

CareManagement

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Chronic respiratory conditions can negatively impact most, if not all, activities of daily living. Shortness of breath and the inability to consistently maintain adequate oxygenation can become a constant and continued focus of the patient, their family, and their caregivers. Part 1 of this review article focuses on the chronic respiratory conditions of bronchiectasis and bronchiectasis COPD overlap syndrome (BCOS) and the unique mechanisms that are associated with impaired airway clearance. We discuss the hypothetical case of a 69-year-old female with advanced bronchiectasis that is complicated by several comorbidities including COPD.

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Gary S. Wolfe

Chronic Kidney Disease

With chronic kidney disease (CKD), kidneys become damaged over time and cannot clean the blood as well as healthy kidneys. When the kidneys don't work well, waste and extra water build up in the body and may cause other health problems. Despite the increasing prevalence of CKD, it is often underrecognized and undertreated. Kidney disease often has no symptoms in its early stages and can go undetected until it is very advanced. For this reason, kidney disease is often referred to as a "silent disease." Evidence for screening and management of the early stages of CKD is limited. Case managers can help educate patients about CKD, which can have a significant impact on patient outcomes.

Some statistics:

- 15% of US adults (37 million people) are estimated to have CKD.
- Most (9 out of 10) adults with CKD do not know they have it.
- 1 in 2 people with very low kidney function who are not undergoing dialysis do not know they have CKD.
- CKD is more common in people aged 65 years or older.
- CKD is more common in women than men.
- African Americans and Mexican Americans are more likely to have CKD than Caucasians.
- About 14% of Hispanics have CKD.
- Patient awareness is <10% for those with stages 1 to 3 CKD.

Common risk factors for the development of CKD include:

- Diabetes
- Hypertension

- Age >55 years
- Family history of kidney disease
- Obesity or metabolic syndrome

Key aspects of the medical history in evaluating patients with CKD include prior kidney disease, incidental albuminuria or hematuria, urinary symptoms, history of nephrolithiasis, family history of kidney disease, diseases that share risk factors with CKD, systemic diseases that might affect kidney function, and a history of use of medications that might affect renal function, especially nonsteroidal anti-inflammatory drugs, herbal medications, lithium, and calcineurin inhibitors.

People who are at risk for CKD should be screened annually.

The following are key elements of patient education for CKD:

- Ensure patient awareness of CKD diagnosis
- "Know your numbers"—make the patient aware of their kidney function (estimated glomerular filtration rate and creatinine) and blood pressure goals
- Ensure that patients are aware of the need for screening and treatment of comorbid conditions such as diabetes, hypertension, and coronary artery disease
- Instruct patients to avoid potentially nephrotoxic medications, especially nonsteroidal anti-inflammatory drugs, herbal medications, and nutritional protein supplements
- Encourage the patient to talk with their physician, nephrologist, or pharmacist before starting a new medication to ensure safety and appropriate renal dosing

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Why Stay Certified?

Professional Commitment Meets Lifelong Learning

Vivian Campagna, MSN, RN-BC, CCM

Congratulations—you're a Certified Case Manager® (CCM®), becoming one of more than 46,000 board-certified professionals currently in practice. Now, it's time to think ahead toward renewal.

CCM certification is valid for 5 years, after which renewal must be achieved either by documenting 80 clock hours of approved continuing education (CE) or by reexamination. For most, pursuing approved CE is the preferred pathway to renewal.

This is more than just an administrative requirement. Rather it's an opportunity to reflect on what certification means to you and your career. After all, when you choose to be certified, there is a cost involved, which your employer may or may not reimburse. Renewal also carries a cost. But the value that certification brings to your career truly is priceless.

Vivian Campagna, MSN, RN-BC, CCM, is the chief industry relations officer for The Commission for Case Manager Certification (CCMC), the first and largest nationally accredited organization that certifies more than 46,000 professional case managers and over 2,600 disability management specialists. Vivian has been involved in case management for more than 25 years, holding staff and administrative positions on both the independent and acute care side of the industry, and is passionate about the value of certification.

Employers increasingly recognize the value of certification. The percentage of employers who require board certification is growing: 44% in 2019 compared with 40.2% in 2014. For example, hospitals seeking magnet status recognize that certified nurses help improve the quality of care, which is also backed by documented evidence. The same can be said for case managers, who come from a

Certification attests that you have attained an advanced level of knowledge to apply to case management practice. You are committed to adhering to the highest levels of ethical and professional standards and to promote autonomy, beneficence, and nonmaleficence to protect clients.

variety of professional disciplines, including social work, rehabilitation, mental health, and pharmacy. Through certification they showcase their professionalism and expertise among their peers on transdisciplinary teams as well as with the clients they serve (individuals receiving case management services).

Importantly, there are intrinsic motivations for getting certified and staying certified. Certification attests that you have attained an advanced level of knowledge to apply to case management practice. You are committed to adhering to the highest levels of ethical and professional standards and to

promote autonomy, beneficence, and nonmaleficence to protect clients. As this shows, certification is not merely a piece of paper to display on the wall or some initials to list after your name. It embodies your attitude, professionalism, and commitment to the practice every day.

Staying Certified: Your “How-To”

Once you commit to staying certified, the next step is pursuing the required CE. The Commission for Case Manager Certification (CCMC) requires 80 hours of CE for renewal every 5 years, including 8 CEs in [ethics](#).

There are many ways to earn approved CEs. The CCM [Renewal Guide](#) lists several options. Among them are workshops, seminars, conferences, and in-service training programs; home studies, distance learning courses, and webinars; college or university courses; development of curriculum; writing articles, books, and chapters in books; development of presentations and in-service training programs; and research/independent study.

Other resources to support renewal, as well as lifelong learning, include the Case Management Body of Knowledge ([CMBOK](#)) and the [CMLearning Network®](#), which features research, case examples, and the latest on regulatory changes, ethics,

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Engaging Employees in the Return-to-Work Process

Ed Quick, MA, MBA, CDMS

Return-to-work (RTW) programs have long track records of success for assisting employees to ease back into the workplace following an injury or illness. Among the best practices is engaging the employee as soon as possible in RTW discussions and strategies and not waiting (as was common in the past) until the person has reached a certain level of improvement. By the time an employee is considered “100%” improved, that individual may be largely disconnected from the workplace, unconditioned to work, and/or less motivated to resume working.

Certified Disability Management Specialists (CDMSs) and Certified Case Managers (CCMs) who have expertise in disability case management play

Ed Quick, MA, MBA, CDMS, a Commissioner with the Commission for Case Manager Certification (CCMC), has more than 15 years of experience in disability and workforce management with Fortune 100 companies and currently works as a global senior benefits manager. CCMC is the first and largest nationally accredited organization that certifies more than 45,000 professional case managers and nearly 2,500 disability management specialists. The Commission oversees the process of case manager certification with its CCM® credential and the process of disability management specialist certification with its CDMS® credential.

crucial roles. These professionals can engage the employee early in the RTW process. The end goal of resuming productivity is present in every discussion from the very beginning.

Return-to-work (RTW) programs have long track records of success for assisting employees to ease back into the workplace following an injury or illness. Among the best practices is engaging the employee as soon as possible in RTW discussions and strategies and not waiting (as was common in the past) until the person has reached a certain level of improvement.

Gathering employees’ input throughout the RTW process is also very important. Employees usually know their jobs best, and when they are part of the RTW process they can contribute perspectives and suggestions of what might be done to allow them to go back to work.

RTW strategies such as job modifications, transitional duties, and temporary work assignments elsewhere in the company are beneficial. Employees can resume working as soon as is medically feasible and with a physician’s approval, sometimes in a part-time or other limited capacity. “Work hardening,” as it’s known, is considered physically therapeutic and brings emotional benefits by reconnecting the individual socially to the workplace while they continue to recuperate.

Many resources exist to help educate employees and employers

about job accommodations, such as the U.S. Department of Labor’s [Job Accommodations Network](#). These resources help illustrate what is possible to facilitate RTW, such as with

reassignments, assistive devices, and other support to remove barriers for people returning to the workplace. While RTW has traditionally been associated with physical injuries covered by workers’ compensation, in larger and more progressive employers in particular, RTW is also offered to

employees who are off work due to nonoccupational health conditions. Such interventions help minimize the impact of disability and unplanned absences on employers while enabling employees to maintain their earnings power.

A Documented Process

As part of the RTW process, CDMS can help reduce or mitigate the employer’s risk by ensuring proper documentation. Employers are responsible for accurate descriptions of a job in terms of physical demands (eg, lifting, standing, or other physical aspects of the job) as well as cognitive demands (eg, making calculations or providing customer service). Such documentation sets a baseline understanding of what a job entails, what the essential functions

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CARF International Invited to Participate in the World Health Organization Second Rehabilitation 2030 Meeting

CARF International was invited to participate in the World Health Organization (WHO) Second Rehabilitation 2030 meeting in Geneva, Switzerland. Case managers should be engaged in understanding their critical role in moving this agenda forward. For those who might not be familiar with this movement, the following synopsis will assist you in considering what role the field of case management has and what it has to offer to move this agenda forward around the world.

In 2017 WHO launched their Rehabilitation 2030 initiative and raised a "Call for Action."

At that point, 15 out of every 100 people internationally had a disability. Disability is increasing due to, among other causes, individuals aging, rising prevalence of noncommunicable diseases, limited health care, war, natural disasters, and lack of nutrition. Rehabilitation was identified as a key health strategy along with promotion, prevention, treatment, and palliative care. Ten key activities were identified in the Call to Action as well as Sustainable Development Goals. To address these Sustainable Development Goals there is a need to strengthen rehabilitation leadership, planning, and integration across health care; to incorporate rehabilitation

into universal health coverage; and to integrate rehabilitation data across health information systems. Universal health coverage should have health services that address the full scope of the population's health needs. This universal coverage needs to include provision of services in health promotion, prevention, treatment, rehabilitation, and palliative care. The health care system at present needs to be strengthened to even come close to

- Lack of resources, assistive technologies, and devices.
- The need for more research and data on rehabilitation.
- Ineffective and underutilized referral pathways to rehabilitation.

When reviewing this list, it becomes evident that this is not limited to only low- to middle-income areas of the world but everywhere since health care coverage is under duress because of the changing determinants of health policy and implementation internationally.

In the past 2 years, WHO and its member states and key stakeholders have been moving forward with the Rehabilitation in Health Systems, Guide for Action (the Guide).

On July 8–9, 2019, in Geneva, Switzerland, the Second Rehabilitation 2030 meeting was held at WHO headquarters. The main emphasis was the integration of rehabilitation into primary care with real examples from countries at various levels of integration and development.

having these services worldwide.

The demand for rehabilitation is largely unmet because of a variety of factors including but not limited to:

- Lack of prioritization, funding, policies, and plans for rehabilitation at national levels.
- Lack of available rehabilitation services outside urban areas and long waiting times.
- High out-of-pocket expenses and nonexistent or inadequate funding mechanisms.
- Lack of trained rehabilitation professionals with less than 10 skilled practitioners per 1 million populations in many low- and middle-income settings.

The Guide is a 4-phase process with guidance to lead governments through health care strengthening with a focus on rehabilitation. It is meant to facilitate leadership and planning for rehabilitation through a situation assessment and strategic planning process. This Guide should strengthen rehabilitation information and accountability through the development of systems that support rehabilitation monitoring and evaluation.

On July 8–9, 2019, in Geneva, Switzerland, the second Rehab 2030 meeting was held at WHO headquarters. There were over 200 participants representing an

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Private Duty Services for All!

By Elizabeth Hogue, Esq.

In order to be appropriate for home care services of all types, patients must be able to care for themselves or have primary caregivers who can meet patients' needs in between visits from professional staff from home care providers. This requirement is necessary to meet the eligibility of many payors, to avoid risk of legal liability, and to help ensure quality of care.

Patients' family members or others may be willing to serve as primary caregivers on a voluntary basis. If not, providers should offer patients and/or their family members the option to pay privately for primary caregivers. These services may be referred to as private duty or nonmedical services.

The option to pay for private duty home care services should be offered to all patients who cannot care for themselves and who have no voluntary primary caregivers. Patients who can care for themselves or have voluntary primary caregivers may also wish to contract for additional assistance, so providers should offer this option to all patients who may benefit from these services.

Specifically, this means that:

- Hospital discharge planners/case managers should offer private duty services to all patients who may benefit from them and assist

patients to arrange for such services postdischarge as part of the discharge planning process.

- Other types of institutional providers such as skilled nursing facilities, long-term acute care hospitals, and independent rehabilitation facilities, should also offer patients who are being discharged the option to arrange for assistance from private duty agencies and should arrange for such services postdischarge.

Providers may be reluctant to offer these services to patients and their families because of their cost. They may also erroneously conclude that patients and their families cannot afford them. Providers should not jump to conclusions about who can afford these services. Instead, private duty home care services should be offered to all patients and their family members who may benefit from them.

A home health agency, for example, decided that a patient no longer met the eligibility requirements of the Medicare Program. The staff of the agency was reluctant to offer the patient the option to private pay for additional services before discharge because the patient lived in a "shack" and drove an old beat-up

truck. They did so anyway. To the staff's surprise, upon receipt of the offer, the patient got out of bed, extracted a wad of cash from under the mattress, and told the staff that there was plenty more money to pay for private duty services!

Private duty care has a very important role to play in the provision of home care services. This type of care should be offered to all patients whenever it seems that patients may benefit from it. [CM](#)

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Hospital discharge planners/case managers should offer private duty services to all patients who may benefit from them and assist patients to arrange for such services postdischarge as part of the discharge planning process.

- Assisted living facilities should offer private duty services to all of their patients who may benefit from such services.
- Home health agencies should offer patients the option to privately pay for services if primary caregivers are no longer available to provide assistance and if patients no longer meet the eligibility requirements of payor sources.
- Home health agencies, hospices, and home medical equipment companies should educate patients about private duty services even though patients may have voluntary caregivers and help patients and their families arrange for these services.

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.

Ambition is a Fabulous Word

Kathleen Fraser, MSN, MHA, RN-BC, CCM, CRRN, FAAN

“Keep away from those who try to belittle your ambitions. Small people always do that, but the really great make you believe that you too can become great.”

—Mark Twain

Everyone has a distinct idea about how they describe or talk about ambition. Often people turn it into an ugly connotation, giving the word a bad reputation. I, however, think the word ambition is fabulous. In my mind it has a lot to do with leadership, and we need a new kind of leadership in many areas of healthcare that govern case management. It is time for case managers to step into these leadership positions without being asked or cajoled into leading. I do not necessarily mean only leading as executives but also as leaders in how we manage our patients. We are very thoughtful about things and rarely say “Oh, me first,” but we must start thinking that way a bit more or nothing will change. Not our systems, our transitions of care (or lack thereof), and/or patient education.

Ambition can instead be defined as or looked upon as an eager or strong desire to accomplish something. These are leadership skills a lot of people don't even recognize. According to Webster, “Here for good” has dual meanings: both “here to do good” and “here for the long term.” These

definitions fit perfectly with case management's desire to create both economic (as financial stewards) and social (as patient advocates) value for our patients. A good case manager's nature, and quite frankly, job, is to have an expansive view and a shared purpose. It should also be marked by high levels of emotional connection, trust, and respect with regard to not only our patients and their families but also our own counterparts and other healthcare stakeholders. Higher-ambition case management leaders, unlike many executives in other fields, are not content with achieving only strong fiscal returns. Rather, they strive to generate high performance on 3 fronts at once: creating long-term economic or fiscal value, producing significant benefits for the wider community, and building a robust social capital within their own organizations. We have all worked with leaders who do well in one of these areas, but a higher-ambition leader unlocks the true value of their organization's full human and business potential to excel in all three.

Any case manager who has direct contact with his or her patients, either in person or telephonically, has changed lives. This gives their world, and therefore our world, value. In my eyes it is simple: case managers who

truly aspire to raise those they touch to greater heights have to have a certain ambitious quality in their personality. Frank Tyger states “Ambition is enthusiasm with a purpose.” At times we all feel we don't really know what we are doing or what our purpose is. However, if we keep our enthusiasm and realize that everyone feels this way at times, our confidence grows in our own leadership skills. As leaders and as case managers, we must feel comfortable working directly with others outside traditional lines of command so that decisions don't continually get bumped up the hierarchy. We need to be able to appreciate different points of view, working styles, and cultures and to build relationships within our environment that are strong enough to transcend those differences. We have done that with our patients, and as leaders we need to do the same with our counterparts and those we lead.

I used to be a ruminator in my 20s and it got me nowhere. I worried all the time, and it was pointless. I recently read a great Maya Angelou quote that said, “If you don't like something, change it. If you can't change it, change your attitude.” When I began looking at the word ambition in a different way and how we can equate it with leadership, I felt like a door opened

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

CE I

Role of Case Managers in Improving Kidney Disease Patients' Outcomes

By **Rajitha Bommakanti, RN, BSN, CCM**

According to the National Kidney Foundation, 30 million Americans have chronic kidney disease (CKD), primarily due to diabetes and hypertension.¹ More than 510,000 patients with end-stage renal disease (ESRD) are on dialysis, and over 100,000 are on kidney transplant lists.¹ Medicare alone spends \$114 billion annually caring for CKD patients, and this does not include the cost of treating CKD patients with private insurance.² The rate of CKD is increasing rapidly in the United States, largely driven by the obesity epidemic.² Despite the high cost of disease burden, there is low awareness about the condition among patients with kidney disease.²

Kidneys are responsible for removing waste and excess fluid from the body and for maintaining the body's electrolytes.¹ Progressive damage to the kidneys can worsen over time is called CKD¹. CKD is classified into 5 stages:

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Stage 1 is very mild damage, and Stage 5 is complete kidney failure¹. When the kidneys reach the fifth and final stage, it is called ESRD.¹ At this stage, individuals either require life-sustaining dialysis treatments or a kidney transplant.¹

Deaths resulting from CKD have increased by 58% in the last 14 years, according to the data from the 2016

in this age group to reduce the burden of CKD.³

There are concerns regarding widely prescribed and used proton pump inhibitors (PPI) because they may cause kidney damage with prolonged usage.⁴ Recent evidence-based studies have shown that prolonged use of PPIs can cause acute kidney injury,

CKD, ESRD, and electrolyte abnormalities.⁴ It is recommended that people who take PPIs follow dosing and duration recommendations established by the U.S. Food and Drug Administration (FDA).⁴ While taking a PPI, it might be helpful to monitor renal function

According to the National Kidney Foundation, 30 million Americans have chronic kidney disease, primarily due to diabetes and hypertension. More than 510,000 patients with end-stage renal disease are on dialysis, and over 100,000 are on kidney transplant lists.

Global Burden of Disease study.³ The CKD burden and death rates due to CKD have significantly increased in the South.³ This has been attributed to an increase in metabolic and dietary risk factors, aging, and overall population growth.³ The study findings indicated that deaths due to CKD increased by 26.8% in individuals aged 20–54 years, primarily due to diabetes.³ The increase in the burden of CKD and the deaths due to CKD among individuals aged 20–54 were correlated with an increase in metabolic and dietary risk factors.³ Metabolic syndrome is a group of risk factors such as high blood pressure, high blood sugar, high unhealthy cholesterol, and abdominal fat. Metabolic syndrome and dietary factors should be aggressively targeted

and electrolytes including potassium, calcium, magnesium, and sodium.⁴

Symptoms of kidney damage are not apparent during disease progression and do not occur until the late stages of kidney damage. These symptoms include nausea, vomiting, decreased appetite, edema of the lower extremities, inadequate urine output, shortness of breath, muscle cramps, and itching. Many individuals with ESRD have poor health outcomes, often due to underlying disease complications and multiple comorbidities, which can lead to high mortality rates. Patients with ESRD often visit multiple providers and follow multiple care plans because of their complex medical issues. Complex care of these patients needs to be coordinated and should

**Managing risk factors is the key to preventing CKD and its complications.
Early CKD has no signs and symptoms, and undetected CKD can lead to kidney failure.
Ninety percent of kidney function is lost before symptoms are apparent.**

focus on creating person-centered care, with an ultimate goal of improving health outcomes.

The most common causes of CKD are diabetes and high blood pressure.³ Over a quarter of kidney failure cases are due to hypertension, and one third of cases are due to uncontrolled diabetes.³ Managing risk factors is the key to preventing CKD and its complications. Early CKD has no signs and symptoms, and undetected CKD can lead to kidney failure. Ninety percent of kidney function is lost before symptoms are apparent.⁵ Kidney disease is progressive, and early diagnosis is the key to better management.⁵ Early identification of failing kidney function allows appropriate treatment before kidney deterioration manifests itself through other complications.⁵

Kidney damage is usually permanent, but steps can be taken to control the progression of the disease. To control the progression of kidney disease, patients should control their sugar levels, keep their blood pressure within acceptable range, eat a low-sodium and low-fat diet, maintain a healthy weight, exercise at least 30 minutes a day, avoid smoking, limit alcohol consumption, and consult a physician to avoid nephrotoxic medications. Early diagnosis and treatment of the underlying cause of kidney damage and/or the establishment of secondary preventive measures are important for patients with chronic CKD.⁵

Case managers can play an

important role in supporting CKD patients and their families by providing comprehensive assistance in all areas related to ongoing education, medications, development of support systems, lifestyle changes, behavior modifications, and financial options. Case managers can play a crucial role by identifying patients with uncontrolled hypertension and diabetes in primary care settings who are at high risk for kidney disease.

Case managers who lead primary care clinics need to identify and target patients who are at high risk for kidney disease. These include patients with diabetes, hypertension, a body mass index >35, cardiovascular disease, and a family history of CKD as well as patients who are receiving nephrotoxic drugs and herbs and those who are older than 65 years.⁶ A CKD prevention committee should be organized, and the case manager should play a pivotal role as an educator and action leader by including a multidisciplinary team of nephrologists, renal dietitians, pharmacists, and social workers. The goal of this committee should be to articulate best practices in the early detection, prevention, and management of CKD. The focus should be on risk factors such as diabetes, hypertension, and hyperlipidemia control. Individuals should be taught to abstain from harmful herbs and nephrotoxic agents, and there should be effective collaboration with patients to make significant lifestyle changes. Kidney disease can be detected early

with serum creatinine levels that are used to determine the estimated glomerular filtration rate, urinary albumin: creatinine ratio, and urine protein from a dipstick.⁵ Individuals who have CKD should be immediately referred to a nephrologist.⁵

Case managers need to reach out to their patients by telephone once every 2 weeks, and they should review their patients' condition with their patients' primary care providers. Case managers can recommend ordering laboratory tests for serum creatinine and estimated glomerular filtration rate to identify patients who could be at high risk for kidney disease and refer them to a nephrologist. Community-based CKD management programs should promote early intervention by offering disease monitoring for patients with high-risk diseases such as diabetes, hypertension, and heart failure; medication reconciliation; and nutritional consults; patients should also be encouraged to adhere to vaccination schedules and should receive psychosocial and financial support. Dedicated case managers should keep patients with CKD engaged, build a relationship with them, proactively assess their plan of care, address risk factors, and provide education about CKD. The goal of these case managers should be to involve patients in their care to delay progression of disease. Patients who are progressing towards Stage 3 disease should be followed more closely by case managers; case managers should educate these patients about their disease

Case managers can play a crucial role by identifying patients with uncontrolled hypertension and diabetes in primary care settings who are at high risk for kidney disease.

so that they are aware of the possibility of dialysis or kidney transplant.

When managing patients with CKD, the goal should be to slow the progression of CKD, reduce the incidence of emergent dialysis, increase the rate of prepared vascular access before initiation of dialysis, and increase penetration of peritoneal dialysis.²

Dr. Rajiv Saran, a professor of internal medicine at the University of Michigan and director of the United States Renal Data System (USRDS) Coordinating Center, stated that “Over a third of patients starting dialysis have not had the benefit of being evaluated by a nephrologist prior to this life-changing event.”² This gap in care can be overcome by implementing nurse case management programs that would be responsible for communicating and developing a care plan.

Cigna Health Insurance Company conducted a pilot study in which patients who were at risk for progression to CKD Stage 4 were identified and assigned to a case manager who followed their care.⁶ The study demonstrated improvement in patient health outcomes and lower health care costs for patients who were at risk for CKD.⁶

A 2015 study by Greer and Boulware⁷ provided a framework for high-quality primary care in which case management and community health

workers collaborated. This model has been shown to improve processes in quality improvement initiatives, with a focus on team approaches to chronic care.⁷ In addressing the CKD population, the results of the study suggested that improving processes in CKD-related care transformed

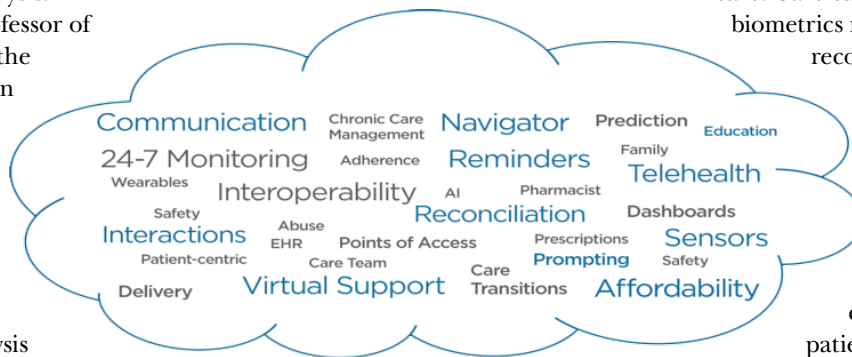


Figure 1. Source: Care Coordination/Aging 2.0 Care Coordination/Aging 2.0. (2019). Care coordination. Retrieved from <https://www.aging2.com/grandchallenges/care-coordination/>

patients' CKD risk factors.⁷ Other models that have been effective in improved processes in relation to CKD care are patient-centered care, disease registries, and decision support interventions.⁷ Case managers who encourage patients to be active participants in their own medical care enhance patients' skills and confidence to self-manage their illness; these case managers also help patients identify barriers that need to be addressed to self-manage their care effectively. Initiation of these interventions in the primary care settings with a multidisciplinary team is the key to the success of these programs.⁷

The virtual team-based model of care with the assistance of teletechnology in assessing and managing care could be a means to improving patient outcomes. This model can be successful if the case manager takes the lead role in coordinating patient-centered care. Care can be mobilized by biometrics reporting, medication reconciliation, appointment reminders, and access to virtual nutrition. This innovation can help advance the prevention, early detection, and treatment of kidney disease, it can manage patient outcomes, and it can engage patients.

Since kidney disease is silent until it progresses to the late stages, only a small number of individuals who have Stage 1 to 3 CKD are aware that they have the disease. Individuals may not be aware that they have CKD because only a small percentage who are at high risk for CKD undergo urine testing for protein. An Israeli digital health company called Healthy.io has developed an FDA-approved home smartphone urinalysis test that allows individuals to test themselves for kidney damage.⁸ The Healthy.io's urinalysis test, Dip.io, uses disposable strips and cups along with a smartphone camera to read and interpret the results.⁸ This is how it works: patients dip a stick in their urine sample, wait for it to develop, and take a picture of it against a card

using the company's app.⁸ The image is anonymized (patient identification is blocked) and goes to cloud-based monitors for details of the test.⁸ This home-based urinalysis test is still in early stages, but if this technology works it will make a big impact on health care cost savings will save lives because of early detection of kidney disease.⁸ If there is enough evidence that the test works, it will change the standard of care for kidney disease.⁸

Figure 1 represents a word cloud depicting the numerous components involved in managing care of older adults with chronic conditions. It is relevant because the case manager is the key health care professional coordinating the required care. All the aspects of care identified are essential for effective care delivery for patients

with chronic conditions.

A proof of principle is to place case managers in primary care settings where they are teamed up with providers to identify high-risk CKD patients. Early intervention is a treatment approach for targeting and attacking disease to prevent and/or delay the development of CKD. The effectiveness of early intervention can be measured in many different ways, first and foremost by the number of patients who live longer without progression of CKD. Early intervention should also include patient empowerment and interdisciplinary team involvement. The primary care team should also include endocrinology and cardiology team providers. I don't think these interventions will make an immediate

difference overnight, but I do suspect that over time they will make a big difference in patient outcomes and will eventually become the standard of care. **CE I**

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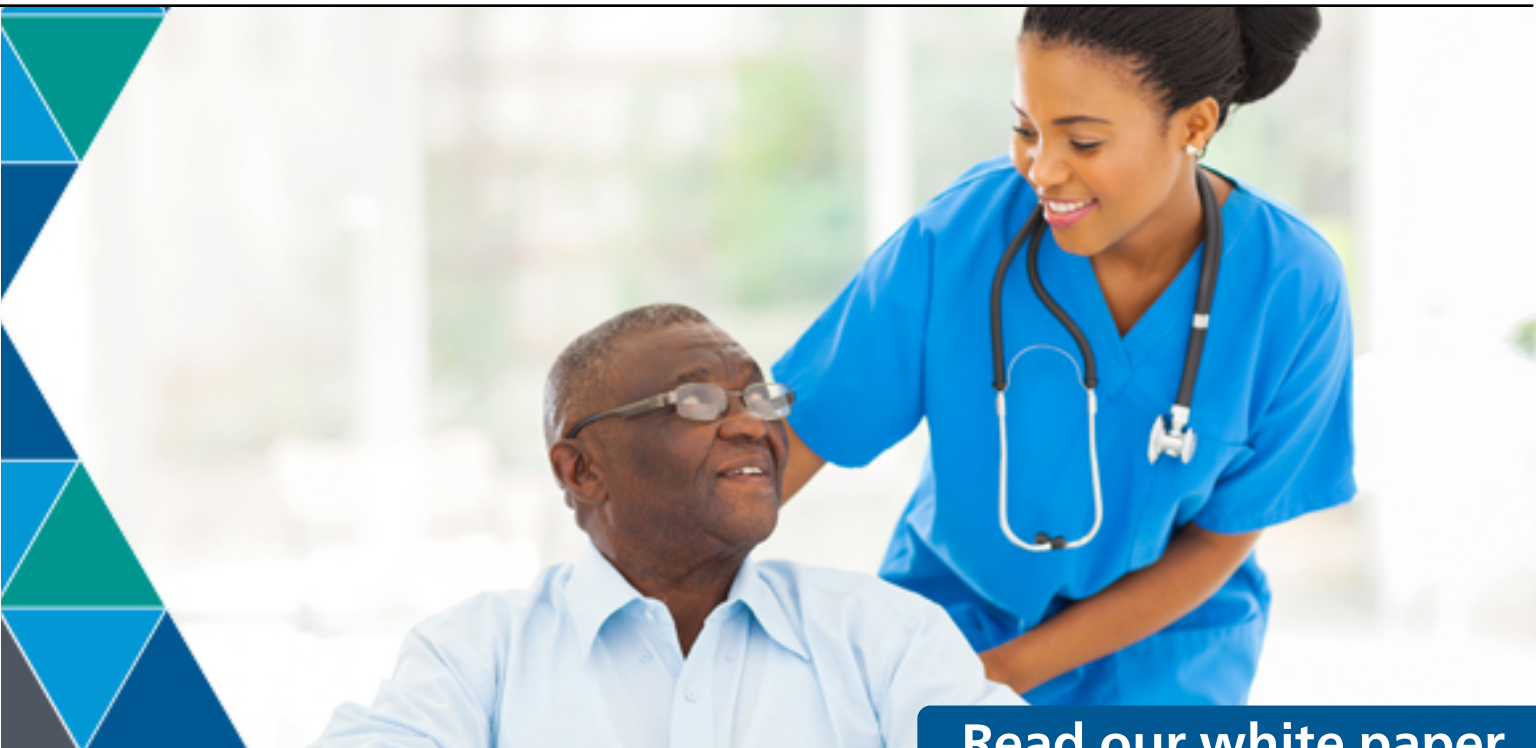
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CE II What Every Case Manager Should Know About Effectively Facilitating Care for Chronic Respiratory Disease Patients with Bronchiectasis: *Part I*

By Nancy Linda and Nancy Skinner

The information contained within this document was developed to assist the professional case manager, care coordinator, or transitional care manager in gaining additional information regarding the unique healthcare journeys that some patients diagnosed with chronic respiratory diseases and conditions may experience.

Introduction and Overview

Chronic respiratory conditions can negatively impact most, if not all, activities of daily living. Shortness of breath and the inability to consistently maintain adequate oxygenation can become a constant and continued focus of the patient, their family, and their caregivers. The initial sections of this document will focus on the chronic respiratory conditions of bronchiectasis and bronchiectasis COPD overlap syndrome (BCOS) and the unique mechanisms that are associated with impaired airway clearance. Subsequent areas for review will include information regarding the timely diagnosis of this condition, the signs and symptoms that serve as the hallmarks of bronchiectasis, and currently recognized treatment and disease management.

In addition to offering information regarding both normal respiratory function and respiratory compromise, this resource will discuss the roles and functions commonly associated with a professional practice of case management. The foundation for that discussion is based on the Standards of Practice that guide that professional practice. For this discussion, both the Standards of Practice & Scope of Services for Health Care Delivery System Case Management and Transitions of Care (TOC) Professionals as presented by

Nancy Skinner, the principal consultant for Riverside HealthCare Consulting, has over 30 years' experience in the practice of case management and advancing programs that promote excellence in care coordination and other transitional care strategies.

Nancy Linda, the National Education Manager at Hillrom Respiratory Care, has over 20 years' experience caring for patients with respiratory disease, mechanically ventilated patients, quadriplegics, closed head injury patients, comatose patients, and other neurologically impaired patients.

the American Case Management Association (ACMA) and the Standards of Practice for Case Management from the Case Management Society of America (CMSA) will be used.

An essential aspect of any review of the case management process includes the role of the case manager as a patient advocate. To support that vital case management function, the final section of this document will offer a review of the specific aspects of the case management process that can be used to enhance a safe, patient-specific journey towards the effective management of chronic respiratory impairment.

Respiratory Function

The respiratory system, on the most basic level, facilitates gas exchange from environmental air into the circulatory system. We breathe in oxygen, which diffuses into the blood for systemic circulation and ultimately produces adenosine triphosphate for use as energy on a cellular level, and we breathe out carbon dioxide along with other metabolic byproducts from the body.¹ The mucociliary escalator and cough reflex maintain optimal function of the respiratory system by removing secretions and preventing airway obstruction. In health, 10–100 mL of airway secretions are continuously produced and cleared by the centripetal movement of the mucociliary escalator and with the aid of transient increases in expiratory air flow. There are a variety of factors that can interfere with the body's natural defense mechanism, making it difficult to mobilize and evacuate secretions from the airways. Airway obstruction and structural damage to the airways and lung parenchyma result from recurring secretion retention, infection, and inflammatory changes. Airway clearance therapy is indicated for individuals whose function of the mucociliary escalator and/or cough mechanics is altered and whose ability to

Chronic respiratory conditions can negatively impact most, if not all, activities of daily living. Shortness of breath and the inability to consistently maintain adequate oxygenation can become a constant and continued focus of the patient, their family, and their caregivers.

mobilize and expectorate airways secretions is compromised. Airway clearance therapy has for decades been considered one of the cornerstones of therapy for the prevention and treatment of pulmonary disease.²

Defining Bronchiectasis

Bronchiectasis is not considered to be a specific disease state but rather a pathological process characterized by generally irreversible dilation of the large airways, bronchi, and bronchioles with progressive destruction of parenchymal tissue. Bronchiectasis may arise from a large array of underlying diseases such as cystic fibrosis (CF), chronic bronchitis, chronic obstructive pulmonary disease (COPD), and asthma that is complicated by mucus hypersecretion and/or impaired mucociliary clearance.³ Nearly all individuals with CF develop bronchiectasis. The term non-cystic fibrosis bronchiectasis (NCFB) includes all cases arising from etiologies other than CF. Exacerbations are commonly prompted by stagnant bacteria-laden mucus pooled in lung cavitations created by the corrosive effects of inflammatory byproducts.⁴ Abnormally viscous mucus contributes to airway obstruction, mucus plugging, diminished gas exchange, and deteriorating lung function. Because chronic airflow limitation is a distinguishing feature, bronchiectasis is classified as an obstructive lung condition.⁵ Until quite recently, NCFB was considered such a rare condition in the industrialized West that it was often called an “orphan disease.”⁶ That impression has changed dramatically since the widespread use of high-resolution computed tomography (HRCT) scanning. Scan results now show that NCFB is a common condition with a rapidly rising prevalence.⁷ Current estimates suggest that diagnosis rates are increasing more than 8% annually and that more than 500,000 Americans are affected.⁷

BCOS: Symptoms, Diagnosis, and Treatment Modalities

In the past decade, a distinct subgroup, or phenotype of NCFB, called BCOS has been identified.⁸⁻¹⁰ Patients diagnosed with BCOS have a more-severe clinical course

and worse outcomes than NCFB patients without comorbid COPD.^{10,11} BCOS might be suspected in older patients with moderate-to-severe COPD who have increased sputum production.¹¹ In a recent meta-analysis, BCOS was associated with significantly higher frequencies of exacerbation and isolation of pathogenic organisms, more-severe airway obstruction, and higher mortality rates.⁸ Although BCOS cannot be cured, modern imaging techniques now make it possible to detect the condition at an earlier stage of development. Appropriate interventions, including effective airway clearance therapy, may limit disease progression and significantly improve symptoms and quality of life.

Following a comprehensive physical examination that may identify crackles, rhonchi, or wheezing on auscultation, HRCT is generally performed to establish a diagnosis of BCOS.⁵ Currently, in most pulmonology offices, clinicians rely greatly upon the Global Initiative for Chronic Obstructive Pulmonary Disease. Guidelines explain that comorbid bronchiectasis is associated with longer exacerbations and increased mortality and that treatment should be conventional for bronchiectasis combined with COPD strategies as indicated. Such treatments should include anti-inflammatory drugs such as inhaled corticosteroids, appropriate antibiotics, and physiotherapies with emphasis on airway clearance therapy.¹²⁻¹⁴

Bronchiectasis is most common in lower lobes, which may reflect gravity-dependent retention of infected secretions.^{1,2} Retained secretions cause obstruction and damage of airways, creating an environment for bacteria to grow that may lead to recurrent infections.³ Keeping airways clear of secretions is key to successful management of bronchiectasis.^{3,5,15}

While generalized information may be interesting, it does not truly capture the unique experiences of the patient who attempts to navigate the healthcare system with a worsening chronic respiratory condition or disease. The following is an example of a fictional patient who experiences a complicated healthcare journey.

Airway clearance therapy is indicated for individuals whose function of the mucociliary escalator and/or cough mechanics is altered and whose ability to mobilize and expectorate airways secretions is compromised. Airway clearance therapy has for decades been considered one of the cornerstones of therapy for the prevention and treatment of pulmonary disease.

CASE REPORT

Refractory Bronchiectasis/COPD Overlap Syndrome (BCOS) in an Older Adult

This hypothetical review considers a 69-year-old female with advanced bronchiectasis that is complicated by several comorbidities including COPD. This patient, referred to as Ms. Davis, is single with no children. Her only surviving relative is an elderly brother who is also single and resides in a neighboring state. Several years ago, she was referred by her primary care physician to a pulmonologist for further evaluation of a worsening cough and increasing sputum production. At the time of review, the patient did not appear to be in acute distress and although she appeared to be thin, the only health concerns she reported were some shortness of breath and increasing fatigue.

Over the previous 2 years, she had visited both her primary care physician and an urgent care center for treatment of shortness of breath, unrelenting cough, and copious amounts of purulent sputum. In each case, she was diagnosed with bronchitis and treated with antibiotic therapy. Other than the recurring symptoms of respiratory disease, Ms. Davis denied having any symptoms of heartburn, acid reflux, choking, or sinus problems. She additionally denied

any family history of lung disease as well as any personal health history of tuberculosis, systemic inflammatory disease, or any other form of chest infections including whooping cough. The results of blood tests, including antibody (immunoglobulin) levels, were normal.

Her medical history included a smoking history of 90 pack-years (45 years smoking 2 packs per day). Ms. Davis reported she had quit smoking 5 years ago because of progressive respiratory distress. Pulmonary function testing demonstrated a decrease in lung capacity with mild airflow obstruction. Based on worsening dyspnea, chronic cough with increasing sputum production, frequent respiratory infections, a history of smoking, and pulmonary function testing that demonstrated a decrease in lung capacity with mild airway obstruction, she was diagnosed with mild to moderate COPD. Her treatment plan initially included an inhaled bronchodilator, antibiotics, and exercise as tolerated.

Although her symptoms continued to progress, she did not follow up with the pulmonologist because of concerns regarding insurance

coverage. As her shortness of breath increased, she became less active and more socially isolated, which led to episodes of depression. The only social support she received was from a neighbor, who was not always available because of employment commitments, and from members of her church who occasionally assisted with shopping and transportation to Sunday services.

Because of frequent respiratory infections and increased sputum production, Ms. Davis began to see her primary care physician with increased frequency. The physician prescribed numerous courses of antibiotic therapy to address a variety of respiratory pathogens and she was again referred to a pulmonologist. Ms. Davis agreed to another pulmonology visit. The pulmonologist identified increased respiratory compromise and noted the progression of COPD from mild-to-moderate disease to moderate-to-severe disease. In addition to reinforcing a treatment plan that included antibiotic therapy, a bronchodilator, and exercise, an oscillating positive expiratory pressure device was prescribed.

Oscillating Positive Expiratory Pressure (OPEP)

OPEP is a technique that offers a combination of positive expiratory pressure with high frequency oscillations.¹⁶ The device uses 2 specific actions to improve respiratory

function. First, the device uses resistance to hold airways open and help air get behind the secretions. This makes it more difficult to breathe out. One must breathe out harder against the resistance, taking about 4 times as long to

Bronchiectasis may arise from a large array of underlying diseases such as cystic fibrosis, chronic bronchitis, chronic obstructive pulmonary disease, and asthma that is complicated by mucus hypersecretion and/or impaired mucociliary clearance. Nearly all individuals with cystic fibrosis develop bronchiectasis.

PATIENT EDUCATION RESOURCES

1. Bronchiectasis

- a. Chest Foundation
<https://foundation.chestnet.org/patient-education-resources/bronchiectasis/#living>
- b. American Thoracic Society
www.thoracic.org/patients/patient-resources/resources/bronchiectasis-pt1.pdf

2. COPD

- a. COPD Educational Library
<https://www.copdfoundation.org/Learn-More/Educational-Materials-Resources/Downloads-Library.aspx>

CONTINUING EDUCATION COURSES

1. Bronchiectasis; A Paradigm Shift in Management and Treatment

<https://library.hill-rom.com/Continuing-Education/CE-Courses/Online-Courses/Bronchiectasis-A-Paradigm-Shift-in-Management-and-Treatment1/>

2. Secretion Mobilization with High Frequency Chest Wall Oscillation (HFCWO)

<https://library.hill-rom.com/Continuing-Education/CE-Courses/Online-Courses/Secretion-Mobilization-With-High-Frequency-Chest-Wall-Oscillation-HFCWO/>

Or access both courses directly through the HealthStream® Website: <http://www.healthstream.com/hlc/hillromcourses>

breathe out than breathe in. Second, the device produces vibrations as the patient exhales.¹⁶ These vibrations seek to move mucus from the surface of the airway and minimize the viscosity of those secretions.^{16,17} After blowing through the device several times, the person huff coughs to clear the mucus from the lungs and out of the body.¹⁶ (Huff coughing involves taking a breath in, holding it for 2–3 seconds, and actively exhaling. Huffing is not as forceful as a cough, but it can work better and be less tiring. Huffing is like exhaling onto a mirror or window to steam it up.¹⁶) The use of the

OPEP technique should be specific to each unique patient's needs and the appropriate process for executing this technique should be taught to the patient by a health care professional with expertise in both technique and in providing patient education.^{16,17}

Patient education regarding the effective use of an OPEP device generally includes the following steps:¹⁶

1. Patients are instructed to inspire more deeply than normal, to briefly hold their breath, and then to exhale through the device with enough flow velocity, against the resistance, using the abdominal muscles at a slightly faster than normal rate.
2. The patient may stabilize their cheeks with their other hand during expiration if necessary, to ensure better airflow reaches the lungs. This is repeated consecutively for the prescribed number of breaths.
3. The optimal oscillation frequency and flow amplitude give reinforcement of resonance in the lower chest and upper abdominal system. Patients are taught how to recognize this and can adapt the technique.

Although this technique is patient-specific, patients typically perform 10 breaths before stopping to cough forcefully or huff cough mucus out of their airways. A typical session of OPEP takes about 20 minutes to complete.¹⁷ **CE II**

Part II of this article will be published in the October/November 2019 issue.

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PharmaFacts for Case Managers



Baqsimi™ (glucagon) nasal powder

INDICATIONS AND USAGE

Baqsimi is an antihypoglycemic agent indicated for the treatment of severe hypoglycemia in patients with diabetes ages 4 years and above.

DOSAGE AND ADMINISTRATION

Important Administration Instructions

Baqsimi is for intranasal use only.

Instruct patients and their caregivers on the signs and symptoms of severe hypoglycemia. Because severe hypoglycemia requires help of others to recover, instruct the patient to inform those around them about Baqsimi and its Instructions for Use. Administer Baqsimi as soon as possible when severe hypoglycemia is recognized.

Instruct the patient or caregiver to read the Instructions for Use at the time they receive a prescription for Baqsimi. Emphasize the following instructions to the patient or caregiver:

- Do not push the plunger or test the device before administration.
- Administer Baqsimi according to the printed instructions on the shrink-wrapped tube label and the Instructions for Use.
- Administer the dose by inserting the tip into one nostril and pressing the device plunger all the way in until the green line is no longer showing. The dose does not need to be inhaled.
- Call for emergency assistance immediately after administering the dose.
- When the patient responds to treatment, give oral carbohydrates to restore the liver glycogen and to prevent recurrence of hypoglycemia.
- Do not attempt to reuse Baqsimi. Each Baqsimi device contains one dose of glucagon and cannot be reused.

Dosage in Adults and Pediatric Patients Aged 4 Years and Above

The recommended dose of Baqsimi is 3 mg administered as one actuation of the intranasal device into one nostril. If there has been no response after 15 minutes, an additional 3 mg dose of Baqsimi from a new device may be administered while waiting for emergency assistance.

DOSAGE FORMS AND STRENGTHS

Nasal Powder:

- 3 mg glucagon: as a white powder in an intranasal device containing one dose of glucagon

CONTRAINDICATIONS

Baqsimi is contraindicated in patients with:

- Pheochromocytoma
- Insulinoma
- Known hypersensitivity to glucagon or to any of the excipients in Baqsimi. Allergic reactions have been reported with glucagon and include anaphylactic shock with breathing difficulties and hypotension.

WARNINGS AND PRECAUTIONS

Catecholamine Release in Patients with Pheochromocytoma

Baqsimi is contraindicated in patients with pheochromocytoma because glucagon may stimulate release of catecholamines from the tumor. If the patient develops a dramatic increase in blood pressure and a previously undiagnosed pheochromocytoma is suspected, 5 to 10 mg of phentolamine mesylate, administered intravenously, has been shown to be effective in lowering blood pressure.

Lack of Efficacy in Patients with Insulinoma

In patients with insulinoma, administration of glucagon may produce an initial increase in blood glucose; however, Baqsimi administration may directly or indirectly (through an initial rise in blood glucose) stimulate exaggerated insulin release from an insulinoma and cause hypoglycemia. Baqsimi is contraindicated in patients with insulinoma. If a patient develops symptoms of hypoglycemia after a dose of Baqsimi, give glucose orally or intravenously.

Hypersensitivity and Allergic Reactions

Allergic reactions have been reported with glucagon; these include generalized rash, and in some cases anaphylactic shock with breathing difficulties and hypotension. Baqsimi is contraindicated in patients with a prior hypersensitivity reaction.

Lack of Efficacy in Patients with Decreased Hepatic Glycogen

Baqsimi is effective in treating hypoglycemia only if sufficient hepatic glycogen is present. Patients in states of starvation with adrenal



insufficiency or chronic hypoglycemia may not have adequate levels of hepatic glycogen for Baqsimi administration to be effective. Patients with these conditions should be treated with glucose.

ADVERSE REACTIONS

The following serious adverse reactions were observed:

- Hypersensitivity and Allergic Reactions

DRUG INTERACTIONS

Beta-blockers

Patients taking beta-blockers may have a transient increase in pulse and blood pressure when given Baqsimi.

Indomethacin

In patients taking indomethacin, Baqsimi may lose its ability to raise blood glucose or may even produce hypoglycemia.

Warfarin

Baqsimi may increase the anticoagulant effect of warfarin.

USE IN SPECIFIC POPULATIONS

Pregnancy Risk Summary

Available data from case reports and a small number of observational studies with glucagon use in pregnant women over decades of use have not identified a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2%–4% and 15%–20%, respectively.

Lactation Risk Summary

There is no information available on the presence of glucagon in human or animal milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production. However, glucagon is a peptide and would be expected to be broken down to its constituent amino acids in the infant's digestive tract and is therefore unlikely to cause harm to an exposed infant.

Pediatric Use

The safety and effectiveness of Baqsimi for the treatment of severe hypoglycemia in patients with diabetes have been established in pediatric patients ages 4 years and above. Use of Baqsimi for this indication is supported by evidence from a study in 48 pediatric patients from 4 to <17 years of age with type 1 diabetes mellitus.

The safety and effectiveness of Baqsimi have not been established in pediatric patients younger than 4 years of age.

Geriatric Use

Clinical studies of Baqsimi did not include sufficient numbers of subjects aged ≥ 65 to determine whether they respond differently from younger subjects. Limited clinical trial experience has not identified differences in responses between elderly and younger patients.

OVERDOSAGE

If overdosage occurs, the patient may experience nausea, vomiting, inhibition of GI tract motility as well as an increase in blood pressure and pulse rate. In case of suspected overdosing, serum potassium levels may decrease and should be monitored and corrected if needed. If the patient develops a dramatic increase in blood pressure, phentolamine mesylate has been shown to be effective in lowering blood pressure for the short time that control would be needed.

CLINICAL STUDIES

Adult Patients

Study 1 (NCT03339453) was a randomized, multicenter, open-label, 2-period, crossover study in adult patients with type 1 diabetes. The efficacy of a single 3 mg dose of Baqsimi was compared to a 1 mg dose of intramuscular glucagon (IMG). Insulin was used to reduce blood glucose levels to <60 mg/dL.

The primary efficacy outcome measure was the proportion of patients achieving treatment success, which was defined as either an increase in blood glucose to ≥ 70 mg/dL or an increase of ≥ 20 mg/dL from glucose nadir within 30 minutes after receiving study glucagon, without receiving additional actions to increase the blood glucose level. Glucose nadir was defined as the minimum glucose measurement at the time of, or within 10 minutes, following glucagon administration.

The mean nadir blood glucose was 54.5 mg/dL for Baqsimi and 55.8 mg/dL for IMG. Baqsimi demonstrated non-inferiority to IMG in reversing insulin-induced hypoglycemia with 100% of Baqsimi-treated patients and 100% of IMG-treated patients achieving treatment success. The mean time to treatment success was 11.6 and 9.9 minutes in the Baqsimi and IMG 1 mg treatment groups, respectively.

Study 2 (NCT01994746) was a randomized, multicenter, open-label, 2-period, crossover study in adult patients with type 1 diabetes or type 2 diabetes. The efficacy of a single 3 mg dose of Baqsimi was compared to a 1 mg dose of intra-muscular glucagon (IMG). Insulin was used to reduce blood glucose levels to the hypoglycemic range with a target blood glucose nadir of <50 mg/dL.

The mean nadir blood glucose was 44.2 mg/dL for Baqsimi and 47.2 mg/dL for IMG. Baqsimi demonstrated non-inferiority to IMG in reversing insulin-induced hypoglycemia with 98.8% of Baqsimi-treated patients and 100% of IMG-treated patients achieving treatment success within 30 minutes. The mean time to treatment success was 15.9 and 12.1 minutes in the Baqsimi and IMG 1 mg treatment groups, respectively.

Pediatric Patients

Study 3 (NCT01997411) was a randomized, multicenter, clinical study that assessed Baqsimi compared to intramuscular glucagon (IMG) in pediatric patients aged 4 years and older with type 1



diabetes. Insulin was used to reduce blood glucose levels, and glucagon was administered after glucose reached <80 mg/dL. Efficacy was assessed based on percentage of patients with a glucose increase of ≥ 20 mg/dL from glucose nadir within 30 minutes following Baqsimi administration.

Across all age groups, all (100%) patients in both treatment arms achieved an increase in glucose ≥ 20 mg/dL from glucose nadir within 20 minutes of glucagon administration.

HOW SUPPLIED/STORAGE AND HANDLING

Baqsimi is supplied as an intranasal device containing one 3-mg dose of glucagon as a preservative free white powder.

- Baqsimi One Pack™ carton contains 1 intranasal device (NDC 0002-6145-11)
- Baqsimi Two Pack™ carton contains 2 intranasal devices (NDC 0002-6145-27)
- Store at temperatures up to 86°F (30°C) in the shrink-wrapped tube provided.
- Keep Baqsimi in the shrink-wrapped tube until ready to use. If the tube has been opened, Baqsimi may have been exposed to moisture and may not work as expected.
- Discard Baqsimi and tube after use.

PATIENT COUNSELING INFORMATION

Advise the patient and family members or caregivers to read the FDA-approved patient labeling.

Recognition of severe hypoglycemia: Inform patient and family members or caregivers on how to recognize the signs and symptoms of severe hypoglycemia and the risks of prolonged hypoglycemia.

Administration: Review the Patient Information and Instructions for Use with the patient and family members or caregivers.

Serious Hypersensitivity: Inform patients that allergic reactions can occur with Baqsimi. Advise patients to seek immediate medical attention if they experience any symptoms of serious hypersensitivity reactions.

Baqsimi is marketed by Lilly USA.

Recarbrio™ (imipenem, cilastatin, and relebactam) for injection, for intravenous use

INDICATIONS AND USAGE

Complicated Urinary Tract Infections (cUTI), including Pyelonephritis

Recarbrio is indicated in patients ≥ 18 years of age who have limited or no alternative treatment options for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, caused by the following susceptible gram-negative microorganisms: *Enterobacter cloacae*, *Escherichia coli*, *Klebsiella aerogenes*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*.

Approval of this indication is based on limited clinical safety and efficacy data for Recarbrio.

Complicated Intra-abdominal Infections (cIAI)

Recarbrio is indicated in patients ≥ 18 years of age who have limited or no alternative treatment options for the treatment of complicated intra-abdominal infections (cIAI) caused by the following susceptible gram-negative microorganisms: *Bacteroides caccae*, *Bacteroides fragilis*, *Bacteroides ovatus*, *Bacteroides stercoris*, *Bacteroides thetaiotaomicron*, *Bacteroides uniformis*, *Bacteroides vulgatus*, *Citrobacter freundii*, *Enterobacter cloacae*, *Escherichia coli*, *Fusobacterium nucleatum*, *Klebsiella aerogenes*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Parabacteroides distasonis*, and *Pseudomonas aeruginosa*.

Approval of this indication is based on limited clinical safety and efficacy data for Recarbrio.

Usage

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Recarbrio and other antibacterial drugs, Recarbrio should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

DOSAGE AND ADMINISTRATION

Recommended Dosage in Adults

The recommended dosage of Recarbrio is 1.25 grams (imipenem 500 mg, cilastatin 500 mg, and relebactam 250 mg) administered by intravenous (IV) infusion over 30 minutes every 6 hours in patients ≥ 18 years of age with creatinine clearance (CLcr) of ≥ 90 mL/min. A dose reduction is recommended for patients with CLcr < 90 mL/min. The severity and location of infection as well as clinical response should guide the duration of therapy. The recommended duration of treatment with Recarbrio is 4 days to 14 days.

Dosage Adjustments in Patients with Renal Impairment

Dosage adjustment is recommended in patients with renal impairment. Patients who have a CLcr < 90 mL/min require dosage reduction of Recarbrio. For patients with fluctuating renal function, CLcr should be monitored.

Preparation of Recarbrio Solution for Intravenous Administration

Recarbrio is supplied as a dry powder in a single-dose vial that must be constituted and further diluted using aseptic technique before intravenous infusion. To prepare the infusion solution, contents of the vial must be constituted with the appropriate diluent as instructed below. A list of appropriate diluents is as follows:



- 0.9% Sodium Chloride Injection, USP
- 5% Dextrose Injection, USP
- 5% Dextrose Injection, USP + 0.9 % Sodium Chloride Injection, USP
- 5% Dextrose Injection, USP + 0.45 % Sodium Chloride Injection, USP
- 5% Dextrose Injection, USP + 0.225 % Sodium Chloride Injection, USP

Recarbrio has low aqueous solubility. To ensure complete dissolution of Recarbrio it is important to adhere to the following instructions:

Step 1. For diluents available in 100 mL prefilled infusion bags, proceed to step 2. For diluents not available in 100 mL prefilled infusion bags, aseptically withdraw 100 mL of the desired diluent and transfer it to an empty infusion bag, then proceed to step 2.

Step 2. Withdraw 20 mL (as two 10 mL aliquots) of diluent from the appropriate infusion bag and constitute the vial with one 10 mL aliquot of the diluent. The constituted suspension is for intravenous infusion only after dilution in an appropriate infusion solution.

Step 3. After constitution, shake vial well and transfer resulting suspension into the remaining 80 mL of the infusion bag.

Step 4. Add the second 10 mL aliquot of infusion diluent to the vial and shake well to ensure complete transfer of vial contents; repeat transfer of the resulting suspension to the infusion solution before administering. Agitate the resulting mixture until clear.

Storage of Constituted Solution

Recarbrio, as supplied in single-dose glass vials upon constitution with the appropriate diluent and following further dilution in the infusion bag, maintains satisfactory potency for at least 2 hours at room temperature (up to 30 °C) or for at least 24 hours under refrigeration at 2°C to 8°C (36°F to 46°F). Do not freeze solutions of Recarbrio.

DOSAGE FORMS AND STRENGTHS

Recarbrio (imipenem, cilastatin, and relebactam) for injection, 1.25 grams is supplied as a white to light yellow sterile powder for constitution in a single-dose glass vial containing imipenem 500 mg (equivalent to 530 mg imipenem monohydrate), cilastatin 500 mg (equivalent to 531 mg cilastatin sodium), and relebactam 250 mg (equivalent to 263 mg relebactam monohydrate).

CONTRAINDICATIONS

Recarbrio is contraindicated in patients with a history of known severe hypersensitivity (severe systemic allergic reaction such as anaphylaxis) to any component of Recarbrio.

ADVERSE REACTIONS

The following are serious adverse reactions:

- Hypersensitivity Reactions

- Seizures and Other Central Nervous System Adverse Reactions
- Increased Seizure Potential Due to Interaction with Valproic Acid
- *Clostridium difficile*—Associated Diarrhea (CDAD)

Clinical Trials Experience

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

Overview of the Safety Evaluation of Recarbrio

Safety was primarily evaluated in two active-controlled, double-blind dose-ranging trials (Trials 1 and 2). In the cUTI trial (Trial 1, NCT01505634) and cIAI trial (Trial 2, NCT01506271), patients in the treatment arms were treated with either imipenem 500 mg/cilastatin 500 mg and relebactam 250 mg or imipenem 500 mg/cilastatin 500 mg and relebactam 125 mg (not an approved dose), and patients in the control arm were treated with imipenem 500 mg/cilastatin 500 mg plus placebo (IV normal saline).

Serious Adverse Reactions and Adverse Reactions Leading to Discontinuation

In Trials 1 and 2, serious adverse reactions occurred in 3.2% of patients receiving imipenem 500 mg/cilastatin 500 mg plus relebactam 250 mg and 5.1% of patients receiving imipenem 500 mg/cilastatin 500 mg. There were no deaths reported in patients receiving imipenem 500 mg/cilastatin 500 mg plus relebactam 250 mg or imipenem 500 mg/cilastatin 500 mg alone. Deaths were reported in 1.4% of patients receiving imipenem 500 mg/cilastatin 500 mg plus relebactam 125 mg (not an approved dose).

Adverse reactions leading to discontinuation occurred in 1.9% of patients receiving imipenem 500 mg/cilastatin 500 mg plus relebactam 250 mg and 2.3% of patients receiving imipenem 500 mg/cilastatin 500 mg.

DRUG INTERACTIONS

Ganciclovir

Generalized seizures have been reported in patients who received ganciclovir concomitantly with imipenem/cilastatin, a component of Recarbrio. Ganciclovir should not be used concomitantly with Recarbrio unless the potential benefits outweigh the risks.

Valproic Acid

Based on case reports in the literature, concomitant use of carbapenems, including imipenem/cilastatin (components of Recarbrio) with valproic acid or divalproex sodium may decrease valproic acid concentrations which may increase the risk of breakthrough seizures. Avoid concomitant use of Recarbrio with valproic acid or divalproex sodium. Consider alternative antibacterials other than carbapenems to treat infections in patients whose seizures are well controlled on valproic acid or divalproex sodium.

[continues on page 29](#)



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.

J Viral Hepat. 2019 Jul 11. doi: 10.1111/jvh.13173. [Epub ahead of print]

[Prevalence, mortality and healthcare utilization among Medicare beneficiaries with hepatitis C in hemodialysis units.](#)

Deshpande R, Stepanova M, Golabi P, et al.

Hepatitis C (HCV) is more common among patients with end-stage renal disease requiring hemodialysis compared to the general population. Thus we aimed to assess trends in prevalence, health resource utilization, and mortality amongst Medicare beneficiaries with HCV on hemodialysis. This is a retrospective study of outpatient and inpatient claims for Medicare beneficiaries receiving hemodialysis (2005-2016). A total of 291,663 subjects on hemodialysis were included (67.3±15.2 years, 55% male, 55% white, 49% age-based eligibility). The prevalence of HCV in subjects on hemodialysis was stable and was significantly higher (mean 4.2% in 2005-2016, $p=0.50$ for the trend) than in subjects not on hemodialysis (<1%). In multivariate analysis, liver cirrhosis (odds ratio=3.4 (95% CI=3.3-3.6)) was an independent predictor of 1-year mortality among hemodialysis patients. Mean total inpatient payments in dialysis patients with HCV remained stable during 2005 (\$73,803) through 2016 (\$72,133) (trend $p=0.54$) while mean total outpatient payment decreased from 2005 (\$53,497) to 2016 (\$35,439; trend $p=0.0013$). In multivariate analysis, after adjustment for age, gender, race, and location, both HCV and cirrhosis remained significant contributors to greater spending [HCV: inpatient +22.1% (+19.2%-25%), HCV: outpatient +18.4% (+14.6%-22.2%), cirrhosis: inpatient +59.7% (+56.9%-62.6%), cirrhosis: outpatient +9.4% (+6.2%-12.6%)]. In conclusion, HCV-infected Medicare patients receiving hemodialysis incur greater resource utilization; mortality is higher in patients with cirrhosis only. Although HCV prevalence in Medicare hemodialysis recipients is higher than in patients without hemodialysis, these rates are lower than reported, suggesting potential under-screening for HCV in this high-risk population. This article is protected by copyright. All rights reserved.

J Acquir Immune Defic Syndr. 2019 Jul 18. doi: 10.1097/QAI.0000000000002142. [Epub ahead of print]

[Antiretroviral adherence level necessary for HIV viral suppression using real-world data.](#)

Byrd KK, Hou JG, Hazen R, et al.

BACKGROUND: A benchmark of near-perfect adherence ($\geq 95\%$) to antiretroviral therapy (ART) is often cited as necessary for HIV viral suppression. However, given newer, more effective ART medications the threshold for viral suppression might be lower. We estimated the minimum ART adherence level necessary to achieve viral suppression.

SETTINGS: The Patient-centered HIV Care Model demonstration project.

METHODS: Adherence to ART was calculated using the Proportion of Days Covered (PDC) measure for the 365-day period prior to each viral load test result, and grouped into five categories (<50%, 50%–<80%, 80%–<85%, 85%–<90%, and $\geq 90\%$). Binomial regression analyses were conducted to determine factors associated with viral suppression (HIV RNA <200 copies/mL); demographics, PDC category and ART regimen type were explanatory variables. Generalized estimating equations with an exchangeable working correlation matrix accounted for correlation within subjects. In addition, probit regression models were used to estimate adherence levels required to achieve viral suppression in 90% of HIV viral load tests.

RESULTS: The adjusted odds of viral suppression did not differ between persons with an adherence level of 80%–<85% or 85%–<90% and those with an adherence level of $\geq 90\%$. Additionally, the overall estimated adherence level necessary to achieve viral suppression in 90% of viral load tests was 82% and varied by regimen type; integrase inhibitor- and non-nucleoside reverse transcriptase inhibitor-based regimens achieved 90% viral suppression with adherence levels of 75% and 78%, respectively.

CONCLUSIONS: The ART adherence level necessary to reach HIV viral suppression may be lower than previously thought and may be regimen dependent.

J Card Fail. 2019 Jul 22. pii: S1071-9164(19)30062-4. doi: 10.1016/j.cardfail.2019.07.011. [Epub ahead of print]

[Associations of advance directive knowledge, attitudes, and barriers/benefits with preferences for advance treatment directives among patients with heart failure and their caregivers.](#)

Kim J, Shin MS, Park YM, et al.

BACKGROUND: Patients with heart failure (HF) have not been considered as major beneficiaries of advance directives (AD). We analyzed factors affecting the preferences for the adoption of AD by patients with HF and their caregivers.

METHODS AND RESULTS: Seventy-one patient (mean age: 68 years)-caregiver (mean age: 55 years) dyads were enrolled during clinic visits for routine care at a single institution and completed questionnaires during in-person visits. Cohen's kappa coefficients and generalized estimating equation models were used to analyze the data. The agreement on dyadic perspectives for aggressive treatments was poor or fair, while agreement relative to hospice care was moderate ($k = 0.42$, 95% confidence interval = 0.087-0.754). Both patients and caregivers demonstrated poor knowledge of AD and similar levels of perceived benefits and barriers to advance care planning. However, the caregivers had more positive attitudes toward AD than patients. Patients and caregivers who were older and/or males had greater odds of preferring aggressive treatments and/or hospice care. Further, those with depressive symptoms had lower odds of preferring hospice care.

CONCLUSION: The dyadic agreement was moderately high only for hospice care preferences. Both patients and caregivers demonstrated knowledge of shortfalls regarding ADs. Timely AD discussions could increase dyadic agreement and enhance informed and shared decision-making regarding medical care.

J Acquir Immune Defic Syndr. 2019 Jul 16. doi: 10.1097/QAI.0000000000002140. [Epub ahead of print]

[The impact of cumulative depression along the HIV care continuum in women living with HIV during the era of universal antiretroviral treatment.](#)

Mills JC, Pence BW, Edmonds A, et al.

BACKGROUND: Data are limited on cumulative impacts of depression on engagement in care and HIV outcomes in women

living with HIV (WLWH) during the era of universal antiretroviral therapy (ART). Understanding the relationship of accumulated depression with HIV disease management may help identify benefits of interventions to reduce severity and duration of depressive episodes.

SETTING: A cohort of WLWH (N=1,491) from the Women's Interagency HIV Study (WIHS) at nine sites across the US.

METHODS: This longitudinal observational cohort study (2013-2017) followed WLWH for a maximum of nine semi-annual visits. Depression was quantified as a time-updated measure of percent of days depressed (PDD) created from repeated assessments using the Center for Epidemiologic Studies Depression (CES-D) scale. Marginal structural Poisson regression models were used to estimate the effects of PDD on the risks of missing an HIV care appointment, <95% ART adherence, and virological failure (≥ 200 copies/mL).

RESULTS: The risk of missing an HIV care appointment [risk ratio (RR)=1.16, 95% confidence interval (CI)=0.93 to 1.45; risk difference (RD)=0.01, -0.01 to 0.03], being <95% ART adherent (RR=1.27, 1.06 to 1.52; RD=0.04, -0.01 to 0.07), and virological failure (RR=1.09, 1.01 to 1.18; RD=0.01, -0.01 to 0.03) increased monotonically with increasing PDD (comparing those with 25 to those with 0 PDD). The total effect of PDD on virological failure was fully (%100) mediated by being <95% ART adherent.

CONCLUSIONS: Time spent depressed increases the risk of virological failure through ART adherence, even in the era of universal ART regimes forgiving of imperfect adherence.

ASAIO J. 2019 Jul 15. doi: 10.1097/MAT.0000000000001041. [Epub ahead of print]

[Impact of durable ventricular assist device support on outcomes of patients with congenital heart disease waiting for heart transplant.](#)

Cedars A, Tecson KM, Zaidi AN, et al.

The number of congenital heart disease (CHD) patients with heart failure is expanding. These patients have a high probability of dying, while awaiting heart transplant. The potential for durable ventricular assist devices (VAD) to improve waiting list survival in CHD is unknown. We conducted an analysis of the Scientific Registry of Transplant Recipients database for the primary outcome of death or delisting due to clinical worsening, while listed for heart transplant. We compared CHD patients with non-CHD patients matched for listing status. Multivariable models were constructed

to account for confounding variables. Congenital heart disease patients were less likely to have a VAD and were more likely to experience the primary outcome of death or delisting due to clinical worsening compared to non-CHD patients. Ventricular assist devices decreased the probability of experiencing the primary outcome for non-CHD but not for CHD patients with a final listing status of 1A. Ventricular assist devices increased the probability of experiencing the primary outcome among CHD patients for those with a final listing status of 1B with no impact in non-CHD patients. Among non-CHD patients who died or were delisted, the time to the primary outcome was delayed by VAD, with a similar trend in CHD. Except for patients with a final listing status of 1B, VAD does not adversely affect waiting list outcomes in CHD patients listed for heart transplant. Ventricular assist devices may prolong waiting list survival among high-risk CHD patients.

Hypertension. 2019 Jul 22:HYPERTENSIONAHA11913258. doi: 10.1161/HYPERTENSIONAHA.119.13258. [Epub ahead of print]

[Masked uncontrolled hypertension is not attributable to medication nonadherence.](#)

Siddiqui M, Judd EK, Dudenbostel T, et al.

Masked uncontrolled hypertension (MUCH) in treated hypertensive patients is defined as controlled automated office blood pressure (BP; <135/85 mm Hg) in-clinic but uncontrolled out-of-clinic BP by ambulatory BP monitoring (awake [daytime] readings \geq 135/85 mm Hg or 24-hour readings \geq 130/80 mm Hg). To determine whether MUCH is attributable to antihypertensive medication nonadherence. One hundred eighty-four enrolled patients were confirmed to have controlled office BP; of these, 167 patients were with adequate 24-hour ambulatory BP recordings. Of 167 patients, 86 were controlled by in-clinic BP assessment but had uncontrolled ambulatory awake BP, indicative of MUCH. The remaining 81 had controlled in-clinic and ambulatory awake BP, consistent with true controlled hypertension. After exclusion of 9 patients with missing 24-hour urine collections, antihypertensive medication adherence was determined based on the detection of urinary drugs or drug metabolites by high-performance liquid chromatography-tandem mass spectrometry. Of the 81 patients with MUCH, 69 (85.2%) were fully adherent and 12 (14.8%) were partially adherent (fewer medications detected than prescribed). Of the 77 patients with true controlled hypertension, 69 (89.6%) were fully adherent with

prescribed antihypertensive medications and 8 (10.4%) were partially adherent. None of the patients in either group were fully nonadherent. There was no statistically significant difference in complete or partial adherence between the MUCH and true controlled groups ($P=0.403$). Measurement of urinary drug and drug metabolite levels demonstrates a similarly high level of antihypertensive medication adherence in both MUCH and truly controlled hypertensive patients. These findings indicate that MUCH is not attributable to antihypertensive medication nonadherence.

Am J Clin Oncol. 2019 Jul 19. doi: 10.1097/COC.0000000000000579. [Epub ahead of print]

[Statins as potential therapeutics for lung cancer: molecular mechanisms and clinical outcomes.](#)

Fatehi Hassanabad A, McBride SA.

Lung cancer is the most common cancer worldwide. It also has the highest malignancy-associated mortality rate. Treatment options are limited by cancer and tumor heterogeneity, resistance to treatment options, and an advanced stage at time of diagnosis, all of which are common. Statins are a class of lipid-lowering medications that have been studied for their antitumor effects in various types of cancers. Multiple mechanisms have been proposed to explain their observed off-target effects. Most of these hypotheses focus largely on statin-induced upregulation of proapoptotic signaling pathways and mediators, and the downregulation of antineoplastic factors secondary to statin use. Preclinical and clinical studies support their use for conferring a mortality benefit and improving treatment effect in some chemotherapy-resistant subtypes of lung cancer. However, their exact mechanism of action, class-dependent effect, dose-dependent effect, potential use as adjuvant chemotherapeutics, and markers of statin-sensitivity in specific lung cancer subtypes remain areas of ongoing investigation. Herein, we review the latest literature pertinent to the role statins can play in the management of lung cancers.

Clin Lung Cancer. 2019 Jun 5. pii: S1525-7304(19)30141-X. doi: 10.1016/j.clc.2019.05.014. [Epub ahead of print]

[Dosimetric predictors of cardiotoxicity in thoracic radiotherapy for lung cancer.](#)

Borkenhagen JF, Bergom CR, Rapp CT, et al.

BACKGROUND: Higher cardiac radiotherapy (RT) doses when



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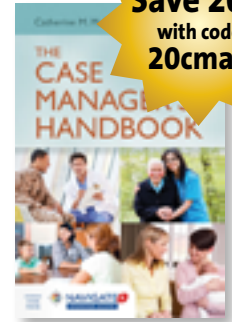
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treating lung cancer are associated with worse overall survival (OS), although the direct association between cardiac dose and early cardiotoxicity is poorly understood. We hypothesized that RT doses to the heart and cardiac substructures are associated with under-reported early cardiotoxicity and worse OS.

PATIENTS AND METHODS: We conducted an institutional retrospective review of lung cancer patients treated with conventionally fractionated RT from 2010 to 2015. Collected data included pre-RT cardiac risk factors, post-RT cardiotoxicities, and dose-volume parameters for cardiac substructures. Univariate and multivariate analyses were performed to identify predictors of cardiotoxicity and OS.

RESULTS: Seventy-six cases were evaluated with 1.2 years median follow-up. Cardiotoxicities included atrial arrhythmia (n = 5), pericardial effusion (n = 16), and valvular disease (n = 1). In univariate analysis, significant dose-volume predictors for cardiotoxicity included mean RT dose to structure of interest, volume of structure of interest receiving ≥ 30 Gy RT dose, and volume of structure of interest receiving ≥ 45 Gy RT dose (V45) to the atria, ventricles, and pericardium. Higher ventricular V45 was associated with post-RT cardiotoxicity in multivariate analysis (hazard ratio [HR], 1.50; P = .027). Cardiotoxicity occurrence was a highly significant predictor of OS in multivariate analysis (HR, 12.7; P < .001), but higher ventricular V45 alone was not (HR, 0.78; P = .450).

CONCLUSION: Early cardiac events were relatively common after lung cancer RT and associated with multiple cardiac dose-volume parameters. Occurrence of early cardiotoxicity was strongly associated with worse OS. In practice, early cardiotoxicity is under-reported, supporting the need for more detailed cardiac evaluations in high-risk patients to detect and address early cardiotoxicity.

Kidney Int. 2019 May 15. pii: S0085-2538(19)30508-3. doi: 10.1016/j.kint.2019.04.030. [Epub ahead of print]

[Direct-acting antiviral therapy slows kidney function decline in patients with hepatitis C virus infection and chronic kidney disease.](#)

Sise ME, Chute DF, Oppong Y, et al.

Hepatitis C virus (HCV) infection is common and can accelerate chronic kidney disease (CKD) progression. Direct-acting antiviral (DAA) therapies against hepatitis C have consistently shown rates of sustained viral remission. However, the effect on kidney function is unknown. In a retrospective observational cohort study of

HCV-infected patients receiving DAA therapies from 2013 to 2017, the slopes of estimated glomerular filtration rate (eGFR) decline were compared in the three years before DAA therapy to the slope after therapy. Pre- and post-treatment albuminuria values were also compared. In all, 1,178 patients were included; mean age of 56, 64% male, 71% white, 21% were diabetic, and 42% with cirrhosis. In patients with eGFR less than 60ml/min per 1.73m², the annual decline in eGFR in the three years prior to treatment was -5.98 ml/min per year (95% confidence interval -7.30 to -4.67) and improved to -1.32 ml/min per year (95% confidence interval -4.50 to 1.88) after DAA therapy. In patients with eGFR greater than 60ml/min per 1.73m² the annual decline in eGFR in the three years prior to treatment was -1.43 ml/min per year (95% confidence interval -1.78 to -1.08) and after DAA therapy was -2.32 ml/min per year (95% confidence interval -3.36 to -1.03). Albuminuria improved significantly in patients without diabetes, but not in those with diabetes. Predictors of eGFR improvement included having CKD at baseline and being non-diabetic. Events of acute kidney injury were rare, occurring in 29 patients, and unrelated to antiviral therapy in 76% of cases. Thus, DAA therapy for HCVs infection may slow CKD progression.

Am J Clin Oncol. 2019 Jul 19. doi: 10.1097/COC.0000000000000578. [Epub ahead of print]

[Clinical utility of a blood-based protein assay on diagnostic colonoscopy referrals for elevated-risk colorectal cancer patients in primary care.](#)

Peabody J, Rahim A, Wilcox B, et al.

BACKGROUND: Colonoscopies are effective in finding early stage colorectal cancer (CRC), which when found in a timely manner, dramatically improve survival rates. A significant number of at-risk patients are still not screened. We investigated the utility of a blood-based protein assay to assess for CRC in patients with elevated risk on the quality of preventive care delivered by board-certified primary care physicians (PCPs) in the United States.

METHODS: We report on the results of a 3-part, longitudinal, randomized controlled trial. Part 1 assessed physicians' ability to identify simulated patients at risk for CRC and found PCPs missed colonoscopy referrals for high-risk patients ~40% of the time. Part 2 randomized PCPs into control and intervention arms and demonstrated that a novel blood-based protein assay increased referral rates for a diagnostic colonoscopy when caring for simulated patients.



Part 3, reported herein, compares real-world colonoscopy rates of actual patients cared for by control versus intervention physicians. Part 3 was executed to confirm whether the use of the assay demonstrated the same utility in their real world, high-risk patients as found in part 2 using simulated patients.

RESULTS: In the simulations, physicians with access to the assay were significantly more likely to order diagnostic colonoscopies. Similarly, in real-world practice, patients were also more likely to be referred for a diagnostic colonoscopy (odds ratio, 4.57; 95% confidence interval, 1.19-17.57).

CONCLUSIONS: An increase in CRC risk, as indicated by the assay in simulated and real-life patients, was associated with a higher likelihood of appropriate patients being referred to diagnostic colonoscopy.

Cancer. 2019 Jul 22. doi: 10.1002/cnct.32347.
[Epub ahead of print]

[Recent trends in the age at diagnosis of colorectal cancer in the US National Cancer Data Base, 2004–2015.](#)

Virostko J, Capasso A, Yankeelov TE, et al.

BACKGROUND: The incidence of colorectal cancer (CRC) in adults younger than 50 years has increased in the United States over the past decades according to Surveillance, Epidemiology, and End Results data. National guidelines conflict over beginning screening at the age of 45 or 50 years.

METHODS: This was a retrospective study of National Cancer Data Base data from 2004 to 2015. The Cochran-Armitage test for trend was used to assess changes in the proportion of cases diagnosed at an age younger than 50 years.

RESULTS: This study identified 130,165 patients diagnosed at an age younger than 50 years and 1,055,598 patients diagnosed at the age of 50 years or older. The proportion of the total number of patients diagnosed with CRC at an age younger than 50 years rose (12.2% in 2015 vs 10.0% in 2004; $P < .0001$). Younger adults presented with more advanced disease (stage III/IV; 51.6% vs 40.0% of those 50 years old or older). Among men, diagnosis at ages younger than 50 years rose only in non-Hispanic whites ($P < .0001$), whereas among women, Hispanic and non-Hispanic whites had increases in younger diagnoses over time ($P < .05$). All income quartiles had a proportional increase in younger adults over time ($P < .001$), with the highest income quartile having the high-

est proportion of younger cases. The proportion of younger onset CRC cases rose in urban areas ($P < .001$) but did not rise in rural areas.

CONCLUSIONS: The proportion of persons diagnosed with CRC at an age younger than 50 years in the United States has continued to increase over the past decade, and younger adults present with more advanced disease. These data should be considered in the ongoing discussion of screening guidelines.

Dig Dis Sci. 2019 Jul 22. doi: 10.1007/s10620-019-05734-z.
[Epub ahead of print]

[County rankings have limited utility when predicting liver transplant outcomes.](#)

Akateh C, Miller R, Beal EW, et al.

BACKGROUND: Evidence of geographical differences in liver transplantation (LT) outcomes has been proposed as a reason to include community characteristics in risk adjustment of transplant quality metrics. However, consistency and utility of rankings in LT outcomes for counties have not been demonstrated.

AIMS: We sought to evaluate the utility of county rankings (county socioeconomic status (SES) or county health scores (CHS)) on outcomes after LT.

METHODS: Using the United Network for Organ Sharing Registry, adults ≥ 18 years of age undergoing LT between 2002 and 2014 were identified. County-specific 1-year survival was calculated using the Kaplan-Meier method for counties with ≥ 5 LT performed during this period. Agreement between high-risk designation by 1-year mortality rate and county ranking was calculated using the Spearman correlation coefficient.

RESULTS: The analysis included 47,769 LT recipients in 1092 counties. County 1-year mortality rates were not correlated with county CHS (Spearman $\rho = 0.01$, $p = 0.694$) or county SES (Spearman $\rho = -0.01$, $p = 0.734$). After controlling for individual-level covariates, a statistically significant variability in mortality hazards across counties ($p < 0.001$) persisted. Although both CHS and SES measures improved the model fit ($p = 0.004$ and $p = 0.048$, respectively), an unexplained residual variation in mortality hazard across counties continued.

CONCLUSIONS: There is poor agreement between county rankings on various socioeconomic indicators and LT outcomes. Although there is variability in outcomes across counties, this appears not to be due to county-level socioeconomic indices. ■

Medicare Advantage Plans Can Offer Social Services to Chronically Ill

Under new guidance from the Trump administration, Medicare Advantage plans will be allowed, but not required, to offer chronically ill enrollees non-medical services starting next year. On [To the Point](#), the Commonwealth Fund says many older Americans are likely to benefit from these services, which include home-delivered meals, transportation for nonmedical needs, and home modifications like wheelchair ramps.

This new coverage flexibility was made possible by the CHRONIC Care Act, part of the Bipartisan Budget Act of 2018 that President Trump signed into law last year. The CHRONIC Care Act opened the door for Medicare Advantage plans to address the social determinants that impact their enrollees' health. The law also gave health plans new flexibility to target benefits to a subset of patients who would particularly benefit from them. Before the legislation, Medicare Advantage plans were required to offer the same benefits to all their Medicare

enrollees.

Of course, there are issues to watch. It's uncertain whether health plans will decide to offer nonmedical services, which will be considered "special supplemental benefits." Based on the feedback we've received from Medicare Advantage plan leaders and health providers, we know they will need practical guidance and support on how to integrate nonmedical services into their data systems, referral networks, payment structure, consumer outreach, and provider education. Decisions to offer these supplemental benefits will likely depend on whether the plans view them as prudent investments.

Health plans that choose to offer nonmedical services will need to develop metrics to monitor and track progress and will need to assess if the availability of social services results in better quality outcomes, greater patient satisfaction, and more efficient use of health care services. ■

Adapting Care Models for High-Need Patients from Around the World

Through a partnership between Duke University and the Commonwealth Fund, experts have identified a set of promising international models for improving care for high-need patients—like the program run by Indian nonprofit Noora Health that is helping families reduce unplanned hospital readmissions. In a [To the Point](#) post, Duke's Kushal Kadakia, Mark McClellan, and colleagues describe their partnership with five US health systems to explore this and other global models. ■

Meeting Individual Social Needs Falls Short of Addressing Social Determinants of Health

There is a growing recognition that medical care alone cannot address what actually makes us sick. Increasing health care costs and worsening life expectancy are the results of a frayed social safety net, economic and housing instability, racism and other forms of discrimination, educational disparities, inadequate nutrition, and risks within the physical environment. These factors affect our health long before the health care system ever gets involved. ■

Failure to Pay

Research predicts that by 2020, 95% of patients will fail to pay off their full medical balance. And, that's got Michael N. Brown, CEO of Fellow Health Partners, concerned.

"Recently, as part of our due diligence for clients, we did a deep dive into trending statistics about medical billing and discovered some worrisome and, at the same time, some positive trends," he said.

He continued, "Our deep dive helps us flag trouble in time to do something proactive about it, while confirming what will help medical practices and hospitals the most."

Physicians, surgery centers, and hospitals are under a lot more pressure today as insurance companies raise deductibles that more patients have trouble paying off.

Trending statistics show that in just 5 years, there was an 88% increase in hospital revenue attributed to patient responsibility. And today, 83% of smaller physician practices (under 5 practitioners) said that slow patient payment on high-deductible plans is their top collection challenge." ■

Syphilis Invading Rural America

Syphilis is spreading from big cities into rural counties across the Midwest and West. One Missouri clinic has seen more than 6 times as many cases in the first few months of 2019 compared with the same period last year. Communities grappling with budget cuts and crumbling public health infrastructure also lack experience in fighting the disease. Read more at KHN. ■

CE II **What Every Case Manager Should Know About Effectively Facilitating Care for Chronic Respiratory Disease Patients with Bronchiectasis: Part I** *continued from page 17*

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PharmaFacts for Case Managers
continued from page 21

HOW SUPPLIED/STORAGE AND HANDLING

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Readers

Have an idea for an article? Send your suggestions for editorial topics to: jmaybin@academyccm.org.

Chronic Kidney Disease *continued from page 2*

- Promote lifestyle modifications
 - Healthy diet with special attention to sodium, potassium, and phosphorus intake
 - Regular exercise
 - Maintenance of a healthy body weight
 - Immunizations
 - Tobacco cessation

The case manager plays an important role in preventing CKD or detecting it early. The key is annual screening for those at risk along with patient education. Let's do our part to reduce the burden of CKD and improve patient outcomes.

Gary S. Wolfe, RN, CCM
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ACCM: Improving Case Management Practice through Education

Ambition is a Fabulous Word

continued from page 9

and I never went back the other way. To be able to express on such a deep level, have joy on such a high level, and celebrate each other pulled it all together for me. It has made me even more determined to work with case managers who haven't been given the opportunities they deserve. It has reinforced the idea that whatever concept lights this burning desire inside of me is worth pursuing, and it has made me even more ambitious in my quest to bring all generations into case management.

Case management has not been multigenerational historically, but we are slowly moving in that direction and we need to change our attitude to make that occur. What I am seeing is

how much more powerful we become as case managers and as leaders when we partner with all generations of case managers and work together. Mutual respect allows both case management and our workplaces to capitalize

Higher-ambition case management leaders, unlike many executives in other fields, are not content with achieving only strong fiscal returns. Rather, they strive to generate high performance on 3 fronts at once: creating long-term economic or fiscal value, producing significant benefits for the wider community, and building a robust social capital within their own organizations.

on diversity and resolve conflicts productively, which is critical to making the high-ambition leadership strategy work. We are all colleagues, whether we happen to be new case managers, seasoned, or counting down to

retirement. We create a bigger impact together and raise each other up so that we can raise up our patients who do not have the opportunities or abilities to do so.

Great ambition is the passion of a great character. It is hard to imagine a more energizing or meaningful way to spend your professional life than to play a central role in building a higher-ambition profession. Do not be afraid or become discouraged in your own role. Let me remind you of my opinion that ambition is a fabulous word. As Mildred McAfee

said, "If you have a great ambition, take as big a step as possible in the direction of fulfilling it. The step may only be a tiny one, but trust that it may be the largest one possible for now." **CM**

Engaging Employees in the Return-to-Work Process *continued from page 6*

of that position are, and what accommodations or alterations are possible for allowing a person to return to that position. Sometimes ergonomic changes (eg, adjusting the height of a workstation) or other accommodations are all it takes. In other cases when disabling conditions are more pervasive or severe, "reasonable accommodations" as defined by the law are insufficient to allow the person to return to a specific job. In these instances, retraining for another position may be possible, depending on what the employer offers and the types of jobs available.

A CDMS can also help ensure that the physician is providing timely and accurate documentation about the

employee's health and work ability status. This information is essential for avoiding misunderstandings that can occur based on how a physician communicates with an employee—or what the employee "hears" the doctor saying. Once a perception is created around limitations or expectations about when and how to return to work, it is hard to change the employee's thinking. Inaccurate perceptions can be avoided with open discussion among all parties, backed by thorough documentation by the physician.

From RTW to Stay-at-Work

Once an employee returns to work following an injury or illness, the case should not be considered "closed." When follow-up is limited to a specific time, that can undermine the success of RTW. There may be other factors

that contributed to the employee being off work—whether a workplace or ergonomic issue or a health risk factor. If that root cause is not identified and mitigated, the employee may be at risk of being off work again.

With stay-at-work programs, the employee receives additional support. This may include health, wellness, and prevention initiatives; resilience strategies; and employee assistance program (EAP) resources, all of which can help improve overall physical and mental well-being and reduce risk factors and obstacles that may impact a sustained return to work. When coupled with RTW, these stay-at-work strategies form a more comprehensive solution with the employee at the center: engaged, informed, and empowered to be part of the process and solution to make it successful. **CM**

Why Stay Certified? Professional Commitment Meets Lifelong Learning *continued from page 4*

and current trends. Every year, the Commission's [New World Symposium](#) offers multiple learning opportunities and CE offerings. In addition, the [Case Management Society](#) of America provides education and learning experiences that can be applied to renewal.

Rather than scramble to acquire CEs at the last minute, CE should be pursued as an ongoing process of enrichment. It's not about "checking the box" on a particular learning requirement. It's about elevating your knowledge and showcasing your commitment to lifelong learning. This is how you distinguish yourself among a community of like-minded professionals who want to make a difference as advocates across the health and human services spectrum. **CM**

CE I Role of Case Managers in Improving Kidney Disease Patients Outcomes *continued from page 13*

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CARF International Invited to Participate in the World Health Organization Second Rehabilitation 2030 Meeting *continued from page 7*

international array of Member States of WHO as well as WHO staff, government officials, professional organizations, associations, and consumers.

The main emphasis was the integration of rehabilitation into primary care with real examples from countries at various levels of integration and development; these issues were discussed as were ways to solve these problems. Setting strategies, budget impacts, value-based care delivery, and workforce implications were also discussed. By 2050, the number of individuals over the age of 60 will double. By 2030, 40 million new jobs will be created for skilled and

regulated therapists, trauma experts, and prevention strategists. Strategies identified were:

- Optimize the workforce
- Anticipate and align investment in future workforce requirements, competencies/skills, and support services
- Strengthen individual and institutional capabilities
- Invest in people accurately
- Invest in health and education.

The ability to have adequate data and research to track function over time will be critical. The political case for function and the need for rehabilitation to assist with the achievement of function is necessary and will be of critical value to moving the Rehabilitation 2030 agenda forward.

All of us that were in attendance must ask ourselves the following

questions: "What is our role?" "What are our organizations ready to do?" Inclusion of all people is a societal commitment. Rehabilitation 2030 hopes to develop the ongoing guide to a global competency model of universal health coverage (ie, discipline, health condition, and a site-neutral guide).

After attending these sessions, the words innovation, cooperation, collaboration, and consensus building are part of the tool kit that everyone must have available to meet the ever-growing needs of individuals around the world with limited ability to function on a daily basis. **CM**

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