CareManagement

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

Vol. 24, No. 1 February/March 2018

CCMC
New World
SYMPOSIUM® 2018
FUTURE DIMENSIONS
OF CASE MANAGEMENT

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Post-Conference Special Edition

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Gary S. Wolfe

Managing Comorbidities and Population Health Management

As the focus in health care changes from treating acute episodes to population health maintenance and disease prevention, providers are faced with the challenges of comorbidities. The staggering statistics say it all:

- Forty-five percent of Americans (or about 133 million people) have at least 1 chronic condition.
- Chronic diseases are responsible for 7 of 10 deaths in the United States each year, killing more than 1.7 million Americans annually.
- More than 75% of the $2 trillion spent on public and private health care in 2009 went toward chronic diseases.
- One in 4 adults in the United States have 2 or more chronic conditions.
- More than half of older Americans have 3 or more chronic conditions.

Because comorbidities can increase as we age and 10,000 Americans will turn 65 each day from now through the end of 2029, it is reasonable to expect that the overall number of patients with comorbidities will increase greatly.

Managing comorbidities is challenging. Even though one condition may contribute or be connected to another, the treatments may conflict. Because of the complexities of the human body, one treatment may result in unexpected changes or problems elsewhere in the body, which generate new health problems.

Because of the increasing number of people with comorbidities, there is a greater need for care coordination so that providers aren't just looking solely at one chronic condition. Case managers should use population health management to look at the big picture of health and wellness for each patient.

Population health management goes beyond looking at individual encounters and addresses the much broader aspects of health and wellness, including all the social issues associated with health and wellness. Population health management is based on data, which require several sources of information including an electronic health record and claims data. These data provide a larger view of populations as well as individual patients. Systems should be designed and made available to case managers. Most current systems are modeled after encounters or visits, which provide a focused picture both from an outcome and cost basis. Systems must do a better job of collecting outcome data—not just what was done but what the results were. A well-defined system will provide clinical, financial, and operational data that show measureable results.

There are 3 areas that can make population health management successful:

1. Information-powered clinical decision making
2. A primary care–led clinical workforce
3. Patient engagement and community integration

In population health management, the focus is on identifying and supporting the sickest patients, managing the disease by minimizing and slowing the progression of the disease, and promoting a culture of wellness.

Case management is what makes population health management successful, but the following must also be taken into account in order to ensure success:

1. Health plans must identify and stratify populations better.

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Policy, Practice, and Personal Commitment: Three Wishes for Case Management in the New Year

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

As the new year begins, my "wishes" for case management fall into three categories—policy, practice, and personal commitment. Together, they align with the strategic vision of the Commission for Case Manager Certification (CCMC) around the importance of getting certified, staying certified, and developing others for the benefit of professional case managers and the field of practice.

1. Policy

As policymakers and employers look to the future of case management, my wish is for more widespread requirement of certification. Professional certification is a mark of competency that helps ensure consumer protection, delivery of quality case management services, and adherence to the highest standards of ethical and professional conduct.

This message is already resonating with employers and policymakers, who increasingly recognize the value of the Certified Case Manager (CCM) credential. The percentage of employers who require board certification is growing (40.2% in 2014 versus 36% in 2004).

Case managers are often encouraged by their employers to become certified within 1 or 2 years of being employed; incentives include promotions and monetary rewards (ie, bonuses). In addition, more employers are willing to make an investment in certification, with 62% of CCM employers reimbursing for the CCM examination and 50% paying for it.

2. Practice

A powerful way to showcase one's professionalism and commitment to excellence is to stay certified, which advances professional practice, personally and collectively. This is particularly important for baby boomers moving into their retirement years, especially those who were among the first to become board-certified case managers starting 25 years ago. (More than 65,000 case managers have earned the CCM since 1992.)

Professional certification is a mark of competency that helps ensure consumer protection, delivery of quality case management services, and adherence to the highest standards of ethical and professional conduct.

To further the practice, we encourage experienced case managers to reach out to the new diverse pool of younger colleagues, to mentor them and to help them develop. CCMs have an important role to play in preparing the next generation of qualified case managers who have the proven ability to interface with culturally diverse populations—a demand that will only continue to grow.

We also urge experienced case managers to make the most of their certification by taking advantage of some of the many opportunities the Commission offers; among them, opportunities to support the development of the CCM certification examination by participating in item writing and item review, or supporting one of the many committees or task forces such as the Ethics and Professional Conduct Committee or the New World Symposium Task Force.

3. Personal Commitment

Certification is the on-ramp to lifelong learning and professional development. Now more than ever, we must work together to develop the next generation of CCMs while striving to keep qualified case managers active, energized, and evolving in their careers. At the same time, we must remember the importance of self-care and improved work/life balance—the "quadruple aim" that expands the original "triple aim" of improving population health, increasing patient satisfaction, and spending smarter to include better health and self-care for care providers and clinicians.

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MaryBeth Kurland, CAE, *is the CEO of the Commission for Case Manager Certification (CCMC), the first and largest nationally accredited organization that certifies case managers. More than 42,000 board-certified case managers with the Certified Case Manager (CCM) credential are in practice today.*

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Centers for Medicare & Medicaid Services (CMS) Clarifies Position on Texting Patient Information Among Health Care Providers

By Elizabeth Hogue, Esq.

On December 28, 2017, David Wright, Director of the Survey and Certification Group at the Centers for Medicare & Medicaid Services (CMS), sent a memorandum to all State Survey Agency Directors to clarify CMS' position regarding texting patient information among health care providers. This memorandum is effective immediately. Here is a summary of the memorandum:

- Texting patient information among members of the health care team is permissible if accomplished through a secure platform
- Texting of patient orders is prohibited regardless of the platform utilized
- Computerized Provider Order Entry (CPOE) is the preferred method of order entry by a provider

CMS goes on to say that it does not permit the texting of orders by physicians or other health care providers. In fact, according to CMS, the practice of texting orders from providers to members of the care team is not in compliance with Conditions of Participation (CoPs) or Conditions for Coverage (CfCs).

CMS also says that CPOE is the preferred method of order entry by providers. Handwritten orders are also permitted. When orders are entered via CPOE with an immediate download into providers' electronic health records (EHR), orders are dated, timed, authenticated, and promptly placed in medical records.

CMS then acknowledges that texting as a means of communication with other members of health care teams has become an essential and valuable means of communication among team members. In order to be compliant with CoPs or CfCs, however, all providers must use and maintain systems/platforms that are secure and encrypted and that minimize risks to patient privacy and confidentiality, consistent with HIPAA (Health Insurance Portability and Accountability Act) regulations and applicable CoPs and CfCs. Providers are also expected to implement procedures/processes that routinely assess the security and integrity of texting systems/platforms being used to avoid negative outcomes that could compromise patient care.

These requirements likely apply to all providers who receive reimbursement from the Medicare and Medicaid Programs, including Medicaid waiver programs. Providers should immediately modify their practices, if necessary, to comply with direction from CMS. CM

Per the Centers for Medicare & Medicaid Services:

- **Texting patient information among members of the health care team is permissible if accomplished through a secure platform**
- **Texting of patient orders is prohibited regardless of the platform utilized**
- **Computerized Provider Order Entry (CPOE) is the preferred method of order entry by a provider**

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

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When Returning to Work Is *Not* the Goal:
Identifying a Roadmap That Works for All

By Ed Quick, MA, MBA, CDMS, CRC

When an employee faces a serious medical issue, it is often assumed that the goal is returning to work as soon as possible. While disability management focuses on interventions to help people resume productivity after an illness or injury, returning to work is not always the desired outcome. In some cases, an occupational or nonoccupational health incident prompts the person to consider other options, such as working part time or even leaving the workforce altogether.

As the advocate for the ill/injured person, the Certified Disability Management Specialist (CDMS) or disability case manager must first understand the baseline of the person's work history. Has he been working 60 to 80 hours a week? Did her professional position require extensive travel? Is the job physically demanding? This understanding will put the conversation with the employee in context. Given the nature of the illness/injury and any lingering limitations, is the person open to engaging in work hardening or work conditioning as she gradually transitions back to full-time work? Have his goals and motivations changed? For example, a 55-year-old who suffers a stroke may have very different views about returning to full-time work than a 40-year-old with a 20-year professional timeline ahead. Being closer to the traditional retirement age, the 55-year-old may be rethinking his goals and working full time may no longer be a priority.

The CDMS working with the employee must discern his/her goals by facilitating a conversation: listen to what is being said and not said about the person's desires and eagerness (or lack thereof) to return to work. Does she express fear about reinjury or talk about making life changes? Is he asking questions such as whether he qualifies for Social Security Disability Insurance or what will happen to his health care benefits if he stops working?

While disability management focuses on interventions to help people resume productivity after an illness or injury, returning to work is not always the desired outcome.

The individual's goals will shape and possibly shift the focus of what comes next. For example, instead of pursuing interventions and accommodations to allow an early return to work, emphasis is on scaling back to part-time work, contractor status, or even retirement. Conversations with the employer and exploration of available resources (for example, the Employee Assistance Program [EAP] if offered by the employer) help the person understand what is possible, given personal and financial circumstances.

The other involved party, of course, is the employer. In some instances, an employer may resist going to extraordinary lengths to bring a difficult employee or one with performance issues back to work after an illness or injury. For example, a supervisor tells the CDMS/disability case manager that the employee had time management issues and could not meet deadlines and expresses concern that these problems will be exacerbated by the injury/illness.

Federal law such as the Americans with Disabilities Act (ADA) and state disability laws offer specific job protections. Employers, particularly large organizations, tend to be aware of the standards of the ADA and other regulations and work closely with employees and their case managers to make sure they protect employees who are able to perform the critical functions of their jobs. If, however, an employee cannot perform these functions, even with accommodations, then Human Resources (HR) and the legal team need to get involved. At the same time, employers must understand that disability leave policies should not be used to resolve the performance management challenges of a difficult employee or one with unsatisfactory performance; these are HR issues and need to be dealt with in the appropriate performance management strategy,

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

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Integrated Case Management

By Mary McLaughlin-Davis, DNP, ACNS-BC, NEA-BC, CCM, CMSA National President, 2016-2018

The emerging Population Health Model focuses on managing the disease states in a designated population. This model requires efficiencies and patient-centric quality outcomes to be successful. The Population Health Model in any of its settings will not demonstrate these outcomes without a solid case management program. Case managers in all settings must be trained in Integrated Case Management (ICM). They must be confident in their ability to manage all aspects of a patient's presenting diagnosis and comorbid conditions and to manage them simultaneously. These include the medical and cognitive/behavioral diagnosis with the social determinants of health.

The case manager counsels the family and not just the patient. She understands that everyone is linked in important ways to one another and that what happens to one person in the family affects everyone in the family.

Public health professionals have long understood the serious impact social determinants have on the health of an individual as well as a population. The medical model focuses on the disease, and typically the treatment is provided in silos and with minimal acknowledgment of the role that social determinants, behavioral health, and health literacy play in disease management.

Mary McLaughlin-Davis, DNP, ACNS-BC, NEA-BC, CCM, *is the current national president of CMSA. She has been a certified case manager since 1993; she is a clinical nurse specialist for adult health and the senior director for care management for Cleveland Clinic, Avon Hospital.*

The medical model cannot be sustained because health care costs in the United States continue to escalate and the underlying causes of chronic diseases are not thoroughly addressed. The ICM Program is essential because it links social and medical problems, which allow for comprehensive patient-centric care plans and realistic outcomes.[1]

An estimated 5% of the population uses 50% of health care resources. The 5% are patients presenting with comorbid medical and behavioral conditions.

To truly improve quality and efficiency, those at the highest risk for poor-quality outcomes and significant costs require a special focus. CMSA's Integrated Case Management approach can be that specific focus.

More than 80% of individuals with a mental health condition diagnosed by clinical interview also have at least one general medical condition, and 29% of individuals with a medical condition have mental health comorbidities.[2] The silo approach to treatment has resulted in higher health care costs and lack of quality in the care received. This fragmentation has also created an environment for duplication of services and medication errors.[3]

Case managers, in addition to working with patients, families, and systems, also must work efficiently. This is a unique skill set and one based on the CMSA *Standards of Practice.* The standards of assessment, identification, and planning speak to the need for an integrated approach in developing a case management plan in collaboration with the patient or the caregiver. The CMSA Model Act describes the case management process to include physical/medical, behavioral/cognitive, and social determinants in the assessment, intervention, and evaluation phase of the process.[4,5]

The health care reform policies implemented in recent years predicted and prioritized the necessity to improve quality and efficiency within health care systems. Health care policies provide the template for better health care outcomes. To truly improve quality and efficiency, those at the highest risk for poor-quality outcomes and significant costs require a special focus. CMSA's Integrated Case Management approach can be that specific focus.[6] The CMSA ICM Program is a structured clinical path to guide the case manager in the integration of the patient's goals with short- and long-term medical, behavioral, and social goals. It is comprehensive in scope, allowing the case manager to collect patient information from the history, current condition, and level of risk if a case management intervention is not implemented.

Medical, social, and behavioral conditions are integrated; therefore, it is critical that our case management practice is integrated and linked to both patients' history as well as the future risk of the patients we serve. Integrated case management is essential to providing value-based care, and the Case Management Society of America (CMSA) provides a program to move case managers to integrated practice. Based on the *Standards of*

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Post-Conference Special Edition

Highlights from CCMC's New World Symposium 2018

About 700 case managers attended CCMC's New World Symposium (NWS) in Nashville, Tennessee, January 18–20, 2018, to help CCMC celebrate its 25th anniversary and to participate in educational sessions and networking opportunities. NWS received support from 70 exhibiting companies and 10 sponsors.

Plenary session speakers included:

- **Karen DeSalvo, MD, MPH, MSC,** Former Acting Assistant Secretary for Health at the U.S. Department of Health and Human Services (HHS)
- **Kana Enomoto,** Senior Advisor to the U.S. Surgeon General and Former Acting Deputy Assistant Secretary, Substance Abuse and Mental Health Services Administration (SAMHSA)
- **Thomas Goetz, MPH,** Iodine Co-Founder
- **Patrick Henry,** Radio personality, SiriusXM
- **Joshua C. Denny, MD, MS, FACMI,** Professor of Biomedical Informatics and Medicine, Vanderbilt University *(replacement for Dana Richardson-Heron, MD, All of Us Research Program, National Institutes of Health, who was unable to speak because of the government shutdown)*

> **"The symposium was fantastic. I will definitely attend again. I connected with several exhibitors who provided services relevant to my practice."**

The Symposium atmosphere was collegial, exuberant, and thoughtful as these case managers listened to speakers on topics from policy, leadership, patient communication and relationships, and entrepreneurship to the opioid epidemic, telehealth, benchmarks, and data and population health, to name a few of the covered topics.

Karen DeSalvo, MD, MPH, MSC, presented the opening plenary session with a discussion of digital health tools and value-based payment. She emphasized that 60% of health depends on environmental, social, and behavioral factors, a topic repeated by many other presenters.

On an encouraging note for case managers, Patrick Henry, CSP, stated in his plenary session "Be Rememer-able," "We are judged by how we meet expectations, but we are known by how we go beyond expectations." His quote marked the spirit of the Symposium and called case managers to lead rather than point the way in working with patients. He also told attendees, "You are the artists behind the art. How you create the emotional connection with your patients is what makes the difference and creates loyalty and trust."

(*continues*)

> **"Excellent vendor support! Love the immediate access to evaluation tool. The food was beyond good! Loved this meeting!!"**

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This was a great conference, I came home feeling motivated to improve my practice.

Several speakers focused on feedback loops to help determine patient engagement with care and to promote good communication techniques that meet patients where they are and where they are going. Communication tips presented by Thomas Goetz included keeping the message simple, using intrinsic behavioral cues, and creating active rather than passive messages. Of particular importance for case managers is understanding the irrationality of human beings and using that to their advantage when helping patients to make better health decisions. Eric Coleman, MD, MPH, cautioned case managers against relying on lack of readmissions as an appropriate feedback loop for the care provided. He suggested using simulation and coaching to engage patients in their own care and to put them in the driver's seat of their own health. Goals, he said, are powerful motivators for patients. Learn what your patient's goals are, and you will have greater success in motivating them. Finally, case managers should focus on small and quick wins to maintain patient motivation.

Kana Enomoto and Monique Yohanan, MD, MPH, addressed the opioid crisis and the role of case managers in recognizing risks for opioid misuse and instituting measures, such as prescription drug monitoring, to lower risk.

Speakers, including plenary presenter Joshua C. Denny, MD, MS, spoke on the importance of data collection and analysis in determining care, engaging patients, and improving outcomes. Topics were educational, thought-provoking, and inspirational at NWS 2018. More information on the many important presenter contributions to the New World Symposium can be found here.

Also read the sponsored session recaps in this issue and visit the exhibitor directory to learn how companies are providing resources and services for you and your patients. CM

Value-Based Care

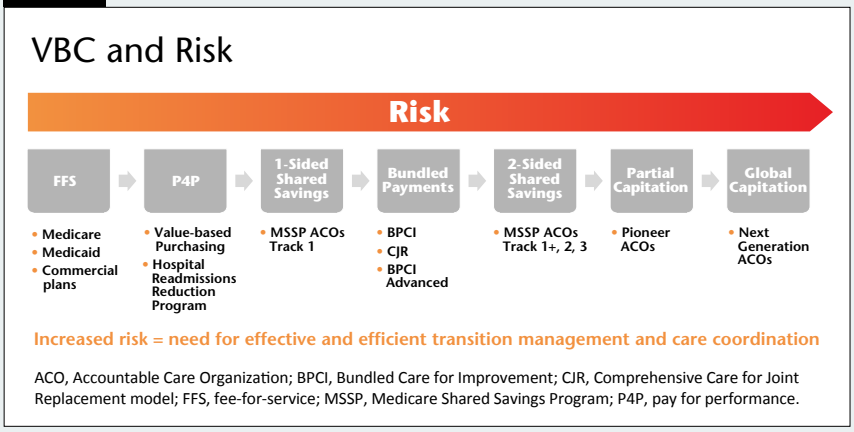
At CCMC's January 2018 New World Symposium in Nashville, Tennessee, Kimberly Hodge, MSN, RN, ACNS-BC, CCRN-K, of naviHealth led an enlightening discussion of value-based care (VBC) to a packed group attending the breakfast symposium. In the presentation, titled "Skills, Technologies, & Attributes Case Managers Need to Succeed in Value-based Care," Hodge focused on the Porter/Teisberg[1] definition of VBC, defined as "health outcomes achieved per dollar spent." Payments to providers and practitioners are aligned to value. Across the continuum of care, this means that providers and practitioners must assume greater financial risk, as shown in Figure 1. On the left is fee-for-service, in which payers assume all the financial risk, and on the right is global capitation, in which providers assume greater and greater amounts of financial risk. The increased risk being shouldered by providers and practitioners requires effective and efficient transition management and care coordination—just the sweet spot for case managers.

Hodge noted that VBC of patients requires "hindsight, current sight, and foresight." For example, the advent of hospitalists was intended to improve patient care in the hospital, but their use has led to more fragmented care because the hospitalist has no context of before and after care. For these three types of insight to occur, case managers must be comfortable using data.

Post-acute care is the big cost-outlier in the care continuum, ranging from $35,000–$40,000 for a long-term care stay to $5000 for home health services. Relatively few patients who are in the acute hospital need to be transitioned to long-term acute care.

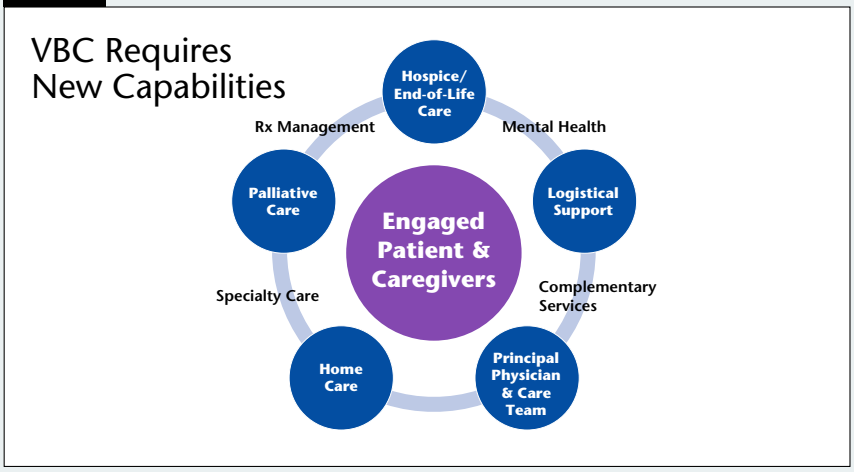
Knowing the settings that drive cost and quality and can drive readmissions is important for case managers.

FIGURE 1 THE MOVE FROM FEE-FOR-SERVICE TO VBC



ACO, Accountable Care Organization; BPCI, Bundled Care for Improvement; CJR, Comprehensive Care for Joint Replacement model; FFS, fee-for-service; MSSP, Medicare Shared Savings Program; P4P, pay for performance.

FIGURE 2 CASE MANAGERS MUST DEVELOP NEW CAPABILITIES



Knowing the settings that drive cost and quality and can drive readmissions is important for case managers.

Bundled payments are designed to promote collaboration among settings and providers by bundling the cost of an episode of care into one lump sum that covers all services provided for that episode. Thus, each provider must assume responsibility for value and quality.

For case managers, understanding their role in VBC is paramount. This type of care requires new capabilities (Figure 2). And one tool that case managers must learn to embrace is data. At the end of the day, health care is a business, and data drives businesses.

Reference

1. Porter ME, Teisberg EO. *Redefining Health Care: Creating Value- Based Competition on Results.* Brighton, MA: Harvard Business Review Press; 2006.

Home Infusion Therapy

Lecia Snell-Kinen, MSN, APRN-CNS, CCTN, of OptionCare presented a lively industry-sponsored breakfast session titled "Considerations for Case Management in Home Infusion Therapy." Opening her presentation, Snell-Kinen said that the goal of home infusion services is that the patient will perform their own therapy eventually, giving them greater independence than they would otherwise have. Home infusion is not always performed in the home but can be done in an ambulatory care center or suite centers.

In terms of patient selection, case managers must choose patients who are well enough and capable of performing home infusion. Considerations for choosing a home infusion service provider include determining if the company is accredited (eg, by URAC, the Accrditation Commission for Health Care, the American Society of Health-System Pharmacists, the Joint Commission, or the Community Health Accreditation Program). Home infusion companies may be local mom and pop ventures that can be very flexible or national organizations that have more resources but may be less flexible.

Also important in choosing home infusion services is knowing the payer that the infusion company partners with. Different payers allow different services and potentially cover different drug therapies. For this reason, case managers should partner with several home infusion agencies so their different patients are covered for a variety of services.

Core medicines that are given by home infusion are antibiotics, chemotherapy agents (although not as much today as previously), enteral nutrition, pain medications, IV immunoglobulin, enzyme replacement, hemophilia treatments, and heart failure drugs.

Pharmacists, case managers, and physicians must all work closely with the infusion nurses. Some companies, like OptionCare, employ nurse liaisons in the hospital so that care transitions to home infusion therapy are smoothly performed and the patient/home caregiver are well prepared with education and training.

Partnerships are important, but having options in home infusion services is just as important in meeting the needs of individual patients, their therapies, and their insurance.

At OptionCare, the multidisciplinary pharmacy team works with clinicians to provide IV therapy teaching and ongoing support; IV line management and education; ordering and delivery of medications, supplies, and equipment; dietitian consultation and monitoring; laboratory support services; medication evaluation; monitoring of therapy effectiveness; side effect prevention and management; and 24-hour on-call nursing and pharmacy services. Home infusion is cost-effective only when patients are eventually able to manage the infusions on their own.

IV access also determines whether home infusion is a good choice. Peripheral IVs are not conducive to home use unless the treatment is very short term. Midlines are used less frequently to avoid the risk of central line-associated bloodstream infection (CLABSI). Central lines are most common and include peripherally inserted central catheters (PICCs), tunneled and nontunneled catheters, and implantable ports. PICCs are the most commonly used IV access in the home even though their placement in the home requires x-rays to verify the position. Nurses may insert and remove them in the home. Midlines may also be placed in the home and are good for 4-6 weeks of therapy (eg, vancomycin). Although nontunneled catheters can be removed in the home, an order is required. Tunneled catheters decrease infection risk.

Home infusion services are paid per diem and all supplies needed for the infusion are included in the per diem payment. Supplies are usually delivered directly to the patient at home. However, state regulations determine some delivery options, such as whether saline flushes can be carried by the nurse or must be delivered to the patient.

Reimbursement of home infusion services is under the health benefit rather than the pharmacy benefit. Commercial plans are just beginning to recognize home infusion. Medicare Part A covers home infusion nursing only for patients who are homebound. Part B covers only four antibiotics for home infusion; otherwise, the patient must be in a skilled nursing facility, where Medicare pays for 30 days of coverage. Part C picks up some infusion costs, and Part D covers prescription costs for some home infusion treatments.

Snell-Kinen emphasized that partnerships are important, but having options in home infusion services is just as important in meeting the needs of individual patients, their therapies, and their insurance. CM

Rehabilitation

Kevin Myers of Benchmark Rehab Partners presented the Theater Showcase "The Need for Speed! How A Coordinated Approach Can Save Time and Money" at the CCMC New World Symposium. He stressed the importance of communication among team members who are treating Worker's Comp and other people needing functional rehabilitation. Effective, clear notes in the patient chart, verbal communication via the phone, and being available for case review are essential to care coordination with case managers.

Myers explained that the purpose of rehabilitation is to help each person

continues on page 49

FIGURE 1 DETERMINING PDL

Activity Frequency*		**Lifting Activity** – Height Definitions
Constant (C)	67%–100% of workday (5.33–8 hours/day)	**High** – above shoulder
Frequent (F)	34%–66% of workday (2.7–5.33 hours/day)	**Mid** – knuckle to shoulder
Occasional (O)	0%–33% of workday (0–2.6 hours/day)	**Low** – floor to knuckle
Not Present (N)	Activity is not performed	**Full** – full vertical work plane

Physical Demand Characteristics of Work*			
PDL	**Occasional** 0%–33% of workday	**Frequent** 34%–66% of workday	**Constant** 67%–100% of workday
Sedentary	1–10 lb	Negligible	Negligible
Light	11–20 lb	1–10 lb	Negligible
Medium	21–50 lb	11–25 lb	1–10 lb
Heavy	51–100 lb	25–50 lb	11–20 lb
Very Heavy	>100 lb	>50 lb	>20 lb

Incontinence Care

During the industry-sponsored Theater Showcase, "Providing the Highest Quality of Continence Care with Compassion and Dignity," presented in the exhibit hall at the CCMC New World Symposium, Medline Industries' Michelle Christiansen, MS, PA, CN-E, CCDS, emphasized the fact that incontinence is NOT a normal part of aging. Yet, 60% of elderly and frail patients require help with toileting, which can lead to incontinence. Exacerbating the problem is that most caregivers do not understand toileting and therefore may be making the condition worse.

More than $16 billion is spent on incontinence care in the United States, of which $53 billion is due to expenses incurred in long-term care facilities. Additional costs of incontinence include quality-of-life issues ranging from social withdrawal, falls, institutionalization, skin breakdown, and declining mental health (Figure 1). In fact, incontinence is the #1 reason why people are institutionalized.

Poor standards of care and lack of training of caregivers, including nurses, contribute to problems related to incontinence. Nurses receive an average of 9 hours of education on continence during and after schooling and are not taught how to choose products or apply and remove them.

About 95% of incontinent patients need help in choosing a product (eg, pads, liners, disposable underwear).

Currently, caregivers spend more than 60% of their time managing incontinence (Figure 2).

About 95% of incontinent patients need help in choosing a product (eg, pads, liners, disposable underwear). Even in health care settings, 50%–60% of patients are using the wrong product or are poorly managed. Christiansen explained that disposable pull-ups are for people who are mobile and can self-toilet. On the other hand, adult briefs are for nonambulatory patients. Both of these products must be properly fitted and must not be too large for the patient. Bladder control pads can aid those with light-to-moderate incontinence. Underpads protect furniture but do not promote patient dryness. Dry pads, better choices for bedding, wick moisture away. Doubling up products, said Christiansen, is a waste of money because today's products are impermeable and doubling simply retains moisture near the skin.

For more information on incontinence and its management, be sure to also read the Medline-supported CE Supplement, "Continence Management: Arming Case Managers With Tools to Improve Outcomes" on *CareManagement*'s website. CM

FIGURE 1

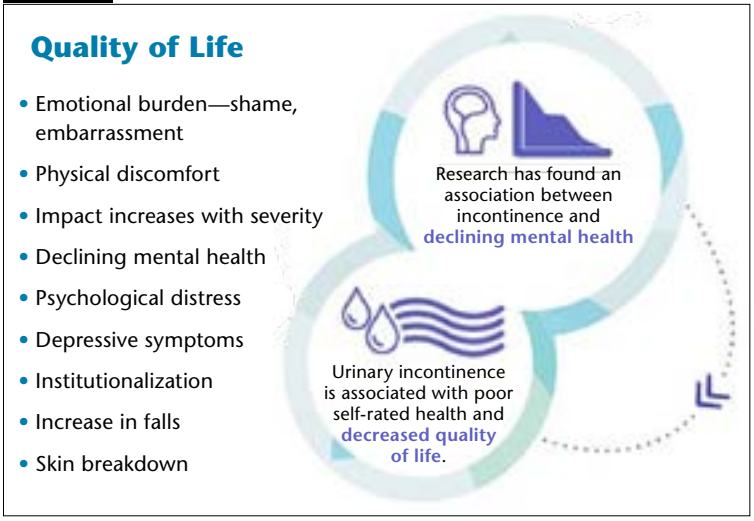
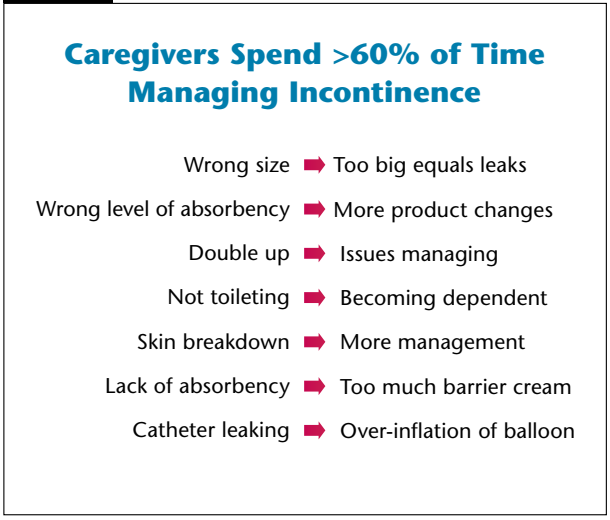


FIGURE 2



Post-Conference Special Edition

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CCM PACE™ Pre-Approved Continuing Education

CE 1

The Expanded Chronic Care Model as an Organizing Theory for the Integration of Behavioral and Physical Health Care

By Thomas J. Blakely, PhD, LMSW, and Gregory M. Dziadosz, PhD

This article describes the importance of integrating physical health with behavioral health using the Expanded Chronic Care Model (ECCM)[1] as an organizing framework. The original Chronic Care Model (CCM) was created as a response to the increasing number of persons with chronic illnesses.[2] The ECCM expands the CCM from clinical concerns about health service delivery to include broader community and population health concepts, which are discussed later in this article.

The concept of integration applies directly to care management. We hope to advance knowledge about system changes that should be made to clear a pathway for integration. Our concern is the integration of behavioral and physical health service delivery in agencies and institutions providing care for persons with chronic illness.

The CCM was developed by Wagner et al. to provide more-appropriate medical care for individuals with a chronic illness.[2] They believed that the existing acute care system was not designed to provide sufficient medical care to this group of individuals. The CCM has a prepared and proactive team working with informed and activated patients toward an outcome where a patient self-manages the chronic illness as much as possible. It has been implemented in many medical settings and has a substantial effect on health care delivery to individuals with a chronic illness.

The ECCM broadens the CCM through the perception of the health care services as a community concern with a focus on population health. This broadened concern does not alter the intent of the CCM. Rather it extends the impact by making the concept of health care one that coordinates service delivery among community systems so that population health becomes a major focus.

We have been actively involved in mental and physical health agencies through the evolution of the development of the major frameworks of health care, which we identify as managed care, disease management, integration, and the medical home. We have been the president of and program consultant for a mental health agency serving individuals with serious and persistent mental illness.

We propose the ECCM as an organizing concept for full integration. We believe that a major element of the original CCM fits the expectations of full integration. Per Wagner et al. "Interventions that encourage people to acquire self-management skills are essential to chronic illness care."[2] This captures the essence of the CCM that has the potential of enhancing the process of integration of behavioral and physical health delivery by providing basic organizing principles.

The ECCM is an improvement. It is a more-effective response to meeting the challenges of integrating behavioral and physical health care. Whereas the Community and the Health Care System are separate entities in the original CCM, in the ECCM there is a porous border between. This suggests an interchange between the elements of each, thus giving the resources of the community a more prominent function. Elements are added to the Health Care System, and the original elements are conceptually expanded.

The focus of the ECCM model is organized around public health rather than chronic illness. The focus of the Health System is altered in favor of broader community response. Self-management in the CCM is expanded to include the development of personal skills. Decision support is expanded to inform the community's overall health. Delivery system design is expanded from team response to community response. Clinical information systems are expanded from patient-oriented data to community-based information systems. Community resources are expanded from agency partnerships to public health policy development. The ECCM adds the creation of health environments that are supportive and community action is strengthened. Finally,

Thomas J. Blakely, PhD, LMSW, ACSW, *is an independent licensed clinical social work practitioner, a licensed and marriage and family therapist, and an Emeritus Professor of Social Work at Western Michigan University.*

Gregory M. Dziadosz, PhD, *is an independent researcher and mental health consultant who is retired from Cherry Health Services, where he was a vice president and formerly the President and Chief Executive officer of Touchstone Innovare, a mental health agency serving adults with serious mental illness.*

Physical health should be integrated with behavioral health using the Expanded Chronic Care Model as an organizing framework.

the productive interaction between a treatment team and patient is expanded from informed and activated patient to activated community and the prepared and proactive team is expanded to prepared and proactive community partners.

Literature Review

Doherty et al.[3] were the first to classify levels of integration. They defined 5 levels of integration:

1. minimal collaboration;
2. basic collaboration at a distance;
3. basic collaboration on site;
4. close collaboration in a partly integrated system; and
5. close collaboration in a fully integrated system.

According to Doherty et al., several attempts at integration have been made but few of them qualify to be fully integrated.

Some investigators believe that a specific workable model has not yet been developed. The randomized controlled trials that have been conducted on integration have demonstrated that it is effective, but these studies have not considered the problems that occur with implementation. According to Davis et al., "this is because approaches used in clinical efficacy studies may not be generalizable to other settings because of differences in staffing, leadership models, diverse patient care needs, or work flow processes".[4] They also noted that studies of clinical trials focus on patients rather than practice. These issues suggest that the design of future research should be focused on implementation approaches that address these problems. These investigators also described the challenges to integration efforts: the design of the ECCM makes it a way to manage these challenges.

An online article from Medicaid, a major payment system for behavioral and physical health services, contained the following statement: "Given the prevalence of mental health conditions in the Medicaid population, the high level of Medicaid spending on behavioral health care, and the adverse impact that uncoordinated care can have on people's health, initiatives to integrate physical and mental health are a top priority for Medicaid Agencies."[5] This suggests support for integration from a major program and funding source.

Nardone et al.[6] described some Medicaid models that included screening for substance abuse in all primary care practice settings, the use of navigators to assist people with behavioral health conditions to make their way through the mental health and substance abuse agency systems to find appropriate treatment, the development of co-locations for the delivery of behavioral and physical health care, establishing health homes authorized by the Affordable Care Act, and the promotion of fully integrated behavioral and physical health care systems. The programmatic aspects of the ECCM include the elements of these models.

Unutzer et al.[7] wrote about the Collaborative Care Model as a way of integrating physical and mental health care in health homes. This model bridges the gap in service delivery by primary practitioners and mental health providers. Many people prefer care from a primary provider even though this professional may not have education and experience in mental health. Those who seek assistance with a mental health condition may consult a mental health specialist who has little or no education and experience regarding physical health issues. The Collaborative Care Model employed in health homes is one way to bring primary practitioners and mental health specialists together so that individuals with chronic conditions receive appropriate treatment. The broader application of the ECCM fits these interests.

Felker et al.[8] reported on outcomes for an integrated primary care team. This team was effective in reducing the number of referrals to mental health providers, and collaborative care was improved. Felker and colleagues[9] also described a study that evaluated a program of managing major depression in primary care practices that improved and maintained collaboration between primary care practitioners and mental health providers. Merrill[10] described integrated programs in which mental health providers were brought into primary health care programs for direct services as well as consultation. The issues discussed were mutual roles, changes in service delivery, referral, and relationships among providers. This resulted in decreasing stigma, increasing prevention because of early detection and referral, increased family awareness, increased care coordination, and less duplication. The expanded community concept of the ECCM encourages the collaboration described by these investigators.

At the federal policy level, the Substance Abuse and Mental Health Services Administration–Health Resources and Services Administration (SAMHSA-HRSA) Center for Integrated Health Solutions (CIHS) is a government agency

that encourages integrated primary and behavioral health services to better address the needs of individuals with mental health and substance abuse conditions whether they are treated in behavioral health or primary care settings.

Health homes is one model for integration established by the Affordable Care Act. It calls for a comprehensive, coordinated care program for Medicaid recipients who have complex health problems. It provides a temporary 90% federal Medicaid matching rate for health home services to individuals who have 2 chronic conditions or 1 chronic condition and are at risk for a second or have 1 serious and persistent mental illness.

Health home services include comprehensive care management; care coordination and health promotion; comprehensive transitional care; patient and family support; referral to community and social support services; and the use of health information technology to support these services. The idea is that health home services connect, coordinate, and integrate the many services and supports, including primary health care, behavioral health care, acute and long-term services, and family- and community-based services, that Medicaid beneficiaries with chronic and often complex conditions need.[6] Home health services are supported by the elements of the ECCM.

However, there are challenges to overcome. First, behavioral health providers must be willing and able to provide the holistic and longitudinal care expected from the health home model, which may not have been their mode of practice previously. Second, state and federal laws intended to protect client confidentiality regarding the use of mental health and substance abuse treatment services have had the unintended consequence of preventing information sharing that is essential to support integrated care for individuals with both physical and behavioral health needs. Third, both low Medicaid reimbursement rates for behavioral health services and fee-for-service payment have worked against a more integrated approach to care. In combination these factors have contributed to a siloed system of behavioral health care, with limited incentives and capacity for coordination and collaboration aimed at producing more comprehensive and integrated care.[6] Even with these challenges, health homes remain a helpful model for integration because of the comprehensive nature of their services and their overall approach.

With regard to these efforts to integrate, Woltmann et al. noted that "organized care management processes—the systematic use of guidelines supported by clinical information systems and care management—are the cornerstone of quality improvement in both primary care and multispecialty group practice"[11] These investigators wrote about the various CCMs for integration of behavioral and physical health

The Expanded Chronic Care Model broadens the Chronic Care Model by perceiving health care services as a community concern with a focus on population health.

delivery. They concluded that "the CCMs are effective in a broad group of domains across mental health conditions treated in a variety of care settings at no net increase in health care treatment costs."[11] Similarly, Hung et al.[12] wrote about the success of the CCM, especially in prevention of chronic illness. In contrast, Oprea et al.[13] reflected on the difference in studies of CCM success and reported that some studies do not indicate success with some elements of CCM such as promoting mutual trust between patients and caregivers. We suggest, however, that the ECCM provides an answer to these observations.

Integrated Care

Integrated care is defined as a comprehensive program that encompasses mental, behavioral, and physical health conditions as well as patient preferences regarding health assessments and treatments.

Fully integrated/merged systems have one reception area and one treatment plan with close collaboration among all of the involved providers. There is integrated funding, one governing board, evidence-based practices for both behavioral and physical health, and an electronic record that can be accessed by all appropriate providers in the system. The facility should have examination rooms for primary care providers, offices for psychotherapeutic interventions, and enough meeting space for the entire clinical staff.

Implementing full integration has some barriers. Funding for integrated care often is complicated and confusing in the existing segregated physical and mental health set of reimbursement policies. Federal and state funding mechanisms don't always complement each other. The same is true for insurance policies that often have separate provider paneling criteria and payment methodologies for what are considered to be physical vs. behavioral procedures or interventions. Some even contract with separate organizations to manage physical and behavioral care. Not all insurance plans or Medicaid provide payment for behavioral interventions for nonbehavioral diagnoses (eg, motivational interviewing). Many payers will not pay for more than one treatment session per day, so payments are excluded for interventions provided by multiple providers in an integrated practice.[14]

Implementation of evidence-based practices also face barriers related to differences in the education and training of agency staff such as psychiatrists, internists, social workers, and psychologists. Full integration requires a complete sharing of assessment and treatment that may be difficult under the best of circumstances. In general, health care personnel have worked in either behavioral or physical health settings and therefore have little or no experience in the field that they have not worked in. For example, primary care physicians may have little training in motivational interviewing, which would limit their ability to provide and reinforce interventions that are needed to enhance patient activation. Social workers may have little training in the causes, symptoms, progression, and treatment of chronic physical conditions such as diabetes, hypertension, and heart disease, which would hamper their ability to provide and reinforce interventions prescribed to treat those conditions. Social workers may therefore not be able to educate the patient about these conditions or explain a physician's standing orders. Both professional groups may have limited education and training in providing treatment to individuals with a substance use disorder. These differences create a culture of beliefs, attitudes, terminology, and perceived value that may impede the development and operations of a fully integrated health care service.

This quote covers the elements needed: "All but one key informant indicated that the greatest barrier to the creation and sustainability of integrated mental condition care in primary care settings was financial challenges introduced by segregated physical and mental health reimbursement practices. For integrated physical and mental health program initiation and outcome changing care to be successful, key components included a clinical and administrative champion-led culture shift, which valued an outcome orientation; cross-disciplinary training and accountability; use of care managers; consolidated clinical record systems; a multidisease, total population focus; and active, respectful coordination of co-located interdisciplinary clinical services"[14]

The ECCM has elements that directly promote a response to these barriers. Inherent in the model is a culture shift resulting from its focus on public health. It promotes cross-fertilization of professional concepts so that differences in education and training are minimized. Care managers continue to be responsible for the processes of service

delivery but from a holistic community view rather than the narrower medical team approach. A consolidated record system is required that is enhanced by a community-based information system. A population health concern is a driving force, and community agency partnerships provide for coordination of clinical services.

As suggested above, an electronic health record that is immediately available to all agency providers is a significant feature of integrated health care. All practitioners must have access to the entire record, including a summary of the patient's chronic health conditions, the stage of change in these conditions, the level of the patient's self-management of the conditions, and the complete intervention plan. The electronic health record system must support the writing of a single comprehensive intervention plan that can be modified as needed by members of the interprofessional practice team, limited only by the restrictions in the scope of practice of their license or certification. This was created in the agency with which the authors were affiliated before the merger.[15] The point is to plan the electronic record system to fit all that will be required of it before implementation.

Extensive cross-training of staff will be necessary for full integration. The internet is a source for training resources for integration, among which the SAMHSA and the Kaiser Family Foundation are listed. An interprofessional team is a powerful source of cross-training. Each profession can provide not only information about the skills it brings to the team but can also practice under the supervision of the other team members. This provides the side benefit of increasing trust and respect within the team.

An example of a successful effort to fully integrate care was the program at the agency with which the authors were affiliated; this program is called Community Treatment and Rehabilitation.[16] The CCM was the organizing theory for Community Treatment and Rehabilitation, and outcomes research demonstrated its effectiveness.[17] During this implementation, we noted that most of the agency's clients presented with both chronic mental and physical illnesses. Clients commonly presented with diabetes, hypertension, and hypercholesterolemia, and these conditions were often complicated by a substance use disorder. In response we established a demonstration project in partnership with a Federally Qualified Health Center to address this constellation of chronic health conditions. Further

integration occurred when an agency serving clients with substance use disorders also merged with the Federally Qualified Health Care Center. The plan was to integrate physical and mental health, including substance use disorder services, in 1 clinic at the merged agency. The hope was that integration would become the standard for all the health care programs of the merged entity.

The team consisted of an internal medicine physician, a psychiatrist, a registered nurse, a licensed master social worker, a bachelor social worker/case manager, and a medical assistant. The licensed master social worker served as the primary point of contact for the team's patients. They were called "health coaches" to make it clear that their responsibilities included education and activation for all of a patient's health conditions as well as providing primary interventions for psychiatric conditions such as anxiety and depression.

All team members received training in motivational interviewing so that interventions that addressed patient activation could be provided seamlessly by all team members. Team members received cross-training that covered the causes, symptoms, and treatment of 13 chronic health conditions (these included serious psychiatric conditions such as schizophrenia and bipolar disorder as well as diabetes and hypertension). Patients were voluntary transfers from other primary care teams within the organization.

Summary and Next Steps

The following summarized why the ECCM is an appropriate organizing concept for the integration of behavioral and physical health delivery:

1. The concept of public health rather than chronic illness changes the nature of the response to the issue.
2. The broader base of community concern supports a comprehensive approach that is integrative.
3. The community response conceptual framework rather than the agency practice concept increases attention to care management programs that are integrated.
4. The increased community involvement enhances public awareness about the necessity of financing for integrated behavioral and physical health programs.
5. The promotion of community involvement has the potential for increasing patient trust in an integrated system.
6. Private insurance and Medicaid payments for health services will be easier to substantiate based on the concern for public health rather than separate behavioral and physical health care.
7. Similarly, payments for behavioral interventions such as motivational interviewing will be easier to substantiate within the framework of public health concern.
8. The distinction between chronic mental health and physical health problems is decreased, which may also may decrease stigma for mental illness.
9. A comprehensive plan for an integrated community response can be outlined and published for all systems based on a common theoretical model.
10. A comprehensive plan lends itself to establishing goals and objectives that can be researched to determine further improvements in the delivery system.
11. The application of existing principles of public health are promoted that will further the concept of integration of behavioral and physical health care.
12. The community concept promotes the conceptualization of an integrated and unified system of community agencies that have been separated traditionally.
13. The health home model of care is a good fit for the expanded care model.

Finally, as Phillips and Holt[18] suggested, the ECCM promotes the creation of a vision statement or strategic plan for a community response that will include established community leaders who have public health experience. This will be a comprehensive plan for a community that can be enlarged as circumstances may require. This also may contribute to unifying county health services that have traditionally been separate, one for mental health and one for public health.

Hopefully the ideas presented have helped the reader to conceptualize a plan of activity to achieve the integration of behavioral health and physical health. If the steps are understood, the implementation of integration can occur in any size organization. Success will depend largely on commitment to integration by administrative leadership and providing the resources to obtain necessary program consultants, staff training, infrastructure, and culture changes that may be required. Additional supportive system interventions, which will include changes in reimbursement regulations, should be planned and implemented. Whatever organization undertakes promoting integration will have to plan and implement political action strategies. Developing a coalition among existing organizations that have a history of political involvement is one idea. Often organizations have a formal or informal membership and some method of communicating with them which can also be of value. The goals and objectives must be clearly focused on patients' and communities' health and must be simple and clear to everyone.

The concept of integration is not difficult for most health care workers to understand. The CCM requires training, particularly because acute care has tended toward an approach that providers are to do for patients because they

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CCM PACE™ Pre-Approved Continuing Education

CE II Managing the Growing Number of Patients with Comorbidities

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

According to the Centers for Disease Control and Prevention (CDC), 25% of the total US population has at least 2 chronic diseases— physical and/or mental illnesses— at the same time. These comorbidities interact to create additional health effects on these patients and increased challenges for health care professionals. There also are significant cost impacts. For example, a recent report by former U.S. Surgeon General Vivek Murthy titled "Facing Addiction in America" noted that individuals with a chronic medical condition and a comorbid substance use disorder incur costs that are 2–3 times higher than those without the comorbidity. Adding to the weight of this problem is the growing number of Americans with comorbidities, mostly due to the graying of America. By 2050, the CDC projects that the number of adults age 65 and older will reach 89 million, more than double the number in 2010.

To provide best in class case management services to their patients with comorbidities, case managers need to understand the challenges they pose; how to best to identify these complex, high-risk patients; and their role in managing these cases.

Challenges Posed by Patients with Comorbidities

Among the most common comorbidities are diabetes, hypertension, osteoarthritis, osteoporosis, chronic obstructive pulmonary disease, atrial fibrillation, angina, and hypercholesterolemia. These chronic conditions last a year or more and require continuous medical treatment. They increase with age and therefore are particularly prevalent in patients age 65 and older who are covered by Medicare; 48% of this patient group have 3 or more chronic conditions according to the Centers for Medicare & Medicaid Services (CMS). Each of these chronic conditions singularly poses challenges for case managers. When experienced in tandem with other medical conditions, the challenges become much greater.

Consider the patient with arthritis who also has obesity, diabetes, and/or heart disease. The CDC estimates that 22.7% of adults in the United States have arthritis and, of this population, 31% are obese, 47% have diabetes, and 49% have heart disease. Managing the case of an arthritic patient with one or more comorbidity can be daunting. The condition itself can be an impediment to compliance with treatment plans such as those specifying physical activity that benefit arthritic patients with obesity, diabetes, and heart disease (ie, weight reduction, lower blood glucose levels, lower blood pressure, and improved moods to avert potential depression).

Patients with a mental illness such as bipolar disorder often have some form of substance abuse. This, in turn, introduces a host of other medical problems such as lung and breathing issues. Treating patients with lung conditions including cancer can be hindered by their common comorbidities such as emphysema or diffuse lung fibrosis, both of which contraindicate transthoracic needle biopsies, thereby hindering an accurate diagnosis.

Comorbidities prevalent in the elderly also present their own set of challenges. Age-related conditions such as Alzheimer's and Huntington's disease make it difficult for case managers to communicate with their patients and to obtain essential patient information, thereby hindering decision making. Other obstacles to quality care include a lack of evidence-based data for managing and prioritizing multiple comorbidities in older patients along with the failure of single-disease clinical practice guidelines to provide direction in care for older patients with comorbidities. For this population and others, case management is further challenged by widespread health literacy problems among the elderly, the less educated, and individuals for whom English is a second language. This is not a small percentage of the US population given our rising multiculturalism; the U.S. Census Bureau American Community Survey, conducted from 2009 through 2013, reported that 350 languages are spoken in the United States as well as an additional 149 immigrant languages.

When a patient has a mental illness, case managers often encounter problems associated with communication, diagnoses, and compliance. When these patients are also homeless, managing the case can be further complicated by a lack of patient records and available family members to provide relevant information. Even for those health care providers

Catherine M. Mullahy, RN, BS, CRRN, CCM, *is President of Mullahy & Associates, LLC (www.mullahyassociates.com), a leading provider of case management education and training programs and resources. Mullahy is the author of* The Case Manager's Handbook, *now in its sixth edition.*

According to the CDC, 25% of the total US population has at least 2 chronic diseases—physical and/or mental illnesses—at the same time. Individuals with a chronic medical condition and a comorbid substance use disorder incur costs that are 2–3 times higher than those without the comorbidity.

following a Health Care for the Homeless (HCH) model in the management of complex comorbidities, there is a lack of a consistency in how these patients are identified, limitations in protocols for extracting accurate data and billing codes, and even a failure to track the top comorbidities at their sites. This was a finding of the Clinicians' Network that interviewed and studied four HCH projects at Mercy Medical Center (Springfield, MA), Peak Vista Community Health Centers (Colorado Springs, CO), Outside In (Portland, OR) and Franklin Primary Care (Mobile, AL). The National Health Care for the Homeless Council reported on this study in its article titled "Managing Complex Comorbidities in Individuals Experiencing Homelessness."

Of course, all of these challenges introduce others that lead to worsening of symptoms and, consequently, increased emergency department visits, health care utilization, and hospital readmissions. It is therefore critical that these complex, high-risk patients with comorbidities be properly identified and that the right treatment plan (including an effective discharge plan) be started early.

Identifying the Complex Patient with Comorbidities

Patients with comorbidities are among the most complex, high-risk patients. They also are among the most costly 1% of all US patients who consume 20%of the nation's total health care spending according to the PwC Health Research Institute's data. The Institute's data on the subset of 9.6 million patients who qualify for Medicare and Medicaid, many of whom have comorbidities, projects that their health care costs will reach $775 billion by 2024, which is less than a decade away. Clearly, identifying these patients is essential and case managers have a vital role in addressing this objective. There are many tools now available to help with the identification of complex, high-risk patients. They include:

- Risk stratification
- Predictive modeling
- Population health management
- Health care informatics

There also are complex care management models, transitions of care, and other transformative health care models specifically designed for these patients. It is imperative that case managers understand how these tools and models of care can help facilitate high-quality case management for complex patients with comorbidities. Following is a breakdown of each of these tools and their application in case management:

Risk stratification is a process wherein patient populations are stratified based on their levels of risk: high risk, low risk, and increasing risk. The process draws on actuarial data, analytics, and real-life experience. Risk stratification can be achieved through several methods. These methods include Hierarchical Condition Categories (eg, CMS Medicare Advantage program has 70 condition categories); Adjusted Clinical Groups developed by Johns Hopkins University, which classifies patient diagnoses in 93 categories; Elder Risk Assessment used for individuals age 60 and older, which assigns a score for each patient based on key metrics (eg, age, gender, marital status, number of hospital stays over the prior 2-year period, and comorbidities); Chronic Comorbidity Count, which is public information gleaned from the Agency for Healthcare Research and Quality (AHRQ) Clinical Classification Software, representing the sum of select comorbidities in six categories; Minnesota Tiering, a method based on Major Extended Diagnostic Groups, which places patients in five tiers from Tier 0 to Tier 4, representing patients with zero conditions to 10 or more conditions; and Charlson comorbidity index, which assesses patients with multiple comorbidities and projects their risk of 1-year mortality.

Predictive modeling is designed to identify both high-risk patients and superutilizer patients. Health care informatics, presenting data relating to a patient's medical history, provider performance, predictive markers, and resource allocation are all used in predictive modeling. This tool can drive health care initiatives that offer incentives to providers for better patient care and outcomes. Several providers are successfully using predictive modeling. One high profile example is the Camden Coalition of Healthcare Providers (Camden, NJ). Its predictive modeling using cluster analysis and a hot-spot technique categorizes patients based on their health care utilization history and social criteria including homelessness, unemployment, and language issues. Through its predictive modeling, the Camden Coalition identified a common element of childhood trauma

among the superutilizer patients. From there, a specific care management program was designed to better treat these individuals. Another example of predictive modeling at work is a collaborative effort between CVS Health and IBM wherein IBM's Watson cognitive computing platform was used in conjunction with predictive analytics and health care information (ie, patient behavior, medications, utilization, and claims history) to achieve improved case management for patients with chronic conditions.

Population health management strives to promote improved delivery of care, contain costs, and achieve better patient outcomes among targeted patient groups such as those with comorbidities. By providing a means to evaluate the population across a continuum of care, the most complex patients are identified and the progression of their diseases and medical conditions can be reduced and better managed. A "Population Health Management" study published by Ernst & Young in 2014 projected that the use of population health management could achieve direct and indirect savings of over $1 million associated with such common chronic diseases as cancer, diabetes, heart disease, hypertension, mental disorders, pulmonary conditions, and stroke. Through specific population health management strategies (eg, smoking cessation and wellness programs) along with new medical homes and community-based transitions of care programs, high-risk, complex patients can realize better quality of care at lower costs.

Health care informatics is a major component of population health management and predictive modeling. Health care informatics is derived through the application of state-of-the-art technologies and is accessible to case managers and other health care professionals. These platforms contain electronic health records as well as other patient data derived through biometrics, remote patient monitoring, e-visits, clinical information exchanges, electronic communications with patients (ie, texts and emails), and aggregated data—all easily accessible via secure patient portals. Going forward, case managers will need to master the retrieval and application of health care informatics on behalf of their complex patients. This will require their becoming computer savvy and facile in the use of new technologies like mobile device texting and navigation of patient portals.

In addition to these tools for identifying and better managing complex patients with comorbidities, the U.S. Department of Health & Human Services (HHS) also has created a strategic framework for managing patients with multiple comorbidities. The HHS report titled "Multiple Chronic Conditions: A Strategic Framework—Optimum Health and Quality of Life for Individuals with

To provide best in class case management services to their patients with comorbidities, case managers need to understand the challenges they pose; how to best to identify these complex, high-risk patients; and their role in managing these cases

Multiple Chronic Conditions," which was published in 2010, encompasses its vision, goals, objectives, and specific strategies for the coordination of care that makes the shift from focusing on single chronic diseases separately to one that considers a multiple chronic condition approach. It is intended to guide both the HHS and its external stakeholders including government agencies such as the CMS, CDC, AHRQ, Administration on Aging, Indian Health Service, Substance Abuse and Mental Health Services, Administration for Children and Families, and U.S. Food and Drug Administration, each of which has mandates within the scope of prevention and management of multiple chronic conditions.

As part of its strategic framework for multiple chronic conditions, the HHS has established four overarching goals on behalf of individuals with multiple chronic conditions. These goals are to:

- Foster health care and public health systems changes to improve their health
- Maximize their use of proven self-care management and other services
- Provide better tools and information to health care, public health, and social services workers who deliver care to them, and
- Facilitate research to fill knowledge gaps about them and to provide interventions and systems to benefit them.The

HHS has developed a number of strategies for achieving these goals, including:

- Identifying populations and subgroups with clusters of conditions and developing care models targeting those at highest risk of poor outcomes
- Developing pilot studies of multidisciplinary, person-centered care models
- Testing care models to ensure their evaluation of multiple chronic condition outcomes
- Utilizing incentives to promote cost-effective care coordination among providers
- Encouraging the meaningful use of electronic health records and health information technology
- Adopting public health policies to target unhealthy and risky behaviors as well as foods associated with increased risk of chronic disease
- Exploring incentives to improve individuals' participation in chronic disease risk behavior prevention
- Improving the efficiency, quality, and cost-effectiveness of evidenced-based, self-care management activities and programs
- Ensuring that developers of clinical guidelines include information on the most common comorbidities

The Role of Case Managers

Case managers have a definite role in helping achieve the goals established by the HHS, in particular, the objectives relating to the use of self-care management and utilization of better tools (eg, predictive modeling, health care informatics) to assist these patients. Of course, the role of case managers is broader and vital to achieving better outcomes for patients with comorbidities. There are evidence-based resources that confirm the need for and significance of professional case management for patients with chronic conditions. This research covers all aspects of case management from diverse practice settings to transitions of care and the reduction of hospital readmissions.

There are evidence-based models that focus on specific goals. For example, the Geisinger Navigator model was designed to contain hospital readmission. It involves a proactive, patient-centered model of care in which the case manager is charged with targeting a small group of patients within a given population of those regarded as high risk for readmission, emergency department visits, and high-cost complications. In this model, the case manager stays in close contact with these patients, calling and seeing them frequently, intervening as required, and communicating with their other health care professionals to maintain the optimum level of care. Just as this evidence-based model has proven effective in reducing both hospital admissions and readmissions, there are others available to case managers. Accessing them first requires the case manager to identify the primary patient concern, followed by a database search to uncover relevant evidence-based resource models, and a thorough assessment of these models of care and their results with broader populations to determine which may be most applicable.

For all case managers, taking a proactive role in caring for high-risk, complex patients with comorbidities must start early. It is important to engage patients and their family

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PharmaFacts for Case Managers

Steglujan™ (ertugliflozin and sitagliptin) tablets, for oral use

INDICATIONS AND USAGE

Steglujan is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both ertugliflozin and sitagliptin is appropriate.

Limitations of Use

Steglujan is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

Steglujan has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using Steglujan.

DOSAGE AND ADMINISTRATION

Recommended Dosage

- The recommended starting dose of Steglujan is 5 mg ertugliflozin/100 mg sitagliptin once daily, taken in the morning, with or without food. In patients tolerating Steglujan, the dose may be increased to a maximum recommended dose of 15 mg ertugliflozin/100 mg sitagliptin, once daily, if additional glycemic control is needed.
- For patients treated with ertugliflozin who are being switched to Steglujan, the dose of ertugliflozin can be maintained.
- In patients with volume depletion, correct this condition before initiating Steglujan.

Patients with Renal Impairment

Assess renal function before initiating Steglujan and periodically thereafter (see WARNINGS AND PRECAUTIONS).

- Use of Steglujan is contraindicated in patients with an estimated glomerular filtration rate (eGFR) <30 mL/min/1.73 m^2
- Initiation of Steglujan is not recommended in patients with an eGFR of 30 mL/min/1.73 m^2 to <60 mL/minute/1.73 m^2
- Continued use of Steglujan is not recommended when eGFR is persistently between 30 and <60 mL/min/1.73 m^2.
- No dose adjustment is needed in patients with mild renal impairment.

DOSAGE FORMS AND STRENGTHS

- Steglujan 5 mg/100 mg: ertugliflozin 5 mg and sitagliptin 100 mg tablets are beige, almond-shaped debossed with "554" on one side and plain on the other side.
- Steglujan 15 mg/100 mg: ertugliflozin 15 mg and sitagliptin 100 mg tablets are brown, almond-shaped debossed with "555" on one side and plain on the other side.

CONTRAINDICATIONS

- Severe renal impairment, end-stage renal disease, or dialysis
- History of a serious hypersensitivity reaction to sitagliptin, such as anaphylaxis or angioedema (see WARNINGS AND PRECAUTIONS and ADVERSE REACTIONS)
- History of a serious hypersensitivity reaction to ertugliflozin

WARNINGS AND PRECAUTIONS

Pancreatitis

There have been postmarketing reports of acute pancreatitis, including fatal and nonfatal hemorrhagic or necrotizing pancreatitis, in patients taking sitagliptin, a component of Steglujan. After initiation of Steglujan, patients should be observed carefully for signs and symptoms of pancreatitis. If pancreatitis is suspected, Steglujan should promptly be discontinued and appropriate management should be initiated. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using Steglujan.

Hypotension

Ertugliflozin, a component of Steglujan, causes intravascular volume contraction. Therefore, symptomatic hypotension may occur after initiating Steglujan (see ADVERSE REACTIONS), particularly in patients with impaired renal function (eGFR <60 mL/min/1.73 m^2), in elderly patients (≥65 years), in patients with low systolic blood pressure, and in patients receiving diuretics. Before initiating Steglujan, volume status should be assessed and corrected if indicated. Monitor for signs and symptoms of hypotension after initiating therapy.

Ketoacidosis

Reports of ketoacidosis, a serious life-threatening condition requiring urgent hospitalization, have been identified in clinical trials and

postmarketing surveillance in patients with type 1 and type 2 diabetes mellitus receiving medicines containing sodium glucose co-transporter-2 (SGLT2) inhibitors; cases have been also been reported in ertugliflozin-treated patients in clinical trials. Across the clinical program, ketoacidosis was identified in 3 of 3,409 (0.1%) of ertugliflozin-treated patients and 0% of comparator- treated patients. Fatal cases of ketoacidosis have been reported in patients taking medicines containing SGLT2 inhibitors. Steglujan is not indicated for the treatment of patients with type 1 diabetes mellitus.

Patients treated with Steglujan who present with signs and symptoms consistent with severe metabolic acidosis should be assessed for ketoacidosis regardless of presenting blood glucose levels because ketoacidosis associated with Steglujan may be present even if blood glucose levels are <250 mg/dL. If ketoacidosis is suspected, Steglujan should be discontinued, the patient should be evaluated, and prompt treatment should be instituted. Treatment of ketoacidosis may require insulin, fluid, and carbohydrate replacement.

In many of the reported cases, and particularly in patients with type 1 diabetes, the presence of ketoacidosis was not immediately recognized and institution of treatment was delayed because presenting blood glucose levels were below those typically expected for diabetic ketoacidosis (often <250 mg/dL). Signs and symptoms at presentation were consistent with dehydration and severe metabolic acidosis and included nausea, vomiting, abdominal pain, generalized malaise, and shortness of breath. In some but not all cases, factors predisposing to ketoacidosis such as insulin dose reduction, acute febrile illness, reduced caloric intake due to illness or surgery, pancreatic disorders suggesting insulin deficiency (eg, type 1 diabetes, history of pancreatitis or pancreatic surgery), and alcohol abuse were identified.

Before initiating Steglujan, consider factors in the patient's history that may predispose to ketoacidosis, including pancreatic insulin deficiency from any cause, caloric restriction, and alcohol abuse. In patients treated with Steglujan consider monitoring for ketoacidosis and temporarily discontinuing Steglujan in clinical situations known to predispose to ketoacidosis (eg, prolonged fasting due to acute illness or surgery).

Acute Kidney Injury and Impairment in Renal Function

Steglujan causes intravascular volume contraction and can cause renal impairment (see ADVERSE REACTIONS). There have been postmarketing reports of acute kidney injury, some requiring hospitalization and dialysis in patients receiving SGLT2 inhibitors. Before initiating Steglujan, consider factors that may predispose patients to acute kidney injury including hypovolemia, chronic renal insufficiency, congestive heart failure, and concomitant medications (diuretics, angiotensin-converting enzyme inhibitors, angiotensin II receptor blockers, nonsteroidal antiinflammatory drugs). Consider temporarily discontinuing Steglujan in any setting of reduced oral intake (such as acute illness or fasting) or fluid losses (such as gastrointestinal illness or excessive heat exposure); monitor patients for signs and symptoms of acute kidney injury. If acute kidney injury occurs, discontinue Steglujan promptly and institute treatment.

Ertugliflozin, a component of Steglujan, increases serum creatinine and decreases eGFR. Patients with moderate renal impairment (eGFR 30 to <60 mL/min/1.73 m^2) may be more susceptible to these changes. Renal function abnormalities can occur after initiating Steglujan. Renal function should be evaluated before initiating Steglujan and periodically thereafter. Use of Steglujan is not recommended when eGFR is persistently between 30 and <60 mL/min/1.73 m^2 and is contraindicated in patients with an eGFR <30 mL/min/1.73 m^2 (see DOSAGE AND ADMINISTRATION and CONTRAINDICATIONS).

There have been postmarketing reports with sitagliptin of worsening renal function, including acute renal failure, sometimes requiring dialysis. A subset of these reports involved patients with renal insufficiency, some of whom were prescribed inappropriate doses of sitagliptin. A return to baseline levels of renal insufficiency has been observed with supportive treatment and discontinuation of potentially causative agents. Consideration can be given to cautiously reinitiating Steglujan if another etiology is deemed likely to have precipitated the acute worsening of renal function. Sitagliptin has not been found to be nephrotoxic in preclinical studies at clinically relevant doses or in clinical trials.

Urosepsis and Pyelonephritis

There have been postmarketing reports of serious urinary tract infections, including urosepsis and pyelonephritis, requiring hospitalization in patients receiving medicines containing SGLT2 inhibitors. Cases of pyelonephritis also have been reported in ertugliflozin-treated patients in clinical trials. Treatment with medicines containing SGLT2 inhibitors increases the risk for urinary tract infections. Evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated (see ADVERSE REACTIONS).

Lower Limb Amputation

An increased risk for lower limb amputation (primarily of the toe) has been observed in clinical studies with another SGLT2 inhibitor. Across seven phase 3 clinical trials in the ertugliflozin development program, nontraumatic lower limb amputations were reported in 1 (0.1%) patient in the comparator group, 3 (0.2%) patients in the ertugliflozin 5-mg group, and 8 (0.5%) patients in the ertugliflozin 15-mg group. A causal association between ertugliflozin and lower limb amputation has not been definitively established.

Before initiating Steglujan, consider factors in the patient history that may predispose them to the need for amputations,

such as a history of prior amputation, peripheral vascular disease, neuropathy, and diabetic foot ulcers. Counsel patients about the importance of routine preventative foot care. Monitor patients receiving Steglujan for signs and symptoms of infection (including osteomyelitis), new pain or tenderness, sores or ulcers involving the lower limbs, and discontinue Steglujan if these complications occur.

Heart Failure

An association between dipeptidyl peptidase-4 (DPP-4) inhibitor treatment and heart failure has been observed in cardiovascular outcomes trials for two other members of the DPP-4 inhibitor class. These trials evaluated patients with type 2 diabetes mellitus and atherosclerotic cardiovascular disease. Consider the risks and benefits of Steglujan before initiating treatment in patients at risk for heart failure, such as those with a prior history of heart failure and a history of renal impairment, and observe these patients for signs and symptoms of heart failure during therapy. Advise patients of the characteristic symptoms of heart failure and to immediately report such symptoms. If heart failure develops, evaluate and manage according to current standards of care and consider discontinuation of Steglujan.

Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues

Insulin and insulin secretagogues (eg, sulfonylurea) are known to cause hypoglycemia. Ertugliflozin, a component of Steglujan, may increase the risk of hypoglycemia when used in combination with insulin and/or an insulin secretagogue. When sitagliptin, a component of Steglujan, was used in combination with a sulfonylurea or with insulin, medications known to cause hypoglycemia, the incidence of hypoglycemia was increased over that of placebo used in combination with a sulfonylurea or with insulin. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with Steglujan.

Genital Mycotic Infections

Ertugliflozin, a component of Steglujan, increases the risk of genital mycotic infections. Patients who have a history of genital mycotic infections or who are uncircumcised are more likely to develop genital mycotic infections. Monitor and treat appropriately.

Hypersensitivity Reactions

There have been postmarketing reports of serious hypersensitivity

reactions in patients treated with sitagliptin, a component of Steglujan. These reactions include anaphylaxis, angioedema, and exfoliative skin conditions including Stevens-Johnson syndrome. Onset of these reactions occurred within the first 3 months after initiation of treatment with sitagliptin, with some reports occurring after the first dose. If a hypersensitivity reaction is suspected, discontinue Steglujan, assess for other potential causes for the event, and institute alternative treatment for diabetes.

Angioedema has also been reported with other dipeptidyl peptidase-4 (DPP-4) inhibitors. Use caution in a patient with a history of angioedema with another DPP-4 inhibitor because it is unknown whether such patients will be predisposed to angioedema with Steglujan.

Increases in Low-Density Lipoprotein Cholesterol (LDL-C)

Dose-related increases in LDL-C can occur with ertugliflozin, a component of Steglujan. Monitor and treat as appropriate.

Severe and Disabling Arthralgia

There have been postmarketing reports of severe and disabling arthralgia in patients taking DPP-4 inhibitors. The time to onset of symptoms following initiation of drug therapy varied from 1 day to years. Patients experienced relief of symptoms upon discontinuation of the medication. A subset of patients experienced a recurrence of symptoms when restarting the same drug or a different DPP-4 inhibitor. Consider DPP-4 inhibitors as a possible cause for severe joint pain and discontinue drug if appropriate.

Bullous Pemphigoid

Postmarketing cases of bullous pemphigoid requiring hospitalization have been reported with DPP-4 inhibitor use. In reported cases, patients typically recovered with topical or systemic immunosuppressive treatment and discontinuation of the DPP-4 inhibitor. Tell patients to report development of blisters or erosions while receiving Stegluan. If bullous pemphigoid is suspected, Steglujan should be discontinued and referral to a dermatologist should be considered for diagnosis and appropriate treatment.

Macrovascular Outcomes

There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with Steglujan.

ADVERSE REACTIONS

The following are important adverse reactions

- Pancreatitis
- Hypotension
- Ketoacidosis
- Acute kidney injury and impairment in renal function
- Urosepsis and pyelonephritis
- Lower limb amputation
- Heart failure
- Hypoglycemia with concomitant use with insulin and insulin secretagogues
- Genital mycotic infections
- Hypersensitivity reactions
- Increases in low-density lipoprotein (LDL-C)
- Severe and disabling arthralgia
- Bullous pemphigoid

CLINICAL STUDIES

Overview of Clinical Studies in Patients with Type 2 Diabetes Mellitus

The efficacy and safety of ertugliflozin in combination with sitagliptin have been studied in 3 multicenter, randomized, double-blind, placebo- and active comparator-controlled, clinical studies involving 1,985 patients with type 2 diabetes mellitus. These studies included white, Hispanic, black, Asian, and other racial and ethnic groups and included patients with an age range of 21 to 85 years.

In patients with type 2 diabetes mellitus, treatment with ertugliflozin in combination with sitagliptin reduced HbA1c compared with placebo or active comparator.

In patients with type 2 diabetes mellitus treated with ertugliflozin in combination with sitagliptin, the change in HbA1c was generally similar across subgroups defined by age, sex, and race.

In Combination with Sitagliptin versus Ertugliflozin Alone and Sitagliptin Alone, as Add-on to Metformin

A total of 1,233 patients with type 2 diabetes mellitus with inadequate glycemic control (HbA1c between 7.5% and 11%) who were receiving metformin monotherapy (≥1,500 mg/d for ≥8 weeks) participated in a randomized, double-blind, 26-week, active controlled study (NCT NCT02099110) to evaluate the efficacy and safety of ertugliflozin 5 mg or 15 mg in combination with sitagliptin 100 mg compared with the individual components. Patients were randomized to one of five treatment arms: ertugliflozin 5 mg, ertugliflozin 15 mg, sitagliptin 100 mg, ertugliflozin 5 mg + sitagliptin 100 mg, or ertugliflozin 15 mg + sitagliptin 100 mg.

At Week 26, ertugliflozin 5 mg or 15 mg + sitagliptin 100 mg provided statistically significantly greater reductions in HbA1c compared with the individual components. More patients achieved an HbA1c <7% while receiving the combination as compared with the individual components.

Ertugliflozin as Add-on Combination Therapy with Metformin and Sitagliptin

A total of 463 patients with inadequately controlled type 2 diabetes mellitus (HbA1c between 7% and 10.5%) who were receiving metformin (≥1,500 mg/d for ≥8 weeks) and sitagliptin 100 mg once daily participated in a randomized, double-blind, multicenter, 26-week, placebo-controlled study (NCT02036515) to evaluate

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LITSCAN FOR CASE MANAGERS

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

Transplantation. 2018 Jan 18. doi: 10.1097/TP.0000000000002099. [Epub ahead of print]

Race, risk, and willingness of end-stage renal disease patients without hepatitis C (HCV) to accept an HCV-infected kidney transplant.

McCauley M, Mussel A, Goldberg D, et al.

BACKGROUND: Despite effective antiviral treatment, hundreds of kidneys from deceased donors with hepatitis C virus (HCV) are discarded annually. Little is known about the determinants of willingness to accept HCV-infected kidneys among HCV-negative patients.

METHODS: At 2 centers, 189 patients undergoing initial or reevaluation for transplant made 12 hypothetical decisions about accepting HCV-infected kidneys in which we systematically varied expected HCV cure rate, allograft quality and wait-time for an uninfected kidney.

RESULTS: Only 29% of participants would accept an HCV-infected kidney under all scenarios, while 53% accepted some offers and rejected others, and 18% rejected all HCV-infected kidneys. Higher cure rate (OR 3.49, 95% CI 2.33-5.24 for 95% vs. 75% probability of HCV cure), younger donor (OR 2.34, 95% CI 1.91-2.88 for a 20-year-old vs. a 60-year-old hypertensive donor), and longer wait for an uninfected kidney (OR 1.43, 95% CI 1.22-1.67 for 5 vs. 2 years) were associated with greater willingness to accept an HCV-infected kidney. Black race modified the effect of HCV cure rate, such that willingness to accept a kidney increased less for blacks vs. whites as the cure rate improved. Patients >60 years and prior kidney recipients showed greater willingness to accept an HCV-infected organ.

CONCLUSIONS: Most patients will consider an HCV-infected kidney in some situations. Future trials using HCV-infected kidneys may enhance enrollment by targeting older patients and prior transplant recipients, but centers should anticipate that black patients' acceptance of HCV-infected kidneys will be reduced compared to white patients.

AIDS. 2018 Jan 13. doi: 10.1097/QAD.0000000000001747. [Epub ahead of print]

Cost-effectiveness of alternative strategies for provision of HIV pre-exposure prophylaxis for people who inject drugs.

Fu R, Owens D, Brandeau ML.

BACKGROUND: Oral HIV pre-exposure prophylaxis (PrEP) has been recommended as a means of HIV prevention among people who inject drugs (PWID) but, at current prices, is unlikely to be cost-effective for all PWID.

OBJECTIVE: To determine the cost-effectiveness of alternative strategies for enrolling PWID in PrEP.

DESIGN: Dynamic network model that captures HIV transmission and progression among PWID in a representative US urban center.

OUTCOME MEASURES: HIV infections averted, discounted costs and quality-adjusted life-years (QALYs), and incremental cost-effectiveness ratios (ICERs).

INTERVENTION: We assume 25% PrEP coverage and investigate four strategies: 1) random PWID are enrolled (Unselected Enrollment); 2) individuals are randomly selected and enrolled together with their partners (Enroll Partners); 3) individuals with the highest number of sexual and needle-sharing partnerships are enrolled (Most Partners); 4) individuals with the greatest number of infected partners are enrolled (Most Positive Partners).

RESULTS: PrEP can achieve significant health benefits: compared to the status quo of no PrEP, the strategies gain 1114 QALYs (Unselected Enrollment), 2194 QALYs (Enroll Partners), 2481 QALYs (Most Partners), and 3046 QALYs (Most Positive Partners) over 20 years in a population of approximately 8500 people. The ICER of each strategy compared to the status quo (cost per QALY gained) is $272,000 (Unselected Enrollment), $158,000 (Enroll Partners), $124,000 (Most Partners), and $101,000 (Most Positive Partners). All strategies except Unselected Enrollment are cost-effective according to WHO criteria.

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Am J Kidney Dis. 2018 Jan 10. pii: S0272-6386(17)31101-0. doi: 10.1053/j.ajkd.2017.10.025. [Epub ahead of print]

Factors associated with withdrawal from maintenance dialysis: a case-control analysis.

Wetmore JB, Yan H, Hu Y, Gilbertson DT, Liu J.

BACKGROUND: Little is known about differences in the clinical course between patients receiving maintenance dialysis who do and do not withdraw from dialysis therapy.

STUDY DESIGN: Case-control analysis.

SETTING & PARTICIPANTS: US patients with Medicare coverage who received maintenance hemodialysis for 1 year or longer in 2008 through 2011.

PREDICTORS: Comorbid conditions, hospitalizations, skilled nursing facility stays, and a morbidity score based on durable medical equipment claims.

OUTCOME: Withdrawal from dialysis therapy.

MEASUREMENTS: Rates of medical events, hospitalizations, skilled nursing facility stays, and a morbidity score.

RESULTS: The analysis included 18,367 (7.7%) patients who withdrew and 220,443 (92.3%) who did not. Patients who withdrew were older (mean age, 75.3±11.5 [SD] vs 66.2±14.1 years) and more likely to be women and of white race, and had higher comorbid condition burdens. The odds of withdrawal among women were 7% (95% CI, 4%-11%) higher than among men. Compared to age 65 to 74 years, age 85 years or older was associated with higher adjusted odds of withdrawal (adjusted OR, 1.61; 95% CI, 1.54-1.68), and age 18 to 44 years with lower adjusted odds (adjusted OR, 0.36; 95% CI, 0.32-0.40). Blacks, Asians, and Hispanics were less likely to withdraw than whites (adjusted ORs of 0.36 [95% CI, 0.35-0.38], 0.47 [95% CI, 0.42-0.53], and 0.46 [95% CI, 0.44-0.49], respectively). A higher durable medical equipment claims-based morbidity score was associated with withdrawal, even after adjustment for traditional comorbid conditions and hospitalization; compared to a score of 0 (lowest presumed morbidity), adjusted ORs of withdrawal were 3.48 (95% CI, 3.29-3.67) for a score of 3 to 4 and 12.10 (95% CI, 11.37-12.87) for a score ≥7. Rates of medical events and institutionalization tended to increase in the months preceding withdrawal, as did morbidity score.

LIMITATIONS: Results may not be generalizable beyond US Medicare patients; people who withdrew less than 1 year after dialysis therapy initiation were not studied.

CONCLUSIONS: Women, older patients, and those of white race were more likely to withdraw from dialysis therapy. The period before withdrawal was characterized by higher rates of medical events and higher levels of morbidity.

Circ Heart Fail. 2018 Jan;11(1):e004005. doi: 10.1161/CIRCHEARTFAILURE.117.004005.

Heart failure in pregnant women: a concern across the pregnancy continuum.

Mogos MF, Piano MR, McFarlin BL, Salemi JL, Liese KL, Briller JE.

BACKGROUND: Heart failure (HF) is a leading cause of maternal morbidity and mortality in the United States, but prevalence, correlates, and outcomes of HF-related hospitalization during antepartum, delivery, and postpartum periods remain unknown. The objective was to examine HF prevalence, correlates, and outcomes among pregnancy-related hospitalizations among women 13 to 49 years of age.

METHODS AND RESULTS: We used the 2001 to 2011 Nationwide Inpatient Sample. Rates of HF were calculated by patient and hospital characteristics. Survey logistic regression was used to estimate adjusted odds ratios representing the association between HF and each outcome, stratified by antepartum, delivery, and postpartum periods. Joinpoint regression was used to describe temporal trends in HF and in-hospital mortality. Over 50 million pregnancy-related hospitalizations were analyzed. The overall rate of HF was 112 cases per 100 000 pregnancy-related hospitalizations. Although postpartum encounters represented only 1.5% of pregnancy-related hospitalizations, ~60% of HF cases occurred postpartum, followed by delivery (27.3%) and antepartum (13.2%). Among postpartum hospitalizations, there was a significant 7.1% (95% confidence interval, 4.4-9.8) annual increase in HF from 2001 to 2006, followed by a steady rate through 2011. HF rates among antepartum hospitalizations increased on average 4.9% (95% confidence interval, 3.0-6.8) annually from 2001 to 2011. Women with a diagnosis of HF were more likely to experience adverse maternal outcomes, as reflected by outcome-specific adjusted odds ratios during antepartum (2.7-25), delivery (6-195), and postpartum (1.5-6.6) periods.

CONCLUSIONS: HF is associated with increased risk of maternal mortality and morbidities. During hospitalization, high-risk mothers need to be identified and surveillance programs developed before discharge.

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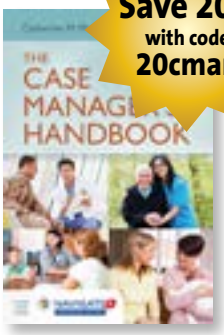

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J Card Fail. 2018 Jan 8. pii: S1071-9164(18)30004-6. doi: 10.1016/j.cardfail.2018.01.001. [Epub ahead of print]

Association of posture and ambulation with function at 30 days post-hospital discharge in older adults with heart failure.

Floegel TA, Dickinson JM, DerAnanian C, McCarthy M, Hooker SP, Buman MP.

PURPOSE: To investigate the predictive value of in-hospital posture and ambulatory activity for 30-d following discharge on functional status in older patients with heart failure.

METHODS: Prospective observational pilot study of 27 patients (78 ± 9.8 yrs; 51.8% female) admitted with heart failure. Participants wore two inclinometric accelerometers to record posture in-hospital, and an ankle accelerometer to record ambulatory activity in-hospital and 30 days after discharge. Function was assessed the day after discharge (Timed Up and Go [TUG], Short Physical Performance Battery [SPPB], hand grip strength) and at 30-d post-discharge.

RESULTS: Length of stay was 5.1 ± 3.9 days. Participants spent 63.0 ± 19.2% of their hospital time lying, 30.2 ± 18.7% sitting, 5.3 ± 4.2% standing, and 1.9 ± 8.6% ambulating. Thirty-day mean post-discharge stepping was 4890 ± 2285 steps/day. Each 10% increase in hospital lying time was associated with 0.7 sec longer TUG time (95% CI, 0.2-1.9) at 30-d. Each 1000 additional daily steps in the post-discharge period was associated with a 0.8-point higher SPPB score (95% CI, 0.1-1.0) at 30-d. Handgrip strength was unchanged.

CONCLUSIONS: Older patients with heart failure were sedentary during hospitalization which may contribute to decreased functional performance. Physical activity post-discharge may minimize this negative effect.

Clin Infect Dis. 2018 Jan 8. doi: 10.1093/cid/ciy012. [Epub ahead of print]

Cancer risk in older people living with human immunodeficiency virus infection in the United States.

Mahale P, Engels EA, Coghill AE, Kahn AR, Shiels MS.

BACKGROUND: Cancer risk is increased in people living with HIV (PLWH). Improved survival has led to an aging of PLWH. We evaluated the cancer risk in older PLWH (age ≥50 years).

METHODS: We included data from the HIV/AIDS Cancer Match Study (1996-2012) and evaluated risk of Kaposi sarcoma (KS), non-Hodgkin lymphoma (NHL), Hodgkin lymphoma, and cervical, anal, lung, liver, oral cavity/pharyngeal, breast, prostate, and colon cancers in older PLWH compared to the general population by calculating the standardized incidence ratios (SIRs) and excess absolute risks (EARs). Cancer risk by time since HIV diagnosis was estimated using Poisson regression.

RESULTS: We identified 10,371 cancers among 183,542 older PLWH. Risk was significantly increased for KS (SIR=103.34), NHL (SIR=3.05), Hodgkin lymphoma (SIR=7.61), and cervical (SIR=2.02), anal (SIR=14.00), lung (SIR=1.71), liver (SIR=2.91), and oral cavity/pharyngeal (SIR=1.66) cancers, and reduced for breast (SIR=0.61), prostate (SIR=0.47), and colon (SIR=0.63) cancers. SIRs declined with age for all cancers; however, EARs increased with age for anal, lung, liver, and oral cavity/pharyngeal cancers. Cancer risk was highest for most cancers within 5 years after HIV diagnosis; risk decreased with increasing time since HIV diagnosis for KS, NHL, lung cancer, and Hodgkin lymphoma.

CONCLUSIONS: Cancer risk is elevated among older PLWH. Although SIRs decrease with age, EARs are higher for some cancers, reflecting a greater absolute excess in cancer incidence among older PLWH. High risk in the first 5 years after HIV diagnosis for some cancers highlights the need for early HIV diagnosis and rapid treatment initiation.

Am J Hypertens. 2017 Jan;30(1):3-7. Epub 2016 Aug 29.

The case for low blood pressure targets.

Flack JM, Nolasco C, Levy P.

The "totality" of hypertension clinical trial endpoint data has shown that the absolute benefit of pharmacological blood pressure (BP) lowering is directly related to the BP level and baseline cardiovascular risk, albeit with attenuation of the relative risk reduction per unit of BP lowering in patients with diabetes and chronic kidney disease. Absolute risk reductions with pharmacological treatment are greater with advancing age. Cardiovascular risk and mortality reductions attributable to pharmacological BP lowering have been demonstrated for progressively lower BP levels extending well below the conventional BP threshold (140/90 mm Hg) for hypertension. Hypertension endpoint trials have shifted from determining the relative clinical benefits of various antihypertensive drugs to exploring whether lower than conventional BP targets in persons with BP levels spanning the prehypertensive

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to much higher BP strata confer clinical benefit. The more recent of these trials were "relatively" agnostic to the drugs used for BP lowering although several trials provided, but did not mandate the use of, specific agents. Pharmacological treatment benefit has been demonstrated at pretreatment BP levels even lower than the intensive SPRINT BP target (<120 mm Hg) and a growing body of evidence suggests that substantial risk reduction can be achieved by maintaining a normal BP over time (rather than waiting for BP to exceed 140/90 mm Hg before treating). Thus there is a compelling rationale to lower the BP threshold not just for a therapeutic goal but also for the initiation of pharmacological intervention.

Clin Lung Cancer. 2017 Dec 21. pii: S1525-7304(17)30346-7. doi: 10.1016/j.cllc.2017.12.007. [Epub ahead of print]

Developing a predictive model for clinical outcomes of advanced non-small cell lung cancer patients treated with nivolumab.

Park W, Kwon D, Saravia D, et al.

INTRODUCTION: Despite significant improvement of clinical outcomes of advanced non-small-cell lung cancer (NSCLC) patients treated with immunotherapy, our knowledge of optimal biomarkers is still limited.

PATIENTS AND METHODS: We retrospectively evaluated 159 advanced NSCLC patients in our institution treated with nivolumab after disease progression during platinum-based chemotherapy. We correlated several variables with progression-free survival (PFS) to develop the immunotherapy, Sex, Eastern Cooperative Oncology Group performance status, Neutrophil-to-lymphocyte ratio (NLR), and Delta NLR (iSEND) model. We categorized patients into iSEND good, intermediate, and poor risk groups and evaluated their clinical outcomes. Performance of iSEND at 3, 6, 9, and 12 months was evaluated according to receiver operating characteristic (ROC) curves and internally validated using bootstrapping. The association of iSEND risk groups with clinical benefit was evaluated using logistic regression.

RESULTS: Median follow-up was 11.5 months (95% confidence interval [CI], 9.4-13.1). There were 50 deaths and 43 with disease progression without death. PFS rates at 3, 6, 9, and 12 months were 78.4%, 63.7%, 55.3%, and 52.2% in iSEND good; 79.4%, 44.3%, 25.9%, and 19.2% in iSEND intermediate; and 65%, 25.9%, 22.8%, and 17.8% in iSEND poor. Time-dependent area under ROC curves of iSEND for PFS at 3, 6, 9, and 12 months were 0.718, 0.74, 0.746, and 0.774. The iSEND poor group was significantly associated with progressive disease at 12 ± 2 weeks (odds ratio, 9.59; 95% CI, 3.8-26.9; P < .0001).

CONCLUSION: The iSEND model is an algorithmic model that can characterize clinical outcomes of advanced NSCLC patients receiving nivolumab into good, intermediate, or poor risk groups and might be useful as a predictive model if validated independently.

Am J Nephrol. 2017;45(2):180-186. doi: 10.1159/000455015. Epub 2017 Jan 21.

Mortality after renal allograft failure and return to dialysis.

Brar A, Markell M, Stefanov DG, et al.

INTRODUCTION: The outcomes of patients who fail their kidney transplant and return to dialysis (RTD) has not been investigated in a nationally representative sample. We hypothesized that variations in management of transplant chronic kidney disease stage 5 leading to kidney allograft failure (KAF) and RTD, such as access, nutrition, timing of dialysis, and anemia management predict long-term survival.

METHODS: We used an incident cohort of patients from the United States Renal Data System who initiated hemodialysis between January 1, 2003 and December 31, 2008, after KAF. We used Cox regression analysis for statistical associations, with mortality as the primary outcome.

RESULTS: We identified 5,077 RTD patients and followed them for a mean of 30.9 ± 22.6 months. Adjusting for all possible confounders at the time of RTD, the adjusted hazards ratio (AHR) for death was increased with lack of arteriovenous fistula at initiation of dialysis (AHR 1.22, 95% CI 1.02-1.46, p = 0.03), albumin <3.5 g/dL (AHR 1.33, 95% CI 1.18-1.49, p = 0.0001), and being underweight (AHR 1.30, 95% CI 1.07-1.58, p = 0.006). Hemoglobin <10 g/dL (AHR 0.96, 95% CI 0.86-1.06, p = 0.46), type of insurance, and zip code-based median household income were not associated with higher mortality. Glomerular filtration rate <10 mL/min/1.73 m^2 at time of dialysis initiation (AHR 0.83, 95% CI 0.75-0.93, p = 0.001) was associated with reduction in mortality.

CONCLUSIONS: Excess mortality risk observed in patients starting dialysis after KAF is multifactorial, including nutritional issues and vascular access. Adequate preparation of patients with failing kidney transplants prior to resuming dialysis may improve outcomes.

Lessening Cancer Bone Pain

A prophylactic therapy is effective in preventing treatment-associated mild-to-moderate bone pain in breast cancer, according to a study published in Supportive Care in Cancer. Mild-to-moderate bone pain is a common adverse event associated with pegfilgrastim supportive therapy for chemotherapy for breast cancer. This adverse event may lead to discontinuation of treatment, which could further result in increased rates of infection, hospitalization, and mortality.

Jeffrey J. Kirshner, MD, Hematology-Oncology Associates of Central New York (East Syracuse, NY), and colleagues conducted a study to evaluate prophylactic naproxen or loratadine compared with no prophylactic treatment on pegfilgrastim-associated bone pain. The open-label study enrolled 600 patients with stage I-III breast cancer who were planning to undergo at least 4 cycles of adjuvant or neoadjuvant chemotherapy with pegfilgrastim support starting in cycle 1. The primary endpoint of the study was all-grade bone pain in cycle 1 from adverse events reporting, while secondary endpoints included bone pain in cycles 2–4 and across all cycles from adverse events reporting and patient-reported bone pain by cycle and across all cycles.

The results of the study showed that patients with all-grade bone pain in cycle 1 from adverse events reporting was 40.3% in those receiving naproxen, 42.5% in those receiving loratadine, and 46.6% in those receiving no prophylaxis. However, researchers acknowledged that differences between the treatment groups were not statistically significant. ■

Diagnosing Multiple Sclerosis: McDonald Criteria Are Updated

The 2017 McDonald criteria for diagnosing multiple sclerosis (MS) contain both old and new elements. The 2010 McDonald criteria have become somewhat outdated. The criteria still apply mainly to typical clinically isolated syndrome, define what is needed to fulfill dissemination in time and space of central nervous system lesions, and stress the need for no better explanation for presentation. In typical clinically isolated syndrome and clinical or MRI evidence of dissemination in space, cerebrospinal fluid–specific oligoclonal bands allow MS diagnosis. Symptomatic lesions can be used to show dissemination in space or time in patients having supratentorial, infratentorial, or spinal cord syndrome. Cortical lesions can be used to show dissemination in space. High-priority areas for research: optic nerve involvement; validation in diverse populations; and incorporation of advanced imaging, neurophysiologic, body fluid markers. ■

New Rule on Sharing Patient Information About Substance Abuse Care

The U.S. Department of Health and Human Services has made final a rule that simplifies the process for sharing patient information about their substance abuse care. The new rule, which took effect February 3, 2018, allows providers and payers to share such patient information with third parties using a single consent form that applies to that company's contractors, subcontractors, and legal representatives. Under the old rule patients would have to consent every time their data was shared or accessed. ■

New Palliative Care Guidelines

The National Comprehensive Cancer Network (NCCN) recently provided a few major updates to their palliative care guidelines. Newly added to the general overview section are these indications:

- Complex psychosocial needs
- Poor prognostic awareness
- Metastatic solid tumors and refractory hematologic malignancies

Additional reassessment bullet points were added, including "Re-evaluate intervention options and intensify as possible" (which is modified throughout the guidelines) and "Consult with other providers and refer to specialist if available." As for the criteria for consultation with a palliative care specialist, the second bullet under assessment "High-risk for persistent complex bereavement disorder" is new to the page, with the corresponding footnote: "Persistent complex bereavement disorder is a chronic heightened state of mourning that significantly impairs functioning."

Within the section for nausea and vomiting is a new update: "Assess nausea and vomiting severity and associated symptoms" and a deletion of "Consider palliative radiation therapy for nausea and vomiting related to brain metastases." In the antidiarrheal interventions and screening section, "Provide immediate antidiarrheal therapy indicated by grade" is now listed, with a note that "If chemotherapy induced, decrease or delay the next dose of chemotherapy." ■

CE I The Expanded Chronic Care Model as an Organizing Theory for the Integration of Behavioral and Physical Health Care

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cannot do for themselves. Patient self-management requires health care personnel to trust that once a patient is informed and activated, they will apply that skill and motivation. As mentioned in this article, it is strongly suggested that organizations considering integration become familiar with the Affordable Care Act and the Centers for Medicare & Medicaid Services regarding their rules.

It is important to remember that state governments play a significant role in the delivery of behavioral and physical health services. It is also important to know the delivery structure of these state services because it may assist or impede organizations' activities toward integration. It is advisable to become familiar with the state department that administers health and mental health programs. It also is important to establish a connection for updates on federal and state legislation that concerns changes in the medical care delivery system.

Those organizations that plan on integration combined with the ECCM should learn the ECCM in detail. They will need to train and orient staff on an interprofessional team approach to service delivery that will not have been characteristic of their operations. One resource is the Education to Practice website of the Michigan Health Council (http://education2practice.org/). Cross-training in integration will be necessary. Because most staff will have been employed in either behavioral health services or physical health services, training in the arena in which they do not have experience will be required.

The complexity of the changes that will have to be made means a clear plan will be required. "Organized, Evidence-Based Care, An Implementation Guide" offers suggestions from the view of integration of behavioral health into primary practice. The suggestions are: 1) create a vision statement or what is often labeled a strategic plan that contains a good reason to change, an idea of what the future will look like that is appealing to all involved, and a clear message of intent; 2) pick leaders to build a team of all levels of staff that can discuss all the challenges and variables involved; and, 3) develop a pathway for the integration that includes the population to be served, the resources available, the existing capacity for service delivery, and a plan to increase capacity if necessary and changes required to deliver integrated care.[18]

Professional education for health care in all forms should include course material on integration of behavioral and physical health so that personnel trained in medicine, psychology, social work, and other health professions understand the necessity of unifying practice principles in health care delivery that are based on a common understanding of its content and process. CE I

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When Returning to Work is Not the Goal: Identifying a Roadmap That Works for All

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up to and including termination.

More commonly, employers may not want to lose a valuable, experienced employee who wants to leave the workforce after an injury or illness. In these circumstances, the employer might negotiate with the employee about continuing to work for a specific period of time (for example, 6 months full time and then a part time or consulting arrangement).

The role of the CDMS/disability case manager is to advocate for the employee while also facilitating an arrangement that works best for all parties. The objective is to develop a roadmap that makes sense for the employee and the employer, which allows for the successful attainment of goals that are unique to the individual and his/her circumstances. CM

Policy, Practice, and Personal Commitment: Three Wishes for Case Management in the New Year

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Self-awareness is crucial: case managers must remember to take time for themselves to refresh and rejuvenate. It's also strategic—by avoiding burnout, case managers can become better able to provide services while modeling good behaviors for others.

As 2018 begins, all of us at CCMC wish case managers a year of growth, professional achievement, and self-care—with the knowledge that what they do every day makes an invaluable contribution to the delivery of health and human services to patients and their support systems/families, across the care continuum. CM

CCMC New World Symposium 2018 Theater Showcase: Rehabilitation
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attain functional expectations and goals. For those returning to work after an injury, it's vital that the rehabilitation provider investigate job-specific tasks and physical demand level (PDL) that the person must perform and then develop a rehab plan that addresses those specific tasks (Figure 1). For example, a worker who must walk a mile to work from his company parking space needs to work out on the treadmill and not ride an exercise bike.

BenchMark's Ready for Work program prepares patients for return to work by stressing work conditioning. BenchMark's health care providers perform functional testing to tie functional demands of the job to the rehab program. Using periodization (increasing volume and intensity), they build a person's function to a level that will allow their quick and successful return to work.

In the process, Myers says, rehab providers must help patients focus on what they can do rather than what they are struggling to do, thereby increasing success and speeding their recovery. CM

FIGURE 2 CRITICAL JOB DEMANDS FORM

Task	**Employee Report**		
Job Description			
Main Purpose of Job (Job exists to perform this function)	1.		
	2.		
	3.		
Main Job Duties (List the 3 main tasks done in the job)	1.		
	2.		
	3.		
Work Schedule (Typical day-to-day work schedule)	Hours		
	Lunch		
	Breaks		
Tools/Equipment (Main tools used or equipment run in job)			
Lifting	Average Weight	Maximum Weight	Reps
Floor to waist			
Waist to shoulder			
Overhead			
What is lifted?			
Carrying	Average Weight	Maximum Weight	Reps
What is carried?			
Pushing and Pulling			
(Amount of force, not weight of object)			
Check off the frequency for each item	**Occasional** (1%-33% of day)	**Frequent** (34%-66% of day)	**Constant** (66%-100% of day)
Sitting			
Standing			
Walking			
Bending			
Squatting			
Reaching			
Kneeling/Crawling			
Climbing			
Person completing form	Signature		

Managing Comorbidities and Population Health Management
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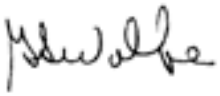
2. Health plans must identify members and assign them into health categories based on need.
3. Health care providers will need enhanced clinical capabilities.

With strong system, clinical, and administrative support, the case manager can successfully manage patients with chronic diseases and comorbidities for improved outcomes.



Gary S. Wolfe, RN, CCM
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Integrated Case Management
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Practice for Case Management, the Integrated Case Management Program offered by CMSA provides a framework and training to successfully prepare case managers to take on this new role and function.[3] Please visit CMSA's website to learn more. CM

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CE II Managing the Growing Number of Patients with Comorbidities *continued from page 36*

members to build a good rapport and trust to facilitate open communications and improved transitions of care. Patients in a hospital setting must be identified as high risk during their hospital stay. Then, as they are being prepared for discharge, a thorough discharge plan is essential. It should rely on more than just the patient's electronic health record and history of hospitalizations and/or readmissions. It requires case managers to delve deeper by applying risk assessment and stratification tools that could serve to uncover risks upon discharge (ie, lack of family support, language and/or communication challenges, mental health problems, a patient's own perception of his/her condition) that can jeopardize compliance with a treatment plan.

When caring for patients in a Medicaid Health Home setting, case managers must recognize the special challenges they will face with an especially vulnerable population whose comorbidities often include multiple chronic illnesses along with mental health disorders, substance abuse, and other socioeconomic problems such as homelessness and social isolation. Recognizing these heightened challenges, many state Medicaid Health Homes reward providers who demonstrate strong outreach performance to these patients with financial incentives for their effective care coordination. This is true, for instance, with the New York State Medicaid Health Homes, which pays a fee that is equivalent to 80% of the active care coordination fee.

In all settings and given today's value-based health care, case managers will assume greater responsibilities in benchmarking clinical measurements and documenting clinical outcome performance in their complex patients with comorbidities. Applying previously noted risk stratification tools in conjunction with best practices in case management, case managers can serve as true catalysts for better care and outcomes of patients with comorbidities. CE II

PharmaFacts for Case Managers

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the efficacy and safety of ertugliflozin. Patients entered a 2-week, single-blind, placebo run-in period and were randomized to placebo, ertugliflozin 5 mg, or ertugliflozin 15 mg.

At Week 26, treatment with ertugliflozin at 5 mg or 15 mg daily provided statistically significant reductions in HbA1c. Ertugliflozin also resulted in a higher proportion of patients achieving an HbA1c <7% compared with placebo.

Initial Combination Therapy of Ertugliflozin and Sitagliptin

A total of 291 patients with type 2 diabetes mellitus inadequately controlled (HbA1c between 8% and 10.5%) by diet and exercise participated in a randomized, double-blind, multicenter, placebo-controlled 26-week study (NCT02226003) to evaluate the efficacy and safety of ertugliflozin in combination with sitagliptin. These patients, who were not receiving any background antihyperglycemic treatment for ≥8 weeks, entered a 2-week, single-blind, placebo run-in period and were randomized to placebo, ertugliflozin 5 mg, ertugliflozin 15 mg in combination with sitagliptin (100 mg), once daily.

At Week 26, treatment with ertugliflozin 5 mg and 15 mg in combination with sitagliptin at 100 mg daily provided statistically significant reductions in HbA1c compared with placebo. Ertugliflozin 5 mg and 15 mg in combination with sitagliptin at 100 mg daily also resulted in a higher proportion of patients achieving an HbA1c <7% compared with placebo

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  - NDC 0006-5368-06 unit-of-use bottles of 90
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Editor-in-Chief: Gary S. Wolfe, RN, CCM
831-443-6847
email: gwolfe@academyccm.org

Executive Editor: Jennifer Maybin, MA, ELS
908-581-2272
email: jmaybin@academyccm.org

Publisher/President: Howard Mason, RPH, MS
203-454-1333, ext. 1
e-mail: hmason@academyccm.org

Art Director: Laura D. Campbell
203-256-1515
e-mail: lcampbell@academyccm.org

Advertising: Sabina Gargiulo
856-380-6831
e-mail: sgargiulo@ccmcertification.org

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Executive Vice President:
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541-505-6380
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Member Services:
203-454-1333, ext. 3
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Phone: 203-454-1333; fax: 203-547-7273
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