CareManagement

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Improving care for high-need, high-cost patients has long been a priority for both public and private sector purchasers of health care. The Intensive Outpatient Care Program (IOCP) aims to improve outcomes for medically complex patients and prevent unnecessary hospital use by providing care coordination, self-management support, and effective ambulatory care. The overall goal of IOCP is to keep participants at home and in their communities by providing intensive, person-centered outpatient care.

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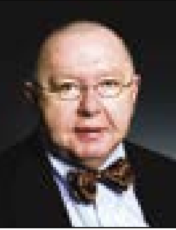

Gary S. Wolfe

Patient Engagement

Patient engagement in health care means that patients and providers are informed about the options for treatment, medications, follow-up/recovery, and all aspects of the health care system. Patient engagement means that providers and patients are working together. You might think it is easy for patients to be engaged in their health care, but it doesn't happen for a lot of reasons. There are many obstacles in the way from the patient's standpoint, including the cost and availability of health insurance. In addition, patients may not have time to be educated about their health care needs and may lack the confidence to engage in their health care or be overwhelmed by their choices. Those with low health literacy may find it difficult to follow instructions on how to care for themselves or adhere to a treatment regimen. These are all real and significant reasons why patients are not engaged in their health care. Providers also contribute to patients not being fully engaged. The health care delivery system is complex and disorganized. Providers may not take sufficient time to educate patients and caregivers, and patients may have multiple providers who might not communicate well with each other. In addition, the health care system is often indifferent to patients' needs and desires. These factors and other factors from both patients' and providers' viewpoints contribute to patients not being fully engaged with their health care.

Patient engagement brings big benefits including:

- Improved outcomes
- Better communication
- Improved care
- Lower costs
- Higher patient and provider satisfaction

The more that providers can do to increase patient engagement, the more likely that patients will ask the right questions, adhere to treatment regimens, and follow up on their condition. Patient engagement is a strategy of empowering the patient to be fully informed about their health care.

Patient engagement is complex, takes time, may be different for each patient, and requires all providers to work together. Patient engagement works along the continuum of care. Elements of patient engagement include the following:

- Display a welcoming attitude and environment.
- Educate the patient. Depending on the patient, education can be written, graphic, verbal, or electronic.
- Communicate, communicate, and communicate. Be sure to communicate at the correct level for your patient and caregivers. Listen to what the patient is saying and respond appropriately. Get feedback so you can validate their understanding of what you have communicated. Use all available resources of communication, particularly social media and cell phone if appropriate.
- Encourage shared decision making between the patient and the providers. The patient and providers should jointly consider the patient's condition, treatment options, the medical evidence for the treatment options, the benefits and risks of the

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CareManagement

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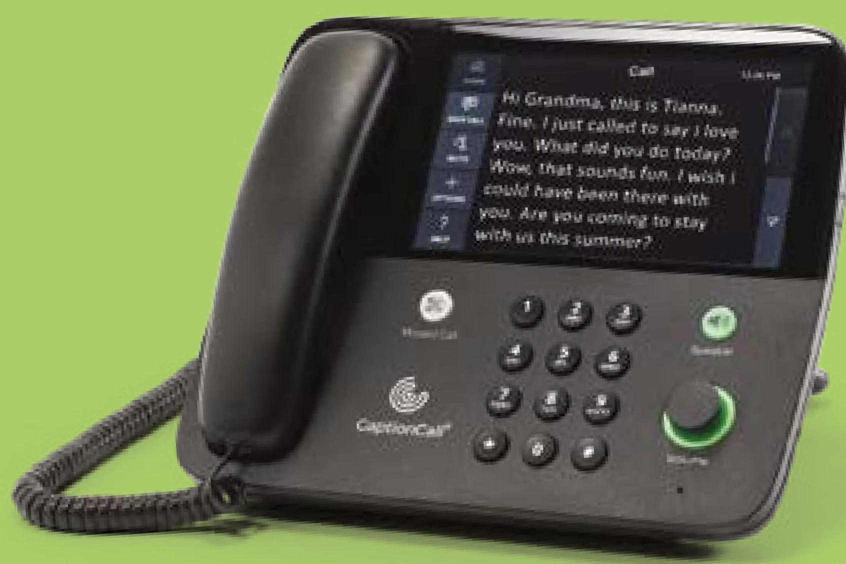

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Preparing a Ready Workforce of Certified Case Managers: Upcoming Certification 360 Workshop Scheduled

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

There is an urgent need today to build a ready workforce of certified professionals to provide services to individuals across the health and human services spectrum. In meeting that need, the Certified Case Manager® (CCM®) credential is recognized as validating knowledge and ethical practice, ensuring professional readiness, and promoting lifelong learning.

Among the many learning resources offered by the Commission for Case Manager Certification (CCMC) is Certification 360,™ a 2-day immersive learning experience led by authorized facilitators. This intensive interactive training is geared for both new and experienced case managers. The workshop is designed to provide insights into the practice of case management for professionals who are new to this role and will also refresh the knowledge base for practicing case managers. Additionally, it can assist case management leaders to breathe new life into their training efforts.

Certification 360™ is offered by CCMC on various dates and at locations around the country. A Certification 360™ Workshop will be held Tuesday, February 26, 2019, through Wednesday, February 27, 2019, immediately preceding CCMC's 2019 New World Symposium at the Gaylord National Resort & Convention Center in National Harbor, Maryland.

We believe this is a unique opportunity for case managers, both new and not-so-new to the practice, to experience Certification 360™ as well as the New World Symposium, which promises to be an exciting and highly relevant event for case managers to learn, network, and interact. Though registration for Certification 360™ is separate from the New World Symposium, timing allows for attendance at both.

Among the many learning resources offered by the Commission for Case Manager Certification (CCMC) is Certification 360,™ a 2-day immersive learning experience led by authorized facilitators. This intensive interactive training is geared for both new and experienced case managers.

See https://ccmcertification.org/ccm-community/events/certification-360tm-workshop for more information about the Certification 360.™ Information on the New World Symposium, February 28–March 2, 2019, can be found at https://symposium.ccmcertification.org/.

Certification 360™ is the fastest and most cost-effective way case managers can:

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- Refresh—Network with case management leaders and boost your practice.
- Rejuvenate—Breathe life into your organization's training efforts.
- Discover—Trends and industry insight, plus tips and resources to use today as you prepare for certification.

Certification 360™ is designed to help case managers enhance their knowledge base with practical state-of-the art takeaways from industry experts. The goal is to help participants improve their practice by expanding their thinking and professional development. Authorized facilitators are experienced at providing both a knowledge base and real-life applications.

The workshops include interactive sessions, case studies, and questions to reinforce learning. The content is built around the Essential Knowledge Domains of Case Management identified by CCMC's Role and Function Survey. The scientifically based field research is conducted every 5 years to identify the evidence base and current practice in case management.

As a global overview of case management, Certification 360™ can assist individuals who are preparing for

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MaryBeth Kurland, CAE, is CEO of the Commission for Case Manager Certification, the first and largest nationally accredited organization that certifies more than 45,000 professional case managers and over 2,600 disability management specialists. The Commission is a nonprofit volunteer organization that oversees the process of case manager certification with its CCM® credential and the process of disability management specialist certification with its CDMS® credential.

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Reducing Rehospitalizations Through Early Patient Mobilization

The dangers of patient immobility are becoming clearer as well as how they are linked to causing hospital readmissions.

Studies show that keeping hospital patients in bed or in a chair can increase the likelihood of muscle atrophy, blood clots and wounds. For some patients, immobilization—even for a few days—can lead to a permanent functional decline.

Research on the Damages of Immobility

A study, published in the *Journal of the American Geriatrics Society* in 2009, found that older patients (the mean age of study participants was 74) on average spend 95% of their hospital stays in bed or sitting in a chair.

"Right now we have an epidemic of immobility," study co-author Cynthia J. Brown told *The Wall Street Journal.* And for these patients, hospital readmissions are more likely to occur.[1]

In 2017, the cost of hospital readmissions within 30 days of discharge increased to $528 million, $108 million more than in 2016.[2]

The federal government has also taken strides to decrease readmissions through Medicare's Hospital Readmissions Reduction Program. For the 2018 fiscal year, 2,573 hospitals faced reduced reimbursement due to higher-than-expected readmission rates.[3]

With this convergent focus on reducing readmissions and research findings on the propensity of immobility to negatively impact patient recovery, it is important to know how some providers are adapting their practices in response.

New CMS Initiatives and Pilot Programs Encourage Mobility

Many hospitals and health systems have launched pilot programs to address this critical need for mobility.

The Center for Medicare and Medicaid Innovation, which is part of CMS, is supporting these efforts through its Mobility Action Group, which aims to identify and share how hospitals can best promote mobility while reducing falls. These ideas could be utilized in your practice or facility.

- At Johns Hopkins, a 2008 review of 24 studies dealing with ICU patients found that early rehabilitation can lead to shorter time on a ventilator and shorter time in the ICU.[4]
- A pilot project at Inova Fairfax Hospital in Falls Church, Virginia, trains nurses to identify when a patient is ready for more physical activity rather than turning the assessment over to physical therapists, which can lead to delays.[1]

The Important Role of Rehabilitation

In addition to pilot programs, healthcare professionals might also consider the important role rehabilitation plays in existing patient care plans.

Rehabilitation is an important thread that weaves throughout the patient care continuum and, as several studies show, the sooner it begins, the better—especially for elderly patients. Because physical, occupational and other kinds of therapies can be present throughout the recovery process, inserting rehabilitation practices early and often in a patient's journey can be used to combat immobility at various stages and care settings, including transitional care hospitals, rehabilitation hospitals and units, and in a home setting.

Rehabilitation therapy has been shown to help with early identification of issues that could potentially lead to a hospital readmission. It also helps improve function, patient satisfaction and quality of care.

How Kindred Implements Early Patient Mobilization

All of our sites of care have developed clinical programs designed to reduce rehospitalizations so that our patients can maximize their independence. Kindred's Move Early Program is one of the clinical programs and is specifically aimed at getting patients moving as early in their recovery as possible to combat the many potential, and detrimental, side effects of immobility in the healing process, even for mechanically ventilated patients—a very challenging patient population in which to maintain and improve functional status and mobility.

We are recognized as a national leader in ventilator weaning, with three decades of experience helping our patients avoid going back to a traditional hospital. Because of our tenured expertise and the recent mobility research, we understand the importance of providing specialized rehabilitation programs aimed at reducing the risk of rehospitalization through early and progressive therapies.

We work to incorporate movement into the patient's routine as early as possible to optimize cardiopulmonary and neuromuscular recovery. We believe early progressive mobility is essential to restoring function, minimizing loss of functional abilities, maximizing independence and facilitating ventilator weaning.

To learn more, please reach out to your Kindred representative or visit us at www.KindredHospitals.com. ■

References:

1. "Hospitals Increasingly Tell Patients to Get Up and Move."
2. "Aiming for Fewer Hospital U-Turns: The Medicare Hospital Readmission Reduction Program"
3. "2,573 Hospitals Will Face Readmission Penalties This Year. Is Yours One of Them?"
4. "Get Moving: Johns Hopkins Research Shows Early Mobility Better Than Bed Rest for ICU Patients"

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Case Management: Celebrating Success

Jose Alejandro, PhD, RN-BC, MBA, CCM, FACHE, FAAN

National Case Management Week celebrated the dedicated work of case managers in all practice areas throughout the health care continuum. Health care organizations need to recognize case managers throughout the year for their ongoing efforts to improve care progression, patient and caregiver experience, and staff engagement. The complexity of health care continues to transform while payment methodologies continue to become barriers for ensuring that patients, residents, or clients receive the right care at the appropriate time and level of care.

Celebrating Success

From time to time, a case management leader may be asked to address a case manager's performance when a concern has been raised or an adverse outcome has occurred. An experienced case management leader will investigate why a process broke versus having a conversation about an isolated incident. Identifying the system breakdown and developing a process improvement plan is critical to prevent the same adverse outcome from reoccurring. Process adoption by the case management team allows the opportunity to hardwire needed changes and celebrate success. Why is it important to celebrate success? Celebrating success allows a case management team to trust future process improvement opportunities versus assuming that they are disciplinary opportunities. Creating a culture that encourages open communication allows for collaboration between leaders and their case management teams.

Celebrating success allows for case management teams to take pride and ownership in things that are going well. Incremental success is also an opportunity to celebrate, especially when revising workflows, changing processes, or improving collaboration between multidisciplinary stakeholders. Health care organizations often make the mistake of setting goals that are unattainable in short periods without allowing the time necessary to hardwire new processes. For example, there might be a metric where the monthly baseline has been 50% for the last year and there is a new expectation to be at 90% in 1 or 2 months. This unattainable expectation can lead to case management teams being deflated or disengaging from the process adoption. An experienced case management leader will set incremental improvement each month with a realistic timeline. Celebrating success is important even if the incremental improvement occurs but does not reach the monthly expectations.

> **Health care organizations need to recognize case managers throughout the year for their ongoing efforts to improve care progression, patient and caregiver experience, and staff engagement.**

Inclusive Practice

An assumption is made that case managers are primarily comprised of registered nurses. On the contrary, case managers come from all health care disciplines with unique experience and skills from their respective practice field. Disciplines include social workers, physical therapists, occupational therapists, rehabilitation counselors, and mental health workers. The case management discipline is inclusive of all independent practitioners. Often, the role of case management (care progression) is combined with the utilization management (revenue capture) component, which requires the blending of medical/clinical skills with business/financial skills. Case managers have a unique opportunity to build a bridge between clinical and business operations.

The practice setting dictates the type of case management professional background and unique competencies required. For example, mental health units often employ social workers as case managers because of their unique training and experience. Health care organizations need to consider how to use highly skilled case managers to meet the unique needs of internal and external stakeholders. Diversity within

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***Jose Alejandro, PhD, RN-BC, MBA, CCM, FACHE, FAAN,** is Director, Care Management, University of California Irvine Health. He also is president of the Case Management Society of America.*

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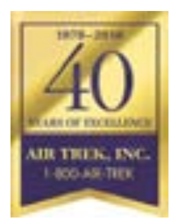

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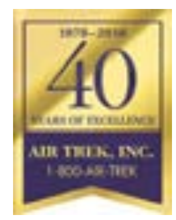

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Palliative Care: Avoiding Anti-Kickback Issues

By Elizabeth Hogue, Esq.

Anecdotally, many health care providers see great value in providing palliative care to patients who may benefit from such care. Although there are a number of definitions of palliative care, the National Hospice and Palliative Care Organization (NHPCO) defines palliative care as follows:

> Palliative care is patient- and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and facilitating patient autonomy, access to information, and choice.

Despite varying definitions of palliative care, many practitioners understand that palliative care is generally provided to patients who have serious long-term illnesses that may or may not be terminal.

A key problem with the provision of these services is that there may be no sources of payment for palliative care. Patients who may benefit from palliative care may, for example, be ineligible to receive services under the hospice benefit of Medicare because they do not have a life expectancy of 6 months or less if their diseases run their normal course. Likewise, patients who benefit from palliative care may not qualify for the home health benefit under Medicare either. They may not be homebound, for example, or have skilled needs.

And yet, at least anecdotally, there is a substantial need for this type of care. Reports from staff members in emergency departments of hospitals are particularly compelling with regard to the ongoing need for palliative care services.

In the absence of payment, providers' ability to render palliative care services is limited by the federal anti-kickback statute. This statute generally prohibits providers from giving free services to patients that may induce them to receive services, such as hospice and home care, paid for by federal healthcare programs.

In the absence of payment, providers' ability to render palliative care services is limited by the federal anti-kickback statute. This statute generally prohibits providers from giving free services to patients that may induce them to receive services, such as hospice and home care, paid for by federal healthcare programs. The federal anti-kickback statute provides in relevant part as follows:

1. Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind–
   a. in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under this subchapter, or
   b. in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under this subchapter,

   shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
2. Whoever knowingly and willfully offers or pays any remuneration (including kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person
   a. to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under this subchapter, or
   b. to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering

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

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CARF New 2019 Technology Standards

Christine M. MacDonell, FACRM

CARF International spent 2018 reviewing and revising the Technology Standards that are housed in Section One of all CARF Standards Manual. They are part of the ASPIRE to Excellence Framework. The process began with an International Standards Advisory Committee (ISAC) that was comprised of leaders in the technology area, providers, surveyors, regulators, and other interested parties. These experts spoke to the necessary changes that are occurring in this area. As we all know, technology is a rapidly changing arena and CARF's goal is to have the field recognize when change is needed and develop standards that will enhance performance in key areas. The ISAC's work then goes to CARF's International Advisory Council (IAC), which is comprised of trade associations and individuals interested in the mission of CARF. They are the very first group to comment on the work of the ISAC. When this input is received, staff make any proposed changes from the IAC. At this point it is then available for general field review. As always, we encourage case managers to provide input for all proposed standards because the industry brings a unique and valuable perspective to the process. Once the field review is completed, all results are analyzed and the final set of standards is established.

The new Technology Standards will be in all 2019 CARF Standards Manuals and implemented on all surveys beginning July 1, 2019, through June 30, 2020.

As with all of our standards, there is a description, which is as follows:

Guided by leadership and a shared vision, CARF-accredited organizations are committed to exploring, and, within their resources, acquiring and implementing technology systems and solutions that will support and enhance:

- Business processes and practices
- Privacy and security of protected information
- Service delivery
- Performance management and improvement
- Satisfaction of person served, personnel, and other stakeholders

This opening statement could be applied to a one-person case management company or a multistate case management company. The terminology "within their resources" allows for flexibility in what your technology will look like.

The first responsibility expressed in standards is a gap analysis that would identify gaps and opportunities in the use of technology. Leadership supports ongoing assessment and review of the current use of technology and data including hardware, software, communication technologies, sensitive data, and services purchased or contracted. This analysis then will identify strategies to improve, update, or enhance current situations. During this analysis it is, as always, critical for personnel, persons served, and stakeholders to give input. As a case manager, if you have a patient portal where the individual can view their information is it accessible? Easy to navigate? Do personnel use technology to complete their work? Are reports electronically generated for referral sources and payers? Getting input about whether technology is working for the key groups is critical.

The new Technology Standards will be in all 2019 CARF Standards Manuals and implemented on all surveys beginning July 1, 2019, through June 30, 2020.

Based on this gap analysis the organization would then develop a technology and system plan. CARF defines a plan as:

Written direction that is action oriented and related to a specific project or defined goal, either present and/or future oriented. A plan may include the steps to be taken to achieve stated goals, a timeline, priorities, the resources needed and/or available for achieving the plan, and the positions or persons responsible for implementing the identified steps.

As you can see this is a dynamic process and may include different individuals and/or departments or may include the owner of a company.

The standards address policies and procedures around critical areas including:

- Acceptable use
- Backup/recovery
- Business continuity/disaster recovery
- Security, including:

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Christine MacDonell, FACRM, *is the Managing Director, Medical Rehabilitation and International Aging Services/Medical Rehabilitation, CARF International.*

Lifelong Education—
A Building Block to Personal and Professional Success

Catherine M. Mullahy, RN, BS, CRRN

John F. Kennedy said, "Leadership and learning are indispensable to each other." I couldn't agree more. Education is the door to so many character-building traits, not the least of which is leadership. In the field of case management, professionals are required to earn a certain number of continuing education (CE) credits each year to maintain their credentials. This is to ensure that nurses, social workers, and certified case managers practicing in the field stay informed about the latest in evidence-based best practices, research, quality controls, and the myriad of other factors affecting the optimum delivery of healthcare. From new laws, models of care, and pharmaceuticals to technologies, population health trends, and changing market dynamics, healthcare is in a constant state of change. Remaining current is critical and enables professionals to provide better patient care while supporting their employers' overall operational objectives. There is much more, however, to be gained from a commitment to lifelong learning.

Professional Advancement

Employers today are seeking out case managers who demonstrate their commitment to the profession's highest standards of knowledge. The Commission for Case Manager Certification (CCMC) has been tracking just how much value employers place on the CCM credential. As it turns out, they place a very high value on it. A CCMC study found that over 40% of employers now require their case managers to be certified, compared with 25% in 2004. Further, the CCMC reports that 62% of employers reimburse their staff for the cost of the CCM examination. Even some government agencies struggling with tight budgets offer reimbursement. For example, the U.S. Department of Veterans Affairs (VA) reimburses under the GI Bill for licensing and certification.

A CCMC study found that over 40% of employers now require their case managers to be certified, compared with 25% in 2004

The CCM credential not only gives case managers better employment opportunities, but it also positions them for greater career advancement and leadership roles. Additionally, case managers who have the CCM credential gain heightened credibility with other medical professionals. This, in turn, gives case managers a stronger voice in demonstrating the value of case management.

Financial Gains

The CCM credential is not only a stature-building tool, but it also is an income booster. Recent PayScale data revealed that nurse case managers with the CCM credential are earning an average of $60,514 to $89,132 annually based on practice setting and area of the country. As they advance in the careers and earn promotions, their salaries also rise. For example, annual salaries for Directors of Case Management are averaging between $75,978 and $145,177.

Personal Responsibility

There is also the personal growth and confidence that comes from lifelong learning. Case managers who keep up with the latest developments in the field feel more confident that they are providing safe and effective patient care and that they are adhering to their professional codes of conduct, standards, and ethics. They can have peace of mind knowing they are doing their best to leverage advanced knowledge to deliver best-in-class case management and patient care.

One of nursing's pioneers and heroines, Florence Nightingale, wrote about continuous learning in her book, Notes on Nursing, published in 1859. In it, she conveys a belief that nurses should enhance the learning they gain through clinical experiences and observations by continually seeking out new information and evidence of improved ways to care for their patients.

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***Catherine M. Mullahy, RN, BS, CRRN,** is the President of Mullahy & Associates, LLC (www.mullahyassociates.com), a leading resource for case management training, certification workshops, online case management training and educational tools.*

CE I Care Transitions for Cardiopulmonary Patients with Hospital Value-Based Purchasing

Jacquelyn Woodworth MBA, RRT, CCM

Cardiopulmonary patients are often chronically critically ill. Many arrive in the acute care hospital setting with a recent history of multiple hospitalizations. They are particularly susceptible to readmissions when they have other chronic diseases such as diabetes or obesity. When patients have chronic diseases and they lack medical knowledge or resources for self management, it is a recipe for readmission, which is why it is so important to avoid labeling the patient as noncompliant. Patient noncompliance may be a failure on many levels of the continuum of care that contribute to readmissions, and medical professionals may be unaware of the patient's difficulties. For example, the inability to pay for maintenance medications or a lack of transportation to appointments are underlying reasons why patients could be mislabeled as noncompliant with their medical care.

Discharge planning is cumbersome to coordinate for some cardiopulmonary patients, especially chronically critically ill patients. Case managers must review the need for additional durable medical equipment, home oxygen, BiPAP therapy, or perhaps regular outpatient testing such as visits to the Anticoagulation Clinic. Hospitals must provide more comprehensive care plans that will assist in patient maintenance and reduce the already high incidence of readmission in cardiopulmonary patients. This additional aspect of follow-up care falls on the acute care facility, home care, and primary health care providers working across the health care continuum. The phrase "treat 'em and stream 'em" was the somewhat humorous pun for the "old way" of doing business under Centers for Medicare & Medicaid Service (CMS)/Fee-for-Service/diagnosis-related group system. Fortunately, some programs are reducing readmission, improving health status, and providing patient education. These lifestyle management and rehabilitation programs are already in place at most acute care and primary care networks but are generally underutilized by patients and are sometimes poorly funded.

To explain some of the techniques for better patient management, the current status of health care reimbursement must be reviewed. According to a January 2017 report by the Organization for Economic Co-Operation and Development, 20% of health care is wasteful.[1] The Organization showed that more spending does not yield improved health outcomes and can even create worse health outcomes. The focus on improving quality and outcomes is driven by insurance and government. Medicare or the CMS use the inpatient prospective payment system. The hospital is paid an adjusted fee according to a diagnosis-related group. Adjustments are made, for example, for a large volume of patients, for low-income patients, and for teaching hospitals. This is a form of the fee-for-service payment system. CMS understands that fee for service is unsustainable at the continuously growing rate for health care costs. Health care costs in the United States made up 18% of the gross domestic product in 2017.[2] Health care is more expensive in the United States than in other developed nations although individuals in the United States do not have better health or longer life expectancy than individuals in other developed nations.

The Advent of Value-Based Purchasing

The Affordable Care Act (ACA) of 2010 ushered in Hospital Value-Based Purchasing (HVBP) and also offered solutions for controlling exploding health care costs. Under the ACA, government, CMS, and the insurance industry are the primary catalysts for reform in the current health care system. CMS began a trial known as HVBP. With the onset of HVBP for CMS patients, earning the quality grade to be reimbursed at full potential became the center of attention. The HVBP Program is funded by reducing all base diagnosis-related group payments to the hospital by 2.0%. Payments are withheld by a percentage that is scheduled to increase over time. Any leftover funds are redistributed to hospitals based on their Total Performance Score (TPS) at the end of the fiscal period.

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Although data are mixed, hospitals that are participating in the voluntary HVBP program in the United States have found ways to improve. Health care costs can be decreased by reducing infections, preventing repeat admissions, and improving patient satisfaction. These quality improvement initiatives provide a starting point for improved integration of health care and focus on eliminating waste as a team. Some participating hospitals have had difficulty earning the annual bonus. Hospitals participating in 1 of the HVBP programs are known as Accountable Care Organizations (ACOs). These organizations are accountable for care under the Shared Savings Programs or HVBP programs currently under trial with CMS. There are three CMS Shared Savings programs for HVBP: Medicare Shared Savings Program, Pioneer ACOs, and Advance Payment ACOs.

There are currently 561 HVBP or ACOs participating in the Shared Savings Programs, and they serve 10.5 million Medicare fee-for service beneficiaries. The ACO, a methodology in its trial phase, is designed to lead payment systems away from paying for volume and towards paying for value and outcomes. The ACO is accountable for the total cost of care against historical benchmarks and quality outcomes for the care provided to their population demographic. ACOs can earn back a share of the savings when quality and performance requirements are met. The ACO coordinates with health care providers to improve quality for CMS patients and reduce the costs for Medicare under Part A and B. The possible outcome for the ACO bottom line is an increase, a decrease, or no change to their Medicare inpatient prospective payment system payments for the applicable fiscal year. Per CMS, the estimated fiscal year 2018 reimbursement totals for HVBP incentive payments is nearly $1.9 billion, which will be distributed to hospitals that have earned it through quality performance measures.

Beginning in fiscal year 2019, CMS will rename the "Patient and Caregiver-Centered Experience of Care/Care Coordination" to "Person and Community Engagement." CMS also added the following measure for fiscal year 2018: Care Transition, patients who "strongly agree" they understood their care when they left the hospital under Patient and Caregiver Centered Experience of Care/Care Coordination domain. Each of the four domains results in the TPS.[3,4] Each of the four domains for fiscal year 2018 and 2019 reporting years for the HVBP program are weighted at 25% to comprise the TPS. Thirty-one quality measures span the 4 quality domains. The benchmarks are updated and payments are adjusted downward on a schedule to phase in the pay for performance. The ACO has the opportunity to earn back a portion of the payments annually.

2018–2019 Hospital TPS components or domains weighted at 25% each:

- Patient/Caregiver experience is comprised of 8 individual survey module measures.
- Care Coordination/Patient Safety domain contains 10 measures, including the electronic medical record (EMR) measure, which is double-weighted.
- Preventive Health is composed of 8 measures.
- At-Risk Populations has 4 measures that assess 3 individual measures and a 2-part diabetes composite measure that is scored as one measure.

Chee et al.[5] provide a more in-depth explanation of the HVBP trial for earning the bonus. The withheld percentage was at 1.75% for the 2016 fiscal year.

In 2016, the HVBP program increased to representing 1.75% of all Medicare payments to hospitals. In practice, hospitals will all have 1.75% of all payments withheld, which they can then earn back depending on their TPS. Some hospitals will earn less than the 1.75% back and have a "penalty," and some hospitals will earn more than the 1.75% back and have a "bonus." In 2016, about half of hospitals will see a minimal change in Medicare payments, with the overall adjustment being between −0.4% and +0.4%. The worst performing hospital will earn back none of the 1.75% withheld, and the highest performing hospital will have a net increase of approximately 1.25%. While long-term studies have not yet been completed, an evaluation of the first year of HVBP showed no improvement in clinical process or in patient experience among hospitals that participated in the program.[6] Grants have already been awarded to fund additional studies.

CMS Examines Readmissions to Improve Quality

The rate of readmission is an area that requires administrative focus in the acute care hospital setting. CMS began to calculate the Excess Readmission Ratio (ERR) to measure hospital performance. Readmission of a patient in the first 30 days after hospitalization is now a metric used to assess quality and value by CMS. In fiscal year 2013, CMS began to use readmissions of acute myocardial infarction, heart failure, pneumonia, and coronary artery bypass graft surgery for benchmarking. Chronic obstructive pulmonary disease (COPD) and elective primary total hip arthroplasty and/or total knee arthroplasty were added in 2015 to adjust payments related to ERR. The ratio is a benchmark measure of the hospital's relative performance ratio of predicted to expected readmissions. Each diagnosis has an assigned ERR. CMS instituted the Hospital Readmission Reduction Plan in fiscal year 2013. CMS counts all unplanned readmissions for the benchmarked diagnosis that occurs within 30 days of discharge from the original admission. Any readmissions to the same hospital or another acute care hospital for any reason within the first 30 days of discharge of the core diagnosis are calculated. CMS does allow for some planned admissions that are not tabulated. It became important for ACOs to reduce readmissions for the high-risk groups in the quality review.

What are the costs and what are hospitals supposed to do for these patients to create value and impact readmissions? Reducing the 30-day readmission rate in the acute-care setting to earn full reimbursement and promote quality takes an integrated team. Under new rules for reimbursement, hospitals are working to coordinate care through the continuum from the acute setting to the home and 30 days after discharge. It can be overwhelming with the multiple factors that affect readmissions. Integrated health care and evidence-based medical care became the buzz words attached to the new initiatives for quality improvement. Health care teams were forced to be more motivated to show they could be successful with clinically based pragmatism and follow-up care. Health care administrators must also plan for the private insurance sector to follow the data and practice of Medicare or CMS in relation to HVBP standards, which are now showing mixed results. Health care leaders are essentially being forced to improve in the middle of tremendous changes in the health care industry. Theoretically, value can be achieved and rewarded financially by improving outcomes or quality, reducing costs, or both. Reducing costs by itself generally does little to impact quality outcomes.

Under readmission reduction efforts, acute care hospitals began targeted approaches for case management. They began concentrating on care transitions and community outreach resources for cardiopulmonary patients. Technology for managing congestive heart failure (CHF) and cardiac disease in the home were mainstreamed as part of cardiac management programs. Hospitals began to integrate care more fully with home care agencies to provide better management after discharge. Case management departments were mostly doing more with the same staff. The staff began calling and following up with patients after discharge, assisting with scheduling follow-up appointments, and scheduling follow-up appointments at the time of discharge instruction. If funds were available, case management departments hired care transition specialists to manage complex patients at home who were at high risk for readmission. Most insurance companies also integrated with hospitals by providing a follow-up case manager at home for those with a qualifying or complicated diagnosis. Directors and administrators of case manager departments began working with insurance case managers in the discharge planning phase of the hospital admission to better coordinate durable medical equipment, medications, and other complex issues. Most of the team building was reactionary even after nearly a decade of sounding the alarm that change was on the horizon. Short-sighted hospitals were actually considering cutting departments like diabetes education and anticoagulation services before 2010 because those departments did not turn a profit.

While hospitals were already scurrying to reduce readmissions for the core diagnosis list, one of the most revealing study results about pulmonary disease was released by the Centers for Disease Control and Prevention (CDC). The results exposed the gap in care and the urgency to provide more care for those at high risk for readmission and to improve disease management. The CDC announced the study results of the total and state-specific medical and absenteeism cost of COPD in 2014. The results further supported the efforts in the acute care setting to address the third leading cause of death in the United States behind heart disease and cancer. The CDC calculated the cost of COPD at $36 billion annually in 2014, with a projected cost of $49 billion by 2020.[7] The study highlighted the use of evidence-based medical treatment for clinical management and tobacco reduction programs. The study also approximated that 80% of COPD deaths are directly related to smoking.

The following are highlights of the CDC research:

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- In 2010, the total national medical costs attributable to COPD were estimated at $32.1 billion dollars annually.
- Absenteeism costs were $3.9 billion, for a total burden of $36 billion in costs attributable to COPD.
- An estimated 16.4 million days of work were lost due to COPD each year.
- Of the medical costs associated with COPD, 18% were paid for by private insurance, 51% by Medicare, and 25% by Medicaid.
- The study also projects a rise in medical costs associated with COPD from $32.1 billion in 2010 to $49 billion by 2020.

Asthma Readmission Reduction Project for Adults with Medicaid

The New York Department of Health created a system to improve health care and reduce costs for Medicaid patients. The comprehensive program is known as the Delivery System Reform Incentive Payment (DSRIP) Program and began in 2014. New York received a federal waiver allowing the state to reinvest $8 billion in federal savings generated by Medicaid Redesign Team reforms. The DSRIP program promotes community-level collaborations with a goal of system reform. The measured goal was to achieve a 25% reduction in avoidable hospital visits over 5 years. The ultimate goal was centered on system transformation, clinical improvement, and population health improvement. All DSRIP funds were based on performance linked to achievement of project milestones. The $8 billion reinvestment was allocated into 3 areas. A temporary and time-limited fund of $500 million designated as the Interim Access Assurance Fund enabled Medicaid providers to fully participate in the DSRIP. Allocations of $6.42 billion provided for DSRIP included DSRIP planning grants, DSRIP provider incentive payments, and DSRIP administrative costs. Lastly, the funding provided $1.08 billion for other supportive Medicaid redesign within Health Home development, long-term care, workforce, and enhanced behavioral health services.

One of the main objectives of the DSRIP was to reduce hospital visits for adult patients with asthma. Edward Stomski, RRT, AEC, Transformation Specialist for Population Health at the Alliance for Better Health, reports the success of the program over a 3-year period.[8] The visit rate to the hospital emergency department was reduced by 25%. The DSRIP's goal of reducing the hospital admission rate by 10% annually was also met over 3 years for Medicaid patients. The project exceeded their gap-to-goal ratio in 4 of 5 parameters in the first year and achieved 5 of 5 parameters the second year. Asthma was better controlled with improved testing, self-care techniques, controlled medication usage, and partnering with community organizations. Community organizations filled in with food pantry assistance, transportation, medication assistance, and assigning a primary care provider for follow-up care (everyone needs a caregiver). The asthma educator working with the community organizations exceeded projections by significantly reducing hospital admissions and visits to the emergency department.

Acute Health Care Engages Patients along the Continuum

Many hospital systems have excellent patient engagement and follow-up programs for outpatient education and disease management. Using EMR systems to activate patients for discharge planning is essential. It is standard practice in the United States for EMR systems to be modified by information technology specialists. The discharge plan is printed with the instructions and referral orders to participate in follow-up outpatient programs. For example, patients may be automatically referred to outpatient cardiopulmonary rehabilitation, the asthma education clinic, diabetes education, management of CHF, or the Anticoagulation Clinic. The referrals are made electronically by the physician at discharge to the department that will provide follow-up outpatient care. The patient has often been visited by health care providers such as the CHF registered nurse (RN) and the COPD registered respiratory therapist (RRT) as well as volunteers. The hospital can easily develop a care pathway by diagnosis with order sets for the physician using the EMR system. The outpatient department already has the order at discharge and contacts the patient for appointments. This prevents the patient from slipping through the system by engaging the interdisciplinary medical team through the continuum. The physician is contacted for any further medical

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clearance required before the start of programs involving monitored physical activity. The physician is also notified if the patient declines follow-up services by the physician in the office medical home.

After reducing hospital admissions for COPD patients became a targeted goal, hospitals developed COPD management programs for inpatients. Ideally, qualifying patients with COPD are automatically enrolled in the inpatient COPD management program through the EMR. Influenced by the new measures to improve care and reduce readmissions, COPD management programs began to appear in the United States after 2015. In Florida and in other states, patients began to meet with the RRT COPD navigator at bedside; the COPD navigator provides disease education and self-care training and the pharmacist provides education about medications during the inpatient experience. The CHF RN navigator also meets and trains EMR-tagged CHF patients. CHF patients are given scales and transtelephonic monitors so that they can monitor their weight and heart electric signals at home.

One area for improvement in the care of COPD patents is the effective use of controller medications at home. Every COPD patient in COPD management is provided with a metered dose inhaler spacer and training on proper use during pharmacist and RRT visits. Patients graduate to traditional cardiopulmonary rehabilitation or asthma clinics after the first physician visit post discharge. These programs include smoking cessation, dietary management, breathing techniques, and other topics to train the patient and caregiver in group settings. Patients in the COPD management program receive basic education about breathing techniques and effective administration of medications to control their symptoms as they start the more intense outpatient rehabilitation and educations programs. In smaller hospitals, cardiopulmonary rehabilitation RRTs and RNs around the country provide bedside education on a smaller scale to train patients and enroll them in cardiopulmonary rehabilitation. The physician must play a supportive role to encourage and enlist patients for these lifestyle management programs as the major player in the integrated team.

Community Outreach Resources

Case managers must work with hospital physicians and administrators to enlist every resource along the continuum of care. In the new era of HVBP, hospitals have developed their own community outreach programs that provide transportation and assess patients' needs to prevent any noncompliance. Directors of care transitions and case management have partnered with their local skilled nursing facilities (SNFs) and home care providers to work as a team. In many cases, the follow through to engage patients for outpatient and follow-up care is successfully moved forward by home care and SNF providers. The SNF case manager identifies patients who are at risk for a more-effective hand off to home care. The SNF case manager alerts the primary physician or medical home. The readmission rate for SNFs is also part of the CMS initiative to reduce hospital readmissions. Integration and partnering with local health care providers and local community services is the key to helping patients. The best patient care and intervention is spearheaded by individuals who take ownership of individual care and seek to make a difference one at a time. Many patients report that one RN, RRT, or physical therapist changed their lives.

Ensuring the best possible patient outcome is what health care providers do every day. Health care administrators have to seek out ways to engage their community for better public health. Think in terms of the influenza vaccine. If more people use preventive health services, there is less cost and illness in the community. An influenza vaccine might prevent the spread of pneumonia to patients who are uninsured or underinsured. It takes the entire health care community to educate and encourage patients, families, and caregivers to make positive health care changes like quitting smoking. Many hospital teams have overcome many barriers with introspective leadership from administrators and physicians. The current health care reform environment is another obstacle for many talented individuals. Case managers and health care professionals working together have already made tremendous changes and are part of the experiment. Case management

should use this opportunity to influence planning at the administrative level and should demonstrate the need for improved practices for long-term solutions. CE I

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CE II

Intensive Outpatient Care Program: A Care Model for the Medically Complex Piloted by Employers

Kristof Stremikis, MPP, MPH, Clare Connors, MPH, and Emma Hoo, BA

Background

Improving care for high-need, high-cost patients has long been a priority for both public and private sector purchasers of health care. In 2009, the Pacific Business Group on Health (PBGH) partnered with Boeing to implement a care management initiative that Boeing had successfully piloted with about 700 of its employees, retirees, and dependents. Called the Intensive Outpatient Care Program (IOCP),[1] the initiative aims to improve outcomes for medically complex patients and prevent unnecessary hospital use by providing care coordination, self-management support, and effective ambulatory care. The overall goal of IOCP is to keep participants at home and in their communities by providing intensive, person-centered outpatient care.

Shortly after IOCP was introduced, the California Public Employees' Retirement System (CalPERS) and Pacific Gas and Electric Company (PG&E) followed suit with a pilot program in Northern California. From 2013 to 2015, PBGH, with a $19.1 million Health Care Innovation Award from the federal Centers for Medicare & Medicaid Services (CMS), expanded the IOCP model to 23 medical groups in 5 states.[2] The grant enabled PBGH to implement IOCP in primary care practice sites in Arizona, California, Idaho, Nevada, and Washington, serving some 15,000 participants, including those enrolled in Medicare Advantage or Medicare fee-for-service, those dually eligible for Medicare and Medicaid, and a small number of Medicaid-only beneficiaries. In 2016 and 2017, PBGH has continued to provide technical assistance and training on the IOCP model to additional providers. Moreover, Boeing has incorporated aspects of the IOCP model in its accountable care organization (ACO) contracts by including specific intervention guidelines and performance guarantees for medically complex patient populations.

While the CMS grant provided an important source of funding for initial training, after the grant period ended 90% of participating delivery systems continued the core elements of the program for Medicare patients and 15 of 23 expanded programs into their commercial populations.

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Key Program Features

The IOCP model calls for embedding dedicated care coordinators in primary care physician practices and medical groups. These care coordinators build relationships with patients and work closely with them to stabilize their health. While IOCP is similar to other models for complex patients, it is differentiated by a unique combination of elements—called the IOCP Guardrails—and close coordination with primary care providers. Participating delivery systems are expected to adhere to the Guardrails (described below) but may adapt implementation to their local environment (Table 1).

IOCP Guardrails

Six necessary elements have been identified as Guardrails in IOCP:

1. A care coordinator (a nurse, social worker, community health worker, or medical assistant) who is trained in person-centered care techniques maintains a close ongoing relationship with the participant over time and across the care continuum.
2. Within 1 month of enrollment, the care coordinator visits the participant at home for up to 90 minutes to review the patient's medical history, complete a needs assessment, establish treatment goals, and develop a shared action plan.
3. The care coordinator and participant communicate regularly, monthly, or more frequently.

TABLE 1 FEATURES OF THE INTENSIVE OUTPATIENT CARE PROGRAM

Targeting the population most likely to benefit	Patients for the Intensive Outpatient Care Program (IOCP) are identified through a combination of predictive risk modeling and retrospective utilization review. Crucially, both types of patient identification are used in tandem with clinical review by a physician or nurse, preferably one who knows the patient. Primary care physicians are also encouraged to refer patients who do not appear on predictive or retrospective lists but may still benefit from the intervention.
Assessing patients' health-related risks and needs	IOCP encourages the use of standardized longitudinal assessment tools for physical function, mental well-being, and patient engagement in care.
Developing patient-centered care plans	The Shared Action Plan is one of the Guardrails of IOCP. The plan includes at least 1 goal chosen by the patient.
Engaging patients and family in managing care	IOCP includes a face-to-face visit in the participant's home within 1 month of enrollment that allows the care coordinator to assess the home environment and family support.
Transitioning patients following hospital discharge	IOCP found that patients are generally willing to enroll in the program when introduced to the care coordinator during a hospital stay. A face-to-face encounter during a crucial time facilitates the transition back to primary care.
Coordinating care and facilitating communication among providers	The care coordinator is the link among primary, specialty, and ancillary services.
Integrating physical/behavioral health care	IOCP uses the Patient Health Questionnaire-9 (PHQ-9) to track depression in patients over time. Those enrolled in the program for at least 9 months experienced an average reduction in depression systems of 33%.
Integrating health and social services	IOCP goes beyond referral to social services by having the care coordinator facilitate a "warm hand-off" to any support service.
Making care or services more accessible	A central tenet of IOCP is 24/7 access to care, with follow-up communication to the care coordinator on the next business day.
Monitoring patients' progress	The care coordinator is required to contact patients at least monthly; most are in contact much more frequently

Note: This exhibit describes common features of effective care models for high-need, high-cost patients; see: McCarthy D, Ryan J, Klein S. *Models of Care for High-Need, High-Cost Patients: An Evidence Synthesis.* The Commonwealth Fund website. Published October 2015. Accessed September 20, 2018.

4. The participant and care coordinator together create a shared action plan that includes at least 1 goal chosen by the patient.
5. In-person introductions—known as "warm hand-offs"—are made to workers from relevant support services (eg, home health, behavioral health, transportation, drug assistance programs, food banks, and other community services).
6. Patients have access to a non-emergency department care provider 24 hours a day, 7 days a week, with follow-up communication to the care coordinator on the next business day.

Financing

In the initial pilot, Boeing paid participating clinicians an additional monthly fee based on the severity of the patient's condition and the number of patients being managed. Anthem also used this model in its ACO contracts in California: medical groups are given a higher per-member-per-month fee for members with more than 2 chronic condition diagnoses.

Funding from the CMS Innovation grant involved both a uniform infrastructure payment per medical group and a per-member-per-month payment. This allowed participating medical groups to hire more than 200 full-time care coordinators across approximately 600 clinical sites. The grant also funded technical assistance and training, including attendance at a 3-day in-person training session for care coordinators and periodic webinars on topics such as end-of-life care and motivational interviewing.

Implementing the IOCP model requires upfront investment in staff training, baseline infrastructure (eg, electronic medical records), and delivery system capacity (eg, after-hours access to non-emergency department care). Sustainable financing for the program is best accomplished within population-based, accountable care systems, which can offset initial outlays with long-term reductions in per-member-per- month spending for medically complex patients. Delivery systems that operate in traditional fee-for-service payment environments can support transformation work through per-member-per-month care coordination fees.

The Intensive Outpatient Care Program (IOCP) aims to improve outcomes for medically complex patients and prevent unnecessary hospital use by providing care coordination, self-management support, and effective ambulatory care.

Challenges

Identifying eligible patients was an initial challenge in the CMS-funded program. Initially, it was thought that patients could be identified through Medicare fee-for-service claims data and Medicare Advantage encounter data. However, the standard risk score reports produced by the program's third-party data vendor used data that were 3–6 months old and medical groups found the data too outdated to help identify suitable IOCP patients. Medical groups devised several alternative methods for identifying patients:

1. **Direct referral from primary care physicians (PCPs).** Once PCPs became familiar with the program, they could refer patients who were good candidates.
2. **Transfer from an existing care management program.** Often patients enrolled in disease-specific care management programs were identified as patients who could benefit from a more-intensive and comprehensive program like IOCP.
3. **Identification from hospital records.** Some groups had access to hospital electronic health records in integrated delivery systems and could use those data to refer patients to IOCP.
4. **Identification from internal reporting.** Some groups had their own reporting systems or risk stratification methods that they used to identify patients for IOCP.

Recruiting patients into the program also proved initially challenging. During the first few months of program operations, care coordinators contacted eligible patients through cold calls and letters, but patients were not receptive to these approaches. Medical groups were more successful when they modified their strategies to incorporate "warm hand-offs." This involved PCPs introducing the care coordinator during a visit or approaching eligible patients during a hospital or skilled nursing facility stay. Eventually, the warm hand-off approach was incorporated not only in patient recruitment but in all relevant referral services.

Results

Previously released data from IOCP in commercial populations show a reduction in costs among medically complex patients by up to 20%.[3] PBGH used several metrics to measure success in patient-reported outcomes, utilization, and cost for the CMS-funded program over the 30-month period between July 1, 2012, and December 31, 2014. The results on patient-reported health status surveys—including the Veterans Rand 12-Item Health Survey (VR12), Patient Health Questionnaire (PHQ), and Patient Activation Measure (PAM)— show statistically significant ($P \leq .05$ levels) improvements in patients' engagement in their own care and in physical and mental health. An actuarial analysis by Milliman shows reduced cost of care. Specifically, the program achieved a:

- 3.6% increase in patient engagement
- 33% reduction in depression symptoms
- 3.4% improvement in mental health functioning
- 4.1% improvement in physical health functioning
- 21% reduction in the cost of care for high-risk patients enrolled for at least 9 months.

Lessons

The IOCP model has been successfully implemented in varied settings with different populations. This has enabled analysts to identify several common factors that contribute to the program's success:

- strong senior leadership support, including a dedicated physician champion
- a commitment to the IOCP Guardrails
- staff who can work collaboratively in a team-based care model
- rigorous performance measurement and quality improvement processes
- modern health IT infrastructure
- in-person care coordinator training

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The IOCP model calls for embedding dedicated care coordinators in primary care physician practices and medical groups. These care coordinators build relationships with patients and work closely with them to stabilize their health.

Next Steps

The IOCP model continues to evolve, and PBGH is training additional providers to implement it. In 2016, elements of the IOCP model were included in technical assistance and training that PBGH led for California Medicaid providers under the Health Homes Program.[4] In 2017 and 2018, with support from The SCAN Foundation, PBGH will provide training to 21 health systems providing care to 250,000 Medicare beneficiaries under its Building Care Solutions program, which builds upon the IOCP model. This work will update the model to ensure it incorporates the most recent patient-centered care principles (such as those used by the National Committee for Quality Assurance's Patient-Centered Medical Home Recognition Program) and provide training to delivery systems on developing a business case for medically complex care programs like IOCP. CE II

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2. The project described was supported by Grant No. 1C1CMS331047 from the U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. The contents of this publication are solely the responsibility of the author and do not necessarily represent the official views of the U.S. Department of Health and Human Services or any of its agencies. The analysis presented was conducted by the awardee. Findings might or might not be consistent with or confirmed by the findings of the independent evaluation contractor.

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Patient Engagement

continued from page 2

treatment options, and the patient's preferences before determining a plan for the patient's health care. They should then execute a plan together.

- Assess your patient's health literacy and plan accordingly.

To be successful in patient engagement, a model of care delivery that supports a clinical information system, decision support, and self-management is necessary. A commitment from top management to entry level workers and across the continuum must be made. Training and tools must be provided.

Evidence demonstrates that patients who are engaged with their health care have better health outcomes and incur lower costs. Case managers are the key to patient engagement. Patient engagement is what we do. Case managers assess, educate, communicate, and evaluate. A successful case management process will help ensure patient engagement.

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PharmaFacts for Case Managers

Tiglutik™ (riluzole) oral suspension

INDICATIONS AND USAGE

Tiglutik is indicated for the treatment of amyotrophic lateral sclerosis (ALS).

DOSAGE AND ADMINISTRATION

The recommended dosage for Tiglutik is 50 mg (10 mL) taken orally twice daily, every 12 hours. Tiglutik should be taken at least 1 hour before or 2 hours after a meal. Gently shake the Tiglutik bottle for at least 30 seconds before administration. Measure serum aminotransferases before and during treatment with Tiglutik.

DOSAGE FORMS AND STRENGTHS

Oral suspension: 50 mg/10 mL (5 mg/mL) slightly brown, opaque, homogeneous suspension in a 300 mL multiple-dose amber bottle.

CONTRAINDICATIONS

Tiglutik is contraindicated in patients with a history of severe hypersensitivity reactions to riluzole or to any of its components (anaphylaxis has occurred).

WARNINGS AND PRECAUTIONS

Hepatic Injury

Tiglutik can cause liver injury. Cases of drug-induced liver injury, some of which were fatal, have been reported in patients taking riluzole. Asymptomatic elevations of hepatic transaminases have also been reported, and in some patients have recurred upon rechallenge with riluzole. In clinical studies, the incidence of elevations in hepatic transaminases was greater in riluzole-treated patients than placebo-treated patients. The incidence of elevations of ALT above 5 times the upper limit of normal (ULN) was 2% in riluzole-treated patients. Maximum increases in ALT occurred within 3 months after starting riluzole. About 50% and 8% of riluzole-treated patients in pooled controlled efficacy studies had at least one elevated ALT level above ULN and above 3 times ULN, respectively. Monitor patients for signs and symptoms of hepatic injury, every month for the first 3 months of treatment, and periodically thereafter. The use of Tiglutik is not recommended if patients develop hepatic transaminases levels greater than 5 times the ULN. Discontinue Tiglutik if there is evidence of liver dysfunction (e.g., elevated bilirubin). Concomitant use with other hepatotoxic drugs may increase the risk for hepatotoxicity.

Neutropenia

Tiglutik can cause neutropenia. Cases of severe neutropenia (absolute neutrophil count <500 per mm^3) within the first 2 months of riluzole treatment have been reported. Advise patients to report febrile illnesses.

Interstitial Lung Disease

Tiglutik can cause interstitial lung disease, including hypersensitivity pneumonitis. Discontinue Tiglutik immediately if interstitial lung disease develops.

ADVERSE REACTIONS

The following adverse reactions are described below and elsewhere in the labeling:

- Hepatic injury
- Neutropenia
- Interstitial lung disease

DRUG INTERACTIONS

Agents That May Increase Riluzole Blood Concentrations

CYP1A2 Inhibitors

Coadministration of riluzole (a CYP1A substrate) with CYP1A2 inhibitors was not evaluated in a clinical trial; however, in vitro findings suggest that an increase in riluzole exposure is likely. The concomitant use of strong or moderate CYP1A2 inhibitors (e.g., ciprofloxacin, enoxacin, fluvoxamine, methoxsalen, mexiletine, oral contraceptives, thiabendazole, vemurafenib, zileuton) with Tiglutik may increase the risk of Tiglutik-associated adverse reactions.

Agents That May Decrease Riluzole Plasma Concentrations

CYP1A2 Inducers

Coadministration of riluzole (a CYP1A substrate) with CYP1A2 inducers was not evaluated in a clinical trial; however, in vitro findings suggest a decrease in riluzole exposure is likely. Lower exposures may result in decreased efficacy.

Hepatotoxic Drugs

Clinical trials in amyotrophic lateral sclerosis (ALS) patients excluded patients on concomitant medications that were potentially hepatotoxic (e.g., allopurinol, methyldopa, sulfasalazine). Tiglutik-

treated patients who take other hepatotoxic drugs may be at an increased risk for hepatotoxicity.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no studies of riluzole in pregnant women, and case reports have been inadequate to inform the drug-associated risk. The background risk for major birth defects and miscarriage in patients with ALS is unknown. In the U.S. general population, the background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively. In studies in which riluzole was administered orally to pregnant animals, developmental toxicity (decreased embryofetal/offspring viability, growth, and functional development) was observed at clinically relevant doses. Based on these results, women should be advised of a possible risk to the fetus associated with use of Tiglutik during pregnancy.

Lactation

Risk Summary

It is not known if riluzole is excreted in human milk. Riluzole or its metabolites have been detected in milk of lactating rats. Women should be advised that many drugs are excreted in human milk and that the potential for serious adverse reactions in nursing infants from Tiglutik is unknown.

Females and Males of Reproductive Potential

In rats, oral administration of riluzole resulted in decreased fertility indices and increases in embryolethality.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

In clinical studies of riluzole, 30% of patients were 65 years and over. No overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Hepatic Impairment

Patients with mild [Child-Pugh's (CP) score A] or moderate (CP score B) hepatic impairment had increases in AUC compared to patients with normal hepatic function. Thus, patients with mild or moderate hepatic impairment may be at increased risk of adverse reactions. The impact of severe hepatic impairment on riluzole exposure is unknown. Use of Tiglutik is not recommended in patients with baseline elevations of serum aminotransferases greater than 5 times upper limit of normal or evidence of liver dysfunction.

Japanese Patients

Japanese patients are more likely to have higher riluzole concentrations. Consequently, the risk of adverse reactions may be greater in Japanese patients.

CLINICAL STUDIES

The efficacy of Tiglutik is based upon bioavailability studies comparing oral riluzole tablets to Tiglutik oral suspension.

The efficacy of riluzole was demonstrated in two studies (Study 1 and 2) that evaluated 50 mg riluzole oral tablets twice daily in patients with ALS. Both studies included patients with either familial or sporadic ALS, disease duration of 5 years, and baseline forced vital capacity ≥60% of normal.

Study 1 was a randomized, double-blind, placebo-controlled clinical study that enrolled 155 patients with ALS. Patients were randomized to receive riluzole 50 mg twice daily (n=77) or placebo (n=78) and were followed for at least 13 months (up to a maximum duration of 18 months). The clinical outcome measure was time to tracheostomy or death.

The time to tracheostomy or death was longer for patients receiving riluzole compared to placebo. There was an early increase in survival in patients receiving riluzole compared to placebo. The study showed an early increase in survival in patients given riluzole. Among the patients in whom the endpoint of tracheostomy or death was reached during the study, the difference in median survival between the riluzole 50 mg twice daily and placebo groups was approximately 90 days.

Study 2 was a randomized, double-blind, placebo-controlled clinical study that enrolled 959 patients with ALS. Patients were randomized to riluzole 50 mg twice daily (n=236) or placebo (n=242) and were followed for at least 12 months (up to a maximum duration of 18 months). The clinical outcome measure was time to tracheostomy or death.

The time to tracheostomy or death was longer for patients receiving riluzole compared to placebo. Although these survival curves were not statistically significantly different when evaluated by the analysis specified in the study protocol (Logrank test p=0.076), the difference was found to be significant by another appropriate analysis (Wilcoxon test p=0.05). Among the patients in whom the endpoint of tracheostomy or death was reached during the study, the difference in median survival between riluzole and placebo was approximately 60 days.

Although riluzole improved survival in both studies, measures of muscle strength and neurological function did not show a benefit.

HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

Tiglutik (50 mg/10 mL) oral suspension is supplied in amber glass bottles closed with child-resistant tamper evident screw caps. Each bottle contains 300 mL of oral suspension and is intended for

multi-dose use.

Tiglutik is supplied in a carton, containing:

- Two bottles, each containing 300 mL oral suspension—Two 10 mL oral syringes
- Two syringe bottle adapters
- Two syringe tip caps
- Prescribing Information, including Instructions for Use

Storage and Handling

Store at 20–25°C (68-77°F), excursions permitted to 15-30°C (59-86°), and protect from bright light. Do not freeze. Store upright.

Use within 15 days after initially opening of each bottle. Discard any unused Tiglutik remaining after 15 days of first opening of the bottle.

Pifeltro™ (doravirine) tablets, for oral use

INDICATIONS AND USAGE

Pifeltro is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adult patients with no prior antiretroviral treatment history.

DOSAGE AND ADMINISTRATION

Recommended Dosage

The recommended dosage regimen of Pifeltro in adults is one 100 mg tablet taken orally once daily with or without food.

Dosage Adjustment with Rifabutin

If Pifeltro is coadministered with rifabutin, increase Pifeltro dosage to one tablet twice daily (approximately 12 hours apart) for the duration of rifabutin coadministration.

DOSAGE FORMS AND STRENGTHS

Pifeltro film-coated tablets are white, oval-shaped tablets, debossed with the corporate logo and 700 on one side and plain on the other side. Each tablet contains 100 mg doravirine.

CONTRAINDICATIONS

Pifeltro is contraindicated when coadministered with drugs that are strong cytochrome P450 (CYP)3A enzyme inducers as significant decreases in doravirine plasma concentrations may occur, which may decrease the effectiveness of Pifeltro. These drugs include, but are not limited to, the following:

- the anticonvulsants carbamazepine, oxcarbazepine, phenobarbital, phenytoin
- the androgen receptor inhibitor enzalutamide
- the antimycobacterials rifampin, rifapentine
- the cytotoxic agent mitotane
- St. John's wort (Hypericum perforatum)

WARNINGS AND PRECAUTIONS

Risk of Adverse Reactions or Loss of Virologic Response Due to Drug Interactions

The concomitant use of Pifeltro and certain other drugs may result in known or potentially significant drug interactions, some of which may lead to loss of therapeutic effect of Pifeltro and possible development of resistance. Consider the potential for drug interactions before and during Pifeltro therapy, review concomitant medications during Pifeltro therapy, and monitor for adverse reactions.

Immune Reconstitution Syndrome

Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapy. During the initial phase of combination antiretroviral treatment, patients whose immune system responds may develop an inflammatory response to indolent or residual opportunistic infections (such as *Mycobacterium avium* infection, cytomegalovirus, *Pneumocystis jirovecii* pneumonia, or tuberculosis), which may necessitate further evaluation and treatment.

Autoimmune disorders (such as Graves' disease, polymyositis, and Guillain-Barré syndrome) have also been reported to occur in the setting of immune reconstitution; however, the time to onset is more variable and can occur many months after initiation of treatment.

ADVERSE REACTIONS

The following adverse reactions are discussed in other sections of the labeling:

Immune reconstitution syndrome

DRUG INTERACTIONS

Effect of Other Drugs on Pifeltro

Coadministration of Pifeltro with a CYP3A inducer decreases doravirine plasma concentrations, which may reduce Pifeltro efficacy. Coadministration of Pifeltro and drugs that are inhibitors of CYP3A may result in increased plasma concentrations of doravirine.

No clinically significant changes in concentration were observed for doravirine when coadministered with the following agents: dolutegravir, TDF, lamivudine, elbasvir and grazoprevir, ledipasvir and sofosbuvir, ritonavir, ketoconazole, aluminum hydroxide/magnesium hydroxide/simethicone containing antacid, pantoprazole, and methadone.

Effect of Pifeltro on Other Drugs

No clinically significant changes in concentration were observed for the following agents when coadministered with doravirine: dolutegravir, lamivudine, TDF, elbasvir and grazoprevir, ledipasvir and sofosbuvir, atorvastatin, an oral contraceptive containing ethinyl estradiol and levonorgestrel, metformin, methadone, and midazolam.

USE IN SPECIFIC POPULATIONS

Pregnancy Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in individuals exposed to Pifeltro during pregnancy.

Healthcare providers are encouraged to register patients by calling the Antiretroviral Pregnancy Registry (APR) at 1-800-258-4263.

Risk Summary

No adequate human data are available to establish whether Pifeltro poses a risk to pregnancy outcomes. In animal reproduction studies, no adverse developmental effects were observed when doravirine was administered at exposures ≥8 times the exposure in humans at the recommended human dose (RHD) of Pifeltro.

The background rate of major birth defects is 2.7% in a U.S. reference population of the Metropolitan Atlanta Congenital Defects Program (MACDP). The rate of miscarriage is not reported in the APR. The estimated background rate of miscarriage in the clinically recognized pregnancies in the U.S. general population is 15-20%. Methodological limitations of the APR include the use of MACDP as the external comparator group. The MACDP population is not disease-specific, evaluates individuals and infants from the limited geographic area, and does not include outcomes for births that occurred at <20 weeks' gestation.

Lactation

Risk Summary

The Centers for Disease Control and Prevention recommend that HIV-1-infected mothers in the United States not breastfeed their infants to avoid risking potential transmission of HIV-1 infection.

It is unknown whether doravirine is present in human milk, affects human milk production, or has effects on the breastfed infant. Doravirine is present in the milk of lactating rats. Because of the potential for HIV-1 transmission (in HIV-negative infants), developing viral resistance (in HIV-positive infants), and serious adverse reactions in a breastfed infant, instruct mothers not to breastfeed if they are receiving Pifeltro.

Pediatric Use

Safety and efficacy of Pifeltro have not been established in pediatric patients <18 years of age.

Geriatric Use

Clinical trials of Pifeltro did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects. In general, caution should be exercised in the administration of Pifeltro in elderly patients, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Renal Impairment

No dosage adjustment of Pifeltro is required in patients with mild, moderate, or severe renal impairment. Pifeltro has not been adequately studied in patients with end-stage renal disease and has not been studied in dialysis patients.

Hepatic Impairment

No dosage adjustment of Pifeltro is required in patients with mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) hepatic impairment. Pifeltro has not been studied in patients with severe hepatic impairment (Child-Pugh Class C).

CLINICAL STUDIES

Adult Subjects with No Antiretroviral Treatment History

The efficacy of Pifeltro is based on the analyses of 48-week data from two randomized, multicenter, double-blind, active controlled phase 3 trials (DRIVE-FORWARD, NCT02275780 and DRIVE-AHEAD, NCT02403674) in HIV-1 infected subjects with no antiretroviral treatment history (n=1494).

In DRIVE-FORWARD, 766 subjects were randomized and received at least 1 dose of either Pifeltro once daily or darunavir 800 mg + ritonavir 100 mg (DRV+r) once daily each in combination with emtricitabine/tenofovir DF (FTC/TDF) or abacavir/lamivudine (ABC/3TC) selected by the investigator. At baseline, the median age of subjects was 33 years, 16% were female, 27% were non-white, 4% had hepatitis B and/or C virus coinfection, 10% had a history of AIDS, 20% had HIV-1 RNA >100,000 copies/mL, 86% had CD4+ T-cell count >200 cells/mm^3, 13% received ABC/3TC, and 87% received FTC/TDF; these characteristics were similar between treatment groups.

In DRIVE-AHEAD, 728 subjects were randomized and received at least 1 dose of either Delstrigo (DOR/3TC/TDF) or EFV 600 mg/FTC 200 mg/TDF 300 mg once daily. At baseline, the median age of subjects was 31 years, 15% were female, 52% were non-white, 3% had hepatitis B or C coinfection, 14% had a history of AIDS, 21% had HIV-1 RNA >100,000 copies/mL, and 88% had CD4+ T-cell count >200 cells/mm^3; these characteristics were similar between treatment groups.

In DRIVE-FORWARD, the mean CD4+ T-cell counts in the Pifeltro and DRV+r groups increased from baseline by 193 and 186 cells/mm^3, respectively.

In DRIVE-AHEAD, the mean CD4+ T-cell counts in the Delstrigo and EFV/FTC/TDF groups increased from baseline by 198 and 188 cells/mm^3, respectively.

HOW SUPPLIED/STORAGE AND HANDLING

Each Pifeltro tablet contains 100 mg of doravirine, is white, oval-shaped and film-coated, and is debossed with the corporate logo and 700 on one side and plain on the other side. Each bottle contains 30 tablets (NDC 0006-3069-01) with silica gel desiccant and is closed with a child-resistant closure.

Store Pifeltro in the original bottle. Keep the bottle tightly closed to protect from moisture. Do not remove the desiccant. Store Pifeltro at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F).

Pifeltro is manufactured and distributed by Merck and Co.

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Hepatol. 2018 Sep 25. pii: S0168-8278(18)32392-4. doi: 10.1016/j.jhep.2018.09.018.

Real-world effectiveness of daclatasvir plus sofosbuvir and velpatasvir/sofosbuvir in hepatitis C genotype 2 and 3.

Belperio PS, Shahoumian TA, Loomis TP, et al.

BACKGROUND & AIM: Understanding the real-world effectiveness of all-oral hepatitis C virus (HCV) regimens informs treatment decisions. We evaluated the effectiveness of daclatasvir+sofosbuvir±ribavirin (DCV+SOF±RBV) and velpatasvir/sofosbuvir (VEL/SOF)±RBV in genotype 2 and genotype 3 patients treated in routine practice.

METHODS: Observational, intent-to-treat cohort of genotype 2 and genotype 3 patients initiating DCV+SOF±RBV or VEL/SOF±RBV at any Department of Veterans Affairs facility.

RESULTS: For genotype 2, SVR rates did not differ between DCV+SOF (94.5%, 241/255) and VEL/SOF (94.4%, 2105/2230) (p=0.94) or between DCV+SOF+RBV (88.1%, 37/42) and VEL/SOF+RBV (89.5%, 221/247)(p=1.00). For genotype 3, SVR rates did not differ between DCV+SOF (90.8%, 366/403) and VEL/SOF (92.0%, 1203/1307) (p=0.50) or between DCV+SOF+RBV (88.1%, 430/488) and VEL/SOF+RBV (86.4%, 370/428) (p=0.51). In multivariate models for genotype 2 and 3 patients, treatment regimen was not a significant predictor of odds of SVR. For genotype 3, significant predictors of reduced odds of SVR were prior HCV treatment-experience (odds ratio (OR) 0.51, 95% confidence interval (CI) 0.36-0.72, p<0.001), FIB-4 >3.25 (OR 0.60, 95%CI 0.43-0.84, p=0.002) and a history of decompensated liver disease (OR 0.68, 95%CI 0.47-0.98, p=0.04). For genotype 2 and 3 patients treated with VEL/SOF±RBV, 89% and 85% received 12-week durations, respectively. For DCV+SOF±RBV, 56% and 20% of genotype 2 patients received 12-weeks and 24-weeks, respectively; for genotype 3, 53% and 23% received 12-week and 24-week durations with most direct-acting antiviral experienced patients receiving 24-weeks.

CONCLUSIONS: In genotype 2 and 3 HCV-infected patients, DCV+SOF±RBV and VEL/SOF±RBV produced similar SVR rates within genotype, and regimen did not have a significant impact on odds of SVR. For genotype 3 patients, prior treatment-experience and advanced liver disease were significant predictors of reduced odds of SVR regardless of regimen.

LAY SUMMARY: In clinical practice, cure rates for genotype 2 HCV were 94% and cure rates for genotype 3 HCV were 90%. The chance of achieving cure was the same whether a person received daclatasvir plus sofosbuvir or velpatasvir/sofosbuvir. Ribavirin did not affect cure rates. The chance of a cure was lowest in people who had received HCV medication in the past.

AIDS Res Hum Retroviruses. 2018 Oct 3. doi: 10.1089/AID.2018.0150.

Effect of testosterone use on bone mineral density in HIV-infected men.

Grant PM, Li Z, Jacobson L, et al.

BACKGROUND: HIV-infected men have increased rates of osteoporosis and fracture compared to HIV-uninfected men. Testosterone use among HIV-infected men is common. In HIV-uninfected men, testosterone increases bone mineral density (BMD), but its effects have not been evaluated in HIV-infected men.

METHODS: In a substudy of Multicenter AIDS Cohort Study (MACS), the Bone Strength Substudy (BOSS) enrolled 202 HIV-infected and 201 HIV-uninfected men age 50 and 69 years. Study participants underwent dual-energy x-ray absorptiometry (DXA) at the lumbar spine (LS), total hip (TH), and femoral neck (FN), and detailed assessment of osteoporosis risk factors. We used multivariable linear regression to determine associations and 95% confidence intervals (CI) between self-reported testosterone use and T-scores at the LS, TH, and FN after adjustment for demographics, behavioral covariates, comorbidities, and other traditional osteoporosis risk factors.

RESULTS: HIV-infected men reported more frequent testosterone use (22% vs. 4%; p<0.001) and had lower median BMD T-score at TH than HIV-uninfected men (0.0 vs. 0.3; p=0.045) but similar T-scores at LS and FN. In the overall study population,

continues on page 30

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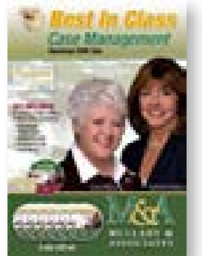

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Advancing Best in Class Case Management

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testosterone use was associated with significantly greater BMD T-score at LS (0.68; 95% CI: 0.22,1.13). In HIV-infected men with virologic suppression, testosterone was significantly associated with higher BMD T-score at LS (0.95; 95% CI: 0.36, 1.54) and TH (0.45; 95% CI: 0.04, 0.86).

CONCLUSIONS: Current testosterone use is common in HIV-infected men and was associated with higher BMD, compared to those not taking testost

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J Acquire Immune Defic Syndr. 2018 Sep 24. doi: 10.1097/QAI.0000000000001872.

Internal working models of attachment relationships and HIV outcomes among women living with HIV.

Turan B, Crockett KB, Kempf MC, et al.

BACKGROUND: Treatment adherence and viral suppression remain sub-optimal in the US. Attachment insecurity may be one understudied factor affecting adherence. According to attachment theory, people develop generalized internal working models of interpersonal relationships, which shape their perceptions of the availability of others at times of stress and how they handle stressors as an individual. Two dimensions of attachment insecurity are attachment-related avoidance (avoidance of intimacy with others and avoidance of negative emotions) and attachment-related anxiety (feeling unable to deal with stressors without others' help). For people living with chronic stressful health conditions that require life-long self-management, attachment-related avoidance and attachment-related anxiety may diminish the ability to cope with stressors as an individual leading to negative health outcomes.

METHODS: We examined cross-sectional associations of the two attachment-related insecurity dimensions with ART adherence, HIV visit adherence, CD4 cell counts, and viral suppression. Survey and clinical data from 453 women living with HIV in four US cities were analyzed controlling for age, education, income, time on ART, illicit drug use, and race.

RESULTS: Attachment-related avoidance was the only unique predictor of sub-optimal ART adherence, viral failure, and low CD4 count, and attachment-related anxiety was the only unique predictor of missed HIV care visits. These effects were over and above the effects of all covariates. ART adherence mediated the association of attachment-related avoidance with both viral failure and low CD4 counts.

CONCLUSIONS: Interventions may need to focus on the vulnerable sub-population with high attachment insecurity and incorporate existing strategies that address insecure attachment models.

Clin Lung Cancer. 2018 Sep 8. pii: S1525-7304(18)30235-3. doi: 10.1016/j.cllc.2018.09.002.

Predictors of distant failure after stereotactic body radiation therapy for stages I to IIA non-small-cell lung cancer.

Miller CJ, Martin B, Stang K, et al.

PURPOSE: The use of stereotactic body radiation therapy (SBRT) has emerged as an effective treatment modality for patients with early-stage non-small-cell lung cancer (NSCLC), with excellent local control rates. Despite this, there is a predominant pattern of distant failure. We sought to identify factors that help predict which patients with stages I to IIA NSCLC treated with SBRT are at highest risk of distant failure, so that we may utilize these factors in the future to help determine which patients may benefit from the addition of systemic therapies.

PATIENTS AND METHODS: We retrospectively reviewed 292 patients treated with SBRT for early stage NSCLC from 2006 to 2016 at 2 institutions. Patients were classified by T stage, tumor size, location and histology, pretreatment positron emission tomography/computed tomography (PET/CT) standardized uptake value (SUV), smoking status, and age. The primary endpoint of the study was distant failure. We aimed to analyze if patient characteristics could be identified that predicted for distant failure through the use of competing risk analysis.

RESULTS: The median follow-up was 21.9 months. The median dose of radiation and fractionation delivered was 50 Gy (range, 45-65 Gy) in 5 fractions (range, 3-13 fractions). The median patient age was 72.8 years (interquartile range, 65.4-79.7 years). The 2-year distant failure was 22.0%, and overall survival at 2 years was found to be 61.0%. For every 1-year increase in patient age, the hazard of distant failure at any given time was 3% lower (hazard ratio, 0.97; 95% confidence interval, 0.94-0.99; P = .04). None of the remaining characteristics emerged as significant risk factors for distant failure on univariable or multivariable analysis.

CONCLUSIONS: Overall, our cohort had distant failure and survival rates comparable with what has been described in the literature. Although we were unable to identify factors outside of age that correlated to risk of distant failure, this topic warrants further investigation, as distant failure is the primary pattern of failure with SBRT when used as the primary management for early-stage

NSCLC. Additional molecular studies are needed to further inform on the role of systemic therapy in patients with early-stage NSCLC to improve clinical outcomes.

Gastroenterology. 2018 Sep 26. pii: S0016-5085(18)35041-8. doi: 10.1053/j.gastro.2018.09.045.

Race/ethnicity-, socioeconomic status-, and anatomic subsite-specific risks for gastric cancer

Gupta S, Tao L, Murphy JD, et al.

Anatomic-subsite risk factors for gastric cancer differ substantially, and subsite-specific distribution of risk factors (such as *Helicobacter pylori*) may vary by race/ethnicity and neighborhood socioeconomic status (nSES). We examined differences in gastric cancer incidence by subsite, stratified by race/ethnicity and nSES utilizing Surveillance Epidemiology and End Results Program 2000-2014 data for 77,881 incident gastric cancer cases (n=23,651 cardia, n=35,825 non-cardia; n=18,405 overlapping/unspecified). Compared to non-Hispanic whites (NHWs), cardia cancer multivariable-adjusted incidence rate ratios (aIRRs) were 35 to 47% lower for Blacks, Hispanics, Asian/Pacific Islanders (API) and American Indian/Alaska Natives (AI); conversely, non-cardia IRRs were 1.7 to 3.9-fold higher for Blacks, Hispanics, APIs, and AIs. Higher aIRRs with decreasing nSES (lowest vs. highest nSES quintile) were observed for all gastric (1.3-fold), and non-cardia (1.3-fold), but borderline significant for cardia (1.1-fold) cancers. Non-cardia cancer incidence is higher among minorities and varies by nSES, but cardia cancer incidence is higher among NHWs and does not vary substantially by nSES. Clarifying reasons for higher cardia risk in NHWs, and targeted interventions to address non-cardia cancer risk in minorities, may reduce burden of gastric cancer.

Dig Sis Sci. 2018 Sep 27. doi: 10.1007/s10620-018-5283-1.

Eight-week hepatitis C treatment with new direct acting antivirals has a better safety profile while being effective in the treatment-naïve geriatric population without liver cirrhosis and hepatitis C virus-RNA<6 million IU/mL.

Yanny B, Saab S, Durazo F, et al.

AIM: Results of recent studies have confirmed the efficacy of an 8-week course of ledipasvir/sofosbuvir (LDV/SOF) in patients who are non-cirrhotics, native to treatment, are infected with hepatitis C (HCV) genotype 1, and have HCV viral load <6 million IU/mL. However, there are limited data on a shortened treatment course in patients who are over the age of 65.

METHODS: A retrospective study was performed to examine the safety, tolerability, and sustained viral response rates (SVR) of the 8-week LDV/SOF therapy compared to the 12-week LDV/SOF therapy among non-cirrhotic, treatment-naïve, genotype 1 HCV patients with viral load <6 million IU/mL who are 65 years of age or older.

RESULTS: A total of 454 patients were identified of which 182 non-cirrhotic, genotype 1 HCV-RNA<6 million IU/mL patients received the 8-week LDV/SOF treatment and 272 received the 12-week LDV/SOF treatment. Mean [± standard deviation (SD)] aspartate aminotransferase to platelet ratio index score for the entire cohort was 0.45 ± 0.03. The mean (± SD) age for the 8-week treatment was 69.7 (± 7) years, 54.7% male and 45.3% female. The mean (± SD) age of the 12-week treatment was 71.7 (± 3) years, 56.4% male and 43.6% female. Overall, SVR-12 for the 8-week regimen was 93% and SVR-12 for the 12-week regimen was 95%. For the 182 treated with the 8-week LDV/SOF treatment, there were no serious adverse events requiring hospitalization or signs of liver failure requiring transplantation. Overall, the 8-week treatment patient cohort experienced less fatigue, headache, dry mouth, and diarrhea. This finding was statistically significant with a P value<0.001.

CONCLUSION: Eight-week LDV/SOF therapy in treatment-naive, non-cirrhotic, genotype 1 HCV patients with RNA<6 million IU/mL was found safe, better tolerated, effective, and required less upfront cost when compared with the 12-week LDV/SOF treatment regimen in properly selected geriatric population.

J ASAIO J. 2018 Sep 28. doi: 10.1097/MAT.0000000000000877.

Clinical outcomes of impella microaxial devices used to salvage cardiogenic shock as a bridge to durable circulatory support or cardiac transplantation.

Cheng R, Tank R, Ramzy D, et al.

Temporary mechanical circulatory support (MCS) can be a bridge to decision for patients in severe cardiogenic shock who may be eligible for durable support or transplantation. Outcomes with Impella microaxial devices for salvage of severe shock in the end-stage heart failure population are not well described. Patients who underwent Impella placement as a bridge to decision, durable MCS, or transplantation were included. Eighty Impella devices (2.5 [1.3%], CP [53.8%], and 5.0 [45.0%]) were placed in 64 patients. Implant age was 56.2 ± 12.5 years. Mean duration of

assisted support was 13.2 ± 15.1 days, and median duration per device was 7 days (interquartile range: 3-14). A total of 48.4% were in Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS 1) shock at implant, 51.6% in profile 2. Recent CPR (26.7%), ventilator use (67.2%), and extracorporeal membrane oxygenation (ECMO) use (26.7%) were frequent. Forty four of sixty four (68.8%) survived to next therapy: durable MCS (40.9%), OHT (36.4%), and recovery (22.7%). Overall 30 and 60 day survival were 67.2% and 65.6%, respectively. Thirty and 60 day survival conditional on having survived to next therapy were 94.1% and 91.2%, respectively. Survivors were less likely to be on ventilators (p = 0.049) or continuous renal replacement therapy (p < 0.001) but were otherwise not different from nonsurvivors by age, sex, INTERMACS profile, CPR, prevalence of ischemic cardiomyopathy, among other characteristics. Sixteen patients were directly bridged to heart transplantation, and all were alive at long-term follow-up. Impella devices can be used to salvage patients in severe heart failure as a bridge to decision, durable MCS, or transplantation. Baseline demographics are not predictive of survival. Their use for this indication is increasing and further investigations are warranted.

Diabetes Care. 2018 Aug;41(8):1646-1653.
doi: 10.2337/dc18-0277.

Diabetes and trajectories of estimated glomerular filtration rate: a prospective cohort analysis of the atherosclerosis risk in communities study.

Warrem B. Rebholz CM, Sang Y, et al.

OBJECTIVE: To characterize long-term kidney disease trajectories in persons with and without diabetes in a general population.

RESEARCH DESIGN AND METHODS: We classified 15,517 participants in the community-based Atherosclerosis Risk in Communities (ARIC) study by diabetes status at baseline (1987-1989; no diabetes, undiagnosed diabetes, and diagnosed diabetes). We used linear mixed models with random intercepts and slopes to quantify estimated glomerular filtration rate (eGFR) trajectories at four visits over 26 years.

RESULTS: Adjusted mean eGFR decline over the full study period among participants without diabetes was -1.4 mL/min/1.73 m^2/year (95% CI -1.5 to -1.4), with undiagnosed diabetes was -1.8 mL/min/1.73 m^2/year (95% CI -2.0 to -1.7) (difference vs. no diabetes, P < 0.001), and with diagnosed diabetes was -2.5 mL/min/1.73 m^2/year (95% CI -2.6 to -2.4) (difference vs. no diabetes, P < 0.001). Among participants with diagnosed diabetes, risk factors for steeper eGFR decline included African American race, APOL1 high-risk genotype, systolic blood pressure ≥140 mm Hg, insulin use, and higher HbA1c.

CONCLUSIONS: Diabetes is an important risk factor for kidney function decline. Those with diagnosed diabetes declined almost twice as rapidly as those without diabetes. Among people with diagnosed diabetes, steeper declines were seen in those with modifiable risk factors, including hypertension and glycemic control, suggesting areas for continued targeting in kidney disease prevention.

Clin Rheumatol. 2018 Oct 2. doi: 10.1007/s10067-018-4314-9.

Chronic lung disease in U.S. veterans with rheumatoid arthritis and the impact on survival.

England BR, Sayles H, Michaud K, et al.

Assess the impact of chronic lung diseases (CLD) on survival in rheumatoid arthritis (RA). Among participants in the Veterans Affairs Rheumatoid Arthritis (VARA) Registry, a prospective cohort of U.S. Veterans with RA, we identified CLD and cardiovascular disease (CVD) using administrative and registry data. Demographics, smoking status, RA characteristics including Disease Activity Score in 28 joints (DAS28), and disease-modifying anti-rheumatic drug (DMARD) use were obtained from registry data, which were linked to the National Death Index to obtain vital status. We evaluated associations of CLD with survival using the multivariable Cox regression models. Among a large (n = 2053), male-predominant (91%) RA cohort, 554 (27%) had CLD at enrollment. Mortality risk was increased 1.51-fold (95% CI 1.26-1.81) in RA patients with CLD after multivariable adjustment, a risk that was similar to that observed with CVD (HR CLD alone 1.46 [1.03-2.06]; CVD alone 1.62 [1.35-1.94]). Survival was significantly reduced in those with interstitial lung disease (ILD) as well as other forms of CLD. Mortality risk with methotrexate and biologic use was not different in those with CLD compared to those without (p interaction ≥ 0.15) using multiple exposure definitions and propensity score adjustment. Mortality risk is significantly increased in RA patients with CLD. This risk is attributable not only to ILD but also to other chronic lung conditions and does not appear to be substantially greater in those receiving methotrexate or biologic therapies. Comorbid lung disease should be targeted as a means of improving long-term outcomes in RA.

Where Do We Stand on Government Expansion of Medicare-Like Health Insurance?

Although movement/discussion of any of the plans outlined below is unlikely before the end of the current session of Congress, according to Kaiser Health News, these are some of the proposals at hand currently:

- Two proposals would create Medicare-For-All, a single national health insurance program for all US residents (Senator Sanders, S. 1804; Rep. Ellison, H.R. 676)
- Three proposals would create a new public plan option, based on Medicare, that would be offered to individuals and some or all employers through the Affordable Care Act (ACA) marketplace (Rep. Schakowsky, H.R. 635/Sen. Whitehouse, S.194; Sen. Bennett, S. 1970/Rep. Higgins, H.R. 4094; Sen. Merkley, S. 2708/Rep. Richmond, H.R. 6117)
- Two proposals would create a Medicare buy-in option for older individuals not yet eligible for the current Medicare program (Sen. Stabenow, S. 1742; Rep. Higgins, H.R. 3748); and
- One proposal would create a Medicaid buy-in option that states can elect to offer to individuals through the ACA marketplace. (Sen Schatz S. 2001 and Rep. Lujan, H.R. 4129)

More information can be found through Kaiser's new issue brief. ■

Gawande Working With Deloitte's Monitor on Amazon Health Venture

Casey Ross at *Stat* reported this week that the still-unnamed Amazon health venture led by Atul Gawande is working with the Monitor Group to devise better ways of managing the care of people with chronic illnesses.

Monitor is part of Deloitte and provides strategic business advice. It's not immediately clear how it will help Gawande run the Amazon venture or implement its programs. The Monitor Group does have some health care in its DNA. It was cofounded by Michael Porter, whose 2006 book *Redefining Health Care* (cowritten with Elizabeth Olmsted Teisberg) helped usher value-based care ideas into this world.

It doesn't seem like Gawande and Amazon are going to shock and awe the American health care system the way some anticipated when the first rumblings about an Amazon-led health venture were heard earlier this year. But the hiring watch continues. ■

Oncology Care Model Practices Face Uphill Battle for Performance Payments

Of the 179 practices that have volunteered to participate in Centers for Medicare & Medicaid Services (CMS) bundled payment program, many will have difficulty earning CMS's performance payments because actual costs of treating patients with acute leukemia and myelodysplastic syndromes as well as lung, liver, pancreatic, gastric, kidney, hand and neck, melanoma, myeloma, central nervous system, ovary, and intestinal cancers exceeded the Oncology Care Model predicted costs. ■

Salary for Case Managers in the United States

How much does a case manager earn in the United States? According to the website Salary.com, the average salary for a case manager in the United States was $77,015 as of September 28, 2018, but the range typically falls between $70,391 and $84,355. Salary ranges vary widely depending on level of education, certifications, additional skills, and number of years in the profession. ■

Kaiser Health News Forum Exposes Medical Overtreatment

During Kaiser Health News' forum in late September, physician participants estimated that 21% of medical care is unnecessary and costs the health care system at least $210 billion a year. It's not only expensive but can harm patients. View forum highlights here. ■

Drug Prices Still on the Rise

Brand-name drug prices are still rising this year. Using data from Elsevier, an investigation by reporters for the AP (Associated Press) found that prices of 4,412 drugs went up this year while the prices of only 46 drugs went down. As AP noted, that works out to a 96-to-1 ratio. The analysis was limited to January through July because of the seasonality of pharma price changes and to make year-to-year comparisons easier. There was some moderation in the size of the price increase. This year, the median price increase was 5.2%. Last year, it was 8%. ■

Sheltering Patients in Need of Health Care

UnitedHealthcare Community Plan (UHCCP)—Arizona is a managed care Medicaid plan that has developed a new plan of care for serving low-income individuals and families who live far from needed health care facilities or are homeless. Instead of paying for services such as emergency helicopter rides to a health care facility, the insurer has paired with a local nonprofit agency that serves low-income families to find housing near a health care facility for families who need ongoing care. It has also partnered with organizations to help homeless people, providing housing and support to address challenges such as substance abuse. An array of support is available to these families. Housing is near bus lines and community centers where participants can access behavioral health services, a GED program, a Dress for Success site, a job-readiness program, an HIV/AIDS prevention program, and a Women, Infants, & Children's (WIC) office. In the first year of its program, UHCCP realized a 58% reduction in total health care spending for patients who were provided housing compared with the costs when they were homeless. ■

Targeted Therapy Can Prevent Type 2 Diabetes in Those at High Risk

According to a retrospective observational study of people at increased risk for type 2 diabetes, published in *Lancet Diabetes Endocrinology*, stratifying patients according to severity of insulin resistance, impaired beta-cell function, and glycemia and then targeting appropriate therapy for each stratification level was able to reduce progression to type 2 diabetes. Treatments offered were:

1. Metformin, pioglitazone, glucagon-like peptide-1 receptor agonist (GLP-1RA), and lifestyle therapy for the highest-risk patients
2. Metformin, pioglitazone, and lifestyle therapy for intermediate-risk patients
3. Lifestyle therapy only for those refusing pharmacologic treatment (both high and intermediate risk)

After 32 months of follow-up, the annual incidence of type 2 diabetes was 4.1% with lifestyle only, 1.7% with metformin/pioglitazone, and 0% for metformin/pioglitazone/GLP-1RA. ■

Centers for Disease Control and Prevention:

Fluoroquinolone-Resistant *Shigella* on the Rise in the United States

The Centers for Disease Control and Prevention (CDC) has warned clinicians that it continues to observe *Shigella* isolates with elevated minimum inhibitory concentration (MIC) values for ciprofloxacin, and it is concerned about clinical treatment failures. The number of isolates with elevated azithromycin MICs are also increasing. The CDC suggests that health care providers consider referring patients with *Shigella* needing antibiotic therapy to an infectious disease specialist; they might be harboring 1 or more resistant isolates requiring alternative treatments. Submit stool samples to a clinical microbiology laboratory for additional antimicrobial susceptibility testing. Monitor patients receiving antibiotic therapy carefully. ■

Delivering Culturally Sensitive Home Visits

In a new program in New York City, EmblemHealth and the Coalition of Asian American IPA, the city's largest independent physician association, launched an initiative late last year to make culturally sensitive house calls by health care providers who can speak a homebound patient's language. The goal is to learn about the patient's overall situation, including physical condition, behavioral health needs, and medication use. In the first 6 months of the program, 40% of patients who received in-home assessments were identified as needing additional support. Twenty-five percent of them were referred for case management. A full 97% of those who agreed to participate indicated satisfaction with the program. ■

American Academy of Pediatrics: Children Should Have Flu Shot, Not Nasal Spray

Despite some changes to the quadrivalent live attenuated influenza vaccine (LAIV4) to boost effectiveness, the American Academy of Pediatrics (AAP) advises that children receive inactivated vaccine this coming season. All children aged 6 months or older should be vaccinated when not contraindicated. Intranasally administered LAIV4 has been a popular choice for children because it avoids an injection. But the AAP recommends that children should still receive the shot with inactivated virus. The spray is specifically not recommended for children with certain chronic medical conditions or for those who are younger than age 2. ■

Preparing a Ready Workforce of Certified Case Managers: Upcoming Certification 360 Workshop Scheduled *continued from page 4*

certification. However, registration and attendance at this workshop session does not, in any way, guarantee that the eligibility requirements will be met, the application will be approved, or that a candidate will pass the examination. This course is not required for potential candidates who are interested in taking the examination.

CCMC is pleased to note that continuing education (CE) credit for this program is awarded by Commonwealth Educational Seminars (CES) for the following professions:

Nurses: Programs from CES, an American Psychological Association-approved provider, are accepted by the American Nurses Credentialing Center (ANCC). Every state Board of Nursing accepts ANCC-approved programs except California and Iowa; however, CES is also an approved CE provider by the California Board of Registered Nursing (Provider Number CEP15567), which is also accepted by the Iowa Board of Nursing. Nurses completing this program receive 14.0 CE hours of credit.

CCMs: Board-certified case managers attending this program (must be present for the full 2 days) will receive 14 CE Contact Hours from CCMC.

More than ever, a diverse workforce must be developed to meet the needs of a diverse population. CCMC is putting special emphasis this year on our research-based examination development to ensure that it reflects current practice, and we are also focusing on expanding learning tools and resources that advance the evolution of case management. We encourage case managers to take advantage of programs that enhance their knowledge and help keep them relevant in the evolving world of health and human services. CM

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US Suicide Rates Show Striking Increase

A CDC report shows significantly rising suicide rates between 1999 and 2016 in 44 states. Twenty-five states experienced increases of greater than 30%. Suicide is the 10th leading cause of death in the United States and 1 of only 3 leading causes of death on the increase. The report identified circumstances that may lead to suicidal acts, including relationship issues and substance use or health, job, or financial problems. Most suicides occurred in individuals with no known mental health conditions. ■

Medication Reconciliation May Improve Outcomes of Patients with Diabetes Mellitus

A retrospective analysis funded by the Patient-Centered Outcomes Research Institute (PCORI) included 31,689 adults taking 1 or more diabetes medication in primary care during 2000-2014. The composite primary outcome was combined emergency department visit frequency and hospitalizations over the subsequent 6 months. Among 261,765 6-month reconciliation assessment periods, 67.3%, 10.6%, and 22.1% periods had all, some, and no diabetes medications reconciled, respectively. Patients with all, some, or no diabetes medications reconciled had a mean of 0.354, 0.377, and 0.384 composite primary outcome events, respectively ($P < .0001$). In multivariable analysis, compared with no diabetes medications reconciled, rate ratios for primary outcome events were 0.94 ($P = .0046$) and 0.92 ($P < .0001$) for patients with some and all diabetes medications reconciled, respectively. In multivariable analysis, individual provider feedback was associated with greater likelihood of reconciliation of all diabetes medications (odds ratio, 2.63; $P < .0001$). A limitation of the study is that retrospective analysis cannot establish causation. ■

Advisory Committee on Immunization Practices Includes LAIV4 in 2018–2019 Influenza Vaccination Recommendations

Because overall influenza vaccination coverage in US children (aged 2–17 years) remains suboptimal, the Advisory Committee on Immunization Practices (ACIP) is including Quadrivalent Live Attenuated Influenza Vaccine (LAIV4) as an option for the 2018–2019 season. Data demonstrate that LAIV4 effectiveness against A(H1N1)pdma09-like virus A/Slovenia/2903/2015 is significantly higher than for its predecessor A/Bolivia/559/2013, with seroconversion rates in children comparable with those obtained in response to prepandemic influenza H1N1 LAIV strains. For the 2018–2019 season, clinicians can choose any licensed, age-appropriate vaccine (inactivated influenza vaccine [IIV], recombinant influenza vaccine, LAIV4). ■

Case Management: Celebrating Success *continued from page 8*

our practice allows our professional practice to consider different perspectives, change mental models, and build generative knowledge. This is critically important because case managers work with diverse at-risk and vulnerable populations. Case managers are critical to the success of health care organizations that are attempting to improve the health of the populations they serve. The role of the case manager is needed to deploy effective population health strategies and interventions as our health care delivery system continues to consolidate across the horizontal continuum. The practice of case management has seen an increase in various titles that now include care coordinator, navigator, and population health coordinator. The title may change, but the core competencies of case management do not and remain in the realm of advanced practice.

Case Management Development Programs

The increasing need of case management professionals will continue as health care organizations become more complex. Health care professionals who want to enter the field of case management have often complained that employers hiring case managers only want those with experience. Health care organizations that hire individuals with limited to no case management experience often feel that they lose those they train to other organizations who are willing to pay more for those with experience. Professional case management development programs are needed to produce enough case managers to meet the needed demand. Case managers from academic medical centers and insurance plans are highly coveted because there is an assumption that they have lower compensation. Finally, every health care organization has differing variables that must be incorporated into their development programs that outside educational opportunities do not address. The fear of losing case managers to other organizations should not be a reason not to have development programs.

Case management practice inclusivity and establishing development and leadership programs will allow a healthcare organization to improve experience, staff engagement, and care progression collaboration. Case management roles and responsibilities often depend on organizational size and practice type. Networking with other case management leaders and practicing case managers through the Case Management Society of America is an opportunity to share evidence-based practices from all practice settings throughout the health care continuum. Don't reinvent the wheel when you can learn from your case management colleagues!! CM

Lifelong Education—A Building Block to Personal and Professional Success *continued from page 13*

Many Ways to Learn

Lifelong learning for case managers is now supported by a myriad of ways to access information. In addition to the wide range of CE courses as well as CCM workshops and seminars sponsored by many dedicated case management education/training firms and professional associations, many long-distance learning programs and materials are available. These on-demand, 24/7 learning tools are ideal for case managers whose professional and/or personal schedules make attending seminars and courses difficult. They are also great employee motivation and team-building tools for employers to use for group learning programs. Formats from online interactive case management courses to seminars on DVDs and home study courses are now readily available to individuals or organizations looking to encourage their staff members' continuous learning. Using educational programs and materials from a variety of sources provides the most comprehensive learning experience, reflecting valuable diverse content and perspectives.

Case management department heads and other individuals who make decisions about their case managers' education should take note that professional development is important to your staff. In fact, many case managers, especially the younger generation professionals who are still building their careers, look to their employers for training and development support. They evaluate future employers based on the organization's culture with respect to employee engagement and empowerment. Failure to engage staff with learning programs often leads to higher turnover rates and the associated costs.

Ultimately, lifelong learning is an individual responsibility that every case manager should embrace. It is an investment in one's professional and personal growth and the highest standard of patient care. CM

CARF New 2019 Technology Standards *continued from page 12*

- Access management
- Audit capabilities
- Data export and transfer capabilities
- Decommissioning of physical hardware and data destruction
- Protection from malicious activity
- Remote access and support
- Updates, configuration management, and change control.

In the manual itself the group that developed the standards has been of great assistance in developing examples in all areas of the standards. Technology is no longer for the "IT guy"; it is for everyone in the organization, no matter how small or large.

Of course, testing of systems for business continuity/disaster recovery are conducted at least annually and analyzed for necessary improvement.

With technology also comes the need for your workforce to be trained and competent in areas such as cybersecurity and the use of any technology they may have to perform their job duties.

If you believe that technology is an area where you need resources to better understand and/or implement technology plans, here are a few we would suggest:

—International Organization for Standardization—ISO/IEC 27000 family—Information security management systems: www.iso.org/isoiec-27001-information-security.html

—Healthcare Information and Management Systems Society: www.himss.org/library/healthcare-privacy-security

—National Institute of Standards and Technology (NIST): https://csrc.nist.gov/publications/sp

—SysAdmin, Audit, Network, Security (SANS) Institute Information Security Templates: www.sans.org/security-resources/policies

—National Cybersecurity & Communications Integration Center (NCCIC): www.dhs.gov/national-cybersecurity-and-communications-integration-center

—U.S. Department of Health and Human Services CyberSecurity Awareness Training document (PDF): www.hhs.gov/sites/default/files/fy18-cybersecurityawarenesstraining.pdf

—Cyber Security Incident Response Guide (PDF): www.crest-approved.org/wp-content/uploads/2014/11/CSIR-Procurement-Guide.pdf CM

Palliative Care: Avoiding Anti-Kickback Issues *continued from page 10*

> any good, facility, service, or item for which payment may be made in whole or in part under this subchapter,

shall be fined not more than $25,000 or imprisoned for not more than five years, or both...

Based on the above statute, the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services, the primary enforcer of fraud and abuse prohibitions, announced that effective on December 7, 2016 the limits on free items and services given to beneficiaries were increased. Specifically, according to the OIG, items and services of nominal value may be given to patients or potential patients if they have a retail value of no more than $15 per item or $75 in the aggregate per patient on an annual basis. The previous limits were $10 per item or $50 in the aggregate per patient on an annual basis.

Under section 1128A(a)(5) of the Social Security Act, persons who offer or transfer to Medicare and/or Medicaid beneficiaries any remuneration that they know or should know is likely to influence beneficiaries' selection of particular providers or suppliers of items or services payable by the Medicare or Medicaid programs may be liable for civil money penalties for up to $10,000 for each wrongful act. "Remuneration" includes waivers of copayments and deductibles and transfers of items or services for free or for other than fair market value.

Consequently, the provision of free palliative services to palliative care patients is generally limited as described above. The OIG has, however, identified free services that may be provided even though they exceed the above limits. If applicable criteria are met, providers may, for example, provide free transportation to patients who participate in their palliative care programs. There are other exceptions that may also apply to palliative care programs.

There are limits on the free services that providers can give to patients in need of palliative care. Providers must carefully review the limits on free services when they develop models of palliative care. CM

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