

Managing the Growing Number of Patients with Comorbidities

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ccording 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 graving 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

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. 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 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 highrisk 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



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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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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.

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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

HOW SUPPLIED/STORAGE AND HANDLING

Steglujan (ertugliflozin and sitagliptin) tablets are available in the strengths listed below:

- 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. They are supplied as follows:
- NDC 0006-5367-03 unit-of-use bottles of 30
- NDC 0006-5367-06 unit-of-use bottles of 90
 NDC 0006-5367-07 bulk bottles of 500
- 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. They are supplied as follows:
 - NDC 0006-5368-03 unit-of-use bottles of 30
 - NDC 0006-5368-06 unit-of-use bottles of 90
 - NDC 0006-5368-07 bulk bottles of 500

Storage of Bottles

Store at 20°C -25°C (68°F -77°F), excursions permitted between 15°C -30°C (between 59°F -86°F) [see USP Controlled Room Temperature]. Protect from moisture. Store in a dry place. Steglujan™ is manufactured by Merck and Co.