Rehabilitation Registered Nurse for BAYADAbility Rehab Solutions.

demographic and payer information, a brief clinical report, and the specific home care services requested. In turn, they will reach out to the appropriate service office and initiate discussions to determine if the local office will be able to accept the case.

Helpful information to share at this time is the availability of family caregivers, along with any information you may have on the family dynamics or home environment. If you have questions about funding sources or need to verify individual benefits, the agency can assist with that.

Once it has been determined that your patient has benefits to cover the services requested, enlist the help of your TCM or home care team member to move forward with care coordination. They can help with authorization paperwork and answer clients' questions. Your TCM or agency liaison will be in regular contact with you about the coordination of your client's home care and benefits before discharge. Invite your TCM to attend discharge meetings in the hospital; they are a wealth of information about what services can be provided safely at home.

This is a great time for discussing medications, medical equipment, and storage ideas for supplies, so everyone is as prepared as possible to ensure a smooth and safe transfer.

If a home assessment was not performed before discharge, an RN clinical manager from the home care agency will complete it along with a physical assessment and review of medications and physician orders. The nurse will speak with the family to determine their comfort level and availability to provide necessary care and discuss staffing schedules.

Ongoing case management

As illustrated in Figure 1, there are specialty practices in home health care that operate slightly differently to meet client needs and abide by payers' expectations and guidelines. In all specialties, the care provided and the client's health condition and progress are documented in a medical record after each visit, and an RN clinical manager will continuously communicate with in-home clinicians, physicians, and the client's external case manager, if they have one.

You can create a communication schedule with your home care provider that works for you and your insurance sources. Typically, a home health care office sends updates to their client's insurance case manager on a monthly basis. If it is a workers' compensation case, the home care office sends weekly notes to the network manager.

Scope of work and early interventions

Depending on the insurance source, clients receiving home health care services may be subject to specific requirements.

FIGURE 1 **TYPES OF HOME CARE**

Personal Care and Companionship

Help at home with everyday activities like bathing and dressing, meal preparation, and household tasks to enable independence and safety

Also known as...

Non-medical care, home health aide services, senior care, homemaker care, assistive care, or companion care

Private Duty Nursing Care

Long-term, hourly nursing care at home by RNs and LPNs for adults with a chronic illness, injury, or disability

Also known as...

Home-based skilled nursing, long-term nursing care, catastrophic care, tracheostomy care, ventilator care, nursing care, shift nursing, hourly nursing, or adult nursing

Home Health Care

Short-term, Medicare-certified physician-directed care designed to help a patient prevent or recover from an illness, injury, or hospital stay

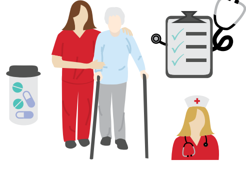
Also known as...

Medicare-certified home health care, intermittent skilled care, or visiting nurse services

Examples of care services

- Assistance with self-care—grooming, bathing, dressing, and using the toilet
- Enabling safety at home by assisting with ambulation, transfer (eg, from bed to wheelchair, wheelchair to toilet), and fall prevention
- Assistance with meal planning and preparation, light housekeeping, laundry, errands, medication reminders, and escorting to appointments
- Companionship and engaging in hobbies and activities
- Supervision for someone with dementia or Alzheimer's disease

- Care for diseases and conditions such as traumatic brain injury (TBI), spinal cord injury (SCI), ALS, and MS
- Ventilator care
- Tracheostomy care
- Monitoring vital signs
- Administering medications
- Ostomy/gastrostomy care
- Feeding tube care
- Catheter care



- A customized care plan based on individual needs, which may include:
- Short-term nursing services
- Physical therapy
- Occupational therapy
- Speech language pathology
- Medical social work
- Home health aide services

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Transitional care managers (TCMs) simplify the continuity of care by serving as one point of contact for the case manager, family, and local home health care service office.

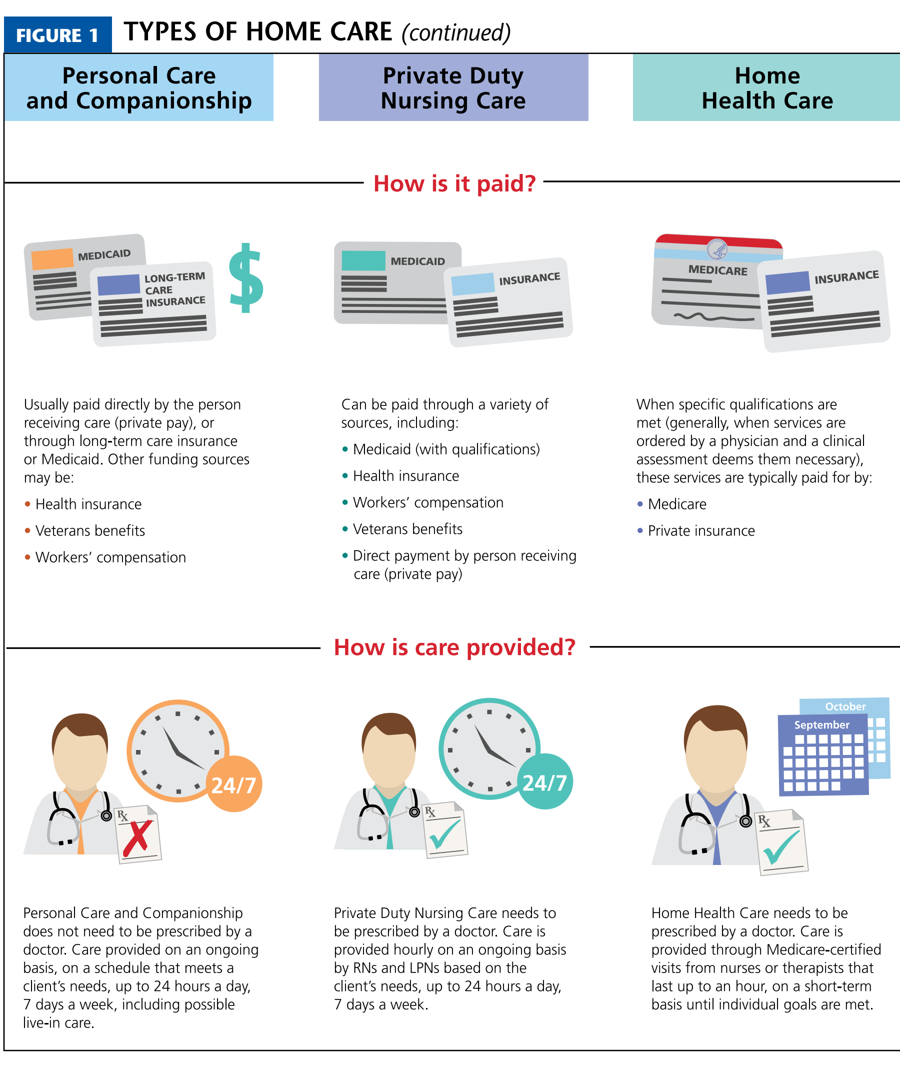

FIGURE 1 TYPES OF HOME CARE *(continued)*

For example, certain federal programs require that a trained family caregiver is living in the home. Some payers allow home nurses to drive clients where they need to go, but others do not. In all cases, though, home nurses are able to provide a broad range of high-quality health care services including high-tech care as long as it has been ordered by a physician, it is within their scope of practice, and it can be provided safely in the home.

If home clinicians detect a change in health condition that could put your client at risk of readmission, such as a fever or early signs of a urinary tract infection, an agency nurse can call the client's physician to get a prescription and doctor's orders to immediately start the new medication. Quick interventions like these go a long way to prevent potential health problems before they become serious.

Emergencies and readmissions

Client safety always comes first. If an emergency arises at home, 911 is activated and all parties involved are notified. The nurse in the home can provide emergency medical services with the current plan of care and often accompanies the client to the hospital to answer any questions.

If a client's condition is progressively deteriorating, proactive steps can be taken to notify the physician and network case managers to determine the best course of action. This allows for any authorizations to be obtained before sending the client to urgent care or an emergency department.

If the client is hospitalized, the home care office will notify the TCM. The TCM will follow the client in the hospital and be your point of contact for progress notes and a discharge plan. The TCM will notify the home care service office of any changes in care upon discharge and ensure that staff is able to care for the client's needs when they return home.

Best Practices In Home Health Care

What to look for in a home health care provider

In addition to the basic checklist in Figure 2, make sure you choose a home care provider with age- and diagnosis-specific expertise to meet your client's special needs. I would also recommend finding a provider who offers a broad range of nursing,

FIGURE 2 CHECKLIST FOR CHOOSING A HOME HEALTH CARE PROVIDER

SERVICES:	
Both assistive care (hourly and live-in) and nursing services based on clients' needs	❑
Free, confidential assessment by a registered nurse (RN)	❑
Assessment-based care plans written by RNs in collaboration with client and family	❑
Regular RN supervision and support of employees in clients' homes	❑
GUARANTEES	
No contracts	❑
No cancellation fees	❑
Caregivers are employees—not contractors—of the provider	❑
Employees fully insured for liability and worker's compensation	❑
CREDENTIALS	
Community Health Accreditation Program (CHAP) accredited	❑
State licensed	❑
Medicare-certified and Medicaid-approved	❑
HIRING AND TRAINING STANDARDS	
Personal interviews	❑
Reference checks	❑
Criminal background checks	❑
Competency evaluation and testing	❑
Ongoing education and training (including in dementia and rehabilitation)	❑
DOCUMENTATION	
Clients' rights and responsibilities	❑
Privacy notices	❑
CUSTOMER SERVICE	
Bills clients' insurance directly	❑
On call 24 hours a day, 7 days a week	❑
Ongoing client satisfaction surveys	❑

therapeutic, and assistive care services. Although you may not need them all now, if your client's needs change, it will be easy to add services, amend a comprehensive plan of care, and rely on one point of contact to coordinate multiple service lines.

Quality standards can vary greatly in this industry. To give you an idea of what to look for, our agency tests the competency and skills of all potential employees, and once they are hired we conduct ongoing in-service education, training, and quality controls. The level of training and clinical oversight we give our nurses enables us to offer the same kind of high-quality, high-tech care available in the hospital, such as feeding tubes, IV medications, respiratory therapies, and tracheostomy and ventilator care.

If your client has complex or high-tech health care needs, I would recommend asking potential providers if they offer simulation laboratory training for their employees and/or client families. Simulation laboratories have become a gold standard in clinical education, training, emergency preparedness, and case-specific skills practice. The laboratory is set up just like a client's home setting, where clinical educators work with employees or family members to practice medical interventions and train them how to quickly recognize and respond to a possible emergency using realistic, high-fidelity medical manikins. I have found that simulation laboratory training gives staff and families the added confidence to be successful in home care.

An experienced nurse preceptor should provide hands-on training and supervision in the home for employees who are new to your client's case before the newcomer is allowed to work there independently. Registered nurse clinical managers should conduct regular

If you have a question about whether your client is a good candidate for home health care, ask a TCM. They can determine if an individual can be served safely at home or if they should be in a hospital or other facility.

home visits to oversee the quality of care, and an RN familiar with your case should be available by phone 24/7 to support and answer employees' and case managers' questions.

Behavioral health needs

If your client has dementia, Alzheimer's disease, or an intellectual or developmental disability (IDD), look for professional caregivers who have the diagnosis-specific knowledge and strategies to serve them compassionately, appropriately, and effectively. Ask if employees on your client's home care team have certifications, disease education, or special training in your client's diagnosis. If you cast your net widely enough around your client's home, you may find specialized practices in behavioral health for people with autism and various IDDs or habilitation services that help people with IDD acquire, maintain, and improve skills to function as meaningfully and independently as possible at home, school, or work.

Hospice care

For clients with a determined life expectancy of 6 months or less, you can engage specialized in-home hospice services—covered by private and government insurance—that provide comprehensive end-of-life medical, social, emotional, and spiritual care for the entire family. If the client is a military veteran, ask for hospice clinicians who are trained and educated to serve veterans' unique needs related to military service, combat experience, or other traumatic events.

Catastrophic cases

High-quality, specialized care is crucial to your client's health and safety when they have a serious, life-altering injury, illness, or disability—such as traumatic brain injury, spinal cord injury, stroke, amyotrophic lateral sclerosis, or multiple sclerosis. More than 20 years ago this wasn't the case, but it's now possible to get the same high level of diagnosis-specific expertise available in a hospital or rehabilitation center in the comfort of home. In fact, with more time for one-on-one attention and intensive therapy, we have seen patients who were discharged as "maintenance only" from a rehabilitation facility make incredible progress at home with proactive and preventive health care and goal-oriented treatment.

As part of my responsibilities, I work on a team of Certified Rehabilitation Registered Nurses (CRRNs) who facilitate a national nursing rehabilitation program that supports local home care service offices across the country. We help with consultation, ongoing clinical oversight, and long-term case management, guiding local field offices to deliver comprehensive in-home solutions for people with catastrophic care needs. As a subject matter expert, a CRRN can serve as your one point of contact on a catastrophic case to help with every stage of case management, from care coordination and transitional care to ongoing rehabilitation nursing and therapy.

As you know, catastrophic cases can be at high risk for rehospitalization. Your home care provider should have the expertise to ensure that proper care and precautions are taken to avoid complications common to your client's condition, such as skin breakdown, urinary tract infection, seizure, or respiratory distress. With the know-how to monitor and recognize changes in a patient's condition, complications that could lead to hospitalization can be prevented entirely or caught and treated early before they become serious, thus lowering readmission rates and utilization costs. When compared with statistical averages, our higher level of specialized home health care saved $260,000 over 6 years for one client with spinal cord injury by preventing complications and keeping him out of the hospital.

Better Outcomes and Client Satisfaction

In today's shifting health care environment—with value-based purchasing in place and penalties for readmission—all stakeholders are challenged to be good stewards of health care dollars. Collaboration across the health care continuum to promote proper utilization of services is crucial to our mutual success. In this way, home health care and case managers are positioned to be trusted, involved, and beneficial strategic partners.

Ongoing clinical oversight in the home can ensure that the right level of care is maintained and that utilization is appropriate. Multiple research projects are underway to demonstrate the positive outcomes of home care involvement, and preliminary evidence has confirmed that home health care can

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CE II

Independent Case Managers—Why Are They Necessary?

By Michelle Greene Rhodes, MHS, RN, CCM, CMCN

The Self-Employed

I hear it often. Healthcare professionals who are either currently working on their own or who are planning on taking the next to step to self-employment wonder whether there is a market for independent case managers and whether they should focus on offering this service (See "Starting a CM Business? Here's Your To-Do List.")

This answer is a resounding "yes." The benefits of individual case management are plentiful and go beyond the particular patient and into the health care system as whole. In fact, if there were more independent case managers, our health care system would be a lot healthier, our patients would be better taken care of, health insurance premiums would be more affordable, and everyone would win.

Starting a CM Business? Here's Your To-Do List

Plan, Plan, Plan

Becoming an independent case manager requires more than simply hanging your shingle. It takes planning. These steps include:

- **Develop a detailed business plan.** Include some alternative plans in case you need them. This is the most important step in the process and is required if you need to take a loan to get started. A business plan should project 3–5 years ahead, outlining the growth plans for the company.
- **Create a financial cushion for yourself.** Most experts say a cushion of 6 months to 1 year of salary is needed.
- **Analyze the market where you plan to practice.** What is the health status and demographics of the town and county where you want to practice? Is there competition in this market? That can be an asset because others have already opened the marketplace for you.
- **Consider specialization.** Assess your expertise and interests. Then research the market and be sure there's a need for your services and that you have enough education and expertise to work in the niche.
- **Learn about business, financing, and record-keeping**. Meet with an accountant to learn about tax issues and what records to keep. An accountant can also help you determine the type of business model you should have (limited liability company, corporation, etc)—preferably one that offers the best tax advantages and shelter from personal liability. Another source of help in this area is your local Small Business Association.

The following types of business structures can be chosen:

– ***Sole proprietorship.*** You are the only owner of the company and are responsible for its assets and liabilities.

– ***Partnership.*** There are two or more people who share in the ownership. A Partnership Agreement determine the shares per partner. All rights and liabilities are shared by the partners.

– ***Corporation.*** This is sometimes referred to as a C corporation and is an independent legal entity owned by shareholders. This means that the corporation itself, not the shareholders that own it, is held legally liable for the actions and debts the business incurs. Corporations are more complex than other business structures because they tend to have costly administrative fees and complex tax and legal requirements.

– ***S Corporation.*** This is a special type of corporation created through an IRS tax election. An eligible domestic corporation can avoid double taxation (once to the corporation and again to the shareholders) by electing to be treated as an S corporation. To be considered an S Corp, you must first charter a business as a corporation in the state where it is headquartered. Having an S Corporation limits the financial liability for which you (the owner or "shareholder") are responsible.

– ***Limited Liability Companies (LLCs).*** This hybrid structure provides the limited liability features of a corporation and the tax efficiencies and operational flexibility of a partnership.

continues

Starting a CM Business? Here's Your To-Do List *continued*

   - **You'll need a *registered agent*** who will receive legal correspondence on behalf of the business. This can be an outside firm or you can be your own registered agent. If you prefer help with this, search the internet for registered agents in your state. There is usually a fee of approximately $100 for this service.
- **Select a name for your company** and file it with the Secretary of State. You'll need to do this before registering your business with the state.
- **Get to know your how state defines and regulates business models** through its Office of the Secretary of State, Department of Corporations, Department of the Treasury, or similar departments. Familiarize yourself with the requirements and rules of engagement.
- **Get legal advice about starting a business in your state.** Find out what business licenses you need and where you need to file paperwork.
- **Know the limits of your practice in your state.** Some states or counties will not allow independent case managers to work in areas such as vocational rehabilitation, child and family services, or elder care.
- **Set up an office.** You should have a private meeting room for your clients that will safeguard their confidential information.
   - Have sufficient space and a separate phone line to use with your clients.
   - You'll need to take notes of phone conversations, and you'll want filing areas for paperwork. The same is true of filing space on your computer.
   - Be sure to have a copier and a fax machine. There are also online fax services that you pay for by the month. These can be quite cost-efficient.
   - You'll need a laptop so you can take it to off-site meetings. Consider one laptop that you can use at the office and on the road. This makes it easier to maintain your files and any email communication.
   - Equip yourself with security for your computer. Consider hiring an expert to make sure your files are safe and your internet service works well.
   - Always include several backup strategies for the information on your computer so you don't lose critical files.
- **Realize that you will likely have to be available to your clients 24/7.**
- **Have an attorney help you create a contract to use with your clients.**
- **Be sure you have malpractice insurance.**
- **Determine how you will charge clients**. Most independents charge by the hour because different clients will require different levels of help. You'll have personal meetings with clients, spend time securing resources, writing letters, and more. Determine how you will track your time. A simple Excel sheet can work as can carrying a calendar in which you note each hour and map it to a client.

Know Your Business Ps and Qs

- **Separate your personal and business funds.** This means a separate checking (and savings account, if desired).
- **Obtain a Federal Tax Identification Number (TIN)** that you can use with your business so that you do not need to give out your personal social security number in business documents and invoices.
- **Being HIPAA compliant** means that you will need to conduct a simple analysis to determine whether you are an Entity or Business Associate. Official information is updated on a regular basis at: http://www.hhs.gov/ocr/privacy, a good starting point for all things HIPAA, compliance, and enforcement.

Market Yourself

Market directly to your client base through advertising, direct mail, or a profile on social media. Ask your clients for referrals. Create your own website (professional website creators can help you with this) and post the referrals on it.

Become involved in professional activities (local Chamber of Commerce, health-related associations), sponsor community events, or speak at local meetings.

Consider getting a business mentor through the Small Business Association to help you get a good start on marketing.

If you are at a loss about how to market your business, consider hiring a consultant to help you create a business tagline and other materials.

Health care professionals who are either currently working on their own or who are planning on taking the next to step to self-employment wonder whether there is a market for independent case managers and whether they should focus on offering this service.

The role of an independent case manager should be clarified. In a health care network that is vast and complex, the independent case manager helps facilitate conversations. This includes the initial conversations that take place with doctors and caregivers as well as the follow-up conversations with family members about the next steps and the best options for the long run.

Independent case managers are also essential when it comes to coordinating with the health care team. For patients with chronic conditions or conditions that require a multifaceted approach to healing, it is important to be organized and to be able to make a large number of decisions. Someone who is well versed in the system and who has a comprehensive view of the situation is the patient's best advocate. Nothing is straightforward, and there is no one simple solution that fits every patient.

Communication

When a patient is simply diagnosed and left to navigate the overwhelming and complicated health care process on his or her own, there is an increased likelihood for miscommunication and for hospital readmission and there can be costly claims.

Patients benefit when they have an independent case manager on their side. Health care and reimbursement processes are constantly changing. Understanding what a policy covers and doesn't cover is an important part of deciding the best care for the patient. Also remember that the patient is emotionally burdened by their circumstances and that deciding the best course for their health care is no easy matter; patients are not necessarily capable of analyzing the ever-changing fine print of their health care policy.

An independent case manager understands the big picture. He or she can help navigate the patient through the ins and outs of the health care system and illuminate the vague and complex language of health insurance plans.

Communication gaps are another hurdle when it comes to patient care, and these gaps cause unexpected barriers and numerous misunderstandings. There simply isn't time to address patients' subtler needs and concerns in standard clinical care, but these gaps aren't going to go away just because we don't deal with them. They are a very real part of the struggle within the system, and an independent case manager has the time and insight to determine what is best for the patient. The case manager also has the time to work with patients whose treatments aren't being followed because they didn't understand what they were being told.

There are many self-diagnosis tools available on the internet and on our smartphones, but we need to consider whether information is being consumed without an understanding of the reliability of sources or if a patient's lack of acquaintance with technology makes parts of their care more difficult. Technology can be a giant barrier for our aging population.

Conditions and their treatments are intensive and expansive. "With the ageing of the population and the advances in the treatment of chronic diseases, teamwork in the context of chronic diseases needs to be reexamined. Successful chronic disease interventions usually involve a coordinated multidisciplinary care team.

Such teams ensure that critical elements of care that doctors may not have the training or time to do well are competently performed. These elements include population management, protocol-based regulation of medication, self-management support, and intensive follow up."[1]

The treatment plan for 1 condition is a lot for a patient to handle, but more and more patients are now dealing with multiple chronic conditions. Standard clinical care is in no way prepared to handle this. They know exactly what to tell you if you fall under the treatment care plan for 1 condition, but having multiple conditions puts a wrench in this approach. It totally reorganizes and disrupts the patient's needs. In cases like this, which are becoming more and more common in a world where preventive measures are almost nonexistent, an independent case manager can help provide a patient with a sense of agency. The case manager can look at the specific situation and prepare a custom treatment plan that makes sense for the patient financially and physically. This is simply not how our health care system is currently structured, and it's a big problem for patients stuck in the system with no one to turn to.

***Michelle Greene Rhodes** is the Owner of Michelle Rhodes, RN, Media LLC located in Tampa, Florida. She disseminates information regarding entrepreneurship in healthcare, she is a women's empowerment lecturer, and she is a four-time self-published author.*

If there were more independent case managers, our health care system would be a lot healthier, our patients would be better taken care of, health insurance premiums would be more affordable, and everyone would win.

Streamlining

Patients are dealing with a slew of other issues in addition to their condition and treatment at the same time that they are trying to navigate the health care system. Depending on the condition they are dealing with, they could have new disabilities, impairments, or corrective procedures as a result of their condition. They are also likely to be dealing with a loss of income and impending financial struggles, and their quality of life could be lower.

Although these issues are important to consider because they directly affect the patient's health and treatment, they are often overlooked. Case managers are in a position to deal with these issues firsthand. The independent case manager has a duty to advocate for a patient who has difficult day-to-day issues that are affecting and possibly interfering with a doctor's prescribed plan.

For example, although a physician is likely to suggest that a patient with diabetes or cardiovascular disease eat a healthy diet, the patient may be struggling with mobility issues or may not be able to prepare a meal for themselves. If the patient is struggling, the nutritious diet is going to seem like a luxury. A case manager takes these issues into consideration when formulating solutions. The resulting care plan is tailored to the patient so that the patient can follow the plan and see the results.

When these issues are overlooked, the consequences can be more significant than feelings of frustration and simple noncompliance with doctors' orders. Issues that seem small can lead directly to readmission. These issues can even contribute to new conditions. When the patient is unable to follow the treatment plan, new problems crop up, life gets harder, patients get readmitted, costs increase, and health care gets more expensive. It's a vicious cycle that doesn't have to continue.

There is no shortage of nurses or individuals with training in nursing. I would argue that if there is a shortage of nurses, it is because they are leaving the field due to burnout and dissatisfaction rather than not entering to begin with. It is not a secret that case managers in typical clinical settings often experience burnout. They are struggling to care for their patients in environments with lots of hierarchies and policies. They often work long hours and have more patients than they are physically able to tend to. Sometimes in a situation like this, it's easy to forget a sense of purpose or what brought you into the field in the first place.

A focus on the daily grind and the sheer volume of work rather than the quality of work decreases a nurse's enthusiasm for helping others. Most nurses get started in the field because they have a desire to help others and because they want to make a difference. But as happens so often, this purpose gets lost once an individual is immersed in the working environment of case management, where caseloads can overwhelm even the most seasoned professional. When you are working as an independent case manager, however, that purpose reemerges. Nurses work one-on-one with patients and are able to truly shine in this type of partnership. Nurses can be their patients' saving grace, helping them to navigate through a complicated health care system. Patients can relax, knowing that their true best interests are being looked after. This gives the patient a sense of empowerment that they are being advocated for, and it gives the nurse a sense of accomplishment because they truly are providing the help that their patient needs.

It's a win-win, and insurance companies win as well. When a case manager is able to provide a comprehensive picture about their patient's condition, including how to treat their patient's condition and how to pay for their patient's health care, their patients are more likely to stick to the treatment plan and to see improvements in their health and reductions in health care costs. In addition, hospitals and insurance carriers will also have reduced health care costs.

Serving as an independent case manager also allows you to have control over your time. Nurses, social workers, and vocational rehabilitation professionals in clinical hospital settings work by the shift. They cram everything they possibly can into long hours and have little control over the '"when" of things. You have more flexibility when you are an entrepreneur. You can then use your excellent multitasking skills to do what makes the most sense when it makes the most sense. You can use your time wisely and get the most important things done more efficiently.

Case managers are likely to have more than one case at a time. In this instance, it makes sense to take care of all their patients' administrative tasks at one time rather than bouncing from patient to patient and reacting to problems after they occur. Because independent case managers juggle

An independent case manager understands the big picture. He or she can help navigate the patient through the ins and outs of the health care system and illuminate the vague and complex language of health insurance plans.

a number of cases simultaneously, they can create a smart schedule for themselves that optimizes the best time to focus on certain types of responsibilities and prioritizes the action steps necessary to create change.

Collaboration

"Collaborative management is care that strengthens and supports self-care in chronic illness while assuring that effective medical, preventive, and health maintenance interventions take place."[2]

Health care is expensive on its own, but it increases exponentially because of factors such as a lack of preventive measures and improper at home care. Patients need to focus on their care and healing, which is difficult to do when they are mired in the logistics of health care and insurance.

As mentioned before, independent case managers have a background in health care. They are part of the system and understand all aspects of it. Patients need an independent case manager in their corner when it comes to navigating through the complicated waters of health care.

Working as an independent case manager allows us to build a legacy. Of course it is satisfying to be a great nurse and to know that you're always doing your best for your patients, but it's exponentially satisfying to be able to truly communicate and to relate to and help patients. In individual cases, nurses get to be a part of the entire process. There is a cause-and-effect relationship between what they

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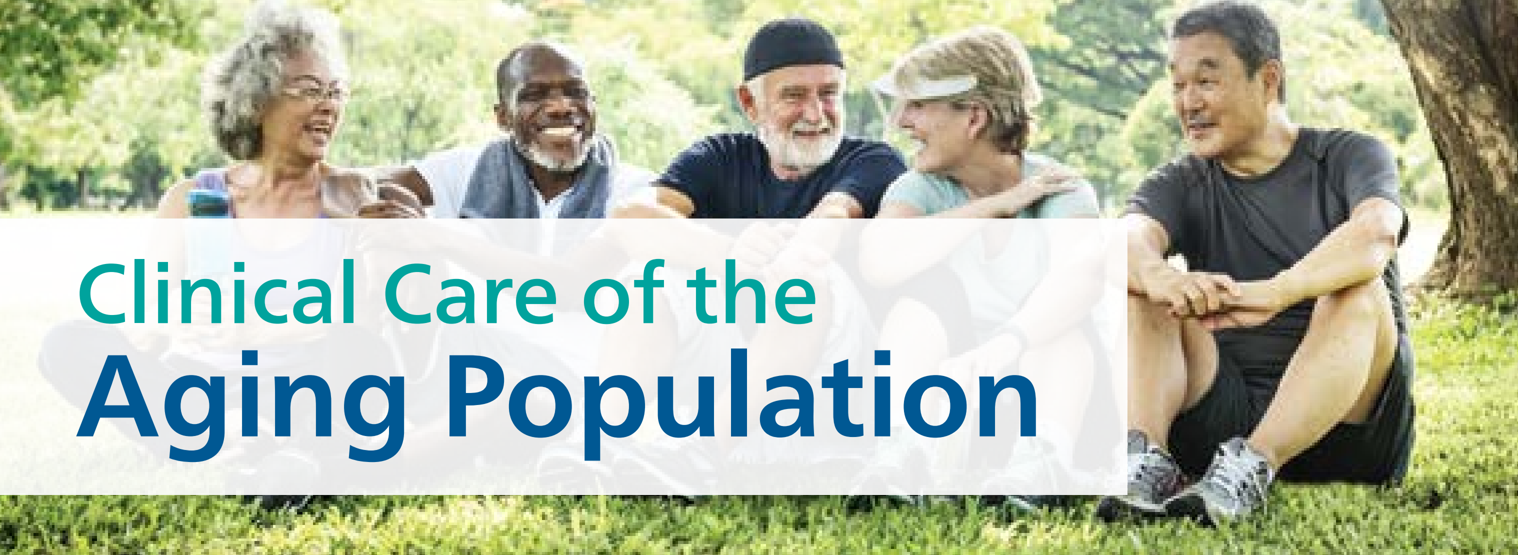
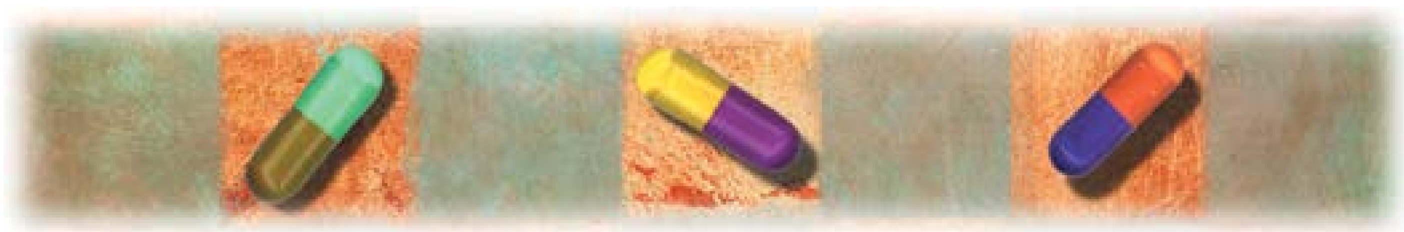


Learn about the national impacts of the aging population, the clinical conditions associated with this group, and the resource obstacles and policy challenges around the cost and quality of care delivery.

FREE WHITE PAPER

PharmaFacts for Case Managers



Doptelet® (avatrombopag) tablets, for oral use

INDICATIONS AND USAGE

Doptelet (avatrombopag) is indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

DOSAGE AND ADMINISTRATION

Recommended Dosage

Begin Doptelet dosing 10-13 days prior to the scheduled procedure. The recommended daily dose of Doptelet is based on the patient's platelet count prior to the scheduled procedure. Patients should undergo their procedure 5 to 8 days after the last dose of Doptelet. Doptelet should be taken orally once daily for 5 consecutive days with food. In the case of a missed dose, patients should take the next dose of Doptelet as soon as they remember. Patients should not take two doses at one time to make up for a missed dose and should take the next dose at the usual time the next day; all five days of dosing should be completed.

Recommended Dose and Duration

Platelet Count ($x10^9/L$)	Once Daily Dose	Duration
Less than 40	60 mg (3 tablets)	5 days
40 to less than 50	40 mg (2 tablets)	5 days

Doptelet has been investigated only as a single 5-day once daily dosing regimen in clinical trials in patients with chronic liver disease. Doptelet should not be administered to patients with chronic liver disease in an attempt to normalize platelet counts.

Monitoring: Obtain a platelet count prior to administration of Doptelet therapy and on the day of a procedure to ensure an adequate increase in platelet count.

DOSAGE FORMS AND STRENGTHS

Tablets: 20 mg avatrombopag as round, biconvex, yellow, film-coated tablets debossed with "AVA" on one side and "20" on the other side.

CONTRAINDICATIONS

None

WARNINGS AND PRECAUTIONS

Thrombotic/Thromboembolic Complications: Doptelet is a thrombopoietin (TPO) receptor agonist and TPO receptor agonists have been associated with thrombotic and thromboembolic complications in patients with chronic liver disease. Portal vein thrombosis has been reported in patients with chronic liver disease treated with TPO receptor agonists. In the ADAPT-1 and ADAPT-2 clinical trials, there was 1 treatment-emergent event of portal vein thrombosis in a patient (n=1/430) with chronic liver disease and thrombocytopenia treated with Doptelet. Consider the potential increased thrombotic risk when administering Doptelet to patients with known risk factors for thromboembolism, including genetic prothrombotic conditions (Factor V Leiden, Prothrombin 20210A, Antithrombin deficiency or Protein C or S deficiency).

Doptelet should not be administered to patients with chronic liver disease in an attempt to normalize platelet counts.

USE IN SPECIFIC POPULATIONS

Pregnancy Risk Summary: Based on findings from animal reproduction studies, Doptelet may cause fetal harm when administered to a pregnant woman. The available data on Doptelet in pregnant women are insufficient to inform a drug-associated risk of adverse developmental outcomes. In animal reproduction studies, oral administration of avatrombopag resulted in adverse developmental outcomes when administered during organogenesis in rabbits and during organogenesis and the lactation period in rats. However, these findings were observed at exposures based on AUC substantially higher than the AUC observed in patients at the recommended dose of 60 mg once daily. Advise pregnant women of the potential risk to a fetus. The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and of miscarriage in clinically recognized pregnancies is 2–4% and 15–20%, respectively.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use: Clinical studies of Doptelet did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clin-

ical experience has not identified differences in responses between the elderly and younger patients.

OVERDOSAGE

In the event of overdose, platelet count may increase excessively and result in thrombotic or thromboembolic complications. Closely monitor the patient and platelet count. Treat thrombotic complications in accordance with standard of care. No antidote for Doptelet overdose is known. Hemodialysis is not expected to enhance the elimination of Doptelet because Doptelet is only approximately 6% renally excreted and is highly bound to plasma proteins.

CLINICAL STUDIES

The efficacy of Doptelet for the treatment of thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure was established in 2 identically designed multicenter, randomized, double-blind, placebo-controlled trials (ADAPT-1 [NCT01972529] and ADAPT-2 [NCT01976104]). In each study, patients were assigned to the Low Baseline Platelet Count Cohort (<40 x10^9/L) or the High Baseline Platelet Count Cohort (≥40 to <50 x10^9/L) based on their platelet count at Baseline. Patients were then randomized in a 2:1 ratio to either Doptelet or placebo. The major efficacy outcome was the proportion of patients who did not require a platelet transfusion or any rescue procedure for bleeding after randomization and up to 7 days following an elective procedure. Additional secondary efficacy outcomes were the proportion of patients who achieved platelet counts of >50 x10^9/L on the day of procedure and the change in platelet count from baseline to procedure day. In addition, both trials demonstrated a higher proportion of patients who achieved the target platelet count of ≥ 50 x10^9/L on the day of the procedure, a secondary efficacy endpoint, in both Doptelet-treated groups versus the placebo-treated groups for both cohorts (Low Baseline Platelet Count Cohort-ADAPT-1: 69% vs 4%, respectively; P <0.0001).

A measured increase in platelet counts was observed in both Doptelet treatment groups over time beginning on Day 4 post-dose, that peaked on Day 10–13, decreased 7 days post-procedure, and then returned to near baseline values by Day 35.

HOW SUPPLIED/STORAGE AND HANDLING

Doptelet 20 mg tablets are supplied as round, biconvex, yellow, film-coated tablets, and debossed with “AVA” on one side and “20” on the other side.

Store at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F). Store tablets in original package.

PATIENT COUNSELING INFORMATION

Advise the patient or caregiver to read the FDA-approved patient labeling (Patient Information). Before treatment, patients should fully understand and be informed of the following risks and considerations for Doptelet.

Risks Thrombotic/Thromboembolic Complications: Doptelet is a thrombopoietin (TPO) receptor agonist and TPO receptor agonists have been associated with thrombotic and thromboembolic complications in patients with chronic liver disease. Portal vein thrombosis has been reported in patients with chronic liver disease treated with TPO receptor agonists.

Pregnancy: Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to inform their prescriber of a known or suspected pregnancy

Manufactured for: AkaRx, Inc., Durham, North Carolina

Distributed and Marketed by Dova Pharmaceuticals, Inc., Durham, North Carolina

Lucemyra™ (lofexidine) tablets, for oral use

INDICATIONS AND USAGE

Lucemyra is a central α-2 adrenergic agonist indicated for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults.

DOSAGE AND ADMINISTRATION

- The usual Lucemyra dosage is three 0.18 mg tablets taken orally 4 times daily at 5- to 6-hour intervals. Lucemyra treatment may be continued for up to 14 days with dosing guided by symptoms.
- Discontinue Lucemyra with a gradual dose reduction over 2 to 4 days.
- *Hepatic or Renal Impairment:* Dosage adjustments are recommended based on degree of impairment.

DOSAGE FORMS AND STRENGTHS

Tablets: 0.18 mg.

CONTRAINDICATIONS

None

WARNINGS AND PRECAUTIONS

- *Risk of Hypotension, Bradycardia, and Syncope:* May cause a decrease in blood pressure, a decrease in pulse, and syncope. Monitor vital signs before dosing and advise patients on how to minimize the risk of these cardiovascular effects and manage symptoms, should they occur. Monitor symptoms related to bradycardia and orthostasis. When using in outpatients, ensure that patients are capable of self-monitoring signs and symptoms. Avoid use in patients with severe coronary insufficiency, recent myocardial infarction, cerebrovascular disease, or chronic renal failure, as well as in patients with marked bradycardia.
- *Risk of QT Prolongation:* Lucemyra prolongs the QT interval. Avoid use in patients with congenital long QT syndrome. Monitor ECG in patients with electrolyte abnormalities, congestive heart failure, bradyarrhythmias, hepatic or renal impairment, or in patients taking other medicinal products that

lead to QT prolongation.

- *Increased Risk of CNS Depression with Concomitant use of CNS Depressant Drugs:* Lucemyra potentiates the CNS depressant effects of benzodiazepines and may potentiate the CNS depressant effects of alcohol, barbiturates, and other sedating drugs.
- *Increased Risk of Opioid Overdose after Opioid Discontinuation:* Patients who complete opioid discontinuation are at an increased risk of fatal overdose should they resume opioid use. Use in conjunction with comprehensive management program for treatment of opioid use disorder and inform patients and caregivers of increased risk of overdose.
- *Risk of Discontinuation Symptoms:* Instruct patients not to discontinue therapy without consulting their healthcare provider. When discontinuing therapy, reduce dose gradually.

ADVERSE REACTIONS

Most common adverse reactions (incidence ≥10% and notably more frequent than placebo) are orthostatic hypotension, bradycardia, hypotension, dizziness, somnolence, sedation, and dry mouth.

DRUG INTERACTIONS

- *Methadone:* Methadone and Lucemyra both prolong the QT interval. ECG monitoring is recommended when used concomitantly.
- *Oral Naltrexone:* Comcomitant use may reduce efficacy of oral naltrexone.
- *CYP2D6 Inhibitors:* Concomitant use of paroxetine resulted in increased plasma levels of Lucemyra. Monitor for symptoms of orthostasis and bradycardia with concomitant use of a CYP2D6 inhibitor.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

The safety of Lucemyra in pregnant women has not been established.

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies carry some risk of birth defect, loss, or other adverse outcomes. The background risk of major birth defects in the U.S. general population is 2% to 4% and of miscarriage is 15% to 20% of clinically recognized pregnancies.

Females and Males of Reproductive Potential

In animal studies that included some fertility endpoints, lofexidine decreased breeding rate and increased resorptions at exposures below human exposures. The impact of lofexidine on male fertility has not been adequately characterized in animal studies

Pediatric Use

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

Geriatric Use

No studies have been performed to characterize the pharmacokinetics of Lucemyra or establish its safety and effectiveness in geriatric patients. Caution should be exercised when it is administered to patients over 65 years of age. Dosing adjustments similar to those recommended in patients with renal impairment should be considered.

Hepatic Impairment

Hepatic impairment slows the elimination of Lucemyra but exhibits less effect on the peak plasma concentration than on AUC values following a single dose. Dosage adjustments are recommended based on the degree of hepatic impairment.

Clinically relevant QT prolongation may occur in subjects with hepatic impairment

Renal Impairment

Renal impairment slows the elimination of Lucemyra but exhibits less effect on the peak plasma concentration than on AUC values following a single dose. Dosage adjustments are recommended based on the degree of renal impairment.

Only a negligible fraction of the Lucemyra dose is removed during a typical dialysis session, so no additional dose needs to be administered after a dialysis session; Lucemyra may be administered without regard to the timing of dialysis.

Clinically relevant QT prolongation may occur in subjects with renal impairment.

CYP2D6 Poor Metabolizers

Although the pharmacokinetics of Lucemyra have not been systematically evaluated in patients who do not express the drug metabolizing enzyme CYP2D6, it is likely that the exposure to Lucemyra would be increased similarly to taking strong CYP2D6 inhibitors (approximately 28%). Monitor adverse events such as orthostatic hypotension and bradycardia in known CYP2D6 poor metabolizers. Approximately 8% of Caucasians and 3–8% of Black/African Americans cannot metabolize CYP2D6 substrates and are classified as poor metabolizers (PM).

OVERDOSAGE

Overdose with Lucemyra may manifest as hypotension, bradycardia, and sedation. In the event of acute overdose, perform gastric lavage where appropriate. Dialysis will not remove a substantial portion of the drug. Initiate general symptomatic and supportive measures in cases of overdosage.

CLINICAL STUDIES

Two randomized, double-blind, placebo-controlled trials supported the efficacy of Lucemyra.

Study 1, NCT01863186

Study 1 was a 2-part efficacy, safety, and dose-response study conducted in the United States in patients meeting DSM-IV criteria

for opioid dependence who were physically dependent on short-acting opioids (e.g., heroin, hydrocodone, oxycodone). The first part of the study was an inpatient, randomized, double-blind, placebo-controlled design consisting of 7 days of inpatient treatment (Days 1– 7) with Lucemyra 2.16 mg total daily dose (0.54 mg 4 times daily) (n=229), Lucemyra 2.88 mg total daily dose (0.72 mg 4 times daily) (n=222), or matching placebo (n=151). Patients also had access to a variety of support medications for withdrawal symptoms (guaifenesin, antacids, dioctyl sodium sulfosuccinate, psyllium hydrocolloid suspension, bismuth sulfate, acetaminophen, and zolpidem). The second part of the study (Days 8–14) was an open-label design where all patients who successfully completed Days 1–7 were eligible to receive open-label treatment with variable dose Lucemyra treatment (as determined by the investigator, but not to exceed 2.88 mg total daily dose) for up to an additional 7 days (Days 8–14) in either an inpatient or outpatient setting as determined by the investigator and the patient. No patient received Lucemyra for more than 14 days.

Study 2, NCT00235729

Study 2 was an inpatient, randomized, multicenter, double-blind, placebo-controlled study carried out in the United States in patients meeting DSM-IV criteria for opioid dependence who were physically dependent on short-acting opioids (e.g., heroin, hydrocodone, oxycodone). Patients were treated with Lucemyra tablets (2.88 mg/day [0.72 mg four times daily]) or matching placebo for 5 days (Days 1–5). Patients also had access to a variety of support medications for withdrawal symptoms (guaifenesin, antacids, dioctyl sodium sulfosuccinate, psyllium hydrocolloid suspension, bismuth sulfate, acetaminophen, and zolpidem). All patients then received placebo on Days 6 and 7 and were discharged on Day 8.

A total of 264 patients were randomized into the study. Of these, 134 patients were randomized to Lucemyra 2.88 mg/day and 130 patients to placebo.

Of the randomized and treated patients, 33% of placebo patients and 49% of Lucemyra patients completed 5 days of treatment. The difference in proportion between the two groups was significant. Patients in the placebo group were more likely to drop out of the study prematurely due to lack of efficacy than patients treated with Lucemyra.

HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

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continues on page 35

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

Clin Infect Dis. 2018 Apr 27. doi: 10.1093/cid/ciy373. [Epub ahead of print]

Disparities and determinants of cancer treatment in elderly Americans living with HIV/AIDS.

Rositch AF, Jiang S, Coghill AE, Suneja G, Engels EA.

BACKGROUND: Previous studies suggest that HIV-infected cancer patients are less likely to receive cancer treatment. The extent to which this disparity affects the growing population of elderly individuals is unknown and factors that mediate these treatment differences have not been explored.

METHODS: We studied 930,359 Americans aged 66-99 years old who were diagnosed with 10 common cancers. SEER-Medicare claims from 1991-2011 were used to determine HIV status and receipt of cancer treatment in 6 months following diagnosis. Mediation analysis was conducted to estimate the direct effect of HIV, and indirect effect of cancer stage at diagnosis and comorbidities, on cancer treatment.

RESULTS: HIV-infected individuals (n=687) were less likely to receive cancer treatment (70% vs. 75% HIV-uninfected; p< 0·01). This difference was larger in individuals ≤70 years, among whom only 65% were treated (vs. 81% HIV-uninfected; p< 0·01), and time from cancer diagnosis to treatment was longer (median 42·5 vs. 36 days HIV-uninfected; p<0·01). Accounting for potential confounders, HIV-infected individuals aged ≤70 remained 20% less likely to receive cancer treatment (hazard ratio=0·81; 95% confidence interval=0·71, 0·92). Seventy-five percent of this total effect was due to HIV itself, with a nonsignificant 25% mediated by cancer stage and comorbidities.

CONCLUSIONS: The lowest cancer treatment rates were seen in the younger subset of HIV-infected individuals, who would likely benefit most from treatment in terms of life expectancy. To develop effective interventions, it is imperative to identify factors that mediate the relationship between HIV and low cancer treatment rates.

Circ Heart Fail. 2018 May;11(5):e004642. doi: 10.1161/CIRCHEARTFAILURE.117.004642.

Risk factor burden, heart failure, and survival in women of different ethnic groups: insights from the women's health initiative.

Breathett K, Leng I, Foraker RE, et al.

BACKGROUND: The higher risk of heart failure (HF) in African-American and Hispanic women compared with white women is related to the higher burden of risk factors (RFs) in minorities. However, it is unclear if there are differences in the association between the number of RFs for HF and the risk of development of HF and death within racial/ethnic groups.

METHODS AND RESULTS: In the WHI (Women's Health Initiative; 1993-2010), African-American (n=11 996), white (n=18 479), and Hispanic (n=5096) women with 1, 2, or 3+ baseline RFs were compared with women with 0 RF within their respective racial/ethnic groups to assess risk of developing HF or all-cause mortality before and after HF, using survival analyses. After adjusting for age, socioeconomic status, and hormone therapy, the subdistribution hazard ratio (95% confidence interval) of developing HF increased as number of RFs increased (P<0.0001, interaction of race/ethnicity and RF number P=0.18)-African-Americans 1 RF: 1.80 (1.01-3.20), 2 RFs: 3.19 (1.84-5.54), 3+ RFs: 7.31 (4.26-12.56); Whites 1 RF: 1.27 (1.04-1.54), 2 RFs: 1.95 (1.60-2.36), 3+ RFs: 4.07 (3.36-4.93); Hispanics 1 RF: 1.72 (0.68-4.34), 2 RFs: 3.87 (1.60-9.37), 3+ RFs: 8.80 (3.62-21.42). Risk of death before developing HF increased with subsequent RFs (P<0.0001) but differed by racial/ethnic group (interaction P=0.001). The number of RFs was not associated with the risk of death after developing HF in any group (P=0.25; interaction P=0.48).

CONCLUSIONS: Among diverse racial/ethnic groups, an increase in the number of baseline RFs was associated with higher risk of HF and death before HF but was not associated with death after HF. Early RF prevention may reduce the burden of HF across multiple racial/ethnic groups.

J Card Fail. 2018 Apr 25. pii: S1071-9164(18)30166-0. doi: 10.1016/j.cardfail.2018.04.006. [Epub ahead of print]

Factors associated with adherence to 14-day office appointments after heart failure discharge.

Distelhorst K, Claussen R, Dion K, et al.

BACKGROUND: Follow-up within 14 days after hospital discharge for heart failure (HF) may prevent 30-day hospital readmission, but adherence varies. The purpose of this study was to determine predictors of non-adherence to scheduled appointments.

METHODS AND RESULTS: A medical record review included patients hospitalized for decompensated HF at 3 health system hospitals, and who had a scheduled 14-day office appointment. Patient demographics, and social, HF and hospital factors were studied for association with appointment adherence. Multivariable modeling was used to determine the odds of missing scheduled appointments. Of 701 cases, mean (SD) age was 73.5 (13.8) years, 46.4% were female and 38.9% were non-white. Appointment non-adherence was 16.2%. In multivariate analyses, 4 factors predicted missed appointments: drug use history (odds ratio [OR], 95% confidence interval [CI], 3.95 [1.70, 9.20] p< 0.001), non-white race (OR 1.85 [CI, 1.08, 3.16], p=0.024), pulmonary disease (OR 1.80 [CI, 1.12, 2.87], p=0.014) and anemia (OR 1.58 [CI, 1.01, 2.46], p=0.044). Scheduling appointments post- vs. pre-discharge was not associated with missed appointments (OR 0.72 [CI 0.45, 1.15], p=0.17).

CONCLUSIONS: Findings may help practitioners identify patients who are likely to miss a follow up visit as all 4 predictors were easily retrievable from medical records during hospitalization.

J Acquir Immune Defic Syndr. 2018 Apr 24. doi: 10.1097/QAI.0000000000001702. [Epub ahead of print]

Factors associated with gaps in Medicaid enrollment among people with HIV and the effect of gaps on viral suppression.

Monroe AK, Myint L, Rutstein R, et al; HIV Research Network.

INTRODUCTION: Gaps in Medicaid enrollment may affect HIV outcomes. We evaluated factors associated with Medicaid enrollment gaps and their effect on viral suppression (VS) within the HIV Research Network (HIVRN).

METHODS: We used a combined dataset with Medicaid enrollment files from 2006-10 and HIVRN demographic and clinical data. A gap was defined as >1 month without Medicaid and gap length was determined. We used multivariable logistic regression (MLR) to determine factors associated with a gap and MLR with generalized estimated equations to evaluate factors associated with VS post-gap.

RESULTS: Of 5,836 participants, the majority were male, of Black race, and aged 25-50. More than half had a gap in Medicaid. Factors associated with a gap included male sex (adjusted odds ratio (aOR) 1.79, [1.53, 2.08]) and younger age (aORs ranging from 1.50 to 4.13 comparing younger age groups to age > 50, p<0.05 for all). About a quarter of gaps had VS information pre- and post-gap. Of those, 53.7% had VS both pre-and post-gap and 25.8% were unsuppressed both pre-and post-gap. The strongest association with VS post-gap was VS pre-gap (aOR 15.76 [10.48, 23.69]). Transition into Ryan White HIV/AIDS Program coverage during Medicaid gaps was common (28% of all transitions).

CONCLUSION: Gaps in Medicaid enrollment were common and many individuals with pre-gap VS maintained VS post-gap, possibly due to accessing other sources of ART coverage. Implementing initiatives to maintain Medicaid enrollment and to expedite Medicaid re-enrollment and having alternate resources available in gaps are important to ensure continuous ART to optimize HIV outcomes.

Ann Thorac Surg. 2018 Apr 20. pii: S0003-4975(18)30538-1. doi: 10.1016/j.athoracsur.2018.03.044. [Epub ahead of print]

Cumulative effect of preoperative risk factors on mortality after pediatric heart transplantation.

O'Connor MJ, Glatz AC, Rossano JW, et al.

BACKGROUND: Risk assessment in heart transplantation is critical for candidate selection, but current models inadequately assess individual risk of postoperative mortality. We sought to identify risk factors and develop a scoring system to predict mortality following heart transplantation in children.

METHODS: The records of patients undergoing heart transplantation at our institution from 2010–2016 were reviewed. Clinical characteristics were recorded and compared between survivors and non-survivors. Using Cox proportional hazard modeling, a risk factor score was developed using factors associated with postoperative mortality.

RESULTS: Seventy-four patients underwent heart transplantation at a mean age of 8.8 ± 6.6 years. Congenital heart disease was the most common indication, comprising 48.6% of the cohort.

Overall mortality was 18.9%, with 10/14 dying ≤30 days of operation or during initial postoperative admission (early mortality). The following preoperative factors were associated with overall mortality: single ventricle congenital heart disease (HR 3.2, p = 0.042), biVAD (HR 4.8, p = 0.043), history of ≥4 sternotomies (HR 3.9, p = 0.023), panel reactive antibody >10% (HR 4.4, p = 0.013), any previous surgery at an outside institution (HR 3.2, p = 0.038), and pulmonary vein disease (HR 4.7, p = 0.045). Each risk factor was assigned a point value, based on similar magnitude of the hazard ratios. A score of ≥4 predicted mortality with 57% sensitivity and 90% specificity.

CONCLUSIONS: In this single-center pediatric cohort, post-heart transplantation mortality could be predicted using patient-specific risk factors. The cumulative effect of these risk factors predicted mortality with high specificity.

AJR Am J Roentgenol. 2018 Apr 30:W1-W5. doi: 10.2214/AJR.17.19042. [Epub ahead of print]

Lung cancer screening guidelines: how readable are Internet-based patient education resources?

Hansberry DR, White MD, D'Angelo M, et al.

OBJECTIVE: Following the findings of the National Lung Screening Trial, several national societies from multiple disciplines have endorsed the use of low-dose chest CT to screen for lung cancer. Online patient education materials are an important tool to disseminate information to the general public regarding the proven health benefits of lung cancer screening. This study aims to evaluate the reading level at which these materials related to lung cancer screening are written.

MATERIALS AND METHODS: The four terms "pulmonary nodule," "radiation," "low-dose CT," and "lung cancer screening" were searched on Google, and the first 20 online resources for each term were downloaded, converted into plain text, and analyzed using 10 well-established readability scales. If the websites were not written specifically for patients, they were excluded.

RESULTS: The 80 articles were written at a 12.6 ± 2.7 (mean ± SD) grade level, with grade levels ranging from 4.0 to 19.0. Of the 80 articles, 62.5% required a high school education to comprehend, and 22.6% required a college degree or higher (≥ 16th grade) to comprehend. Only 2.5% of the analyzed articles adhered to the recommendations of the National Institutes of Health and American Medical Association that patient education materials be written at a 3rd- to 7th-grade reading level.

CONCLUSION: Commonly visited online lung cancer screening-related patient education materials are written at a level beyond the general patient population's ability to comprehend and may be contributing to a knowledge gap that is inhibiting patients from improving their health literacy.

J Thorac Cardiovasc Surg. 2018 Apr 4. pii: S0022-5223(18)30895-X. doi: 10.1016/j.jtcvs.2018.03.113. [Epub ahead of print]

Effect of the number of lymph nodes examined on the survival of patients with stage I non-small cell lung cancer who undergo sublobar resection.

Yendamuri S, Dhillon SS, Groman A, et al.

OBJECTIVES: Early stage lung cancer is being detected at a higher frequency with the implementation of screening programs. At the same time, medically complex patients with multiple comorbidities are presenting for surgery, with a concomitant rise in rates of sublobar resection. We sought to examine the effect of sampling lymph nodes on the outcomes of patients who undergo sublobar resection for small (<2 cm) stage I non-small cell lung cancer (NSCLC).

METHODS: All patients in the Surveillance, Epidemiology, and End Results database from 2004 to 2013 with small (<2 cm) stage I NSCLC who underwent sublobar resection (wedge/segmentectomy) and no other cancer history were included. The association of the number of lymph nodes examined (LNE; categories none, 1-3, 4-6, 7-9, >9) with the overall survival as well as disease-specific survival were examined using univariate as well as multivariate analyses while controlling for covariates such as age, size (<1 cm, >1 cm), grade, histology (adenocarcinoma vs others), and extent of resection (wedge/segmentectomy).

RESULTS: Data from 3916 eligible patients were analyzed. Seven hundred fifteen patients (18.3%) had segmentectomy. No lymph nodes were examined in 49% and 23% of wedge resection and segmentectomy patients, respectively. Among all eligible patients, 1132 (29%), 474 (12%), 228 (6%), and 328 (8%) patients had 1 to 3, 4 to 6, 7 to 9 and >9 LNE, respectively. Univariate analyses showed significant associations between overall and disease-specific survivals with age, grade, histology, sex, extent of surgery, and LNE. The association between the number of LNE and survival remained significant even after adjusting for significant covariates including extent of sublobar resection (hazard ratio for groups with LNE 1-3, 4-6, 7-9, and >9 compared with 0 LNE were 0.79, 0.77,

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0.68, and 0.45 for overall survival; P < .001) and 0.85, 0.77, 0.71, and 0.44 for disease-specific survival (P < .05), respectively. In multivariate modeling, LNE was retained as a significant variable and extent of resection was not. In patients in whom at least 1 lymph node was examined, extent of resection was not predictive of outcome. CONCLUSIONS: Many patients having sublobar resection for early stage NSCLC in the United States do not have a single lymph node removed for pathologic examination. The number of LNE is associated with improved survival, presumably due to avoidance of mis-staging. This association seems greater than the association with extent of resection (segmentectomy vs wedge resection). Appropriate lymph node examination remains an important part of resection for lung cancer even if the resection is sublobar.

J Asthma. 2018 May 1:1-14. doi: 10.1080/02770903.2018.1471705. [Epub ahead of print]

Perceptions of non-traditional tobacco products between asthmatic and non-asthmatic college students.

Martinasek MP, White RM, Wheldon CW, Gibson-Young L.

OBJECTIVE: Electronic nicotine delivery systems (ENDS) use is common among college students and there are perceptions that ENDS are not as harmful as traditional cigarettes. The aim of this study was to examine differences in ENDS use, risk perceptions and co-occurring smoking behaviors between college students with and without asthma.

METHODS: The study consisted of a cross-sectional online survey with a final sample size of 898 college students. The voluntary participation survey was disseminated to all undergraduate and graduate students at a mid-sized liberal arts university in the Southeast U.S. in the fall of 2014.

RESULTS: Approximately 19.7% reported that they had been previously diagnosed with asthma. Forty three percent of participants (n = 384) used ENDS in the past 30 days. Equivalent percentages of college students with asthma (46.9%) and college students without asthma (46.9%) have tried ENDS. Overall participants indicated that they perceived ENDS use as less (44%) or equally (38%) as harmful as cigarettes. College students with asthma had 2.85 (95% CI: 1.18-6.89) greater odds of being in the poly user class, which was characterized by dual use of ENDS, combustible cigarettes, hookah, and marijuana.

CONCLUSIONS: In this study, college students with asthma were similar to their peers with regard to their use of ENDS and related risk perceptions; however, a small subsample of those with asthma exhibited problematic smoking behaviors characterized by dual use of multiple tobacco products including marijuana.

Semin Dial. 2018 May 2. doi: 10.1111/sdi.12703. [Epub ahead of print]

Patient-to-patient peer mentor support in dialysis: improving the patient experience.

Bennett PN, St Clair Russell J, Atwal J, Brown L, Schiller B.

Greater focus on patient-reported outcome measures for dialysis patients and an increased patient engagement focus has highlighted a lack of formal patient-generated strategies. Patient-to-patient peer mentoring is one approach that may improve the outcomes for people receiving dialysis. This review aims to synthesize quantitative and qualitative studies investigating dialysis-associated patient-to-patient peer mentor support among adults with chronic kidney disease and end stage kidney disease. Research studies describe the benefits of peer mentor programs in dialysis to include: improved goal setting, decision-making and increased self-management. While a variety of program formats exist, a combination of face-to-face and telephone peer support models are recommended and formal training of mentors is required. In addition, the formal support of dialysis clinicians, nephrologists and administrators is vital for the success of a dialysis patient-to-patient peer mentor program.

Arthritis Res Ther. 2018 May 2;20(1):79. doi: 10.1186/s13075-018-1580-5.

Factors associated with physicians' prescriptions for rheumatoid arthritis drugs not filled by patients.

Kan HJ, Dyagilev K, Schulam P, et al.

BACKGROUND: This study estimated the extent and predictors of primary nonadherence (i.e., prescriptions made by physicians but not initiated by patients) to methotrexate and to biologics or tofacitinib in rheumatoid arthritis (RA) patients who were newly prescribed these medications.

METHODS: Using administrative claims linked with electronic health records (EHRs) from multiple healthcare provider organizations in the USA, RA patients who received a new prescrip-

continues on page 35

Lung Ultrasound More Accurate Than X-Ray

A systematic review and meta-analysis of 10 observational studies (n = 543) plus 4 abstracts(n = 323), funded by VU University Medical Center in Amsterdam, examined accuracies of either chest X-ray or lung ultrasound to chest computed tomography in critically ill adults with respiratory symptoms.

The findings of the meta-analysis showed that lung ultrasound (LUS) is far more sensitive than and comparably specific to chest X-ray (CXR) as the first-line diagnostic tool for critically ill patients with respiratory symptoms, which contradicts the widely held belief that X-ray is the first-line diagnostic tool.

Key results included:

- CXR sensitivity 0.49 (95% CI, 0.40-0.58); specificity 0.92 (95% CI, 0.86-0.95; high heterogeneity)
- LUS sensitivity 0.95 (95% CI, 0.92-0.96); specificity 0.94 (95% CI, 0.90-0.97; moderate-to-high heterogeneity)
- LUS sensitivity and specificity were both ≥90% for lung contusion, interstitial syndrome, pleural effusion, and consolidations.

Although CT is more accurate than CXR, it has higher risks, costs, and logistical hurdles. Therefore, LUS is a more accurate diagnostic tool at lower cost. ■

Traumatic Brain Injury Linked to Dementia

In the largest study of its kind, researchers found that traumatic brain injury (TBI) is associated with an increased risk of dementia. The risk of dementia was highest among individuals who had had multiple TBIs, but even a single mild TBI was tied to an increased risk of dementia.

The study in Lancet Psychiatry used Danish health databases that included all residents as of January 1, 1995, who were at least 50 years old at some time during the 36-year follow-up from 1977 to 2013. Among 2,794,852 individuals, they found 132,093 who had had at least one TBI.

After adjusting for medical, neurological, and psychiatric illnesses, they found that compared with people who had never had a TBI, those who had had any TBIs were at a 24% increased risk for dementia, and those who had had 5 or more TBIs had nearly triple the risk. Even a single mild TBI increased the risk by 17%. ■

Anticholinergic Drugs Linked to Dementia

The largest and most detailed study of the long-term impact of anticholinergic drugs, a class of drugs commonly prescribed in the United States and United Kingdom as antidepressants and incontinence medications, found that their use is associated with increased risk of dementia, even when taken 20 years before diagnosis of cognitive impairment.

An international research team from the United States, United Kingdom, and Ireland analyzed more than 27 million prescriptions that were recorded in the medical records of 40,770 patients over age 65 diagnosed with dementia compared with the records of 283,933 older adults without dementia.

The researchers found a greater incidence of dementia among patients prescribed anticholinergic antidepressants, anticholinergic bladder medications, and anticholinergic Parkinson's disease medications than among older adults who were not prescribed these drugs. See more in BMJ. ■

Suicide Risk Often Sharply Higher for Patients With Neurologic Disorders

Danish researchers have found that the risk of suicide attempt by self-poisoning is elevated in 9 of 10 neurologic disorders. The risk was elevated among patients with stroke (odds ratio [OR], 3.1; P < .0001), Huntington's disease (OR 8.8; P < .0001), amyotrophic = .0003).

The findings were generally similar after adjustment for chronic nonpsychiatric and psychiatric comorbidities. Abuse of alcohol and other psychoactive substances partly explained associations seen for epilepsy and Alzheimer's disease. The risk for suicide attempt is higher for men than for women with neurologic disorders (OR, 4.2 vs 3.3; P = .0026). ■

Patient Charities Scrutinized

The *Washington Post* published a long-form piece about the patient charities that cover drug copayments and in some cases insurance premiums for people who need treatment with high-priced drugs.

The findings? On the one hand, people get treatments they might not otherwise get and are protected from expensive prices—the financial toxicity that researchers and doctors have been talking about.

On the other hand, the charities shield the drug companies from pressure to lower their price.

The Post reporter, Carolyn Y. Johnson, cites a Citi Research report that found that a $1 million donation to a patient charity can generate up to $21 million in drug sales for a pharmaceutical company. ■

ZOSTER VACCINATION UPDATE

The U.S. Food and Drug Administration approved a zoster vaccine recombinant adjuvant by GlaxoSmithKline plc known as Shingrix® as a 2-dose vaccine. And on January 26, 2018, the Advisory Committee on Immunization Practices (ACIP) recommended that this vaccine be administered to all immunocompetent adults older than 50 years.

The previous single zoster vaccine Zostavax® (Merck & Co., Inc., Kenilworth, NJ, USA) contained live attenuated varicella virus in an amount that is approximately 14 times greater than that in regular varicella vaccine. It was recommended by the ACIP for patients 60 years of age and older and was administered subcutaneously.

The Shingles Prevention Study looked at more than 38,000 adults older than 60 years and found that the new vaccine was about 51% effective in preventing shingles and about 67% effective in preventing postherpetic neuralgia. As they followed up this study in the Shingles Prevention Study, at 7-11 years they found the efficacy was only about 21%. The investigators were not clear whether a "booster" dose would be effective at this point.

For more information, see *The New England Journal of Medicine*.

Acupuncture Safe But Largely Ineffective for Hip Osteoarthritis

The National Institutes of Health, National Natural Science Foundation of China, and Shanghai University performed a meta-analysis and qualitative review of 6 randomized controlled trials on the use of acupuncture for hip osteoarthritis. The findings revealed that acupuncture, when compared with sham acupuncture, had little to no benefit for pain and function. Acupuncture compared with nonsteroidal anti-inflammatory drugs or advice plus exercise had uncertain results. Acupuncture plus education vs education alone had uncertain results. Acupuncture had minor side effects (bruising, bleeding, or pain at the needle-insertion site) but was considered safe although ineffective. Some benefit for acupuncture added to primary care (in a low-quality study) was seen in pain and function. ■

Four-Day OCD Treatment Shows Lasting Benefit

Cognitive behavior therapy is effective for treating obsessive-compulsive disorder, but the results are not long term in more than half of patients. The Bergen 4-day concentrated exposure treatment was proven in a 12-month follow-up study to be effective out to 12 months. The dropout rate was 1.3% less than the rate of 15% that is typical of other types of exposure and response prevention. At 12 months, 83.1% of patients were classified as responders and 67.7% as recovered. ■

HCV-1/4 Highly Effective for Black Patients

Elbasvir/grazoprevir (EBR/GZR) is highly effective for clearing HCV genotypes 1 and 4 in black patients; safety is comparable vs nonblack patients, according to a study of 322 black and 1310 nonblack patients. Comorbidities were similar between groups and sustained viral response at 12 weeks was also similar. Unknown was the proportion of African Americans and other blacks. ■

CAN DRUGS COSTS BE CUT?

AARP has published a report on the costs of drugs in America. The President thinks "price fixing" would stifle innovation and that costs can be cut by speeding up the FDA approval process. In Congress, some legislative efforts are gaining traction. Democrats support legislation to allow Medicare to negotiate prices directly with drug companies. Other congressman have supported legislation to support the safe importation of less-expensive drugs from other countries. A bipartisan FAIR Drug Pricing Act would establish price transparency standards for drug companies. Yet other congressional bills would remove barriers to cheaper generic drugs. State governments are involving themselves deeply in drug-price battles. AARP supports making drug comparisons easier and implementing value-based pricing.

What is clear is that Americans pay 3 times more for the world's 20 top-selling drugs compared with UK citizens. The US leaves pricing to market competition, whereas other governments control medication costs directly or indirectly.

There's a war on, but it's unclear who will win it. ■

Ecstasy Therapy May Boost PTSD Therapy

According to a small study published in the *Lancet*, a therapeutic dose of 3,4-methylenedioxymethamphetamine (MDMA, or Ecstasy), when added to psychotherapy, produces a large effect on symptom severity in patients with posttraumatic stress disorder (PTSD). In the study, this effect lasted for a year. The study was a phase 2 trial of 26 veterans and first responders with PTSD. ■

CE I **Simplifying Continuity of Care: The Home Health Care/Case Manager Partnership** *continued from page 16*

make a significant difference in reducing readmissions and avoidable emergency department visits. Our industry is currently partnering with large insurers and rehabilitation hospitals to conduct larger, longer-term studies to measure comparative patient outcomes.

Undoubtedly, when compared with other care options, high-quality home health care can be a high-value investment that pays off not only in better health outcomes and lower costs but in higher client and family satisfaction. There are so many intangibles that a good home health care provider brings to the table that can't come from any other professional source or health care setting. These intangibles include the peace of mind that caring human beings understand their everyday challenges and are there to help; real-life education that helps clients and family caregivers feel confident and empowered in their own care and health care decisions; everyday oversight and interventions to prevent illness and injury; and coordination of medical supplies, bills, and services. All of these very personalized support systems relieve stress on the entire household and ensure a more calm and peaceful home environment that allows your client to live their best life and achieve the best possible healing and well-being.

In my work, I am always amazed by the resilience and positive outlook of our clients and families. The individual attention they get in the home care setting really makes a difference, and I love helping them on their journey. My peers and I often act as an advocate, educator, friend, and the ultimate cheerleader, encouraging them to keep moving forward. Being an integral part of each client's success story is our greatest reward. **CE I**

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We Are Case Management in Chicago
continued from page 10

and there are special rates for chapter leaders, groups of 3 or more registering together, and members of the military, Department of Defense, and Veterans Affairs. And, don't forget: when you register as a full conference participant, you receive a complimentary 1 year CMSA membership!

We can't wait to see so many of you at our premier, international case management conference in Chicago. Many thanks to those of you who attend year after year. If you've never attended, what are you waiting for? There's still time. We Are Case Management, in Chicago and beyond! **CM**

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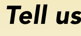

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CE II **Independent Case Managers—Why Are They Necessary?** *continued from page 21*

advocate for on behalf of the patient and the results that occur because of it. In this way, nurses are building legacies that they couldn't otherwise have built.

Case managers are with their patients through the entire process: the ups, the downs, the workarounds, the successes, and the failures. The entire care plan is customized as you go along. When something works, do more of it. When something doesn't, change it. The latter is where standard clinical methods fail. Too often patients are left to their own devices, repeating poor practices that can worsen their condition. But either they don't know any better, didn't understand the initial instructions, or were simply physically unable to achieve what was required and self-corrected. Whatever the reason, the effects can be detrimental, and no one is around to see what is slipping through the cracks.

An independent case manager can be like a great lawyer. It's not so much the crime committed that determines the punishment, but the particular lawyer's ability to provide guidance in another system that is very complex. Similarly, when it comes to health care, it's not about what condition or set of conditions a patient is diagnosed with that determines the outcome but rather how well that patient can navigate the complex health care system. And in this instance, an independent case manager is a critical ally.

An independent case manager can be valuable for patients, but it is not clear whether enough patients know to look for such an advocate to make job opportunities feasible and lucrative. As individuals become more educated about the role of an independent case manager, using a case manager will be no different than turning to a financial expert to help with your investments.

We have established that independent case managers are valuable, but the important question now is whether case management as a resource is common enough to be a viable offering in an entrepreneurial nursing business. After all, if the client doesn't know they need you, it becomes difficult to market yourself. We fill in the gaps in health care, keep lines of communication clear, and provide direct educational services on the spot. Medicare, Medicaid, insurance carriers, third party administrators, and private pay patients need us. Trust that you are indeed needed to advocate for your patients more than ever. **CE II**

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Working with Home Health Care Agencies *continued from page 2*

If these questions are satisfactorily answered, you are prepared to facilitate the appropriate physician orders to this agency for your patient.

Communication is key to ensuring an effective working relationship with a home health care agency. Negotiate your expectations about communication at the outset. Factor to consider include:

- Frequency
- Format: written or verbal
- Method: regular mail, fax, or email
- When do you want to be notified immediately?

You also may want to participate in patient care conferences when your patient's care plan is discussed. The home health care agency is your eyes and ears for your patient. Regular communication will promote a good working relationship and help ensure that the care received is needed and appropriate for your patient.

Home health care is a valuable service for patients across their health care continuum. Case managers working with home health care agencies can ensure that patients receive care that benefits them and helps them achieve the desired outcome.

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ACCM: Improving Case Management Practice through Education

coated tablets, imprinted with "LFX" on one side and "18" on the other side; approximately 7 mm in diameter.

Bottles of 36 tablets

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Store in original container at controlled room temperature, 25°C (77°F); with excursions permitted between 15°C to 30°C (59°F to 86°). Keep Lucemyra away from excess heat and moisture both in the pharmacy and after dispensing. Do not remove desiccant packs from bottles until all tablets are used. Keep Lucemyra and all medicines out of the reach of children.

PATIENT COUNSELING INFORMATION

Advise patients to read the FDA-approved patient labeling.

Lucemyra may mitigate, but not completely prevent, the symptoms associated with opioid withdrawal syndrome, which may include feeling sick, stomach cramps, muscle spasms or twitching, feeling of cold, heart pounding, muscular tension, aches and pains, yawning, runny eyes and sleep problems (insomnia). Patients should be advised that withdrawal will not be easy. Additional supportive measures should be clearly advised, as needed.

Hypotension and Bradycardia

Inform patients to be alert for any symptoms of low blood pressure or pulse (e.g., dizziness, lightheadedness, or feelings of faintness at rest or on abruptly standing). Advise patients on how to reduce the risk of serious consequences should hypotension occur (sit or lie down, carefully rise from a sitting or lying position).

Patients being given Lucemyra in an outpatient setting should be capable of and instructed on self-monitoring for hypotension, orthostasis, and bradycardia and advised to withhold Lucemyra doses and contact their healthcare provider for instructions if they experience these signs or related symptoms.

Advise patients to avoid becoming dehydrated or overheated, which may potentially increase the risks of hypotension and syncope.

Concomitant Medications

Review with patients all concomitant medications being taken and request that they immediately inform their healthcare provider of any changes in concomitant medications, including any other medications that may be used to treat individual symptoms of withdrawal.

Increased Risk of CNS Depression with Concomitant use of CNS Depressant Drugs

Inform patients of the increased risk of CNS depression with concomitant use of benzodiazepines, alcohol, barbiturates, or other sedating drugs.

Advise patients using Lucemyra in an outpatient setting that, until they learn how they respond to Lucemyra, they should be careful or avoid doing activities such as driving or operating heavy machinery.

Sudden Discontinuation of Lucemyra

Inform patients not to discontinue Lucemyra without consulting their healthcare provider.

Risk of Opioid Overdose After Discontinuation of Opioids

Advise patients that after a period of not using opioid drugs, they may be more sensitive to the effects of opioids and at greater risk of overdosing.

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tion for methotrexate or biologics/tofacitinib were identified from EHRs. Claims data were used to ascertain filling or administration status. A logistic regression model for predicting primary nonadherence was developed and tested in training and test samples. Predictors were selected based on clinical judgment and LASSO logistic regression.

RESULTS: A total of 36.8% of patients newly prescribed methotrexate failed to initiate methotrexate within 2 months; 40.6% of patients newly prescribed biologics/tofacitinib failed to initiate within 3 months. Factors associated with methotrexate primary nonadherence included age, race, region, body mass index, count of active drug ingredients, and certain previously diagnosed and treated conditions at baseline. Factors associated with biologics/tofacitinib primary nonadherence included age, insurance, and certain previously treated conditions at baseline. The area under the receiver operating characteristic curve of the logistic regression model estimated in the training sample and applied to the independent test sample was 0.86 and 0.78 for predicting primary nonadherence to methotrexate and to biologics/tofacitinib, respectively.

CONCLUSIONS: This study confirmed that failure to initiate new prescriptions for methotrexate and biologics/tofacitinib was common in RA patients. It is feasible to predict patients at high risk of primary nonadherence to methotrexate and to biologics/tofacitinib and to target such patients for early interventions to promote adherence.

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Vol. 24, No. 3, June/July 2018.
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