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Chikita Mann, MSN, RN, CCM

Medication nonadherence is a national and global concern, and the consequences of medication nonadherence are financial and medical. The World Health Organization estimates that approximately 125,000 people die each year in the United States because of improper medication usage. Health care costs related to medication nonadherence have reached up \$528 billion in the United States. Exploring the reasons why clients are nonadherent and/or noncompliant is key to addressing medication nonadherence. The board-certified case manager must be able to anticipate applicable ethical dilemmas that could arise in the course of coordinating care for clients who are nonadherent with their medication regimen.

15 Impact of a Paper Reminder Prompt on Increasing the Administration Rate of Influenza Vaccine

Gracelle Toussaint, DNP, APRN, ANP-BC

Vaccines are critical in safeguarding individuals against various illnesses, yet Healthy People 2020 announced that the annual rate of influenza infection in the United States continues to remain high at over 200,000 occurrences and 36,000 deaths, even though influenza infection is a vaccine-preventable illness. Some clinicians fail to assess their patients' immunization status for the influenza vaccine, which results in a large population of adults who have not been immunized against the influenza virus. My practice site and I undertook a project to determine if a simple, low-cost intervention—a paper reminder prompt—could promote the assessment of patients' influenza vaccination status by practice clinicians, thereby leading to an increased administration rate of the influenza vaccine at the point-of-care.

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Gary S. Wolfe

Flu Season: It's Time for Case Managers to Take Action

Influenza (flu) is a potentially serious disease that can lead to hospitalization and even death.

The flu season generally runs from October through April, and every flu season is different. Millions of people get flu every year, hundreds of thousands of people are hospitalized, and thousands to tens of thousands of people die from flu-related causes every year. An annual seasonal flu vaccine is the best way to help protect against flu, and vaccination has been shown to have many benefits.

Flu vaccines cause antibodies to develop in the body about 2 weeks after vaccination. These antibodies provide protection against infection with the viruses that are used to make the vaccine.

The seasonal flu vaccine protects against the influenza viruses that research indicates will be most common during the upcoming season. Most flu vaccines in the United States protect against four different flu viruses ("quadrivalent"); an influenza A (H1N1) virus, an influenza A (H3N2) virus, and two influenza B viruses.

Everyone 6 months of age and older should get a flu vaccine every season with rare exception. The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices has made this recommendation since the 2010-2011 influenza season.

Vaccination to prevent flu is particularly important for people who are at high risk of developing serious flu complications. High-risk groups include:

- Individuals aged 65 or older
- Children younger than 6 months of age
- Pregnant women
- Individuals of any age with certain chronic medical conditions including:
 - Asthma
 - Neurological conditions
 - Blood disorders

- Chronic obstructive pulmonary disease
- Heart disease
- Kidney disease
- Liver disorders
- Metabolic disorders
- People with weakened immune systems due to disease

Benefits of the flu vaccine include:

- Not getting sick with the flu
- Reducing the risk of flu-associated hospitalizations
- Helping to protect women from getting the flu during and after pregnancy
- Lifesaving in children
- Reducing the severity of illness in people who get vaccinated but still get sick
- Protecting people around you who are at risk
- Protective tool for people with chronic health conditions

The single best way to prevent seasonal flu is to get vaccinated, but good health habits should also be followed:

1. Avoid close contact.

Avoid close contact with people who are sick. When you are sick, keep your distance from others to protect them from getting sick too.

2. Stay home when you are sick.

If possible, stay home from work and school and don't run errands when you are sick. This will help prevent spreading your illness to others.

3. Cover your mouth and nose.

Cover your mouth and nose with a tissue when coughing or sneezing. It may prevent those around you from getting sick. Flu and other serious respiratory illnesses, like respiratory syncytial virus, whooping cough, and severe acute respiratory syndrome, are spread by cough, sneezing, or unclean hands.

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Embracing Leadership Development

Patty Nunez, MA, CRC, CDMS, CCM

At year end, as we reflect on our lives and careers, we often set goals for the coming year. A good question for each of us to consider is: How can I develop as a leader?

Leadership is neither defined by a specific role nor limited to those who run a company or a department. It is grounded in personal values, such as choosing each day to embody the principles, standards, and ethics of one's profession, licensure, and/or certification. All of us can exhibit leadership as we positively influence clients (the individuals who receive our services), colleagues, and service delivery providers.

As a professional, I hold three board certifications: Certified Case Manager (CCM), Certified Disability Management Specialist (CDMS), and Certified Rehabilitation Counselor (CRC). Having multiple certifications reflects my professional identity. My training and background are in rehabilitation counseling. I spent the first decade of my career providing direct services as a counselor to people with disabilities. As my career path took me into an insurance setting, I began working in a case management environment, with a strong focus on disability management. The CCM and CDMS credentials became important as

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reflections of my expanded knowledge.

As a CCM, I advocate for the individual, ensuring that the right resources are available at the right time. As a CDMS, I advocate for people with illnesses, injuries, and disabilities as they explore ways to return to work or stay at work. CDMSs also help employers mitigate the impact of employee

Leadership is neither defined by a specific role nor limited to those who run a company or a department. It is grounded in personal values, such as choosing each day to embody the principles, standards, and ethics of one's profession, licensure, and/or certification.

illness or injury on productivity. As a CRC, I draw from my foundation as a rehabilitation counselor.

Today, working in an insurance setting, I believe my multiple credentials speak to my credibility and skill set. Through certification, I demonstrate my understanding and expertise across multiple practice settings. Through communication and collaboration with professionals from varied backgrounds, I can establish common ground that unites all of us in a shared purpose.

While leadership may also involve sitting on boards, setting policy, and effecting change in the practice, the greatest impact we can make is on another person's life. A leadership mindset encourages us to provide services to people with even greater confidence as we implement the evidence-based best practices, as

required by certification. This goes to the heart of our role as leaders and advocates, whether for a "patient" in a caregiving setting, an "employee" in the workplace, or a "member" in insurance.

Leadership and Championing Others

In addition to our daily practice, there are other ways to assume a leadership role, personally and professionally. Professional organizations, accreditation boards, and certifying bodies need highly qualified volunteers to serve on task forces and take part in specific activities. One example is item-writing workshops in support of national certification examinations. By volunteering to become more involved in the practice, we have opportunities to both learn and practice new leadership skills.

Embracing leadership often requires the encouragement of others. Looking back, I acknowledge the influence of a respected colleague who suggested that I apply for a leadership role. My initial reaction was: "There is no way I could do that—I'm not qualified!" But my colleague saw something in me, and I decided to take a chance. The rest is history: more than 2 decades of service, including working with a state group to pass counselor licensure in California and multiple positions (including leadership) at a certifying body and an accreditation board. The more involved I became, the more confident I was in my ability to offer something meaningful.

My leadership today compels me to do the same for others. All of us who are experienced in our fields and comfortable in leadership roles must identify that potential in others. We are well positioned to be mentors and

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Every Case Manager Is a Leader: Advocacy and Empowerment

Michelle Baker, BS, RN, CRRN, CCM

To lead is to influence. This is the essence of what professional case managers do, regardless of their job titles or whether they have supervisory responsibilities. In their daily practice, professional case managers lead through advocacy for and empowerment of individuals (“clients”) who receive case management services. While never imposing their opinions or personal choices, professional case managers influence and support informed decision-making by clients and their support systems.

The Commission for Case Manager Certification (CCMC) Code of Professional Conduct for Case Managers captures the leadership aspect of advocacy. As the Code states, Certified Case Managers (CCMs) “believe that case management is a means for improving client health, wellness, and autonomy through

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advocacy, communication, education, identification of service resources, and service facilitation” (CCMC, Code, Rev. 2015).¹ CCMs further exhibit their leadership by adhering to the principles of the Code such as to “place the public interest above their own at all times” and to “respect the rights and inherent dignity of all their clients” (CCMC, Code, Rev. 2015).¹

Professional case managers also play

In their daily practice, professional case managers lead through advocacy for and empowerment of individuals (“clients”) who receive case management services. While never imposing their opinions or personal choices, professional case managers influence and support informed decision-making by clients and their support systems.

key roles on multidisciplinary teams, at the center of which is the individual and his/her support system. As they facilitate communication and encourage collaboration among all members of the team, professional case managers exhibit leadership that transcends any title. Furthermore, they hold themselves accountable to the team, such as by ensuring that every member is in the information loop as the care plan is carried out.

Board-certified case managers must uphold the highest of professional and ethical standards. Thus, by their behaviors and actions, CCMs can become role models. In this way, CCMs lead by example: becoming certified, staying certified, and committing to continuous education to integrate the latest evidence-based practices.

Leaders on a Care Team

At the same time, case managers are team members. Professional case managers work side-by-side with multiple stakeholders: individuals and their support systems, case management colleagues from multiple disciplines and in varied care settings, and other clinicians and care providers.

In my practice of field case management, I was in a leadership role as I advocated for clients who were severely and often catastrophically injured. Yet when I walked into facilities where an individual was being treated, I became part of the team. In some instances, I was supporting an onsite team that had never provided direct care to patients with such severe injuries or complex medical complications. This was a delicate balance between leading and collaborating with a team.

Developing Leadership

The more CCMs embrace their leadership, the better they become at their jobs. This is crucial today as health care continues to evolve and more emphasis is placed on self-care. By recognizing the interconnection between advocacy and leadership, CCMs can practice at “the top of their license” to bring the best of their knowledge, skills, and experience to every case.

Learning, incorporating, and refining leadership skills should be a priority for all case managers. There are so many ways to increase

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Cultural Influences on Health Care Literacy

Melanie Prince, RN, MSN, RN-BC, CCM

There is an extensive body of literature on health literacy and the impact case management may have on improving health literacy knowledge, skills, and abilities. The U.S. Department of Health and Human Services defines health literacy as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.¹ “To make appropriate health decisions” is an outcome where the means are typically language, communication, knowledge and navigation of health system, understanding of mathematical concepts of risk, comprehension of basic biology, disease processes, and health topics.¹ I believe a case can be made to expand the competencies of health literacy to include a larger emphasis on cultural factors. To that end, should case managers assess health literacy from the perspective of Social Determinants of Health and a significant consideration of cultural factors that influence these determinants?

Healthy People 2020 describes five determinants as Economic Stability, Education, Social and Community Context, Health and Health Care, Neighborhood and Built Environment.² “Culture” is typically a reference to ethnic beliefs and traditions or lifestyle activities associated with a specific group. But are there other descriptors for culture that may transcend ethnicity or a specific group? For example, a culture of multigenerational poverty or environments of sustained and toxic

stress? What about cultures evolved from generational cycles of abuse, discrimination, or societal wealth gaps? Should we consider generations of recurring victimization such as losses suffered from natural disasters that require individuals to cycle through devastation, recovery, risk?

A recent experience as an observer and sideline participant in a friend’s health care crisis inspired these

cancer diagnosis and treatment scarred with the recent memories of her mother’s, father’s, and sister’s death from cancer. At the same time, her daughter’s reaction to this generational diagnosis contributed to unimaginable stress and feelings of guilt.

While my friend was not too concerned with body image, people close to her could not imagine that she would “have these people cut a

part of your body that God made.” Religious beliefs ran strong, but to a degree that was unfamiliar to me as a health care clinician. The breasts also represented a significant aspect of

sexual identity to a single, mature woman who is seriously dating with the intent of finding a lifelong partner. Thus, she lacked family support during this time due to “feeling judged.”

During the postoperative period, I prepared questions for my friend to ask the health care team. The questions related to medical aspects such as anatomical location of the tumor and nodal involvement, drains, and blood transfusions. The doctors’ and nurses’ consistent responses were “don’t worry about all that stuff, it’s too complicated for you to understand... we will take good care of you”. I confirmed later that my friend did not recall explanations or options for surgery but rather complied with the decision made for her. Yes, she gave consent to the surgery but it was based on the provider determination (because “her life was in his hands, so he knew best”). No if-this-than-that discussions occurred. Where does the health literacy responsibility lie if this is

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The U.S. Department of Health and Human Services defines health literacy as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.

questions. My friend is a well-educated mother and grandmother employed in the food manufacturing industry. I accompanied her through the stages of the diagnosis, treatment, and surgery for breast cancer. I consider myself to be well-informed about human anatomy, disease process, patient response to treatments, postoperative care, case management, insurance plans and benefits, and, in this case, the local and health care community where all of this took place. However, both of us would have scored low on a health literacy scale if an assessment was conducted in the absence of cultural considerations as questioned above.

These were some of the questions and scenarios we were required to manage throughout this ordeal.

My friend was asked to make life-altering health decisions in real time that would have permanent consequences for her future, during a mental state of extreme anxiety, emotional stress, and fear. She was faced with confronting her

Digital Transformation in Health Care Is Not Happening As Fast As It Should

—And There’s One Reason No One is Talking About

By Juan Pablo Segura

At first glance, the health care field seems to be a goldmine for digital innovation. An overextended workforce, outdated protocols, hundreds of wasted hours in administrative tasks, a patient population that is wide open to digital solutions, a multitude of inefficiencies

seemingly insurmountable barriers to its adoption are two sides of a coin. They spring from the same root causes: the lack of financial incentives to implement digital solutions; the high stakes that necessitate a cautious approach; and, most significantly, providers’ seemingly unwillingness to abandon proven

these solutions. As it is, the amount of patients that a physician sees in a day ([the most rewarding part of their jobs, according to 80% of doctors](#)) has been reduced in recent years to make time for the mountains of nonclinical paperwork and administrative duties that they are responsible for.

Clinicians are the primary end users of digital health, and a clinical champion can make all the difference in whether a solution is adopted. But in the face of the physician shortage in the United States, doctors don’t have time to trade out their proven workflows to take a risk on a solution that may or may not be successful and will almost certainly take time to learn and implement into their practice.

and redundancies—the opportunities for digital overhaul in healthcare are myriad. Yet every year the graveyard of digital health tools gets more crowded as innovators fail to overcome health care’s uniquely complex barriers to their adoption.

Goldmine and graveyard, the tremendous opportunities for digital transformation in health care and the

Juan Pablo founded Babyscripts in 2014 with the vision that internet-enabled medical devices would transform the delivery of pregnancy care. Since 2014, Juan Pablo has been named a Healthcare Transformer by the Startup Health Academy in New York and a Wireless Lifechanger by CTIA for his work in detecting problems in pregnancy faster. Juan Pablo is also the architect of the first “Prenatal Care Moonshot” focused on eliminating preterm birth by 2027 through mobile/digital technology, and Babyscripts has been named Champions of Change in Precision Medicine by Barack Obama and the White House.

workflows or sunk costs to take a chance on a disruptive solution.

This last cause is often the greatest barrier to getting innovation through the door. Clinicians are the primary end users of digital health, and a clinical champion can make all the difference in whether a solution is adopted. But in the face of the physician shortage in the United States, doctors don’t have time to trade out their proven workflows to take a risk on a solution that may or may not be successful and will almost certainly take time to learn and implement into their practice. Most providers are already at capacity—[80% have no time to see more patients or take on more duties](#). Thus what seems like an unwillingness to change is often an inability to find the time to change.

Many physicians agree that digital tools and solutions are worthwhile in theory, but with [an average workload of 40-60 hours a week](#), they don’t have the space in their schedules to evaluate

Because of their packed schedules, physicians often default to the status quo for sanity’s sake: [40% of physicians see up to 20 patients per day, with another 40% seeing more \(anywhere from 21 to over 70\)](#), and all physicians spend almost a quarter of their day on administrative duties like inputting data into electronic medical records. If physicians do have a chance to sit down with innovators, it’s in the margins of their day—instead of an exciting opportunity for change, a pitch meeting with an innovator represents another 15 minutes they have to take from their family at the end of a long day, an extra 10 minutes of sleep lost in the morning to get into the office early, the interruption of the small respite of a lunch break.

It’s no surprise that in a [2018 survey conducted by the Physician’s Foundation](#), 89% of physicians polled felt that they had somewhat to very little

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Centers for Medicare & Medicaid Services Issues New Conditions of Participation for Discharge Planning for Hospitals and Home Health Agencies

By Elizabeth Hogue, Esq.

The Centers for Medicare & Medicaid Services (CMS) has issued new Conditions of Participation (COPs) for hospitals and home health agencies. These new rules are effective on November 29, 2019. New COPs for hospitals are applicable to acute care hospitals, long-term care hospitals (LTCHs), inpatient rehabilitation facilities (IRFs), inpatient psychiatric facilities, children's hospitals, cancer hospitals, and critical access hospitals (CAHs).

These new COPs generally require the discharge planning process to include:

- Focus on patients' goals of care and treatment preferences
- Assistance to patients, their families, and representatives to select post-acute care (PAC) services providers or suppliers by using and sharing PAC data on quality measure and resource use measures that is relevant and applicable to patients' goals of care and treatment preferences
- Transfer and referrals of patients

along with necessary medical information at the time of discharge to appropriate PAC services providers and suppliers, facilities, and agencies and to other patient service providers and practitioners responsible for patients' follow-up or ancillary care

- Compliance with requests made by receiving facilities or health care practitioners for additional clinical information necessary for treatment of patients

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Truth, Lies, and The Evidence

Read More

The Controversy About Screening Mammography





Beginning the Discussion of the New 2020 CARF Standards

In October 2018, CARF initiated an International Standards Advisory Committee (ISAC) with the task of revising the current Section One standards of 1.M Performance Measurement and Management and Section 1.N Performance Improvement. The release of the new standards will be available in January 2020 and will be used on all surveys after July 1, 2020.

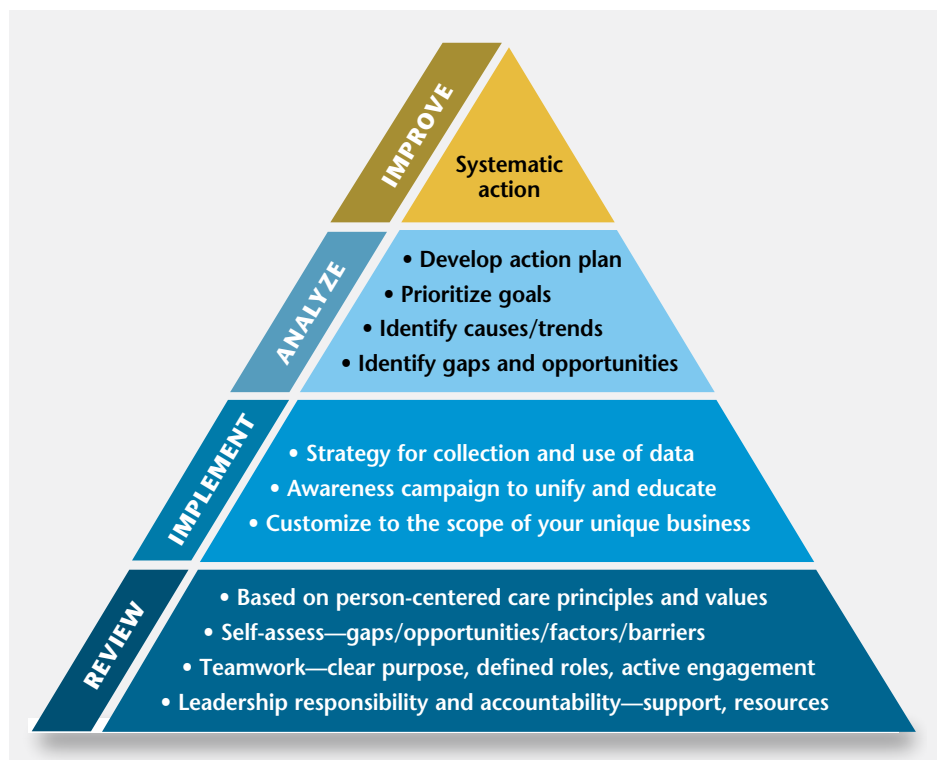
Here is a schematic of potential ways to address and consider the new standards (Figure 1).

First, person-centered approaches surround and influence the development, revision, implementation, and disclosure of performance in a quality organization. It is always good for organizations to review the values of person-centered practice.

To begin the process there is a REVIEW process beginning with the involvement, commitment, and accountability of identified leadership. Their responsibilities will ensure that an organization has support and the appropriate resources (personnel, technology, competencies) to have a robust performance system. For performance measurement and management to succeed, every individual in the organization has to know their vital role in the success of the system. Employee engagement in this critical system begins at induction and is reinforced through identification of specific competencies, ongoing training on the competencies, defined roles for personnel, and the understanding that data will drive decision making. In the REVIEW process there is ongoing review to determine where the system needs to be enhanced and/or changed

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FIGURE 1 Steps to Establishing Performance Measurement Management and Improvement (PMMI) Systems



PERSON-CENTERED PRACTICE IS:

- **Collaborative**
- Aimed at **cooperation** with persons by demonstrating **respect** and **tailoring care**
- **Involving** and **empowering** them in decision making
- **Advocating** with and for them to meet their needs
- Recognizing the person's experiences and knowledge
- Involves **team** and **organization** factors

CORE VALUES OF PERSON-CENTERED CARE:

- **Respect** the person
- **Information** gathered from the person and used to develop plan
- **Establish** and **maintain** care to enable collaboration with the person
- The person is the **expert**



Approved for 2 hours ethics credit

CE I Ethical Considerations with Medication Adherence

Chikita Mann, MSN, RN, CCM

Scenario 1: A 62-year-old female presents to the emergency department with symptoms of severe hypoglycemia and altered mental capacity. After her family members were questioned because of her decreased mental acuity, it was discovered that she had not been taking her insulin because she couldn't afford it. She also has not been taking her medications for gout because of financial restraints.

Scenario 2: A 44-year-old Hispanic woman presents to her primary care physician with increased blood pressure readings. In addition to being hypertensive, she has been recently diagnosed with diabetes. After getting an interpreter, her physician discovers that she did not understand that she needed to get refills after her initial prescription was finished.

Scenario 3: A 30-year-old male presents to the emergency department after experiencing extreme restlessness, mood swings, and heart palpitations. He has not slept in 3 days and indicated that he did not feel he was in control of his life. He also mentioned he was having suicidal ideations. After questioning him and his partner, it was discovered that although mood stabilizer and anti-psychotic medications had been prescribed for the patient, he did not get the prescriptions filled. He was worried about possible side effects from taking the medications and believed that he could manage his symptoms without medications.

Although these scenarios may initially appear different, they are not. In all three scenarios, the patients would be considered nonadherent to their medication regimen. Medication

nonadherence is of great concern today, mainly because of the rise of chronic illnesses. These three scenarios include some of the population groups that are most likely to be nonadherent to their prescribed medication regimen: the elderly, those who have been diagnosed with a mental disorder, and those with more than one chronic illness. Worldwide, nearly half of adults and 8% of individuals aged 5-17 years old have a chronic condition. Research has shown that individuals over the age of 60 use over 50% of dispensed prescription medications.¹⁻³ Only 41% of those diagnosed with bipolar disorder are found to be adherent with their medication regimen.⁴

Medication nonadherence is a national and global concern.^{5,6} The consequences of medication nonadherence are financial and medical. The World Health Organization (WHO) estimates that approximately 125,000 people die each year in the United States because of improper medication usage.⁶ Health care costs related to medication nonadherence have reached up \$528 billion in the United States and 1.25 billion pounds in Europe. Medication nonadherence costs related to diabetes have reached up to \$1.16 billion. The medical effects of nonadherence include increased hospitalizations, increased severity of comorbid conditions, and sometimes death.^{7,8}

The reasons for nonadherence are varied and multifaceted. Exploring the reasons why the client is nonadherent and/or noncompliant is key to addressing this issue. The board-certified case manager must be able to anticipate

applicable ethical dilemmas that could arise in the course of coordinating care for clients who are nonadherent with their medication regimen.

Definitions and Reasons for Nonadherence

Initially, "compliant" and "noncompliant" were terms used to describe the client's medication-taking behavior and their congruence with the prescribing physician's recommendations. This, however, did not take into consideration the client's autonomy and the involvement of other factors (ie, prescribing physicians,

Chikita Mann, MS, RN, CCM, has been a registered nurse for over 25 years. She received her master's degree in nursing in 2012 and is a Certified Case Manager. She has served as a Commissioner with the Commission for Case Manager Certification (CCMC) for the past 5 years, as a workers' compensation subject matter expert, and is currently on the CCMC Executive Board as Treasurer. Her past job experience includes working as an IV RN for a hematology/oncology unit, disability case management, supervising a virtual nurse team of 20 field case managers, and being a nurse advocate for claims issues from a medical condition/treatment. Her skills include educational presentations both in person and virtually, quality assurance, and writing policies and procedures as well as performing clinical treatment audits. She has written articles on various subjects such as cultural competence and the LGBTQ individual, aging workforce, informed advocacy and medication, ethical dilemmas with those with mental health issues, and medication nonadherence. She is currently employed as a District Manager with Paradigm CCS.

“Drugs don’t work in patients who don’t take them.”
 —Former US Surgeon General C. Everett Coop, 1985

health care system, socioeconomic). The terms “adherent” and “nonadherent” incorporate the concept of a therapeutic and collaborative relationship between the client and prescribing physician(s) and informed consent.⁹ Going forward, these terms will be used.

Medication nonadherence can be described as an intentional or unintentional failure to take prescribed medications. This can be broken down further as primary (intentional) and secondary (unintentional) nonadherence. Primary nonadherence is an active process, ie, the client makes a decision to not begin the prescribed medication. The patient’s belief system and cognition form the foundation for primary nonadherence. Conversely, secondary nonadherence, a passive process, involves obstacles that prevent the client from following the prescribed medication regimen. These obstacles include age, physical and cognitive impairments, and financial constraints.⁹ Knowing the differences between the two can assist the board-certified case manager in working with the prescribing physician(s) to address this issue.

Reasons for Nonadherence

Medication nonadherence is a multidimensional issue. Several factors could contribute to the client’s nonadherence. These factors fall within five dimensions: patient related, health care system related, condition related, therapy related, and socioeconomic. Figure 1 gives a detailed view of each of these factors. Some characteristics that can predict nonadherence include lack of knowledge and understanding about medications, forgetfulness, cognitive

limitations, depression, and frequently missed physician visits (Figure 1).¹⁰

Ethical Dilemmas with Medication Nonadherence

Conscious and Unconscious Bias

“...the uncomfortable truth is that we live in a society in which stereotypes about groups of people are ubiquitous, and it follows that almost everyone has some implicit bias.”—Institute for Healthcare Improvement’s Chief Scientific Officer Emeritus and Senior Fellow Don Goldmann¹¹

As the statement above says, none of us is immune to having unconscious and conscious bias. So, as board-certified case managers, everyone must examine their own conscious and unconscious bias. Why? One can’t be an effective advocate for someone that they have preconceived and possible discriminatory ideas about. It can also be challenging to

be a good advocate with a patient who intentionally and deliberately does not take his or her medications. Conscious and unconscious bias infringes on the ethical principle of justice—being treated fairly and equitably in terms of access to resources and treatment.¹² Per Principle 3 of the Certification of Disability Management Specialists Commission, disability specialists must always maintain objectivity in their relationships for clients.¹³

Beneficence

When dealing with a client who is nonadherent to their medication regimen, the board-certified case manager likely sees this as an opportunity to employ the ethical principle of beneficence. This involves doing actions that are seen as being in the best interest of the client. But what happens when the client decides he/she will not adhere to a prescribed

FIGURE 1 Five Factors Related to Medication Adherence

Patient-Related	Health Care System-Related	Condition-Related	Therapy-Related	Socioeconomic
Mental status	Lack of patient education	Comorbidities	Complex medication regimen	High cost of medication
Physical health	Lack of medication schedule	Lack of symptoms	Actual and perceived side effects	Unemployment
Fear of taking medication	Client-provider relationship	Severity of symptoms	Polypharmacy	Stigma associated with medications
Limited health literacy	Poor access to care		Duration of therapy	Unstable living conditions
Belief system			Packaging not user friendly	Inadequate insurance coverage
Lack of motivation				

“Indeed patient adherence is currently one of the biggest challenges that the pharmaceutical and health care industries are facing.”—Alan Davies²¹

medication regimen because of unfavorable side effects and high costs? Who determines what is in the client’s best interest? As board-certified case managers we have to be careful to not be coercive or to be overly insistent that the client adhere and/or comply with a medication regimen that the client refuses to adhere and/or comply with.¹²

Privacy and Confidentiality

In an effort to act in the client’s best interest, it may seem feasible to engage family members or friends who are in regular contact with the client. However, if the client has not given permission to provide information to family members or friends, then engaging with them could be a breach of confidentiality and would disregard the client’s right to privacy. This could also be seen as not honoring the client’s right to autonomy. An exception could be if the client has a communicable disease.

Autonomy

The right to decide what happens to one’s body is an important component of health care consent capacity. It is an extension of the client’s right to exercise autonomy or self-determination. Clients have the right to determine if they will, or will not, adhere to their prescribed medication regimen. As board-certified case managers, we are bound by the Commission for Case Manager Certification (CCMC) and Certification of Disability Management Specialist Code of Conduct to respect the client’s autonomy. This can be a challenge when the client is consistently nonadherent to their medication regimen, even more so when this behavior causes rehospitalizations and

other serious medical complications.

Within the precept of autonomy lies another source of an ethical dilemma: does the client have adequate decision-making capacity? Decision-making capacity is the client’s ability to consent to or refuse health care. It involves four criteria that must be present for the client to be viewed as being capable of making health care decisions: understanding, appreciation, reasoning, and expression of a choice. Did the client comprehend pertinent information communicated by the prescribing physician(s) about his/her prescribed medications? Was the client able to associate the information obtained from the prescribing physician(s) to his/her own situation? Did the client verbalize that they understood the benefits of taking prescribed medications and the consequences for being nonadherent to a prescribed medication regimen? Was the client able to convey their preferred treatment options (ie, medication or no medications)?

Another aspect of respecting the client’s autonomy is realizing that the client has a right to know about other options other than medication. Does the client believe that the physician made a choice to prescribe medications without discussing other options? More clients want a collaborative approach in addressing their health care needs, not a paternalistic one.

Improving Medication Adherence

Two pivotal parts of the foundation of improving medication adherence are implementing patient-centered care and encouraging behavioral changes. Patient-centered care is multidimensional, and therefore it

FIGURE 2 Elements of Medication Nonadherence

PATIENT-CENTERED CARE

- Education, communication, and information
- Emotional support
- Client’s needs, values, and preferences respected
- Physical support
- Care continuity with transitions of care
- Social support involvement
- Accessibility to services and care

can address all the varied elements of medication nonadherence (Figure 2). Patient-centered care is compassionate, empathetic, well-coordinated, and actively involves the client in decision-making; this makes it ideal for addressing medication nonadherence.

Adherence and nonadherence are behaviors, and thus positive health behavior changes should be encouraged in patients who are nonadherent to their medication. There are two health behavior models that should be familiar to board-certified case managers: Rosenstock’s Health Belief Model and the Theory of Planned Behavior. The Health Belief Model explains and predicts health-related behaviors. The Theory of Planned Behavior’s goal is to show the correlation between a person’s behavior and their health beliefs. One particular behavioral health model that was created specifically to address medication nonadherence is the Information-Motivation-Strategy Model. This model focuses on social, environmental, and cognitive factors from the perspectives of both client and

“Increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatment.” —WHO, 2003²²

prescribing physician(s). The client must comprehend what to do, determine why they want to do it, and create the means to carry out what needs to be done.

By combining patient-centered care and health belief models, these recommendations are within the board-certified case manager’s repertoire.^{7,14-20} The board-certified case manager should take the following steps for patients who are nonadherent to their medications:

1. Thoroughly assess the client.

Perhaps the reason why the client is refusing the prescribed treatment regimen is because of low health literacy. Another reason for nonadherence could be that the prescribed medication regimen is too complicated for the client to implement.

2. Emphasize shared decision-making to the client. Shared decision-making encourages autonomy and development of self-management skills (ie, behavior change). Research shows that shared decision-making increases the chances of the client being committed to the medical regimen.
3. Strengthen the client’s understanding about his/her medication regimen. As stated before, low health literacy is highly associated with medication nonadherence, especially unintentional nonadherence. This is also a time to inquire about the client’s health beliefs as these are often shaped by his/her health literacy. The board-certified case manager should try to keep the instructions simple and use teach-back methods to verify understanding.

4. Assist the client in breaking down the medication regimen. Studies have consistently shown that polypharmacy and complicated dosing requirements increase the chances of medication nonadherence. The simplified medication regimen should be incorporated into the client’s daily life to ensure adherence. Written instructions are also beneficial. It could be advantageous to include the client’s pharmacist because of their vast pharmacological knowledge.

5. Use the motivational interviewing (MI) approach, which is also patient-centered, to stimulate motivation. Because this approach allows the board-certified case manager to gain insight into the client’s social, financial, mental, and emotional status, an individualized approach is used to help the board-certified case manager discover the reasons for medication nonadherence. The MI approach helps to develop a respectful, collaborative, and trusting relationship with the client. The MI approach enables the case manager to respect the client’s autonomy and right to choose or decline medical treatment. Patient empowerment is another benefit gained with implementing the MI approach.
6. If possible, include family and friends. Research has shown strong support systems increases self-efficacy and adherence. Social support groups have also proven to be effective in improving medication adherence. These groups can help the client learn problem-solving skills and establish relationships with others who have similar health issues.

Conclusion

Dealing with medication adherence means seeing the issue as not just a patient issue—it also includes the actual treatment plan and the prescribing health care provider(s). Working through the multifaceted reasons for medication nonadherence is necessary to improve clients’ health and reduce health care costs domestically and internationally. Board-certified case managers can be a part of multidisciplinary efforts to increase medication adherence. **CE I**

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CE II Impact of a Paper Reminder Prompt on Increasing the Administration Rate of Influenza Vaccine

Gracelle Toussaint, DNP, APRN, ANP-BC

Background

Vaccines are critical in safeguarding individuals against various illnesses, yet Healthy People 2020 announced that the annual rate of influenza infection in the United States continues to remain high at over 200,000 occurrences and 36,000 deaths, even though influenza infection is a vaccine-preventable illness.¹ The importance and benefits of receiving their recommended adult immunizations elude many individuals who don't realize that, just like in childhood, vaccination is a critical element of disease prevention and health maintenance for adults. Some people are aware of the health benefits of receiving the annual influenza vaccine, but very few understand the safety and nationally recommended guidelines for the vaccines. This lack of awareness is further perpetuated by clinicians who fail to capture the opportunity to assess their patients' knowledge regarding the importance of influenza vaccination and their patients' immunization status for the influenza vaccine. The result is a large population of adult individuals who have not been immunized against the influenza virus. My practice site and I undertook a project to determine if a simple paper immunization prompt could help increase influenza vaccination.

Our health care practice uses an electronic health record (EHR) system. It is comprehensive for initial visits and follow-up visits, but there is

no dedicated immunization section included as part of the EHR for either initial or follow-up visits. Instead, the influenza vaccination screening questionnaire is embedded under the general heading of HEDIS (Healthcare Effectiveness Data and Information Set) in the EHR. None of the clinicians assess for immunization status routinely, likely because the immunization questionnaire is somewhat hidden. This lack of vaccination screening by the clinicians is an example of behavior that is caused by a system failure at the point-of-care and is rooted in the inability of the providers to recognize and address the immunization needs of their patients.² Implementing a process in which vaccination status is consistently assessed should help ensure that such a procedure will be followed routinely by all staff members.

Objective

The objective of this study was to determine if a simple, low-cost intervention—a paper reminder prompt—could promote the assessment of patients' influenza vaccination status by practice clinicians, thereby leading to an increased administration rate of the influenza vaccine at the point-of-care. A similar quality improvement project by Grivas and colleagues³ concluded that a low-cost intervention that included the onsite administration of the influenza vaccine was successful in increasing the influenza vaccination rate from 10% to over 40% in a specific medical center.

Known barriers to immunization are clinicians' lack of consistent assessment of patients for their influenza vaccination status. Hurley and

colleagues² conducted a descriptive survey that highlighted the importance of a clinician's consistent evaluation of their patients' immunization status for increasing their patients' vaccination rate. Findings revealed that only a low percentage of primary care providers and general internists (29% and 32%, respectively) consistently assessed for vaccine status and none used a reminder system for vaccination assessment of their patients. Likewise, Rockwell⁴ conducted a systematic review of 98 studies, both randomized and nonrandomized controlled trials, that support Hurley's findings. Both articles make a strong case for the use of chart reminders to promote clinicians' assessment of their patients' immunization status to influence their administration and uptake rate of immunization of patients in an upward manner.

Study Methods and Patient Population

For this study, the intervention of interest was the use of a low-cost influenza vaccine paper assessment tool. The tool would be used by the provider assigned as the intervention clinician to identify the influenza immunization status of patients aged 19 to 75. Influenza vaccine administration, when not contraindicated, would occur at the point-of-care after confirmation of its need. The control group was the primary care provider treating adult patients (aged 19–75) who was not required to use the immunization assessment tool.

The outcome of interest was an increased administration rate of influenza vaccine by the intervention/experimental clinician in the practice of at

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Vaccines are critical in safeguarding individuals against various illnesses, yet Healthy People 2020 announced that the annual rate of influenza infection in the United States continues to remain high at over 200,000 occurrences and 36,000 deaths.

least 20%. This is a measurable goal or outcome that was evaluated through the assessment and review of Current Procedural Terminology codes to identify patients who received the vaccine through the intervention and the control physician's patients.

To implement the system, clinicians and medical assistants received proper training regarding the efficacy, correct use, storage, documentation, contraindications, and potential adverse effects of the dedicated influenza vaccine to be administered. They were also trained on the epidemiology and morbidity and mortality rate of influenza infection.

Patients were adults with Medicaid, Medicare, or private insurance health plans. The bulk of the adult population (80%) were individuals with chronic illnesses such as diabetes, hypertension and other cardiovascular diseases, chronic kidney disease, chronic obstructive asthma, and chronic obstructive pulmonary disease.

Three medical assistants were responsible for triaging the patients before they got to the clinician and attaching a paper vaccination prompt on each patient chart.

Initial Phase

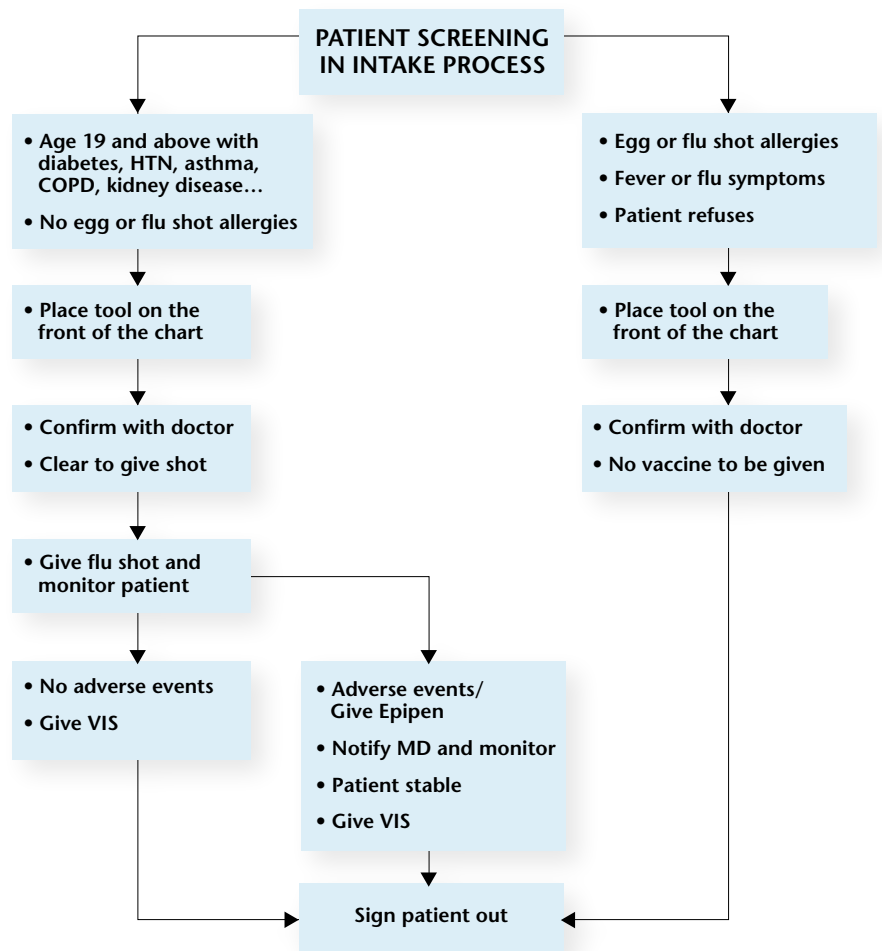
Taking stock of the stakeholders, the environment for change, and the adaptability of both of those elements to change occurred at Weeks 1 and 2. This was called the *unfreezing phase*. Observed barriers were reflex resistance to change by all providers on all levels while they were contemplating whether the use of the prompt and initiating a dialogue with patients regarding their vaccination status and needs would hinder their workflow.

Second Phase

The creation of movement occurs during the *changing phase* and includes training sessions, discussions, and implementation of the change. During this stage, I discussed the potential health risks for patients who were not properly immunized with the influenza vaccine. A preintervention

survey assessed and confirmed the staff's readiness or lack of readiness and tested their level of knowledge about influenza vaccine, its storage requirements, and overall management of the vaccine. Stakeholders also received a tutorial on the current vaccine being used by the office, the Fluzone® Quadrivalent influenza

FIGURE 1 VACCINATION ALGORITHM



Abbreviations: COPD, chronic obstructive pulmonary disease; HTN, hypertension; VIS, vaccine information statement.

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vaccine. Medical assistants were also oriented to the proper use of the paper reminder prompt as part of the project protocol during the presentation. Consents to participate in the project were obtained from all the stakeholders at the end of the presentation.

The intervention took place during the changing stage, and data collection was started on Week 7. During the intervention period, staff were encouraged to provide feedback on the change process as the project evolved. I conducted meetings to assess and discuss the progression of the project.

Third Phase

Refreezing is the level of adaptation by individuals as behaviors become sustained.⁵ The refreezing stage sets the tone for project evaluation. May 31, 2017, was the last day of the 2016-2017 influenza season, and influenza vaccines were no longer administered beyond this date. The time span of the refreezing stage extended from Week 4 until Week 5. That time frame afforded me the opportunity to assess staff behavior, long after the completion of the project, for sustainability and adherence purposes as they transitioned from

the changing stage to the refreezing stage. That time frame also provided both the interventional and the control clinicians with additional opportunities to aggressively identify patients who needed to be immunized before the termination of the current influenza season when influenza vaccines should no longer be used.

Protocol: Using the Paper Vaccine Prompt

Medical assistants placed the paper vaccine algorithm (Figure 1) on the front of charts of patients who were scheduled to be seen by the interventional physician. The interventional physician, prompted by the vaccine tool, initiated a dialogue regarding influenza immunization with the patient. That dialogue included confirmation of the patient's allergies, the benefits of taking the vaccine, and the potential side effects of the vaccine. Once the patient agreed to receive the vaccine, the interventional physician confirmed with the medical assistant that the patient could be vaccinated. After being monitored for 15 minutes in the office, as recommended by the Centers for Disease Control and Prevention and the Advisory

Committee on Immunization Practices, the patient was provided with the Vaccine Information Statement pamphlet and dispositioned to home. Every attempt was made to control extraneous variables such as patients who presented to the office for the sole reason of vaccination. All the resources needed to carry out the project were furnished by the medical director (Table 1).

Results

Comparative data were assessed by primary data collection (daily visit appointment list for each doctor) and limited to the patients who were seen. A minimum of 88 patients needed to be seen to achieve statistical significance. A total of 932 patients were seen during the 9-week implementation period. The summative evaluation examined the effect of using the paper reminder prompt when patients are seen by the interventional clinician. I used the Influenza Vaccine Quality Project⁶ tool to evaluate the project outcome (Figure 2). The tool was tested for reliability and validity by its original creators.⁶ The type of data produced by the vaccine tool was nominal data.

Formative evaluation was ongoing even before the intervention was implemented and beyond the completion of the project. I continuously observed medical assistants for their use of proper vaccination administration technique and their knowledge of the manifestations and management of adverse events until proficiency was confirmed.

The long-term objectives were randomly evaluated using chart audits to confirm project sustainability and staff adherence and adaptability to the change process at Weeks 3 and 6. The

FIGURE 2 INFLUENZA VACCINE QUALITY PROJECT

Have you had a flu shot this year? Yes No

If yes, when? _____ where? _____

If no, would you like to have a flu shot today? Yes No

If no, please document reason for refusal: _____

Provider: Experimental Control

Patients: Age _____ Male Female

Instrument courtesy of Drs. Pierson, Malone, Haas. Amended by permission only.

Patients whose provider received a chart prompt had significantly higher rates of vaccination (21.5%) than patients whose provider did not receive a chart prompt (7.1%).

TABLE 1 INCREASING THE RATE OF FLU VACCINE

EXPENSES		REVENUE	
Direct Costs		Billing	
Salary and benefits	N/A	Grants	N/A
Supplies • Toner (3000-page yield) (\$79.99) • 500 sheets 8 1/2" x 11" (\$8.99)	\$88.98	Institutional budget support	\$88.98
Services	N/A	Personal budget support	\$650
Statistician	\$600		
Lunch presentation	\$50		
Indirect Costs			
Overhead			
Total expenses	\$738.98	Total revenue	\$738.98

Abbreviation: N/A = not available.

summative evaluation of the planned change project was ongoing during the implementation phase.

Data analysis was performed using a two-way contingency table analysis to evaluate the hypothesis that patients whose providers received a chart prompt are as likely to receive a vaccination as those whose providers did not receive a chart prompt. Patients whose provider received a chart prompt had significantly higher rates of vaccination (21.5%) than patients whose provider did not receive a chart prompt (7.1%), *P* < .001 (Table 2). The odds of receiving a vaccination for patients

whose provider received a chart prompt (48/175 = 0.27) was more than 3.5 times the odds of receiving a vaccination for patients whose provider did not receive a chart prompt (17/221 = 0.077) (Figure 3), indicating that the effect size of receiving a chart prompt was moderate.

The percentage of patients who were not vaccinated in the absence of the vaccine tool was unsurprisingly high at 92.9% (221 patients), and the rate of patients who were vaccinated in the absence of the vaccine tool was 7.1% (17 patients). The nominal amount for the administration of the influenza vaccine by the control physician was expected,

although such a low value is extremely disappointing. The numbers for the interventional physician revealed a different tale. The number of patients who did not receive the influenza vaccine with the use of the vaccine tool was 175 patients (78.5%) and the number of patients who received the vaccine was 48 (21.5%) (Table 2.) For the interventional physician, the pool of 175 patients who were not vaccinated refused the vaccine, were allergic to the influenza vaccine, or had already been vaccinated.

Of the 175 patients whose charts had a prompt but were not vaccinated, 157 patients (90%) refused to be vaccinated. This high rate indicates that more education and awareness must take place about the benefit, efficacy, and safety of the influenza vaccine overall.

Discussion and Implications for Nursing and Health Care

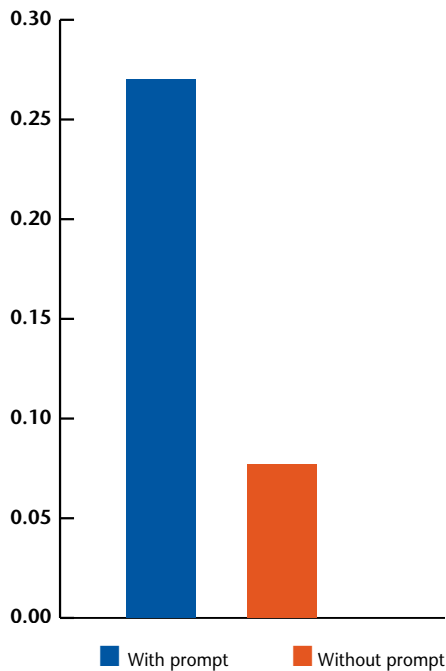
As expected, the study yielded the projected and targeted increase in the influenza vaccination rate of patients seen by the interventional clinician. Another successful element of the project was its sustainability beyond the implementation phase. Postimplementation surveys and audits revealed that, even after the implementation period ended, the medical assistants, more so than the clinicians, were still in active implementation mode.

The medical assistants were still using the vaccine tool at the time of patients' screening and were communicating to both physicians when patients would benefit from the vaccines.

The project was successful at the organizational level in increasing clinicians' administration rate of the

TABLE 2 PREVALENCE OF VACCINATION BY CHART PROMPT

Prompt	Did not receive vaccination	Received vaccination	Total
No chart prompt	221 (92.9%)	17 (7.1%)	238 (100%)
Chart prompt	175 (78.5%)	48 (21.5%)	223 (100%)
Total	396 (85.9%)	65 (14.1%)	461 (100%)

FIGURE 3 ODDS OF VACCINATION

influenza vaccine by 14.1%. However, this number falls extremely short of the targeted Healthy People 2020 goal of a

vaccination rate of 90%. The inability of the project to even come close to the 90% goal for vaccinated patients set by Healthy People 2020 is multifactorial. A large part of patient refusal is based on cultural, ethnic, financial, and education determinants.

We must also consider the attitude and the perspective of the clinicians themselves about immunizations. An excellent example of how a clinician's perspectives and attitudes can influence how they engage with patients about being vaccinated can be found in the behavior of my control group physician. Analysis of his data proves that providers like him who are not interested in vaccinations and do not see the benefits of vaccines will rarely initiate a dialogue about vaccinations with a patient.

The internal validity of the project was affected by elements of the provider's perspective and attitude about vaccines, patients' fear of vaccinations, and, of course, the financial cost that comes with being vaccinated as many patients must pay a

copay. One of the major limitations of the project was the time line for implementation. The implementation period started on February 13, 2017, one of the 2 months in which influenza infections are most prevalent. Correcting this implementation period to include the entire flu season would increase the data for study. **CE II**

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Centers for Medicare & Medicaid Services Issues New Conditions of Participation for Discharge Planning for Hospitals and Home Health Agencies [continued from page 9](#)

- Sending necessary medical information to receiving facilities or appropriate PAC providers and practitioners responsible for patients' follow up care after patients are discharged from hospitals or transferred to other PACs or, for HHAs, other HHAs
 - Hospitals ensuring and supporting patients' rights to access their medical records in the form and format requested by patients, if information is readily producible in such form and format, including in electronic form or format when medical records are maintained electronically
- A potential game changer is the

requirement to use quality and resource use measures relevant and applicable to patients' goals of care and treatment

CMS has issued new Conditions of Participation (COPs) for hospitals and home health agencies. New COPs for hospitals are applicable to acute care hospitals, long-term care hospitals, inpatient rehabilitation facilities, inpatient psychiatric facilities, children's hospitals, cancer hospitals, and critical access hospitals.

preferences in the discharge planning process. PAC providers have complained for years that hospital discharge

planners/case managers "play favorites" by referring patients to PAC providers that they prefer for a variety of reasons that may be unrelated to quality of care. New requirements to share quality data as part of the discharge planning may help patients make choices and disrupt historic patterns of referrals **CM**

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PharmaFacts for Case Managers



Vumerity™ (diroximel fumarate) delayed-release capsules, for oral use

INDICATIONS AND USAGE

Vumerity is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

DOSAGE AND ADMINISTRATION

Obtain the following before treatment with Vumerity:

- A complete blood cell count (CBC), including lymphocyte count
- Serum aminotransferase, alkaline phosphatase, and total bilirubin levels

Dosing Information

The starting dosage for Vumerity is 231 mg twice a day orally. After 7 days, the dosage should be increased to the maintenance dosage of 462 mg (administered as two 231-mg capsules) twice a day orally. Temporary dosage reductions to 231 mg twice a day may be considered for individuals who do not tolerate the maintenance dosage. Within 4 weeks, the recommended dosage of 462 mg twice a day should be resumed. Discontinuation of Vumerity should be considered for patients unable to tolerate return to the maintenance dosage. Administration of non-enteric coated aspirin (up to a dose of 325 mg) 30 minutes before Vumerity dosing may reduce the incidence or severity of flushing.

Administration Instructions

Swallow Vumerity capsules whole and intact. Do not crush, chew, or sprinkle the capsule contents on food.

If taken with food, avoid a high-fat, high-calorie meal/snack; the meal/snack should contain no more than 700 calories and no more than 30 g of fat.

Avoid coadministration of Vumerity with alcohol.

Blood Tests to Assess Safety After Initiation of Vumerity

Obtain a CBC, including lymphocyte count, 6 months after initiation of Vumerity and then every 6 to 12 months thereafter, as clinically indicated.

Obtain serum aminotransferase, alkaline phosphatase, and total bilirubin levels during treatment with Vumerity, as clinically indicated.

Patients with Renal Impairment

No dosing adjustment is recommended in patients with mild renal

impairment. Vumerity is not recommended in patients with moderate or severe renal impairment.

DOSAGE FORMS AND STRENGTHS

Vumerity is available as hard, delayed-release capsules containing 231 mg of diroximel fumarate. The capsules have a white cap and a white body, printed with “DRF 231 mg” in black ink on the body.

CONTRAINDICATIONS

Vumerity is contraindicated in patients with known hypersensitivity to diroximel fumarate, dimethyl fumarate, or to any of the excipients of Vumerity.

Vumerity is also contraindicated in patients who are taking dimethyl fumarate.

WARNINGS AND PRECAUTIONS

Anaphylaxis and Angioedema

Vumerity can cause anaphylaxis and angioedema after the first dose or at any time during treatment. Signs and symptoms in patients taking dimethyl fumarate (which has the same active metabolite as Vumerity) have included difficulty breathing, urticaria, and swelling of the throat and tongue. Patients should be instructed to discontinue Vumerity and seek immediate medical care should they experience signs and symptoms of anaphylaxis or angioedema.

Progressive Multifocal Leukoencephalopathy

Progressive multifocal leukoencephalopathy (PML) has occurred in patients with MS treated with dimethyl fumarate. PML has occurred in patients taking dimethyl fumarate in the postmarketing setting in the presence of lymphopenia persisting for more than 6 months. While the role of lymphopenia in these cases is uncertain, most cases occurred in patients with lymphocyte counts $<0.5 \times 10^9/L$.

At the first sign or symptom suggestive of PML, withhold Vumerity and perform an appropriate diagnostic evaluation. Magnetic resonance imaging (MRI) findings may be apparent before clinical signs or symptoms.

Lymphopenia

Vumerity may decrease lymphocyte counts. In the MS placebo-controlled trials with dimethyl fumarate, mean lymphocyte counts decreased by approximately 30% during the first year of treatment with dimethyl fumarate and then remained stable.

In controlled and uncontrolled clinical trials with dimethyl fumarate, 2% of patients experienced lymphocyte counts $<0.5 \times 10^9/L$ for at



least 6 months, and in this group most lymphocyte counts remained $<0.5 \times 10^9/L$ with continued therapy. Neither Vumerity nor dimethyl fumarate have been studied in patients with preexisting low lymphocyte counts.

Obtain a CBC, including lymphocyte count, before initiating treatment with Vumerity, 6 months after starting treatment, and then every 6 to 12 months thereafter, and as clinically indicated. Consider interruption of Vumerity in patients with lymphocyte counts $<0.5 \times 10^9/L$ persisting for more than 6 months. Given the potential for delayed recovery of lymphocyte counts, continue to obtain lymphocyte counts until their recovery if Vumerity is discontinued or interrupted because of lymphopenia. Consider withholding treatment from patients with serious infections until resolution. Decisions about whether to restart Vumerity should be individualized based on clinical circumstances.

Liver Injury

Clinically significant cases of liver injury have been reported in patients treated with dimethyl fumarate in the postmarketing setting. The onset has ranged from a few days to several months after initiation of treatment with dimethyl fumarate. Signs and symptoms of liver injury, including elevation of serum aminotransferases to greater than 5-fold the upper limit of normal and elevation of total bilirubin to greater than 2-fold the upper limit of normal have been observed. These abnormalities resolved upon treatment discontinuation. Some cases required hospitalization. None of the reported cases resulted in liver failure, liver transplant, or death. However, the combination of new serum aminotransferase elevations with increased levels of bilirubin caused by drug-induced hepatocellular injury is an important predictor of serious liver injury that may lead to acute liver failure, liver transplant, or death in some patients.

Elevations of hepatic transaminases (most no greater than 3 times the upper limit of normal) were observed during controlled trials with dimethyl fumarate.

Obtain serum aminotransferase, alkaline phosphatase, and total bilirubin levels before treatment with Vumerity and during treatment, as clinically indicated. Discontinue Vumerity if clinically significant liver injury induced by Vumerity is suspected.

Flushing

Vumerity may cause flushing (e.g., warmth, redness, itching, and/or burning sensation). In clinical trials of dimethyl fumarate, 40% of dimethyl fumarate-treated patients experienced flushing. Flushing symptoms generally began soon after initiating dimethyl fumarate and usually improved or resolved over time. In most patients who experienced flushing, it was mild or moderate in severity. Administration of Vumerity with food may reduce the incidence of flushing. Studies with dimethyl fumarate show that administration of non-enteric coated aspirin (up to a dose of 325 mg) 30 minutes before dosing may reduce the incidence or severity of flushing.

ADVERSE REACTIONS

The following important adverse reactions were reported in clinical trials:

- Anaphylaxis and angioedema
- Progressive multifocal leukoencephalopathy
- Lymphopenia
- Liver injury
- Flushing

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary: There are no adequate data on the developmental risk associated with the use of Vumerity or dimethyl fumarate in pregnant women. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively. The background risk of major birth defects and miscarriage for the indicated population is unknown.

Lactation

Risk Summary: There are no data on the presence of diroximel fumarate or metabolites (MMF, HES [2-hydroxyethyl succinimide]) in human milk. The effects on the breastfed infant and on milk production are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Vumerity and any potential adverse effects on the breastfed infant from the drug or from the underlying maternal condition.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

Clinical studies of dimethyl fumarate and Vumerity did not include sufficient numbers of patients aged 65 years and over to determine whether they respond differently from younger patients.

Renal Impairment

No dosage adjustment is necessary in patients with mild renal impairment. Because of an increase in the exposure of a major metabolite (HES), use of Vumerity is not recommended in patients with moderate or severe renal impairment.

CLINICAL STUDIES

The efficacy of Vumerity is based upon bioavailability studies in patients with relapsing forms of MS and healthy subjects comparing oral dimethyl fumarate delayed-release capsules to Vumerity delayed-release capsules.

HOW SUPPLIED/ STORAGE AND HANDLING

How Supplied

Vumerity is available as delayed-release capsules for oral administration, containing 231 mg of diroximel fumarate. The 231 mg capsules have a white cap and a white body, printed with "DRF 231 mg" in black ink on the body. Vumerity is available as follows:

- 30-day Starter dose bottle (bottle of 106 capsules).
- 30-day Maintenance dose bottle (bottle of 120 capsules)



Storage and Handling

Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F).

Vumerity is manufactured for Biogen.

Rybelsus® (semaglutide) tablets, for oral use

INDICATIONS AND USAGE

Rybelsus is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use

- Rybelsus is not recommended as first-line therapy for patients with inadequate glycemic control on diet and exercise because of the uncertain relevance of rodent C-cell tumor findings to humans.
- Rybelsus has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Rybelsus is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of patients with diabetic ketoacidosis, as it would not be effective in these settings.

DOSAGE AND ADMINISTRATION

Important Administration Instructions

- Instruct patients to take Rybelsus at least 30 minutes before the first food, beverage, or other oral medications of the day with no more than 4 ounces of plain water only. Waiting less than 30 minutes, or taking Rybelsus with food, beverages (other than plain water), or other oral medications, will lessen the effect of Rybelsus by decreasing its absorption. Waiting more than 30 minutes to eat may increase the absorption of Rybelsus.
- Swallow tablets whole. Do not split, crush, or chew tablets.

Recommended Dosage

- Start Rybelsus with 3 mg once daily for 30 days. The 3-mg dose is intended for treatment initiation and is not effective for glycemic control.
- After 30 days on the 3-mg dose, increase the dose to 7 mg once daily.
- Dose may be increased to 14 mg once daily if additional glycemic control is needed after at least 30 days on the 7-mg dose.
- Taking two 7-mg Rybelsus tablets to achieve a 14-mg dose is not recommended.
- If a dose is missed, the missed dose should be skipped and the next dose should be taken the following day.

DOSAGE FORMS AND STRENGTHS

Rybelsus tablets are available as:

- 3 mg: white to light yellow, oval shaped debossed with “3” on one side and “novo” on the other side
- 7 mg: white to light yellow, oval shaped debossed with “7” on one side and “novo” on the other side
- 14 mg: white to light yellow, oval shaped debossed with “14” on one side and “novo” on the other side

CONTRAINDICATIONS

Rybelsus is contraindicated in patients with:

- A personal or family history of medullary thyroid carcinoma (MTC) or in patients with multiple endocrine neoplasia syndrome type 2 (MEN 2).
- Known hypersensitivity to semaglutide or to any of the components in Rybelsus

WARNINGS AND PRECAUTIONS

WARNING: RISK OF THYROID C-CELL TUMORS

- In rodents, semaglutide causes dose-dependent and treatment-duration dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether Rybelsus causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined.
- Rybelsus is contraindicated in patients with a personal or family history of MTC or in patients with multiple endocrine neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of Rybelsus and inform them of symptoms of thyroid tumors (e.g. a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Rybelsus.

Pancreatitis

In glycemic control trials, pancreatitis was reported as a serious adverse event in 6 patients treated with Rybelsus (0.1 events per 100 patient-years) versus 1 in comparator-treated patients. After initiation of Rybelsus, observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back and which may or may not be accompanied by vomiting). If pancreatitis is suspected, Rybelsus should be discontinued and appropriate management initiated; if confirmed, Rybelsus should not be restarted.

Diabetic Retinopathy Complications

In a pooled analysis of glycemic control trials with Rybelsus, patients reported diabetic retinopathy-related adverse reactions during the trial (4.2% with Rybelsus and 3.8% with comparator). Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy.

Hypoglycemia with Concomitant Use of Insulin Secretagogues or Insulin

The risk of hypoglycemia is increased when Rybelsus is used in combination with insulin secretagogues (e.g., sulfonylureas) or insulin. Patients may require a lower dose of the secretagogue or insulin to reduce the risk of hypoglycemia in this setting.



Acute Kidney Injury

There have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis, in patients treated with GLP-1 receptor agonists, including semaglutide. Some of these events have been reported in patients without known underlying renal disease. Most of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function when initiating or escalating doses of Rybelsus in patients reporting severe adverse gastrointestinal reactions.

Hypersensitivity

Serious hypersensitivity reactions (e.g., anaphylaxis, angioedema) have been reported with GLP-1 receptor agonists, including semaglutide. If hypersensitivity reactions occur, discontinue use of Rybelsus; treat promptly per standard of care, and monitor until signs and symptoms resolve. Do not use in patients with a previous hypersensitivity to Rybelsus. Anaphylaxis and angioedema have been reported with GLP-1 receptor agonists. Use caution in a patient with a history of angioedema or anaphylaxis with another GLP-1 receptor agonist because it is unknown whether such patients will be predisposed to anaphylaxis with Rybelsus.

ADVERSE REACTIONS

The following serious adverse reactions are described below or elsewhere in the prescribing information:

- Risk of thyroid C-cell tumors
- Pancreatitis
- Diabetic retinopathy complications
- Hypoglycemia with concomitant use of insulin secretagogues or insulin
- Acute kidney injury
- Hypersensitivity

USE IN SPECIFIC POPULATIONS

Pregnancy: Available data with Rybelsus use in pregnant women are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. There are clinical considerations regarding the risks of poorly controlled diabetes in pregnancy. Rybelsus should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. The estimated background risk of major birth defects is 6–10% in women with pregestational diabetes with an HbA1c >7 and has been reported to be as high as 20–25% in women with a HbA1c >10. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2–4% and 15–20%, respectively.

Lactation: There are no data on the presence of semaglutide in human milk, the effects on the breastfed infant, or the effects on milk production. There are no data on the presence of salcaprozate sodium (SNAC) in human milk. Since the activity of UGT2B7, an enzyme involved in SNAC clearance, is lower in infants compared to

adults, higher SNAC plasma levels may occur in neonates and infants. Because of the unknown potential for serious adverse reactions in the breastfed infant due to the possible accumulation of SNAC from breastfeeding and because there are alternative formulations of semaglutide that can be used during lactation, advise patients that breastfeeding is not recommended during treatment with Rybelsus.

Females and Males of Reproductive Potential: Discontinue Rybelsus in women at least 2 months before a planned pregnancy due to the long washout period for semaglutide.

Pediatric Use: Safety and efficacy of Rybelsus have not been established in pediatric patients (younger than 18 years).

Geriatric Use: In the pool of glycemic control trials, 1229 (29.9%) Rybelsus-treated patients were 65 years of age and over and 199 (4.8%) Rybelsus-treated patients were 75 years of age and over. In PIONEER 6, the cardiovascular outcomes trial, 691 (43.4%) Rybelsus-treated patients were 65 years of age and over and 196 (12.3%) Rybelsus-treated patients were 75 years of age and over. No overall differences in safety or efficacy were detected between these patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Renal Impairment: The safety and efficacy of Rybelsus was evaluated in a 26-week clinical study that included 324 patients with moderate renal impairment. In patients with renal impairment including end-stage renal disease, no clinically relevant change in semaglutide pharmacokinetics (PK) was observed.

OVERDOSAGE

In the event of overdose, appropriate supportive treatment should be initiated according to the patient's clinical signs and symptoms. A prolonged period of observation and treatment for these symptoms may be necessary, taking into account the long half-life of Rybelsus of approximately 1 week.

CLINICAL STUDIES

Overview of Clinical Studies

Rybelsus has been studied as monotherapy and in combination with metformin, sulfonylureas, sodium-glucose co-transporter-2 (SGLT-2) inhibitors, insulins, and thiazolidinediones in patients with type 2 diabetes. The efficacy of Rybelsus was compared with placebo, empagliflozin, sitagliptin, and liraglutide. Rybelsus has also been studied in patients with type 2 diabetes with mild and moderate renal impairment. In patients with type 2 diabetes, Rybelsus produced clinically significant reduction from baseline in HbA1c compared with placebo. The efficacy of Rybelsus was not impacted by baseline age, gender, race, ethnicity, BMI, body weight, diabetes duration and level of renal impairment.

HOW SUPPLIED/STORAGE AND HANDLING

Rybelsus tablets are available as follows:

- 3 mg, white to light yellow, oval shaped debossed with “3” on one side and “novo” on the other side. Carton of 30 tablets (3 x 10 count blister packs).

[continues on page 31](#)



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.

Circ Cardiovasc Interv. 2018 Dec;11(12):e007175. doi: 10.1161/CIRCINTERVENTIONS.118.007175.

[Association of anemia with outcomes among ST-segment-elevation myocardial infarction patients receiving primary percutaneous coronary intervention.](#)

Moghaddam N, Wong GC, Cairns JA, et al.

BACKGROUND: Anemia may confer a poor prognosis among patients with the acute coronary syndrome. However, few data exist on the association of anemia with in-hospital outcomes, including bleeding, among ST-segment-elevation myocardial infarction patients receiving primary percutaneous coronary intervention.

METHODS AND RESULTS: We identified 1919 ST-segment-elevation myocardial infarction patients who had undergone primary percutaneous coronary intervention within the Vancouver Coastal Health Authority (2007-2016) of whom 322 (16.8%) had anemia on admission. Between-group differences in (unadjusted) in-hospital outcomes, including heart failure, cardiogenic shock, major bleeding, and death were examined. Spearman correlation (r_s) and multivariate logistic regression were used to evaluate the relationship of anemia on admission with clinical outcomes. Compared with nonanemic patients, anemic patients were more likely to have preexisting hypertension, diabetes mellitus, and prior myocardial infarction. Anemic patients had higher unadjusted rates of in-hospital death (8.1% versus 3.7%; $P < 0.001$), bleeding (18.2% versus 9.4%; $P < 0.001$), and were more likely to develop heart failure (odds ratio [OR], 1.62; 95% CI, 1.19-2.22), shock (OR, 2.35; 95% CI, 1.62-3.40), or cardiac arrest (OR, 1.94; 95% CI, 1.10-3.40) during their hospital stay. Baseline anemia was independently associated with major bleeding (OR, 1.78; 95% CI, 1.25-2.56) but not all-cause mortality (OR, 0.99; 95% CI, 0.57-1.73). There was no significant correlation between anemia and overall reperfusion times (OR, 0.95; 95% CI, 0.74-1.22).

CONCLUSIONS: In a contemporary ST-segment-elevation myocardial infarction cohort receiving primary percutaneous coronary intervention, nearly 1 in 5 patients were anemic. Anemia was associated with increased comorbidities and higher-risk features on presentation and was independently associated with subsequent major in-hospital bleeding but not all-cause mortality. These results suggest that anemic ST-segment-elevation myocardial infarction patients may safely receive timely primary percutaneous coronary intervention but with particular consideration for bleeding avoidance strategies.

J Viral Hepat. 2019 Oct 24. doi: 10.1111/jvh.13224. [Epub ahead of print]

[HCV in the hemodialysis population: treat now or later?](#)

Martin P, Jadoul M, Pol S.

Hepatitis C virus (HCV) infection remains commoner in patients with chronic kidney disease (CKD) than the population at large. In the hemodialysis (HD) population HCV infection in part reflects acquisition of infection within dialysis units where its transmission can be effectively prevented by meticulous attention to body fluid precautions. A series of studies have confirmed that HCV transmission on HD reflects lack of adherence to these precautions. In contrast to the prevention of hepatitis B transmission in this setting, dedicated dialysis machines for HCV infected patients are not recommended. The likelihood of HCV acquisition while on HD is increased in units with a higher background prevalence of HCV infection so an infected HD patient also places others at risk.

Dig Dis Sci. 2019 Oct 23. doi: 10.1007/s10620-019-05877-z. [Epub ahead of print]

[Provider perceptions of hepatitis C treatment adherence and initiation.](#)

Zhang G, Patel K, Moghe A, et al.

BACKGROUND: Significant disparities in hepatitis C (HCV) treatment existed in the interferon treatment era, such that patients with mental health and substance use disorders were less likely to be treated. We aimed to evaluate whether these perceptions continue to influence HCV treatment decisions.

METHODS: We e-mailed HCV providers a survey to assess their perceptions of barriers to HCV treatment adherence and initiation. We assessed the frequency of perceived barriers and willingness to initiate HCV treatment in patients with these barriers. We identified a group of providers more willing to treat patients with perceived barriers to adherence and determined the associated provider characteristics using Spearman's rho and Wilcoxon rank-sum tests.

RESULTS: A total of 103 providers (29%) responded to the survey. The most commonly endorsed perceived barriers to adherence were homelessness (65%), ongoing drug (58%), and ongoing alcohol

use (33%). However, 90%, 68%, and 90% of providers were still willing to treat patients with these comorbidities, respectively. Ongoing drug use was the most common reason providers were never or rarely willing to initiate HCV treatment. Providers who were less willing to initiate treatment more frequently endorsed patient-related determinants of adherence, while providers who were more willing to initiate treatment more frequently endorsed provider-based barriers to adherence (e.g., communication). **CONCLUSIONS:** Most responding providers were willing to initiate HCV treatment in all patients, despite the presence of perceived barriers to adherence or previous contraindications to interferon-based treatments. Ongoing substance use remains the most prominent influencer in the decision not to treat.

J Acquir Immune Defic Syndr. 2019 Dec 1;82 Suppl 2:S94-S98. doi: 10.1097/QAI.0000000000002166.

[Ten things we need to do to achieve the goals of the end the HIV epidemic plan for America.](#)

Kelly JA.

PROBLEM: DHHS announced a plan for Ending the HIV Epidemic (EtHE) by reducing new HIV infections in the United States by 75% within 5 years and 90% within 10 years through early diagnosis of all individuals with HIV, immediate treatment to achieve viral suppression, protection of high-risk but uninfected individuals including with pre-exposure prophylaxis (PrEP), and quickly responding to emerging HIV clusters.

APPROACH: Ten steps are outlined that will help the field achieve EtHE Plan goals.

FINDINGS: Steps needed to reach EtHE goals are: (1) better reaching, understanding, and meeting the HIV prevention and care needs of Black men who have sex with men; (2) deployment of interventions that address social, cultural, behavioral, and structural determinants of HIV disparities; (3) improving uptake in biomedical HIV-prevention strategies in mid-sized cities across the country's center; (4) addressing with long-term commitment the urgent HIV-prevention needs in the US Southeast; (5) encouraging more frequent and regular HIV testing; (6) developing better strategies to not only encourage initiation but also the long-term and sustained use of PrEP by persons at high risk for contracting HIV infection; (7) improving the comfort and capacity of primary care providers to prescribe PrEP; (8) increasing HIV medical care retention and care re-engagement, especially among persons with competing life stressors; (9) developing sustainable implementation efforts; and (10) addressing policies that can facilitate or impede success in eliminating the HIV epidemic in the United States.

CONCLUSION: EtHE goals are achievable but will require concerted, sustained effort.

J Acquir Immune Defic Syndr. 2019 Dec 1;82(4):399-406. doi: 10.1097/QAI.0000000000002154.

[Hypertension control and retention in care among HIV-infected patients: the effects of co-located HIV and chronic noncommunicable disease care.](#)

Osetinsky B, Genberg BL, Bloomfield GS, et al.

BACKGROUND: As the noncommunicable disease (NCD) burden is rising in regions with high HIV prevalence, patients with comorbid HIV and chronic NCDs may benefit from integrated chronic disease care. There are few evaluations of the effectiveness of such strategies, especially those that directly leverage and extend the existing HIV care system to provide co-located care for NCDs.

SETTING: Academic Model of Providing Access to Healthcare, Kenya, provides care to over 160,000 actively enrolled patients in catchment area of 4 million people.

METHODS: Using a difference-in-differences design, we analyzed retrospective clinical records of 3603 patients with comorbid HIV and hypertension during 2009–2016 to evaluate the addition of chronic disease management (CDM) to an existing HIV care program. Outcomes were blood pressure (BP), hypertension control, and adherence to HIV care.

RESULTS: Compared with the HIV standard of care, the addition of CDM produced statistically significant, although clinically small improvements in hypertension control, decreasing systolic BP by 0.76 mm Hg ($P < 0.001$), diastolic BP by 1.28 mm Hg ($P < 0.001$), and increasing the probability of BP $< 140/90$ mm Hg by 1.51 percentage points ($P < 0.001$). However, sustained control of hypertension for > 1 year improved by 7 percentage points ($P < 0.001$), adherence to HIV care improved by 6.8 percentage points ($P < 0.001$) and retention in HIV care with no gaps > 6 months increased by 10.5 percentage points ($P < 0.001$).

CONCLUSION: A CDM program that co-locates NCD and HIV care shows potential to improve BP and retention in care. Further evaluation of program implementation across settings can inform how to maximize hypertension control among patients with comorbid HIV, and better understand the effect on adherence.

Circ Cardiovasc Qual Outcomes. 2018 Dec;11(12):e004763. doi:10.1161/CIRCOUTCOMES.118.004763.

[Facility-level variation and clinical outcomes in use of cardiac resynchronization therapy with and without an implantable cardioverter-defibrillator.](#)

Kramer DB, Normand ST, Volya R, et al.

BACKGROUND: Little is known about real-world facility-level preferences for cardiac resynchronization therapy devices with (CRT-

D) and without (CRT-P) defibrillator backup. We quantify this variation at the facility level and exploit this variation to compare outcomes of patients receiving these 2 devices.

METHODS AND RESULTS: Claims data from fee-for-service Medicare beneficiaries were used to identify new CRT-P and CRT-D implants, 2006 to 2012. We modeled factors associated with receipt of each device, and compared mortality, hospitalizations, and reoperations for patients receiving each using both logistic regression and instrumental variable analysis to account for confounding. Among 71 459 device recipients (CRT-P, 11 925; CRT-D, 59 534; 31% women), CRT-P recipients were older, more likely to be women, and had more comorbidities. Variation in device selection among facilities was substantial: After adjustment for patient characteristics, the odds of receiving a CRT-P (versus CRT-D) device were 7.6× higher for a patient treated at a facility in the highest CRT-P use quartile versus a facility in the lowest CRT-P use quartile. Logistic modeling suggested a survival advantage for CRT-D devices but with falsification end points indicating residual confounding. By contrast, in the instrumental variable analysis using facility variability as the proposed instrument, clinical characteristics and falsification end points were well balanced, and 1-year mortality in patients who received CRT-P versus CRT-D implants did not differ, while CRT-P patients had a lower probability of hospitalizations and reoperations in the year following implant.

CONCLUSIONS: CRT-P versus CRT-D selection varies substantially among facilities, adjusted for clinical factors. After instrumental variable adjustment for clinical covariates and facility preference, survival was no different between the devices. Therefore, CRT-P may be preferred for Medicare beneficiaries considering new CRT implantation.

J Heart Lung Transplant. 2019 Nov;38(11):1197-1205. doi: 10.1016/j.healun.2019.08.020. Epub 2019 Aug 24.

[Increasing heart transplant donor pool by liberalization of size matching.](#)

Holzhauser L, Imamura T, Bassi N, et al.

BACKGROUND: The heart transplant (HT) guidelines recommendation to match recipient and donors within 30% of body weight lacks a strong evidence base and is not well established in patients bridged to transplant with left ventricular assist devices (LVAD). In light of the scarcity of donor hearts, we investigated the effect of size mismatch on hemodynamics, one-year survival and length of stay (LOS) following HT.

METHODS: Single-center retrospective analysis of consecutive HT patients from April 2007 to September 2017. Recipients were divided into 3 cohorts based on donor-to-recipient weight ratio (DRWR): (1) undersized (<0.7), (2) size-matched, (0.7-1.3); (3) oversized (>1.3).

RESULTS: 288 consecutive patients were identified (mean age 53 ± 11 years; 76% male), 46 were undersized (0.61 ± 0.05), 210 size-matched (0.94 ± 0.16), and 32 oversized (1.65 ± 0.38). There was no significant difference in donor left ventricular end diastolic diameter (LVEDD) between the 3 groups ($p = 0.11$). The donor/recipient (D/R) predicted heart mass (PHM) was lowest in the undersized group (0.92 ± 0.13). There were no significant differences in 1-year survival in the overall and LVAD cohort ($p = 0.65$ and 0.59 , respectively). Neither donor LVEDD nor D/R PHM differed among survivors or non-survivors. LOS was longer in the undersized group than the size-matched cohort ($p = 0.004$). The undersized group had hearts with the highest filling pressures and lowest cardiac index at 1 week among the remaining groups ($p = 0.009$, 0.017 , and $p = 0.05$, respectively). There were no clinically significant differences in hemodynamics at 1 or 6 months.

CONCLUSIONS: HT undersizing affects hemodynamics early but not later in the course and does not impact 1-year survival. The liberalization of size matching may increase the HT donor pool significantly.

J Vasc Surg Venous Lymphat Disord. 2019 Oct 13. pii: S2213-333X(19)30440-8. doi: 10.1016/j.jvsv.2019.06.022. [Epub ahead of print]

[Risk factors for venous thromboembolism in individuals undergoing coronary artery bypass grafting.](#)

Du W, Zhao X, Nunno A, et al.

OBJECTIVE: Venous thromboembolism (VTE) can easily occur after coronary artery bypass grafting (CABG). We assessed the proportion of patients with a diagnosis of VTE after CABG and determined the associated risk factors and complications in these patients.

METHODS: We assessed all the patients included in the American College of Surgeons National Surgical Quality Improvement Program database from 2012 to 2015 who had undergone CABG. The demographic characteristics, surgical parameters, and complications were analyzed using single-factor and binary logistic regression analyses to identify the risk factors for VTE after CABG.

RESULTS: Overall, 8956 patients were identified. Postoperative VTE was found in 1.75% of these patients, with pulmonary embolism and deep vein thrombosis accounting for 0.61% and 1.28%, respectively; 0.15% of the patients had both conditions. The patients who had developed VTE had greater odds of being white and having an American Society of Anesthesiologists classification of ≥ 5 . Multivariate analysis showed that a history of bleeding disorders, congestive heart failure, and operative time of ≥ 310 minutes were risk factors for the development of postoperative VTE. Patients with VTE had worse outcomes, including greater odds of returning to the operating room,



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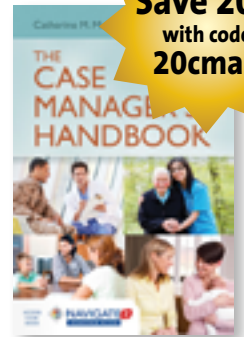
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hospitalization, unplanned reoperation, and readmission. The occurrence of VTE was associated with several postoperative complications, including emergency intubation, ventilator time >48 hours, pneumonia, urinary tract infection, peri- and postoperative transfusions, gradual kidney function reduction, acute kidney failure, cardiac arrest necessitating cardiopulmonary resuscitation, myocardial infarction, and septic shock.

CONCLUSIONS: The overall VTE rate after CABG has been low. However, the condition has been associated with worse 30-day postoperative outcomes and complications. The independent predictors of VTE development included a history of bleeding disorders, congestive heart failure in the 30 days before surgery, and operative time of ≥ 310 minutes. Understanding these risk factors should aid physicians in the decisions regarding prophylaxis and treatment.

J Hum Hypertens. 2019 Oct 29. doi: 10.1038/s41371-019-0275-y. [Epub ahead of print]

[Relationship between arterial stiffness and chronic kidney disease in patients with primary hypertension.](#)

Zuo J, Hu Y, Chang G, et al.

To investigate the association of noninvasive indices of arterial stiffness with chronic kidney disease (CKD) in patients with primary hypertension, 547 (mean age 60 years, 63% males) hypertensive hospital inpatients were recruited, comprising 337 hypertensives without CKD and 210 hypertensives with CKD. Noninvasive arterial stiffness indices were obtained, including central arterial haemodynamics derived from the radial artery waveform using SphygmoCor V8.0 system, carotid-femoral pulse wave velocity (cfPWV), large and small artery elasticity indices (C1, C2 respectively). Intima-media thickness (IMT) was evaluated by ultrasonography. The diagnosis of CKD was assessed by the estimated glomerular filtration rate (eGFR) or urinary albumin creatinine ratio (ACR). Compared with hypertension without CKD, hypertensive patients with CKD were older, had higher central systolic blood pressure, cfPWV, and IMT (all $P < 0.01$). With decreasing eGFR, cfPWV and augmentation index adjusted to heart rate of 75 bpm increased progressively whereas C2 decreased ($P < 0.05$) in subjects with CKD. In the overall population, cfPWV showed a significant trend of a negative association with eGFR ($P = 0.04$) after adjusting for age, gender, and brachial systolic blood pressure. Multiple logistic analysis showed that 1 SD (3 m/s) increase in cfPWV entailed a 1.35 (95% CI: 1.018-1.790) times higher likelihood of the presence of CKD even after adjustment for confounding factors. The association of arterial stiffness and CKD suggests that cfPWV may be a potential hemodynamic index to evaluate cardiovascular risk in CKD patients with primary hypertension.

Am J Nephrol. 2019 Oct 29;1-8. doi: 10.1159/000503918. [Epub ahead of print]

[Ultrafiltration rate effects declines in residual kidney function in hemodialysis patients.](#)

Lee Y, Okuda Y, Sy J, et al.

BACKGROUND: High ultrafiltration rate (UFR) has been associated with increased mortality in hemodialysis (HD) patients. However, the impact of UFR on decline of residual kidney function (RKF) has not been elucidated among patients receiving conventional HD.

METHODS: We performed a retrospective cohort study of 7,753 patients who initiated conventional HD from 2007 to 2011 and survived the first year of dialysis with baseline UFR and renal urea clearance (KRU) data at baseline and 1 year (5th patient-quarter). The primary exposure was average UFR at the 1st patient-quarter from dialysis initiation (<4, 4 to <6, 6 to <9, 9 to <13, and ≥ 13 mL/h/kg). Decline in RKF was defined as the percent change in KRU and decline in urine output during the first year after initiation of dialysis. We used a logistic regression model for rapid decline in RKF and a linear regression model for change in urine volume.

RESULTS: In our HD cohort, mean baseline UFR was 7.0 ± 3.1 mL/h/kg, and median (interquartile range) baseline KRU was 3.5 (2.1-5.3) mL/min/1.73 m². There was a graded association between UFR and a rapid decline in RKF; the expanded case mix-adjusted ORs and 95% CIs were 1.21 (1.04-1.40), 1.34 (1.16-1.55), 1.73 (1.46-2.04), and 1.93 (1.48-2.52) for baseline UFR 4 to <6, 6 to <9, 9 to <13, and ≥ 13 mL/h/kg, respectively (reference: <4 mL/h/kg). KRU trajectories showed a greater KRU decline over time in higher UFR categories. Higher UFR was also associated with a greater decline in urine output after 1 year.

CONCLUSION: Higher UFR was associated with a rapid decline in RKF among conventional HD patients. Further clinical trials are needed to elucidate a causal effect of UFR on RKF among HD patients.

J Thorac Oncol. 2019 Oct 26. pii: S1556-0864(19)33573-7. doi: 10.1016/j.jtho.2019.10.014. [Epub ahead of print]

[Efficacy of platinum/pemetrexed combination chemotherapy in ALK-positive non-small cell lung cancer refractory to second-generation ALK inhibitors.](#)

Lin JJ, Schoenfeld AJ, Zhu VW, et al.

BACKGROUND: The current standard initial therapy for advanced ALK-positive non-small cell lung cancer (NSCLC) is a second-generation ALK tyrosine kinase inhibitor (TKI) such as alectinib. The optimal next-line therapy after failure of a second-generation ALK TKI remains

to be established; however, standard options include the third generation ALK TKI lorlatinib or platinum/pemetrexed-based chemotherapy. The efficacy of platinum/pemetrexed-based chemotherapy has not been evaluated in patients refractory to second-generation TKIs.

METHODS: This was a retrospective study performed at three institutions. Patients were eligible if they had advanced ALK-positive NSCLC refractory to ≥ 1 second-generation ALK TKI(s) and had received platinum/pemetrexed-based chemotherapy.

RESULTS: Among 58 patients eligible for this study, 37 had scans evaluable for response with measurable disease at baseline. The confirmed objective response rate to platinum/pemetrexed-based chemotherapy was 29.7% (11/37; 95% CI, 15.9% to 47.0%), with median duration of response of 6.4 months (95% CI, 1.6 months to not reached). The median progression-free survival (PFS) for the entire cohort was 4.3 months (95% CI, 2.9 to 5.8 months). PFS was longer in patients who received platinum/pemetrexed in combination with an ALK TKI, compared to those who received platinum/pemetrexed alone (6.8 months vs 3.2 months, respectively; HR 0.33, $p=0.025$).

CONCLUSIONS: Platinum/pemetrexed-based chemotherapy shows modest efficacy in ALK-positive NSCLC after failure of second-generation ALK TKIs. The activity may be higher if administered with an ALK TKI, suggesting a potential role for continued ALK inhibition.

Pediatr Nephrol. 2019 Oct 30. doi: 10.1007/s00467-019-04372-x. [Epub ahead of print]

[Colostomy in children on chronic peritoneal dialysis.](#)

Chan EYH, Borzych-Duzalka D, Alparslan C, et al.

BACKGROUND: This study aimed to evaluate outcome of children on chronic peritoneal dialysis (PD) with a concurrent colostomy.

METHODS: Patients were identified through the International Pediatric Peritoneal Dialysis Network (IPPN) registry. Matched controls were randomly selected from the registry. Data were collected through the IPPN database and a survey disseminated to all participating sites.

RESULTS: Fifteen centers reported 20 children who received chronic PD with a co-existing colostomy. The most common cause of end stage kidney disease was congenital anomalies of the kidney and urinary tract ($n = 16$, 80%). The main reason for colostomy placement was anorectal malformation ($n = 13$, 65%). The median age at colostomy creation and PD catheter (PDC) insertion were 0.1 (IQR, 0-2.2) and 2.8 (IQR 0.2-18.8) months, respectively. The colostomies and PDCs were present together for a median 18 (IQR, 4.9-35.8) months. The median age at PDC placement in 46 controls was 3.4 (IQR, 0.2-7.4) months of age. Fourteen patients (70%) developed 39 episodes of peritonitis. The annualized

peritonitis rate was significantly higher in the colostomy group (1.13 vs. 0.70 episodes per patient year; $p = 0.02$). Predominant causative microorganisms were *Staphylococcus aureus* (15%) and *Pseudomonas aeruginosa* (13%). There were 12 exit site infection (ESI) episodes reported exclusively in colostomy patients. Seven colostomy children (35%) died during their course of PD, in two cases due to peritonitis.

CONCLUSION: Although feasible in children with a colostomy, chronic PD is associated with an increased risk of peritonitis and mortality. Continued efforts to reduce infection risk for this complex patient population are essential.

Cancer. 2019 Oct 28. doi: 10.1002/cncr.32567. [Epub ahead of print]

[Direct-to-member mailed colorectal cancer screening outreach for Medicaid and Medicare enrollees: Implementation and effectiveness outcomes from the BeneFIT study.](#)

Coronado GD, Green BB, West II, et al.

BACKGROUND: Colorectal cancer screening uptake is low, particularly among individuals enrolled in Medicaid. To the authors' knowledge, little is known regarding the effectiveness of direct-to-member outreach by Medicaid health insurance plans to raise colorectal cancer screening use, nor how best to deliver such outreach.

METHODS: BeneFIT is a hybrid implementation-effectiveness study of 2 program models that health plans developed for a mailed fecal immunochemical test (FIT) intervention. The programs differed with regard to whether they used a centralized approach (Health Plan Washington) or collaborated with health centers (Health Plan Oregon). The primary implementation outcome of the current study was the percentage of eligible enrollees to whom the plans delivered each intervention component. The primary effectiveness outcome was the rate of FIT completion within 6 months of mailing of the introductory letter.

RESULTS: The health plans identified 12,000 eligible enrollees (8551 in Health Plan Washington and 3449 in Health Plan Oregon). Health Plan Washington mailed an introductory letter and FIT kit to 8551 enrollees (100%) and delivered a reminder call to 839 (10.3% of the 8132 attempted). Health Plan Oregon mailed an introductory letter, and a letter and FIT kit plus a reminder postcard to 2812 enrollees (81.5%) and 2650 enrollees (76.8%), respectively. FIT completion rates were 18.2% (1557 of 8551 enrollees) in Health Plan Washington. In Health Plan Oregon, completion rates were 17.4% (488 of 2812 enrollees) among enrollees who were mailed an introductory letter and 18.3% (484 of 2650 enrollees) among enrollees who also were mailed a FIT kit plus reminder postcard.

CONCLUSIONS: The implementation of mailed FIT outreach by health plans may be effective and could reach many individuals at risk of developing colorectal cancer. ■

Cultural Influences on Health Care Literacy *continued from page 7*

how “it’s always done” at this facility?

My friend was given 2 days’ worth of pain medication following a major surgery, including discharge home with three drains and collateral pain in legs. The reason that she only received 2 days’ worth of pain medication was “because there is a bad epidemic of drug overdoses in the town and many people sell the pain pills.” When attempting to fill the prescription, the store clerk required a detailed description of the surgery, a pain score, and whether there was a prior prescription for the same surgery in the past. I asked why this information is required and where the answers were documented. The response: the pharmacist needed to know to determine if this was a legitimate prescription or an unnecessary prescription that could contribute to the street epidemic of pill selling.

There were more examples. There was confusion about her job status since disability payments ceased. Was she terminated or was she on unpaid leave? (She was too afraid to inquire.) Was health coverage in play and when would that cease? (She was paying premiums out of pocket.) Was it appropriate for the home health agency to change the nursing requirement from registered to licensed vocational nursing services, despite provider instructions? Was it acceptable to not address pain management with medications but rather instruct the patient to seek care in an emergency department?

Additionally, the social environment did not lend well to recovery. As a victim of financial catastrophe that resulted in living arrangements with family members, my friend had little control of her postoperative environment. The cultural expectation is that you do not live with someone else “for free.” Therefore, “paying” for lodging is not only in the form of shared rent but also included as

in-home childcare, cooking, and household maintenance. These activities were necessary despite recent discharge from hospital because “the other family member’s work/financial situation can’t change” to accommodate time to heal. There were many more examples of cultural norms at play.

Although I certainly do not intend to generalize this experience, I am aware of other patients, friends, family, and acquaintances with similar circumstances. The difference this time, was that I, with my knowledge and experience, found it difficult to break through the cultural realities of the environment and norms of the health care system within this environment. After many attempts to facilitate literacy directly with my friend and then later to advocate for her after being afforded temporary power of attorney, I only succeeded after presenting my professional credentials and demonstrating my knowledge of the subject matter at hand. Before that, my challenges, questioning, and knowledge-seeking were dismissed outright and opportunities for influencing health literacy were not engaged.

How can we become change agents? It begins with cultural sensitivity and active listening to discern the influence of culture on social determinants. Recognizing that social determinants impact health literacy, it is important to understand how these determinants are actualized within the context of not only the patients’ culture but also the culture in which the health care system operates. There may be barriers that are broader than language or educational level or ability to communicate because of cultural norms. Patient engagement may be stifled due to fear, anxiety, or guilt as opposed to a lack of health literacy. Simply functioning at Maslow’s lower hierarchy of needs may affect capacity for health literacy.

Case managers are influencers. How can we ensure that cultural sensitivity,

competency and social determinants are baked into assessments of health literacy? If we are successful with influencing health care professionals and care teams to embrace an expanded view of health literacy, positive patient outcomes may be achieved sooner and more consistently. I advocate for more research in this area.

Disclaimer: This opinion editorial is based on personal observations and is not intended to represent the clinical, business, or health care operations of any facility or disparage any professional in the context of my personal reflections.

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Flu Season: It's Time for Case Managers to Take Action

[continued from page 2](#)

4. Wash your hands.

Washing your hands often will help protect you from germs. If soap and water are not available, use an alcohol-based hand rub.

5. Avoid touching your eyes, nose, or mouth.

Germs are often spread when a person touches something that is contaminated with germs and then touches his or her eyes, nose, or mouth.

6. Practice other good health habits.

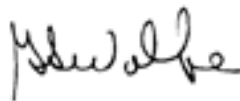
Clean and disinfect frequently touched surfaces at home, work, and school, especially when someone is ill. Get plenty of sleep, be physically active, manage your stress, drink plenty of fluids, and eat nutritious food.

You should get a flu vaccine before flu viruses begin spreading in your community because it takes about 2 weeks after vaccination for antibodies to develop in the body and provide protection against flu. Make plans to get vaccinated early in fall, before flu season begins. The Centers for Disease Control and Prevention recommends that individuals get a flu vaccine by the end of October. Getting vaccinated later, however, can still be beneficial and vaccination should continue to be offered throughout the flu season, even into January or later.

Getting vaccinated early (for example, in July or August) is likely to be associated with reduced protection against flu infection later in the flu season, particularly among older adults.

Case managers play an important role in making sure all individuals over the age of 6 months receive a flu vaccine. Every case manager should talk with their patients, regardless of the reason they are receiving case management services, to educate them about the benefits of a flu vaccine. Flu vaccines are widely available in hospitals, clinics, providers' offices, and pharmacies and are generally covered by insurance plans. Patients should discuss flu vaccines with their provider or pharmacist before receiving a flu vaccine.

The flu vaccine is the most effective method of preventing the flu, but the vaccine cannot prevent flu unless patients receive their flu shots. Case managers play an important role in advocating for the health of their patients and educating them about the flu vaccine.



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ACCM: Improving Case Management Practice through Education

Every Case Manager Is a Leader: Advocacy and Empowerment

[continued from page 6](#)

leadership skills, including, but not limited to, courses and seminars that can be pursued at any stage of one's careers. Leadership books can also be extremely helpful and inspiring.

Two of my favorite leadership books are *Leading from the Front: No-Excuse Leadership Tactics for Women* by Angie Morgan and Courtney Lynch and *Spark: How to Lead Yourself and Others to Greater Success* by these two authors along with Sean Lynch. In addition to reading these books on my own, I discuss them as part of a team exercise at work. Through self-reflection and sharing thoughts with others, we see how we can each apply the leadership principles in our daily practice and our lives.

As we look ahead to a new year, my hope is that every case manager considers how they too can embrace and build their leadership. By doing so, they will not only enhance themselves personally but also help to advance our practice as professional case managers.

CM

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Embracing Leadership Development

[continued from page 4](#)

champions and to encourage the next generation of CCMs and CDMSs to see their potential and seize opportunities to develop.

As we look to the new year, it is worth considering adding another resolution to the list: to always be on the lookout for ways to further develop our own leadership—and to encourage others to do the same. **CM**



PharmaFacts for Case Managers | [continued from page 23](#)

- 7 mg, white to light yellow, oval shaped debossed with “7” on one side and “novo” on the other side Carton of 30 tablets (3 x 10 count blister packs).
- 14 mg, white to light yellow, oval shaped debossed with “14” on one side and “novo” on the other side. Carton of 30 tablets (3 x 10 count blister packs).

Storage and Handling

Store at 68° to 77°F (20° to 25°C); excursions permitted to 59° to 86°F (15° to 30°C). Store and dispense in the original carton. Store tablet in the original blister card until use to protect tablets from moisture. Store product in a dry place away from moisture.

Rybelsus is manufactured by Novo Nordisk. 

CE I Ethical Considerations with Medication Adherence

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CE II Impact of a Paper Reminder Prompt on Increasing the Administration Rate of Influenza Vaccine

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Beginning the Discussion of the New 2020 CARF Standards

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to address any identified gaps and/or opportunities.

The IMPLEMENTATION stage included the defining of objectives, indicators, and targets to answer the questions that are being asked by stakeholders, persons served, and personnel both on the business and service delivery of the organization. Once chosen, personnel are trained how to use measurement in a reliable and valid fashion. It is imperative that within the organization, personnel become aware how critical this performance information is

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Digital Transformation in Health Care Is Not Happening As Fast As It Should—And There’s One Reason No One is Talking About

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influence on changes in health care—they have no time to research chances to optimize their practice and thus essentially no voice in its improvement. Yet only a physician has the kind of intimate knowledge of his or her needs and workflow that can drive effective innovations. Perhaps digital innovations have failed to take hold because the people making decisions around tools to help doctors are not doctors.

If we are going to break the barriers to digital transformation in health care, we need to expect physicians to think critically about how their job needs to evolve. And no one can do this without time to reflect on and evaluate the status quo. In the corporate world, executives and other employees are encouraged to do research and to take time in their schedules for professional development. Many tech giants—most famously Google, but also Facebook, LinkedIn, Apple, and others—employ the 20% time model, where roughly one-fifth of an employee’s schedule

is focused on personal side projects (those side projects have turned into Gmail, Google Maps, Twitter, Slack, and Groupon, to name a few). This is the model that we need to embrace in the health care system.

We need to look past the excuse that “doctors are traditionally conservative” and that is why innovation is dead in the water. While that narrative may have explained why cutting-edge technology is not more readily adopted by physicians, there are other problems that it doesn’t account for—like why rates of compliance for new protocols and best practices are abysmally low. Those symptoms should point us to a different solution, a solution we can do something about. Not “doctors need to get with the times” but doctors need to get some time.

One solution is to advocate for a higher price per consultation that can eliminate the existential need to pack daily schedules with patient appointments. Under the current model, doctors are incentivized to take as many appointments as possible, double—even triple—booking slots to squeeze as much productivity out of current rates of reimbursement. But with increased reimbursement per consultation,

physicians can more easily cover the cost of their salaries for their employers, which can then allow providers to take more time out of the clinic and in the office, thinking critically about their roles and how to improve their delivery of care.

Of course, this begs the question—who pays? The ones who stand to benefit most, of course. Giving physicians more time to develop professionally and research solutions is in the best interest of those who take on the burden of health costs, health insurance providers and the government (ie, taxpayers). Patient outcomes are almost guaranteed to improve when physicians have the time to stay up to date on best practices, and this directly reduces the burden of cost on those stakeholders.

Physician salaries represent a very small part of health care costs, piling in comparison with drugs and diagnostic care. If more money was paid to the physician on the front end to develop and implement more preventative solutions—by payers or government subsidies—the cost savings would increase exponentially, making an increase in physician salary an astute business move as well as one that can have a dramatic impact on patients’ lives. **CM**

Beginning the Discussion of the New 2020 CARF Standards

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to drive quality, enhance decision making, and distinguish the difference in their organization compared with other organizations.

Once information is collected in a complete, accurate, reliable, and valid manner, there is the ANALYSIS component. Various individuals and groups could be involved with this process. Initially the areas that did not meet established targets are identified. This begins the discussion of causes, trends, and identification of the steps toward improvement. Once an action plan is developed, the next step is the

implementation of the plan. There may be often be multiple business and service delivery areas that need to be improved. In this step of ANALYSIS there also comes a responsibility to prioritize what action plans will be implemented and when. A systematic way to roll out these potential action plans is important to have the buy in and participation of personnel. Bottom line is this is about problem solving rather than blaming any one person or department. Leadership drives and endorses change but frontline staff have to implement change.

There is no finish line or completion when it comes to IMPROVEMENT in an organization. These philosophies, values, and principles have to be imbedded

as a critical component. There is a systematic approach for success and improvement with transparency of results to persons served, personnel, and stakeholders. In these new 2020 standards, organizations are urged to review these different steps in performance measurement, management, and improvement (PMM&I) to ensure their PMM&I system is relevant and critically important for persons served, personnel, and stakeholders.

We hope that this schematic will encourage you to review how you look at your business and service delivery practice in a person-centered approach. In upcoming columns we will share other tools that will assist in this critical component of case management. **CM**

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