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By Thomas Brewer, PhD; Shannon DeBra, Esq.; Laura Kukral, MBA, LNHA
Implicit and explicit in the discharge planning process has been the idea that patient freedom of choice must be protected. So has anything changed?

30 Cultural Competence and the Lesbian, Gay, Bisexual, Transgender and Queer (LGBTQ) Patient  
By Chikita Brown Mann, MSN, RN, CCM
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Case Management of Lesbian, Gay, Bisexual, Transgender and Queer (LGBTQ) People

Have you had a LGBTQ person in your case load? Would you know if you did? Perhaps not unless the individual disclosed to you or you had obtained such information from the patient’s history. The LGBTQ community is diverse. LGBTQ represents a wide range of people of different races, ethnicities, ages, socioeconomic status, and identities. What binds them together as social and gender minorities are common experiences of stigma and discrimination, the struggle of living at the intersection of many cultural backgrounds and trying to be a part of each, and specifically with respect to health care, a long history of discrimination and lack of awareness of health needs by health professionals. As a result, LGBT people face a common set of challenges in accessing culturally competent services and achieving the highest possible level of health. As a case manager, you have an important role to ensure that happens.

Sexual orientation consists of three components: identity, behavior, and desire. These components may not be congruent in each individual.

It is difficult to define the size and distribution of the LGBTQ community. Recent multiple population-based studies suggest that approximately 3.5% of the population are lesbian, gay, or bisexual, and 0.3% of adults are transgender. This translates to over 9 million people in the United States.

Why is LGBTQ health care important? There is a long history of anti-LGBTQ bias in health care that shapes the behavior and access to health care for LGBTQ individuals even as social acceptance increases. Although there are no LGBTQ-specific diseases, clinicians and case managers must be informed of the health disparities that affect members of these communities. These disparities stem from structural and legal factors, social discrimination, and lack of competent cultural health care.

How can you start to address the health care needs of your patients? Create a welcoming environment. LGBTQ individuals notice subtle nuances of acceptance such as wording on forms, greetings, and how they are referred to. Become educated about LGBTQ health. Know your resources. Seek out knowledge. Identify and resolve your own biases.

I recommend to you “Cultural Competency and the Lesbian, Gay, Bisexual, Transgender and Queer (LGBTQ) Patient” by Chikita Brown Mann, MSN, RN, CCM, which is published in this issue of CareManagement.

Your success depends upon providing high-value care to patients that optimizes quality and clinical effectiveness while remaining cost effective and efficient. In the case of LGBTQ people, we must end LGBTQ invisibility in health care by identifying the sexual orientation and gender of our patients and then use this information continues on page 46
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Case Management Society of America (CMSA) Issues Revised Standards of Practice: Philosophy and Guiding Principles

By Elizabeth Hogue, Esq.

The Case Management Society of America (CMSA) has issued revised Standards of Practice for Case Management. The Standards were first published in 1995 and were revised in 2002 and again in 2010. The general purpose of the Standards is to identify important knowledge and skills for case managers, regardless of practice setting. CMSA decided to revise the Standards again this year in order to emphasize the professional nature of the practice and role of case managers as an integral and necessary component of the health care delivery system. These standards likely apply to all case managers, regardless of practice setting or whether they are certified.

Recent revisions to CMSA’s standards state that the philosophy of case management is based on the following:

• When individuals reach their optimum levels of wellness and functional capability, everyone benefits, including clients, clients’ families and caregivers, the health care delivery system, payors, employers and consumer advocates.
• Professional case managers work to achieve the wellness and autonomy of their clients through advocacy, ongoing communication, health education, identification of resources for services and facilitation of services.
• Professional case management services are likely to be more effective if they include engagement with clients and direct communication with everyone involved in patients’ care.

The primary changes regarding philosophy, as reflected in the most recent revisions, are an emphasis on case management as a professional discipline and an enhanced emphasis on engagement of and communication with patients and their families. The “bottom line” with regard to the philosophy of case management is realization of the goals of the “Triple Aim,” including improved health outcomes of individuals and populations, enhanced encounters with health care and reductions in the cost of care. According to the revised standards, guiding principles of case management based on the above philosophy include the following:

• Use of a collaborative approach that takes into account clients, culture, preferences, needs, and values
• Facilitation of clients’ self-determination and self-management through advocacy, shared and informed decision making, counseling, and health education
• Use of a comprehensive, holistic, compassionate approach that integrates clients’ medical, behavioral, social, psychological, functional and other needs
• The practice of cultural and linguistic sensitivity
• Identification and implementation of evidence-based care guidelines in the care of clients
• Promotion of client safety
• Integration of behavioral change science and principles
• Facilitation of awareness and use of community supports and resources
• Assistance to ensure safe and manageable navigation through the health care system to enhance timely access to services and successful outcomes
• Pursuit of professional knowledge, excellence and maintenance of excellence
• Promotion of systematic approaches to quality management and improved health outcomes
• Maintenance of compliance with federal, state and local laws and regulations and other applicable standards
• Demonstration of knowledge, skills and competence regarding standards of practice and codes or ethics and professional conduct

A tall order, indeed, especially in view of what may be a chronic lack of available resources. Nonetheless, these revised national standards must direct the practice of case managers in all practice settings.

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A powerful tool in the case manager's toolkit is motivational interviewing. This person-centered communication skill is very effective for gathering information about an individual's health status, as well as his or her emotional, psychosocial, and financial status. But that's not all. Motivational interviewing helps unearth what is helping or hindering the person in achieving his or her desired health goals.

The Commission for Case Manager Certification's Case Management Body of Knowledge® (CMBOK®) defines motivational interviewing as "supportive, empathic, and counseling-like." This style of communication helps patients (also known as "clients," meaning the person receiving case management services) move toward more successful and desirable change. The CMBOK defines motivational interviewing in the follows steps:

- change in lifestyle behavior(s)
- need for counseling, teaching, or consultation for change

Communication that is:

- collaborative and goal-oriented
- partnership that honors client autonomy and builds trust

Interaction to:

- guide clients through targeted behavior change
- recognize clients' need for change and resolving ambivalence

Conversation about:

- help clients make their own health decisions
- encourage clients to recognize own ability to change and act upon it

A fuller understanding of the individual, his/her health status, and current challenges allows the case managers to see what support the person needs in pursuit of desirable and sustainable change, for example, around diet, exercise, self-care, adherence to medications, and follow-up care. (Tahan and Sminkey, 2012)

Just as the case management process is iterative, so motivational interviewing is used frequently in interactions between the case manager and the patient, as progress is made and outcomes are achieved. When setbacks occur, motivational interviewing can help uncover the obstacles, while also tapping into the patient's motivation to get back on track.

So how can case managers engage in motivational interviewing? The process begins with asking open-ended questions, meaning those that cannot be answered simply by "yes" or "no." Asking patients about their health goals, their desired outcomes, and the experience of previous setbacks encourages sharing. When people feel heard they are more likely to engage in the process. In addition, people who have a better understanding of their conditions and their choices are more likely to be engaged and make informed decisions. (Harkey et al, 2017)

Through motivational interviewing, case managers get a fuller picture of the "whole person," beyond a particular episode of care. With more complete and accurate information, the case manager can better assess where the individual is and what he/she needs to achieve the desired goals and achieve positive outcomes.

References


Jane Harkey, RN-BC, MSW, CCM, is the Chair of the Commission for Case Manager Certification (CCMC), the first and largest nationally accredited organization that certifies case managers. She is also a geriatric case manager.
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When the Practice of Case Management Was Lost

By Stefani Daniels, MSNA, RN, ACM, CMAC

For over 20 years I have been advocating for the practice of hospital case management as it was originally intended. If you read the literature of the late 1980s, early 1990s, you will understand, as I did, that case management was adopted in the acute care setting to facilitate the patient’s progression of care when the prospective payment system was introduced. By designating the admitting nurse as the nurse case manager, the patient’s acute episode of care was under the oversight of the nurse case manager wherever the patient was cared for in the hospital setting. The original goal—in keeping with the false assumption that lower length of stay (LOS) equated to lower resource costs (see “The Myth of Length of Stay” in HealthLeaders)—was to lower LOS by expediting care, preventing duplicative or excessive interventions, and influencing a timely transition.

It was only when the management engineers were called into the hospitals by frantic execs who were floundering under the new diagnostic-related group (DRG) payment model, that we saw the integration of the utilization review departments and the social work departments to create “functional” case management departments—but, and this is important reminder—the practice of case management as intended was lost.

The publication of To Err is Human in 1999, the Medicare Modernization Act (MMA) of 2003, which announced pay for performance (P4P), the precursor of value-based pricing (VBP), and the Deficit Reduction Act (DRA) of 2005 (which foretold the Recovery Audit Contractors [RACs] and Medicare Administrative Contractors [MACs]) together prompted a focus on outcomes. With these came the redesign of the case management programs in many hospitals...from completing the tasks associated with discharge planning (DCP) and utilization review (UR), to generating objective improvements in clinical and financial outcomes. Around the same time, we saw the Feds growing weary of the failure of the Professional Standards Review Organizations to monitor medical necessity. They restructured the whole process under a Professional Review Organization program that eventually turned into the Quality Improvement Organization program.

It was a combination of these marketplace challenges that told those of us in the C-suite at the time that we better do something to more effectively monitor and manage patient care. That’s when I knew that the functional model of case management just wouldn’t work. Reading Zander’s experiences at New England Medical Center convinced me that case managers must be positioned to work in tandem with the patient’s physician and care team to safely, effectively, and efficiently manage progression of care.

The demands to ensure medical necessary have not gotten easier over time. Indeed, demands have escalated significantly; to consider the expertise needed by a UR specialist as being an ‘add-on’ to the role of the care manager is inadequate and inappropriate. Hospitals must determine and are now financially accountable to make sure that patients accessing acute care services require acute care services. The rules and regulations governing those requirements are staggering. It’s not unusual to encounter clients that have integrated UR activities into the revenue management program under finance. And with a fully automated electronic medical records (EMR) system, centralized UR and even virtual UR models are not uncommon.

At the same time, the risks associated with hospitalization have increased dramatically so that many patients truly need a real-time advocate to avoid excessive, wasteful, duplicative, or potentially harmful medical interventions. And because advocacy is the hospital case managers’ primary ethical obligation, how better to exercise that obligation than to be partnered with the physician and to

continue on page 45
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The Commission for Case Manager Certification (CCMC) held its second annual New World Symposium 2017, January 26–28, 2017, in Dallas, Texas at the Gaylord Texan Resort & Convention Center. Nearly 640 case managers attended the Symposium for education, networking, and visits with resource companies in the Exhibit Hall. The Symposium began as a continuation of CCMC’s Case Management Body of Knowledge® education program and continues to add networking opportunities for case managers with their peers as well as product conversations with industry partners.

Symposium goals and objectives were to:
• Create awareness of the current and future landscape influencing the patient, family, and care provider(s) across the care continuum
• Empower the leadership role of the case manager through education, advocacy, and ethical practice
• Establish a forum for discussion related to outcomes through research and evidence-based practices
• Provide resources, knowledge, and skill development related to the field of case management across all practice settings

“This was my first symposium and will definitely not be the last. Such a great experience and such knowledgeable speakers. I was very impressed.”
• Promote networking with colleagues to establish a more integrated community of health care team members advancing enhanced patient experience, improved population health, smarter spending, and improved work/life balance for health care providers

The Symposium opened with a plenary session on Thursday, January 26, presented by Allison Hickey and titled “Expertise for the Future: Cultural Awareness and Care for Those in Need.”

I have met some fascinating nurses at this symposium and would like to share my knowledge with others. Mentoring is a great way to sponsor growth and development in our organization.

I was happy to meet our CEO and a few commissioners this trip. Keep up the great work.
General sessions on Thursday were “A Rising Tide: Influencing the Next Generation of Case Managers,” presented by Linda Burnes Bolton, DrPh, RN, FAAN, and “Why Measure? Advancing the Value of Case Management,” presented by Peggy E. O’Kane.

Thursday’s closing plenary session featured Jason Kotecki discussing “Escape Adulthood: Living and Working with Less Stress and More Success.”

Sessions on Friday featured a plenary session by Michael Millenson of Health Quality Advisors, LLC, titled, “Will Value-Based Care Increase Your Value?” Benjamin Miller, PsyD, of the University of Colorado Denver School of Medicine presented the general session “Closing the Circle: Integrated Behavioral and Physical Health.” Tammy Richards, RN, MSN, CPXP, of Intermountain Healthcare presented “Ask the Right Questions: Patient...”
Engagement as an Integrated Strategy.” Other Friday topics included entrepreneurship, coordinating coordinators, and high-value care for high-need, high-cost patients.

Catherine Mullahy, RN, BS, CRRN, CCM, signed her latest edition of *The Case Manager’s Handbook* before attendees broke for refreshments and exhibits in the Exhibit Hall.

Saturday’s sessions included topics covering advocacy in the age of consumerism, expert communication, excellence and ethics, and data and analytics in the shift to value-based care. The closing plenary address was presented by Rishi Manchanda, MD, of The Wonderful Company and HealthBegins. His topic was “The Upstream Effect: A New Vision for Health and Whole-Person Care.”

Another great year at the CCMC New World Symposium! We noticed that attendees were all so interested in going from booth to booth to learn about various products and services and it showed us that CCMC puts a real emphasis on collaboration in the healthcare industry.

—Athena Forum Institute
Applying Patient-centered Predictions to Reduce Readmissions

By CareManagement Staff

During the CCMC New World Symposium in January 2017 in Dallas, Texas, Autumn Foy, RN, of Onslow Memorial Hospital (OMH) shared a case study of the facility’s implementation of Jvion’s predictive analytics solutions. The 162-bed hospital in coastal North Carolina wanted to reduce readmissions related to all causes, as well as those related to sepsis and pressure ulcers.

The Potential Impact

**Improved Health & Better Outcomes**
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- Increased Engagement
- Better Intervention Effectiveness
- Decreased Waste
- Increased Patient Satisfaction
- Increased Caregiver Satisfaction

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First, Ms. Foy discussed the working definition of patient-centered predictive analytics. Predictive analytics, she said, is a term that describes “any approach that is designed to make an educated guess about the future.”

Foy explained two of the many approaches to generating predictions to reduce readmissions: one that relies on the aggregation of data and one that relies on machine-learning. The data approach relies on a data warehouse in which disparate data is normalized and advanced statistical models are applied to the data to predict risk. This model, which takes 1 to 2 years to build, requires heavy IT investment, data scientists, statisticians, and testing resources. The machine-learning model relies on artificial intelligence (AI) to predict patient risk. IT involvement is limited, and the timeline for implementation is about 6 to 8 weeks.

At OMH, Jvion’s system moves beyond machine learning to cognitive science that works like a high-performance appliance to deliver recommendations that lead to better interventions, health outcomes, and application of resources. More than a quadrillion dimensions are applied across self-learning Eigen spheres to make accurate predictions and recommendations. The solution can use dirty, incomplete, invisible, and inconsistent data because the machine has inferential intelligence and capability.

According to Foy, the machine at OMH works like a lab test or an MRI. The difference is that it is able to see far (30/60/90 days...even a year) into the future so that adverse events can be stopped before they happen.”

The solution OHM has adopted can be applied across the continuum. Within the outpatient/community setting, patient-level predictions can target individuals who carry the highest risk of a condition and the highest propensity for engagement with outreach. Examples include 30-day risk of an emergency department (ED) or inpatient admission, 6-month risk of an acute myocardial infarction, 6-month risk of diabetes, and identification of ED frequent fliers and rising risk individuals. Within the acute care setting, predictions can be delivered at an established frequency to identify patients at risk, individual-level risk factors, and possible interventions. Examples include readmissions, pressure ulcers, surgical-site infections, catheter-associated urinary tract infection, sepsis, and length-of-stay outliers. Finally, within the post-acute setting, predictions are delivered to ensure the most appropriate discharge disposition, reduce risk of a condition or illness, and optimize length of stay. Examples of this include re-hospitalization risk, ED admission risk, and patient-level deterioration.

Because the machine works as a cognitive appliance, it plugs directly into the existing workflow so that risk and intervention predictions are delivered directly to OMH caregivers. Using the Jvion system with outputs that are part of the standard care for all patients, OMH caregivers receive the outputs directly through the MEDITECH electronic health record. The outputs are designed to work just like a Vital Sign Capture. The risk information is provided on the Worklist. New data are entered daily, and interventions are applied, so that the patient risk level may change. Interventions are then automatically added to the worklist. These interventions include:

- Follow-up appointment within 7 days of discharge
- Nursing notification of the admitting provider of patient’s risk
- Patient education consultation
- Patient service consultation
- Discharge planning consultation
- Notification to patient call manager

OMH has been using this system for 10 months and has seen a significant uptick in adoption. The total number of avoided readmissions is 88, reflecting savings of $985,600 (calculated at $11,290 per readmission) and avoidance of 441.5 length-of-stay days (5.4 average LOS multiplied by avoided readmissions).
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Post-Acute Networks: The Discharge Planner’s Dilemma

By Thomas Brewer, PhD; Shannon DeBra, Esq.; Laura Kukral, MBA, LNHA

Care managers increasingly are expected to ensure patients make choices for themselves that result in high-value care and are asked to introduce patients to a hospital-chosen network of post-acute providers. These networks are concerning to some care managers as potentially being counter to payers’ terms and conditions of participation regarding steering patients. They wonder if their hospital’s network is “ok” or if they should be asking more questions.

To safeguard patients from being unduly influenced by those who might have some sort of financial interest in

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their choice of nursing homes or home care, current discharge planning rules as set forth in the Medicare statute, regulations, and Interpretive Guidelines seem very clear and unambiguous—thou shalt not steer patients to any particular post-acute care provider. And that has been the mantra of discharge planners for years.

Implicit and explicit in the discharge planning process since its inception has been the idea that patient freedom of choice must be protected. This tenet is set forth generally in Section 1802 of the Social Security Act, which guarantees Medicare beneficiaries freedom to choose their health care providers. And recognizing the position of influence that hospital discharge planners hold with respect to patients’ choice of post-acute care providers, Congress went a step further to protect Medicare beneficiaries from improper influence in the discharge planning process with Section 1861(ee). In addition to setting forth the basic requirements for the discharge planning process (see Box 1), Section 1861(ee) also includes provisions intended to address the possibility that the discharge planning process could be used improperly to steer patients, not to the most appropriate post-acute care provider, but instead to one that perhaps financially benefited the discharge planner, hospital, or post-acute care provider.

The Centers for Medicare & Medicaid Services (CMS) has also continue on page 28
**DISCHARGE PLANNING PROCESS**

(1) A discharge planning process of a hospital shall be considered sufficient if it is applicable to services furnished by the hospital to individuals entitled to benefits under this title and if it meets the guidelines and standards established by the Secretary under paragraph (2).

(2) The Secretary shall develop guidelines and standards for the discharge planning process in order to ensure a timely and smooth transition to the most appropriate type of and setting for post-hospital or rehabilitative care. The guidelines and standards shall include the following:

   (A) The hospital must identify, at an early stage of hospitalization, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning.

   (B) Hospitals must provide a discharge planning evaluation for patients identified under subparagraph (A) and for other patients upon the request of the patient, patient’s representative, or patient’s physician.

   (C) Any discharge planning evaluation must be made on a timely basis to ensure that appropriate arrangements for post-hospital care will be made before discharge and to avoid unnecessary delays in discharge.

   (D) A discharge planning evaluation must include an evaluation of a patient’s likely need for appropriate post-hospital services, including hospice care and post-hospital extended care services and the availability of those services, including the availability of home health services through individuals and entities that participate in the program under this title and that serve the area in which the patient resides and that request to be listed by the hospital as available and, in the case of individuals who are likely to need post-hospital extended care services, the availability of such services through facilities that participate in the program under this title and that serve the area in which the patient resides.

   (E) The discharge planning evaluation must be included in the patient’s medical record for use in establishing an appropriate discharge plan and the results of the evaluation must be discussed with the patient (or the patient’s representative).

   (F) Upon the request of a patient’s physician, the hospital must arrange for the development and initial implementation of a discharge plan for the patient.

   (G) Any discharge planning evaluation or discharge plan required under this paragraph must be developed by, or under the supervision of, a registered professional nurse, social worker, or other appropriately qualified personnel.

   (H) Consistent with section 1802, the discharge plan shall—

     (i) not specify or otherwise limit the qualified provider which may provide post-hospital home health services, and

     (ii) identify (in a form and manner specified by the Secretary) any entity to whom the individual is referred in which the hospital has a disclosable financial interest (as specified by the Secretary consistent with section 1866(a)(1)(S)) or which has such an interest in the hospital.

(3) With respect to a discharge plan for an individual who is enrolled with a Medicare+Choice organization under a Medicare+Choice plan and is furnished inpatient hospital services by a hospital under a contract with the organization—

   (A) the discharge planning evaluation under paragraph (2)(D) is not required to include information on the availability of home health services through individuals and entities which do not have a contract with the organization; and

   (B) notwithstanding subparagraph (H)(i), the plan may specify or limit the provider (or providers) of post-hospital home health services or other post-hospital services under the plan.
The IMPACT Act requires hospitals to consider quality and resource use measures to assist patients and their families during the discharge planning process, with the goal of having patients and their families be well-informed of their choices of post-acute care providers in the hope of reducing the patients’ chances of rehospitalization.

published Interpretive Guidelines regarding the discharge planning process. The Interpretive Guidelines reiterate the statutory and regulatory requirements regarding patient freedom of choice and even instruct surveyors in the Survey Procedures for 42 CFR 482.43(c)(7) to interview patients and their families to determine whether patient freedom of choice was emphasized during the discharge planning process. Interestingly, although not officially part of the Interpretive Guidelines or survey procedures, the “advisory box” notes to hospitals for the discharge planning section of the Interpretive Guidelines suggests that hospitals refer patients and their families to the Nursing Home Compare and Home Health Compare websites for additional information regarding Medicare-certified SNFs and HHAs, as well as Medicaid-participating SNFs. These websites include SNF data such as overall performance rating, performance on quality measures, inspection results, and nursing staff information and HHA quality data such as how the HHAs perform with respect to managing daily activities, managing pain and treating symptoms, treating wounds and preventing pressure sores, preventing harm, and preventing unplanned hospital care. CMS notes: “Having access to the information found at these sources may assist in the decision making process regarding post-hospital care options.” The Interpretive Guidelines also state that hospitals “are expected to be knowledgeable about the care capabilities of area long-term care facilities and to factor this knowledge into the discharge planning evaluation.” CMS explains that this knowledge is necessary “to develop a discharge plan that not only meets the patient’s needs in theory, but also can be implemented.” The Interpretive Guidelines suggest that a best practice is to ensure that patients are assisted in accessing data related to HHAs and SNFs that will help guide them to select high-quality post-acute care providers. But no steering, right? Well.

Changes in the Law Affecting Post-Acute Choice
There was little incentive under the current CMS Conditions of Participation (CoP) to coordinate care or avoid unnecessary costs across the continuum. A fundamental aim of the Patient Protection and Affordable Care Act (PPACA) is to reduce the cost of health care delivery in the United States. One way in which the law seeks to achieve this goal is by creating financial incentives for providers who are able to streamline and provide high-quality care at a lower cost. Alternate Payment Models (APM) that reimburse hospitals and physicians based on episode target costs and outcomes incentivize accountable providers (hospitals and physicians) to form relationships with downstream providers who deliver the highest quality of care at the lowest cost. The tension created by downstream accountability in payment policies was articulated at an October 2014 meeting of the Medicare Payment Advisory Commission (MEDPAC) when members of the committee discussed preferred networks. Commission member Craig Sammit’s commented that MEDPAC should “…consider relaxation of some of the accountable care organization (ACO) rules to allow providers a more effective influence and steerage of choice of post-acute care, specifically also in the opportunity to create incentives for beneficiaries.”

So what is changing, exactly? Well, the law, for one. The Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) was signed into law by President Obama on October 6, 2014. The IMPACT Act requires hospitals to consider quality and resource use measures to assist patients and their families during the discharge planning process, with the goal of having patients and their families be well-informed of their choices of post-acute care providers in the hope of reducing the patients' chances of rehospitalization. This is a shift even from the “best practices” suggestion in the Interpretive Guidelines referenced above, which merely suggests that hospitals point patients and their families to websites where certain data may be found. The IMPACT Act requires hospitals to actually use the data. The IMPACT Act also directs the Department of Health & Human Services to modify the hospital CoPs and Interpretive Guidelines related to discharge planning to require post-acute care providers, hospitals, and critical access hospitals
The Interpretive Guidelines suggest that a best practice is to ensure that patients are assisted in accessing data related to HHAs and SNFs that will help guide them to select high-quality post-acute care providers. 
But no steering, right? Well. . . .

to consider quality data, resource use measures, and other measures to assist with the discharge planning process.

CMS issued a Proposed Rule on November 3, 2015, proposing modifications to the discharge planning requirements for Medicare-participating hospitals to address and implement the IMPACT Act requirements and to continue CMS’s efforts to reduce avoidable readmissions. The Proposed Rule, if finalized in its current form, would significantly modify and formalize the discharge planning process. A proposed new requirement that would be included in regulation 42 C.F.R. 482.43(c)(8) would require hospitals to assist patients and their families and caregivers in selecting a post-acute care provider by using and sharing quality and resource use data about the post-acute care providers in the community that is relevant to the patient and applicable to the patient’s goals of care and treatment preferences. The type of data that would be required to be shared about the post-acute care providers include quality indicators such as functional status, cognitive function, skin integrity, and medication reconciliation measures and resource use data such as total estimated Medicare spend per individual, discharge to community, and measures to reflect all-condition risk-adjusted preventable hospital readmission rates. Under the Proposed Rule, hospitals would be required to document in the patient’s medical record that these data were shared with the patient and used to assist the patient, family, and caregivers during the discharge planning process. The hope is that by engaging hospitals in the process and helping patients evaluate the quality of available post-acute care providers, patients will ultimately select higher-quality post-acute care providers and have better outcomes, including fewer complications and lower rates of avoidable re-hospitalization.

The Proposed Rule explains how CMS envisions this revised discharge planning process:

For example, the hospital could provide quality data on PAC providers that are within the patient’s preferred geographic area. In another instance, hospitals could provide quality data on HHAs based on the patient’s need for continuing care post-discharge and preference to receive this care at home. Hospitals should assist patients as they choose a high quality PAC provider. However, we would expect that hospitals would not make decisions on PAC services on behalf of patients and their families and caregivers and instead focus on person-centered care to increase patient participation in post-discharge care decision making. Person-centered care focuses on the patient as the locus of control, supported in making their own choices and having control over their daily lives.

The Proposed Rule falls short of explicitly authorizing patient steering by name. However, it will be virtually unavoidable in practice. The large amount of specialized and highly technical data that must be collected, analyzed, presented, and explained to the patient seems to almost require steering. Gone are the days when care managers could avoid charges of steering by simply providing an alphabetical list of facilities or referring patients to an external rating source. The IMPACT Act and the Proposed Rule require explicit discussions, memorialized in the patient’s chart, of information that is beyond the reach or understanding of patients and families. The discretion left to providers on what information to emphasize, particularly given the fact that the data must be presented in the context of each patient’s individual “goals of care and treatment preferences,” would blur the line between “assisting” and “steering” to the point where it would be unrecognizable.

One would believe that a good-faith error toward steering would be forgivable were it motivated solely by a concern for quality and fit for the patient’s needs. Conversely, steering motivated purely by potential financial benefit to the institution would most certainly run afoul of numerous compliance provisions. For better or for worse, the advent of APMs inextricably tie quality and financial benefit by their very design. In fact, you would assume hospitals use many of the very same measures mandated by the IMPACT Act in their selection criteria for preferred provider networks. This overlap can cause further anxiety over complying with the IMPACT Act and its regulatory progeny.

Considerations for Care Managers
As of the date this article is submitted, continues on page 47
Cultural competence has received a great deal of attention in the past 10 years. The Institute of Medicine published Crossing the Quality Chasm and Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care, which drew attention to the interrelationship between patient-centered care and cultural competency. The only true way to provide patient-centered care is to be cognizant of the patient’s way of life, which entails their beliefs and values, and being able to provide this care without bias or prejudice (Ard & Makadon, 2012). Cultural competence has been noted as an effective tool in decreasing health disparities, a major cause of increasing health care costs in the US. Three central constituents of culturally competent care are knowledge, expertise, and attitudes (Fredrikson-Goldsen, Hoy Ellis, Goldsen, Emlet, and Hooyman, 2014).

Most of us are acutely aware of the health care disparities that involve race and ethnicity. However, health care disparities based on sexual orientation have become more prevalent, with statistics to prove it. Gay men and men who have sex with men (MSM), especially those of communities of color, are more likely to contract human immunodeficiency virus (HIV) and sexually transmitted disease. Lesbian women are more likely to avoid seeking or obtaining preventive gynecological testing (ie, mammograms and Pap smears). Lesbian and bisexual women have a high risk of being obese or overweight. Older LGBTQ adults have higher incidence of poor mental health and increased cardiovascular disease (Fredrikson-Goldsen, Hoy Ellis, Goldsen, Emlet, and Hooyman, 2014; Ard & Makadon, 2012). Higher rates of substance and alcohol abuse are known within this population. This population additionally endures mistreatment, refusal of care, and restricted access to quality, timely treatment. (Ard & Makadon, 2012). Depending on their ethnicity, they may also have to deal with racial discrimination. These statistics have caught the attention of Healthy People 2020 and the Joint Commission, who have created specific initiatives to better understand and improve the lesbian, gay, bisexual, and transgender (LGBTQ) population’s health.

As case managers, we would be remiss in not making cultural competence with this population a high priority. One guiding principle of the Case Management Society of America (CMSA) is to provide culturally competent care by embracing and respecting diversity (CMSA’s Standards of Practice for Case Management, 2016). The Commission for Case Management Certification (CCMC) mandates that “Board Certified Case Managers will respect the right and dignity of a client” and will “maintain objectivity in their relationships with clients” (CCMC Code of Professional Conduct for Case Managers, 2015). The National Association of Social Workers (NASW) has dedicated standards for cultural competence for social workers to possess and pursue definitive knowledge related to sexual orientation and gender identity to effectively coordinate care (Standards and Indicators for Cultural Competence).
One guiding principle of the Case Management Society of America (CMSA) is to provide culturally competent care by embracing and respecting diversity.

in Social Work Practice, 2015). The foundation of the Certification of Disability Management Specialist (CDMS) Code of Professional Conduct includes the ethical behaviors of beneficence, nonmaleficence, justice, and fidelity (The CDMS Code of Professional Conduct, 2015). Legally, the Consumer Bill of Rights states that a patient has a right to receive care regardless of their race, ability, timely treatment, and cultural-specific data are needed to provide culturally competent care. Sixth, health care professionals who can assess, plan, intervene, and analyze in a culturally competent style will likely be more effective in care coordination. Lastly, each individual has the inherent right to be respected for their own unique culture. Fifth, cultural-general and cultural-specific data are needed to provide culturally competent care. Sixth, health care professionals who can assess, plan, intervene, and analyze in a culturally competent style will likely be more effective in care coordination. Lastly, each meeting with the patient is a cultural encounter (Purnell, 2013). A full listing of Dr. Purnell’s 20 assumptions can be found in Transcultural Health Care: A Culturally Competent Approach.

What is Cultural Competence?
Dr. Josepha Campinha-Bacote created a conceptual model called the process of cultural competence in the delivery of health care services. According to this model, cultural competence is defined as the process in which the health care professional works proficiently within the cultural context of the patient. The primary focus of this model requires the health care professional to see cultural competence as an ongoing process. Becoming culturally competent requires the incorporation of cultural desire, cultural awareness, cultural knowledge, cultural skills, and cultural encounter. These are considered as the five constructs of Dr. Campinha-Bacote’s model. (Rose, 2013). For this article, we will expound on cultural awareness, cultural desire, cultural knowledge, and cultural encounter.

Cultural Awareness
The case manager does self-examination of their own feelings, biases, and stereotypes toward their own cultural background, beliefs, and values. This self-examination is necessary to prevent cultural imposition—imposing one’s beliefs and values on someone of a different cultural background. The results of this self-examination are then compared to their biases and beliefs toward other cultures. It is usually in this process that the case manager realizes how their preconceived opinions of other cultures could be helping or hindering their ability to coordinate care effectively. The case manager admits and affirms the reality of sexism, racism, and other types of discrimination experienced by other cultures (Rose, 2013). Cultural awareness usually leads to cultural desire.

Cultural Desire
Cultural desire is fundamental to cultural competence as it encompasses caring. Knowledge is irrelevant until it is evident how much a person cares. Cultural desire involves the case manager recognizing their lack of knowledge about a particular culturally diverse population. The case manager
aspires to be culturally competent. The case manager makes a concerted effort to learn about a different culture that is totally opposite from their own. Learning about another culture is not done because it is a requirement. The case manager is able to motivate themselves to learn more about other cultures. The case manager is committed to care for all patients, regardless of their cultural practices, beliefs, and values. The case manager sees the LGBTQ as an individual, not a stereotype (Rose, 2013).

Cultural Knowledge
The case manager intentionally seeks information about the other culture. He or she goes the extra mile to apply this knowledge in care coordination. The information obtained should be the culture’s health-related beliefs practices and cultural values (Rose, 2013). Another point of consideration for cultural knowledge is the case manager knowledge of laws and policies that offer protection for this particular population.

Securing cultural knowledge concerning LGBTQ patients involves learning what the acronym LGBTQ stands for. Now let’s define each to expand our knowledge. A lesbian is a woman who is attracted emotionally, sexually, or romantically to other women. Gay is defined as a person who is attracted primarily to the same gender. Transgender, also known as transsexual, describes a person whose gender identification and assigned birth sex do not correspond. Queer is defined as an individual who thinks of their gender identity or sexual orientation as outside of societal standards. (For a more expansive glossary of LGBTQ terms for health care professionals, visit LGBT Health Education.org. (Glossary of LGBT Terms for Health Care Teams, 2015).

Cultural Encounter
Cultural encounter consists of the case manager deliberately interacting with patients with culturally diverse backgrounds. The case manager seeks out opportunities to connect and collaborate to modify their existing beliefs and values. Cultural encounters enhance cultural awareness and acquisition of cultural knowledge (Campinha-Bacote, 2011). The case manager has to bear in mind that interaction with one or two members of a specific cultures does not make one an authority on that culture. There are always variations within a culture.

The cultural encounter also entails the case manager understanding that they are representing case management as a whole. Each encounter is an opportunity for the case manager to show empathy and understanding. Each opportunity should include the case manager being an advocate and actively caring for the patient.

Special Consideration for Transgender Individuals
A transgender person can be confounding to someone who is not familiar with the LGBTQ population. Two dominant transgender classifications are female-to-male (FTM) and male-to-female (MTF). FTM means a person whose assigned birth sex was male but who lives and identifies as a male. MTF means a person whose assigned birth sex was male but who lives and identifies as a female (Ard & Makadon, 2012). Care coordination for the transgender individual can be challenging, especially if the individual has undergone surgical or hormonal treatment to transition to their gender of choice.

Special Consideration for LGBTQ Adolescents and Older Adults
Adolescence can be a challenging time for any adolescent, but even more so for the LGBTQ adolescent. This is a time of understanding and exploration of gender identification and establishment of gender roles. Others may not be receptive to the LGBTQ youth’s sexual orientation or gender expression. This youth may be estranged or rejected by their parents. He or she also have high risk of bullying and psychological abuse (The Joint Commission, 2011). It is anticipated that by 2030, there will be at least 3 million lesbian, gay, or bisexual elders. LGBTQ older adults experience a great deal of isolation due to rejection from family. Their “adopted” family may be a small group of close LGBTQ friends. Senior centers are not generally accepting of LGBTQ elders. These elders are at a greater risk of living alone. LGBTQ elders are less likely to be financially secure (Portz et al, 2014; The Joint Commission, 2011).

Delivering Culturally Competent Care Coordination
Cultural competence has to start on an organizational level. Culturally competent organizations will produce
culturally competent health care professionals. The policies and procedures and standards of care for health care organizations should embody the core principles of cultural competency (The Joint Commission, 2011). This helps to ensure that culturally competent practices are executed by all in the organization who will be in constant contact with patients.

Suggestions for organization include the following (The Joint Commission, 2011):

• Post in plain sight the organization’s nondiscrimination policy or bill of rights.
• Designate unisex restrooms, if possible.
• Make sure that visitation policies are executed in a nondiscriminatory manner.
• Create forms that are inclusive and contain gender-neutral language that encourage authentic self-identification.
• Enforce among staff that disclosure of one’s LGBTQ status is protected by HIPAA and is considered to be sensitive and confidential information.
• Provide LGBTQ training to all staff, especially those who have constant patient interaction.

Individual Case Manager Recommendations

Role of Communication

Communication has the power to unite or divide. Effective communication skills will be the foundation for the cultural encounter with the LGBTQ patient. Therefore, breaking down barriers to communication is pivotal for quality and patient-centered care coordination (Epner & Baile, 2012). The case manager must be willing to identify and utilize different communications skills. Why? The LGBTQ community has endured discrimination, rejection, abuse, and denial of access to basic health care services. They are also vulnerable, which can sometimes be disguised by a tough persona. They have built up a protective wall around themselves that will only be broken down by effective communication skills.

Another point of consideration regarding communication is that communication is both verbal and nonverbal. Verbal elements of communication include using the right vocabulary—hence, another reason to be familiar with commonly used LGBTQ terms (Epner & Baile, 2012). Using terms that offend will quickly shut down communication between the case manager and LGBTQ patient. Keep in mind—words have power. Additionally, style of communication is paramount. Because of the rejection and discrimination LGBTQ patients have endured, most tend to be very straightforward. The case manager must not be offended or intimidated by this but should be willing to adapt to it.

Motivational interviewing can be an effective tool to facilitate verbal communication. Four elements of the underlying essence of motivational interviewing are partnership, acceptance, compassion, and evocation. Acceptance of and compassion for the LGBT patient—two things that are very important to the LGBT individual—will assist in promoting effective communication (Miller & Rollnick, 2013).

Nonverbal communication has a profound impact on dialogue also. Keep in mind that because of what they have been through, LGBTQ individuals are very adept at reading people. They can sense fear, disdain, judgment, and disapproval. And how you truly feel and think will be written on your face—hence, the reason for cultivating cultural desire and cultural knowledge. The LGBTQ patient may also be hard to “read.” Observation of facial expressions will, therefore, be beneficial for the case manager too. The case manager will need to be perceptive and adaptive to be ready for when the LGBTQ patient lets their guard down. Other considerations for nonverbal communication include eye contact, physical space, and body language (Epner & Baile, 2012)

Other Points of Consideration for Individual Case Managers

The following points can enhance your ability to establish rapport with patients (The Joint Commission, 2011):

• Commit to getting rid of individual ethnocentrism—thinking that one’s way of thinking and acting is the only way to think and act.
• When caring for transgender individuals, acknowledge and address them according to their gender of choice. Being respectful of the gender of choice has a positive influential effect on strengthening communication.
• Encourage the LGBTQ individual to include their support system when making health care decisions.
• When doing patient interviews and
Cultural competence has to start on an organizational level. Culturally competent organizations will produce culturally competent health care professionals.

References


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Rubraca (rucaparib) tablets, for oral use

INDICATIONS AND USAGE
Rubraca is indicated as monotherapy for the treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA-approved companion diagnostic for Rubraca.

DOSAGE AND ADMINISTRATION

Patient Selection
Select patients for the treatment of advanced ovarian cancer with Rubraca based on the presence of a deleterious BRCA mutation (germline and/or somatic). Information on the FDA-approved test for the detection of a tumor BRCA mutation in patients with ovarian cancer is available at: www.fda.gov/CompanionDiagnostics.

Recommended Dose
The recommended dose of Rubraca is 600 mg (two 300 mg tablets) taken orally twice daily with or without food. Continue treatment until disease progression or unacceptable toxicity.

If a patient misses a dose of Rubraca, instruct the patient to take the next dose at its scheduled time. Vomited doses should not be replaced.

Dose Modifications for Adverse Reactions
To manage adverse reactions, consider interruption of treatment or dose reduction. Starting dose is 600 mg twice a day; first dose reduction is 500 mg twice a day; second-dose reduction, 400 mg twice daily; and third dose reduction, 300 mg twice daily.

DOSE FORMS AND STRENGTHS
• Tablets (200 mg): blue, round, immediate-release, film-coated, debossed with “C2”.
• Tablets (300 mg): yellow, oval, immediate-release, film-coated, debossed with “C3”.

WARNINGS AND PRECAUTIONS
Myelodysplastic Syndrome/Acute Myeloid Leukemia
Myelodysplastic syndrome (MDS)/Acute Myeloid Leukemia (AML) was reported in 2 of 377 (0.5%) patients with ovarian cancer treated with Rubraca. The duration of Rubraca treatment prior to the diagnosis of MDS/AML was 57 days and 539 days. Both patients received prior treatment with platinum and other DNA damaging agents.

In addition, AML was reported in 2 (<1%) patients with ovarian cancer enrolled in a blinded, randomized trial evaluating Rubraca versus placebo. One case of AML was fatal. The duration of treatment prior to the diagnosis of AML was 107 days and 427 days. Both patients had received prior treatment with platinum and other DNA damaging agents.

Monitor complete blood count testing at baseline and monthly thereafter. Do not start Rubraca until patients have recovered from hematological toxicity caused by previous chemotherapy (≤ Grade 1). For prolonged hematological toxicities, interrupt Rubraca and monitor blood counts weekly until recovery. If the levels have not recovered to Grade 1 or less after 4 weeks, refer the patient to a hematologist for further investigations, including bone marrow analysis and blood sample for cytogenetics. If MDS/AML is confirmed, discontinue Rubraca.

Embryo-Fetal Toxicity
Rubraca can cause fetal harm when administered to a pregnant woman based on its mechanism of action and findings from animal studies. In an animal reproduction study, administration of rucaparib to pregnant rats during organogenesis resulted in embryo-fetal death at maternal exposure that were 0.04 times the AUC in patients receiving the recommended dose of 600 mg twice daily. Apprise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for 6 months following the last dose of Rubraca.

ADVERSE REACTIONS
Adverse reactions reported by 20% or more of patients with ovarian cancer who were treated with Rubraca included nausea, vomiting, constipation, diarrhea, and abdominal pain; anemia/fatigue; anemia and thrombocytopenia; dysgeusia; decreased appetite; and dyspnea.

USE IN SPECIFIC POPULATIONS
Pregnancy

Based on findings from animal studies and its mechanism of action, Rubraca can cause fetal harm when administered to pregnant women. There are no available data in pregnant women to inform the drug-associated risk. In an animal reproduction study, administration of rucaparib to pregnant rats during organogenesis resulted in embryo-fetal death at maternal exposure that were 0.04 times the AUC0-24h in patients receiving the recommended dose of 600 mg twice daily. Informed pregnant women of the potential risk to a fetus.

The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

CLINICAL STUDIES

The efficacy of Rubraca was investigated in 106 patients in two multicenter, single-arm, open-label clinical trials, Study 1 and Study 2, in patients with advanced BRCA-mutant ovarian cancer who had progressed after 2 or more prior chemotherapies. All 106 patients received Rubraca 600 mg orally twice daily as monotherapy until disease progression or unacceptable toxicity. Objective response rate (ORR) and duration of response (DOR) were assessed by the investigator and independent radiology review (IRR) according to Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1.

The median age of the patients was 59 years (range 33 to 84), the majority were Caucasian (78%), and 100% had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. All patients had received at least two prior platinum-based chemotherapies and 43% had received 3 or more prior lines of chemotherapy. There were 18/106 patients (17%) who had deleterious BRCA mutations detected in tumor tissue and not in whole blood specimens. Tumor BRCA mutation status was verified retrospectively in 96% (64/67) of the patients for whom a tumor tissue sample was available by the companion diagnostic FoundationFocus CDxBRCA™ test, which is FDA approved for selection of patients for Rubraca treatment.

Complete response was seen in 9% and partial response in 45% of patients with BRCA-mutant ovarian cancer who received 2 or more chemotherapies in studies 1 and 2.

Rubraca is distributed by Clovis Oncology, Inc.

Arymo ER (morphine sulfate) extended-release tablets, for oral use

INDICATIONS AND USAGE

Arymo ER is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve Arymo ER for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Arymo ER is not indicated as an as-needed (prn) analgesic.

DOSAGE AND ADMINISTRATION

Important Dosage and Administration Instructions

Arymo ER should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain.

A single dose of Arymo ER greater than 60 mg, or a total daily dose greater than 120 mg, are only for use in patients in whom tolerance to an opioid of comparable potency has been established. Patients who are opioid tolerant are those receiving, for one week or longer, at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydrocodone per day, 25 mg oral oxymorphone per day, 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid.

- Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals.
- Initiate the dosing regimen for each patient individually, taking into account the patient's severity of pain, patient response, prior analgesic treatment experience, and risk factors for addiction, abuse, and misuse.
- Monitor patients closely for respiratory depression, especially within the first 24-72 hours of initiating therapy and following dosage increases with ARYMO ER and adjust the dosage accordingly.

Instruct patients to take Arymo ER tablets whole, one tablet at a time, with enough water to ensure complete swallowing immediately after placing in the mouth. Instruct patients not to pre-soak, lick, or otherwise wet the tablet prior to placing in the mouth. Cutting, breaking, crushing, chewing, or dissolving Arymo ER tablets will result in uncontrolled delivery of morphine that could lead to overdose and death.

Arymo ER is administered orally every 8 or 12 hours.

Initial Dosing

Use of Arymo ER as the First Opioid Analgesic (opioid-naïve patients): Initiate treatment with Arymo ER with 15 mg tablets orally every 8 or 12 hours.

Use of Arymo ER in Patients who are not Opioid Tolerant (opioid-non-tolerant patients): The starting dose for patients who are not opioid tolerant is Arymo ER 15 mg orally every 8 or 12 hours.

Use of higher starting doses in patients who are not opioid tolerant may cause fatal respiratory depression.

Conversion from Other Oral Morphine to Arymo ER: Patients

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receiving other oral morphine formulations may be converted to Arymo ER by administering one-half of the patient’s 24-hour requirement as Arymo ER on an every-12-hour schedule or by administering one-third of the patient’s daily requirement as Arymo ER on an every-8-hour schedule.

Conversion from Other Opioids to Arymo ER: Discontinue all other around-the-clock opioid drugs when Arymo ER therapy is initiated.

There are no established conversion ratios for conversion from other opioids to Arymo ER defined by clinical trials. Initiate dosing using Arymo ER 15 mg orally every 8 to 12 hours.

It is safer to underestimate a patient’s 24-hour oral morphine dosage and provide rescue medication (eg, immediate-release morphine) than to overestimate the 24-hour oral morphine dosage and manage an adverse reaction due to an overdose. While useful tables of opioid equivalents are readily available, there is inter-patient variability in the potency of opioid drugs and opioid formulations.

Close observation and frequent titration are warranted until pain management is stable on the new opioid. Monitor patients for signs and symptoms of opioid withdrawal and for signs of oversedation/toxicity after converting patients to Arymo ER.

Conversion from Parenteral Morphine or Other Opioids (Parenteral or Oral) to Arymo ER: When converting from parenteral morphine or other non-morphine opioids (parenteral or oral) to Arymo ER, consider the following general points:

Parenteral to oral morphine ratio: Between 2 to 6 mg of oral morphine may be required to provide analgesia equivalent to 1 mg of parenteral morphine. Typically, a dose of morphine that is approximately three times the previous daily parenteral morphine requirement is sufficient.

Other parenteral or oral non-morphine opioids to oral morphine sulfate: Specific recommendations are not available because of a lack of systematic evidence for these types of analgesic substitutions. Published relative potency data are available, but such ratios are approximations. In general, begin with half of the estimated daily morphine requirement as the initial dose, managing inadequate analgesia by supplementation with immediate-release morphine.

Conversion from Methadone to Arymo ER: Close monitoring is of particular importance when converting methadone to other opioid agonists. The ratio between methadone and other opioid agonists may vary widely as a function of previous dose exposure. Methadone has a long half-life and can accumulate in the plasma.

Titrating and Maintenance of Therapy
Individually titrate Arymo ER to a dose that provides adequate analgesia and minimizes adverse reactions. Continually reevaluate patients receiving Arymo ER to assess the maintenance of pain control and the relative incidence of adverse reactions, as well as monitoring for the development of addiction, abuse, or misuse. Frequent communication is important among the prescriber, other members of the healthcare team, the patient, and the caregiver/family during periods of changing analgesic requirements, including initial titration. During chronic therapy periodically reassess the continued need for the use of opioid analgesics.

Patients who experience breakthrough pain may require a dose increase of Arymo ER, or may need rescue medication with an appropriate dose of an immediate-release analgesic. If the level of pain increases after dose stabilization, attempt to identify the source of increased pain before increasing the Arymo ER dose. Because steady-state plasma concentrations are approximated in 1 day, Arymo ER dosage adjustments may be done every 1 to 2 days.

If unacceptable opioid-related adverse reactions are observed, the subsequent doses may be reduced. Adjust the dose to obtain an appropriate balance between management of pain and opioid-related adverse reactions.

Discontinuation of Arymo ER
When the patient no longer requires therapy with Arymo ER tablets, taper the dose gradually, by 25% to 50% every 2 to 4 days, while monitoring carefully for signs and symptoms of withdrawal. If the patient develops these signs or symptoms, raise the dose to the previous level and taper more slowly, either by increasing the interval between decreases, decreasing the amount of change in dose, or both. Do not abruptly discontinue Arymo ER.

DOSAGE FORMS AND STRENGTHS
- Arymo ER (morphine sulfate) extended-release tablets 15 mg light orange film coated, capsule shaped tablets debossed with “EGLT 15”
- Arymo ER (morphine sulfate) extended-release tablets 30 mg light purple film coated, capsule shaped tablets debossed with “EGLT 30”
- Arymo ER (morphine sulfate) extended-release tablets 60 mg light orange film coated, capsule shaped tablets debossed with “EGLT 60”

CONTRAINDICATIONS
Arymo ER is contraindicated in patients with significant respiratory depression; acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; concurrent use of monoamine oxidase inhibitors (MAOIs) or use within the last 14 days; known or suspected gastrointestinal obstruction, including paralytic ileus; and hypersensitivity (eg, anaphylaxis) to morphine.

WARNING: ADDICTION, ABUSE, and MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL INGESTION; NEONATAL OPIOID WITHDRAWAL SYNDROME; AND RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

Addiction, Abuse, and Misuse
Arymo ER exposes patients and other users to the risks of opioid...
addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient’s risk before prescribing ARYMO ER, and monitor all patients regularly for the development of these behaviors or conditions.

**Life-Threatening Respiratory Depression**
Serious, life-threatening, or fatal respiratory depression may occur with use of Arymo ER. Monitor for respiratory depression, especially during initiation of Arymo ER or following a dose increase. Instruct patients to swallow Arymo ER tablets whole; crushing, chewing, or dissolving Arymo ER tablets can cause rapid release and absorption of a potentially fatal dose of morphine.

**Accidental Ingestion**
Accidental ingestion of even one dose of Arymo ER, especially by children, can result in a fatal overdose of morphine.

**Neonatal Opioid Withdrawal Syndrome**
Prolonged use of Arymo ER during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

**Risks From Concomitant Use With Benzodiazepines Or Other CNS Depressants**
Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death.

- Reserve concomitant prescribing of Arymo ER and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.
- Limit dosages and durations to the minimum required.
- Follow patients for signs and symptoms of respiratory depression and sedation.

**Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, Head Injury, or Impaired Consciousness**
In patients who may be susceptible to the intracranial effects of CO2 retention (eg, those with evidence of increased intracranial pressure or brain tumors), Arymo ER may reduce respiratory drive, and the resultant CO2 retention can further increase intracranial pressure.

Monitor such patients for signs of sedation and respiratory depression, particularly when initiating therapy with Arymo ER.

Opioids may also obscure the clinical course in a patient with a head injury. Avoid the use of Arymo ER in patients with impaired consciousness or coma.

**Difficulty in Swallowing and Risk for Obstruction in Patients at Risk for a Small Gastrointestinal Lumen**
Moistened Arymo ER tablets may become sticky leading to difficulty in swallowing the tablets. Patients could experience choking, gagging, regurgitation and tablets stuck in the throat. Instruct patients not to pre-soak, lick, or otherwise wet Arymo ER tablets prior to placing in the mouth, and to take one tablet at a time with enough water to ensure complete swallowing immediately after placing in the mouth.

Tablet stickiness and swelling may also predispose patients to intestinal obstruction and exacerbation of diverticulitis. Patients with underlying GI disorders such as esophageal cancer or colon cancer with a small gastrointestinal lumen are at greater risk of developing these complications. Consider use of an alternative analgesic in patients who have difficulty swallowing and patients at risk for underlying GI disorders resulting in a small gastrointestinal lumen.

**Risks of Use in Patients with Gastrointestinal Conditions**
Arymo ER is contraindicated in patients with gastrointestinal obstruction, including paralytic ileus.

- The morphine in Arymo ER may cause spasm of the sphincter of Oddi. Opioids may cause increases in the serum amylase.
- Monitor patients with biliary tract disease, including acute pancreatitis, for worsening symptoms.

**Increased Risk of Seizures in Patients with Seizure Disorders**
The morphine in Arymo ER may increase the frequency of seizures in patients with seizure disorders, and may increase the risk of seizures occurring in other clinical settings associated with seizures. Monitor patients with a history of seizure disorders for worsened seizure control during Arymo ER therapy.

**Withdrawal**
Avoid the use of mixed agonist/antagonist (ie, pentazocine, nalbuphine, and butorphanol) or partial agonist (eg, buprenorphine) analgesics in patients who have received or are receiving a course of therapy with a full opioid agonist analgesic, including Arymo ER. In these patients, mixed agonists/antagonist and partial agonist analgesics may reduce the analgesic effect and/or may precipitate withdrawal symptoms.

When discontinuing Arymo ER, gradually taper the dose. Do not abruptly discontinue Arymo ER.

**Risks of Driving and Operating Machinery**
Arymo ER may impair the mental or physical abilities needed to perform potentially hazardous activities such as driving a car or operating machinery. Warn patients not to drive or operate dangerous machinery unless they are tolerant to the effects of Arymo ER and know how they will react to the medication.

**ADVERSE REACTIONS**
The following serious adverse reactions reported in Clinical Trials: addiction, abuse, and misuse; life-threatening respiratory depression; neonatal opioid withdrawal syndrome; interactions with 3 and 6.
LitScan for Case Managers reviews medical literature and reports abstracts that are of particular interest to case managers in an easy-to-read format. Each abstract includes information to locate the full-text article if there is an interest. This member benefit is designed to assist case managers in keeping current with clinical breakthroughs in a time-effective manner.


Associations between at-risk alcohol use, substance use, and smoking with lipohypertrophy and lipoatrophy among patients living with HIV.

Noorhasan M, Drozd D, Grunfeld C, et al. OBJECTIVE: To examine associations between lipohypertrophy and lipoatrophy and illicit drug use, smoking, and at-risk alcohol use among a large diverse cohort of persons living with HIV (PLWH) in clinical care. METHODS: 7,931 PLWH at 6 sites across the US completed 21,279 clinical assessments including lipohypertrophy and lipoatrophy, drug/alcohol use, physical activity level, and smoking. Lipohypertrophy and lipoatrophy were measured using the FRAM body morphology instrument and associations were assessed with generalized estimating equations. RESULTS: Lipohypertrophy (33% mild, 4% moderate-to-severe) and lipoatrophy (20% mild, 3% moderate-to-severe) were common. Older age, male sex, and higher current CD4 count were associated with more severe lipohypertrophy (p values <0.001-0.03). Prior methamphetamine or marijuana use, and prior and current cocaine use, were associated with more severe lipohypertrophy (p values <0.001-0.009). Older age, detectable viral load and low current CD4 cell counts were associated with more severe lipoatrophy (p values <0.001-0.003). Prior methamphetamine or marijuana use, and prior and current cocaine use, were associated with more severe lipoatrophy (p values <0.001-0.003). In addition, current smoking, marijuana, and opiate use were associated with more severe lipoatrophy (p values <0.001-0.03). Patients with very low physical activity levels had more severe lipohypertrophy and also more severe lipoatrophy than those with all other activity levels (p values <0.001). For example, the lipohypertrophy score of those reporting high levels of physical activity was on average 1.6 points lower than those reporting very low levels of physical activity (-1.6, 95% CI: -1.8 to -1.4, p < 0.001). CONCLUSIONS: We found a high prevalence of lipohypertrophy and lipoatrophy among a nationally distributed cohort of PLWH. While low levels of physical activity were associated with both lipohypertrophy and lipoatrophy, associations with substance use and other clinical characteristics differed between lipohypertrophy and lipoatrophy. These results support the conclusion that lipohypertrophy and lipoatrophy are distinct, and highlight differential associations with specific illicit drug use.


Accelerated decline of renal function in type 2 diabetes following severe hypoglycemia.

Tsujimoto T, Yamamoto-Honda R, Kajio H, et al. AIMS: This study aimed to evaluate whether the pronounced elevation in blood pressure during severe hypoglycemia is associated with subsequent renal insufficiency. METHODS: We conducted a 3-year cohort study to assess the clinical course of renal function in type 2 diabetes patients with or without blood pressure surge during severe hypoglycemia. RESULTS: Of 111 type 2 diabetes patients with severe hypoglycemia, 76 exhibited an extremely high systolic blood pressure before treatment, whereas 35 demonstrated no such increase (179.1 ± 27.7 mmHg vs. 131.1 ± 20.2 mmHg, P < 0.001). At 12h after treatment, systolic blood pressure did not differ significantly (131.5 ± 30.7 mmHg vs. 123.5 ± 20.7 mmHg; P=0.39). The estimated glomerular filtration rate (GFR) before and at the time of severe hypoglycemia did not significantly differ between both groups. A multivariate Cox proportional hazards regression analysis revealed that blood pressure surge during severe hypoglycemia was independently associated with a composite outcome of a more than 15 mL/min/1.73 m(2) decrease in the estimated GFR and initiation of chronic dialysis (hazard ratio, 2.68; 95% confidence interval, 1.12-6.38; P=0.02). CONCLUSIONS: Renal function after severe hypoglycemia was significantly worse in type 2 diabetes patients with blood pressure surge during severe hypoglycemia than those without blood pressure surge.

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Long-acting combination anti-HIV drug suspension enhances and sustains higher drug levels in lymph node cells than in blood cells and plasma.

Kraft JC, McConnachie LA, Koehn J, et al. OBJECTIVE: To determine if a combination of anti-HIV drugs-tenofovir (TFV), lopinavir (LPV), and ritonavir (RTV)-in a lipid-stabilized nanosuspension (called TLC-ART101) could
enhance and sustain intracellular drug levels and exposures in lymph node and blood cells above those in plasma. DESIGN: Four macaques were given a single dose of TLC-ART101 subcutaneously. Drug concentrations in plasma and mononuclear cells of the blood (PBMCs) and lymph nodes (LNMCs) were analyzed using a validated combination LC-MS/MS assay. RESULTS: For the two active drugs (TFV, LPV), plasma and PBMC intracellular drug levels persisted for over two weeks; PBMC drug exposures were 3-4-fold higher than those in plasma. Apparent terminal half-lives (t1/2) of TFV and LPV were 65.3 hr and 476.9 hr in plasma, and 169.1 hr and 151.2 hr in PBMCs. At 24 and 192 hr, TFV and LPV drug levels in LNMCs were up to 79-fold higher than those in PBMCs. Analysis of PBMC intracellular TFV and its active metabolite TFV-diphosphate (TFV-DP) indicated that intracellular exposures of total TFV and TFV-DP were markedly higher and persisted longer than in humans and macaques dosed with oral TFV prodrugs-tenofovir disoproxil fumarate (TDF) or tenofovir alafenamide (TAF). CONCLUSIONS: A simple, scalable three-drug combination lipid-stabilized nanosuspension exhibited persistent drug levels in cells of lymph nodes and the blood (HIV host cells) and in plasma. With appropriate dose adjustment, TLC-ART101 may be a useful HIV treatment with potential to impact residual virus in lymph nodes.


**Comparative analysis of online patient education material pertaining to hepatitis and its complications.**

Gulati R, Nawaz M, Pyrsopoulos NT.

BACKGROUND AND AIMS: Approximately 50% of patients leave the doctor’s office with a poor understanding of their diagnosis. Online patient education websites are becoming a major source of information for many of the patients. Here, we determine the reading grade level of online patient education materials on hepatitis B, hepatitis C, cirrhosis, and hepatocellular cancer and compare it with the National Institutes of Health-recommended reading grade level of sixth to seventh grade or under. METHODS: A Google search was performed to retrieve patient reading materials. Text was modified to remove medical terms that were defined within the article. Documents were then divided into categories of introduction, risk factors, symptoms, diagnosis, treatment, and prevention. Each document was then analyzed using six validated readability tests to determine the grade level and complexity on the basis of the number of words, syllables, or number of uncommon words. RESULTS: Modified documents had a mean readability score of 10.23, although the recommended score is less than 7.0. Cirrhosis had the highest reading grade level, with a median of 11.3, whereas hepatitis B and hepatocellular carcinoma had the easiest readability, with a median of 9.5. Furthermore, treatment subsection was the most difficult, with a median score of 10.8. CONCLUSION: Patient reading materials reviewed in this study were written well above the recommended reading grade level. These findings suggest review of patient education materials in an effort to close the gap between the average reading level and the reading materials.


**Comparative effectiveness and safety of direct oral anticoagulants (DOACs) versus conventional anticoagulation for the treatment of cancer-related venous thromboembolism: A retrospective analysis.**

Ross JA, Miller MM, Rojas Hernandez CM.

PURPOSE: The standard of care for the treatment of cancer-related venous thromboembolism (VTE) is a low molecular weight heparin (LMWH) formulation. The recent development of direct oral anticoagulants (DOACs) and their approval for the treatment of VTE has resulted in several new options for treatment. If equivalent to LMWH in terms of safety and effectiveness, the use of DOACs in the treatment of cancer-related VTE would reduce the risk of VTE recurrence while potentially improving the quality of life of many cancer patients. METHODS: We performed a retrospective analysis of adult patients with cancer-related VTE treated in our benign hematology clinic. Among the 153 patients included in our final analysis, 123 (80%) were treated with LMWH and 30 (20%) were treated with DOACs. Patients had 36 different histological types of cancer. The primary outcome was the rate of recurrence of VTE evaluated at 6 and 12 months after the initiation of anticoagulation. Secondary outcomes were the rate of anticoagulant-associated clinically relevant bleeding and event-free survival for VTE recurrence. RESULTS: In comparing the 2 treatment groups, there was no statistically significant difference in the cumulative rates of VTE recurrence at 6 and 12 months or in the rates of major or non-major bleeding at both 6 and 12 months. The median VTE recurrence-free survival rates were not reached and they were not statistically different. CONCLUSION: DOACs appear to be as safe and effective as conventional therapy for the treatment of cancer-related VTE. Results of ongoing randomized clinical studies may provide definitive evidence and clarify the role of the DOACs in the setting of malignancy.

Effect of exercise training on endothelial function in heart failure patients: a systematic review meta-analysis.

Pearson MJ, Smart NA.

OBJECTIVE: Endothelial dysfunction contributes to the development and progression of cardiovascular disease and heart failure (HF) and is associated with an increased risk of mortality. Flow-mediated dilation (FMD) is widely utilised to assess endothelial function and is improved with exercise training in heart failure patients. The aim of this meta-analysis is to quantify the effect of exercise training in patients with heart failure. BACKGROUND: A large number of studies now exist that have examined endothelial function in patients with heart failure. We sought to add to the current literature by quantifying the effect of exercise training on endothelial function. METHODS: We conducted database searches (PubMed, EMBASE, PROQUEST and Cochrane Trials Register to June 2016) for exercise based rehabilitation trials in heart failure, using search terms exercise training, endothelial function, flow-mediated dilation (FMD) and endothelial progenitor cells (EPCs).

RESULTS: The 16 included studies provided a total of 529 participants, 293 in an intervention and 236 in control groups. FMD was improved with exercise training in exercise vs. control, SMD of 1.08 (95%CI 0.70 to 1.46, p<0.00001). CONCLUSION: Overall exercise training improved endothelial function, assessed via FMD, and endothelial progenitor cells in heart failure patients.


Prevalence of masked hypertension among US adults with nonelevated clinic blood pressure.


Masked hypertension (MHT), defined as nonelevated blood pressure (BP) in the clinic setting and elevated BP assessed by ambulatory monitoring, is associated with increased risk of target organ damage, cardiovascular disease, and mortality. Currently, no estimate of MHT prevalence exists for the general US population. After pooling data from the Masked Hypertension Study (n = 811), a cross-sectional clinical investigation of systematic differences between clinic BP and ambulatory BP (ABP) in a community sample of employed adults in the New York City metropolitan area (2005-2012), and the National Health and Nutrition Examination Survey (NHANES; 2005-2010; n = 9,316), an ongoing nationally representative US survey, we used multiple imputation to impute ABP-defined hypertension status for NHANES participants and estimate MHT prevalence among the 139 million US adults with nonelevated clinic BP, no history of overt cardiovascular disease, and no use of antihypertensive medication. The estimated US prevalence of MHT in 2005-2010 was 12.3% of the adult population (95% confidence interval: 10.0, 14.5)-approximately 17.1 million persons aged ≥21 years. Consistent with prior research, estimated MHT prevalence was higher among older persons, males, and those with prehypertension or diabetes. To our knowledge, this study provides the first estimate of US MHT prevalence-nearly 1 in 8 adults with nonelevated clinic BP-and suggests that millions of US adults may be misclassified as not having hypertension.


Cardiac dose and survival after stereotactic body radiotherapy for early-stage non-small-cell lung cancer.

Tembhekara AR, Wright CL, Daly ME.

INTRODUCTION: Recent analyses have identified cardiac dose as an important predictor of overall survival (OS) after chemoradiation for locally advanced non-small-cell lung cancer (NSCLC). However, the survival influence of the cardiac dose after stereotactic body radiotherapy (SBRT) is unknown. We performed a dose-volume histogram (DVH) analysis of patients treated with SBRT for early stage NSCLC to examine survival and cardiac toxicity. MATERIALS AND METHODS: We reviewed the medical records of patients who had undergone SBRT for early-stage NSCLC from June 2007 to June 2015 and documented the cardiac DVH parameters, including the maximum and mean dose and percentage of volume receiving >5, >10, >20, and >30 Gy (V5, V10, V20, and V30, respectively). The biologically effective doses and 2-Gy equivalent doses were also calculated. The DVH parameters were assessed as predictors of OS using Cox regression analysis. RESULTS: We identified 102 patients with 118 treated tumors. At a median follow-up period of 27.2 months (range, 9.8-72.5 months), the 2-year OS estimate was 70.4%. The cardiac DVH parameters were as follows: maximum dose, median, 14.2 Gy (range, 0.3-77.8 Gy); mean dose, median, 1.6 Gy (range, 0-12.6 Gy); and V5, median, 8.7% (range, 0%-96.4%). We identified no correlation between OS and any cardiac dose parameter. No patient developed acute (within 3 months) cardiac toxicity. Four patients died of cardiac causes; all had had preexisting heart disease. CONCLUSION: In our cohort, cardiac dose was not...
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For more information about these and other Mullahy & Associates’ learning tools and programs, click here or call: 631-673-0406.
Patients receiving frequent hemodialysis have better health-related quality of life compared to patients receiving conventional hemodialysis.


Most patients with end-stage kidney disease value their health-related quality of life (HRQoL) and want to know how it will be affected by their dialysis modality. We extended the findings of two prior clinical trial reports to estimate the effects of frequent compared to conventional hemodialysis on additional measures of HRQoL. The Daily Trial randomly assigned 245 patients to receive frequent (six times per week) or conventional (three times per week) in-center hemodialysis. The Nocturnal Trial randomly assigned 87 patients to receive frequent nocturnal (six times per week) or conventional (three times per week) home hemodialysis. All patients were on conventional hemodialysis prior to randomization, with an average feeling thermometer score of 70 to 75 (a visual analog scale from 0 to 100 where 100 is perfect health), an average general health scale score of 40 to 47 (a score from 0 to 100 where 100 is perfect health), and an average dialysis session recovery time of 2 to 3 hours. Outcomes are reported as the between-treatment group differences in one-year change in HRQoL measures and analyzed using linear mixed effects models. After one year in the Daily Trial, patients assigned to frequent in-center hemodialysis reported a higher feeling thermometer score, better general health, and a shorter recovery time after a dialysis session compared to standard thrice-weekly dialysis. After one year in the Nocturnal Trial, patients assigned to frequent home hemodialysis also reported a shorter recovery time after a dialysis session, but no statistical difference in their feeling thermometer or general health scores compared to standard home dialysis schedules. Thus, patients receiving day or nocturnal hemodialysis on average recovered approximately one hour earlier from a frequent compared to conventional hemodialysis session. Patients treated in an in-center dialysis facility reported better HRQoL with frequent compared to conventional hemodialysis.
have real-time conversations with him or her and the clinical team to try to influence the patient’s treatment plan, delivery of care processes, progression of care goals, and transition planning.

Chart review, in my mind, is never the case manager’s primary source of information—ever. (It’s why doctors still speak of the “chart police” when they really mean their professional case management colleagues.) I expect the case manager to speak to the nurses; round with the doctors; visit with the patient and family; reach out to the therapists, pharmacists, and other members of the patient’s care team; and, if necessary, advocate on the patient’s behalf with the insurer.

With the evolving marketplace changes, hospital care managers are well positioned to extend care management principles beyond the walls of the hospital. This is why predictive analytics and population health concepts are being used to identify selected inpatients for case management oversight and then follow them post-acute as part of innovative transitional care programs. Unless hospital case managers see themselves as true advocates to coordinate care for their patients, I’m afraid (and I see some evidence already) that they will lose out on future opportunities.

The question remains—which model is best for your hospital? And the best answer I can give you is to first ask: what is the purpose of YOUR case management program? And to get that answer you MUST poll the C-suite. If they just want UR and DCP, then you really don’t need case management. Bite the bullet, sunset case management, and return to separate functions. But if the Board and the C-suite are looking to case management to improve quality and safety outcomes of care; reduce resource utilization and lower costs per case; promote the use of evidence-based protocols; engage the patient and family to promote self-care and patient satisfaction; identify and resolve delivery of care bottlenecks that delay or impede the patient’s progression of care; and engage the medical staff as colleagues in the mission of the organization, then I suspect you want to go back to the future and consider a contemporary care management model.
other CNS depressants; adrenal insufficiency; severe hypotension; gastrointestinal adverse reactions; seizures; and withdrawal.

**DRUG INTERACTIONS**
Numerous drug interactions occur with benzodiazepines and other CNS depressants. Read the label carefully.

**DRUG ABUSE AND DEPENDENCE**

**Controlled Substance**
Arymo ER contains morphine, a Schedule II controlled substance.

**Abuse**
Arymo ER can be abused and is subject to misuse, addiction, and criminal diversion. The high drug content in extended-release formulations adds to the risk of adverse outcomes from misuse and abuse. All patients treated with opioids require careful monitoring for signs of abuse and addiction because use of opioid analgesics products carries the risk of addiction even under appropriate medical use.

**Risks Specific to Abuse of Arymo ER**
Arymo ER is for oral use only. Abuse of Arymo ER poses a risk of overdose and death. This risk is increased with concurrent abuse of Arymo ER with alcohol and other central nervous system depressants. Attempting to cut, break, chew, crush, or dissolve Arymo ER tablets may compromise some of the extended-release properties, resulting in delivery of morphine that could lead to overdose and death.

Parenteral abuse of ARYMO ER can be expected to result in local tissue necrosis, infection, pulmonary granulomas, and increased risk of endocarditis and valvular heart injury. Parenteral drug abuse is commonly associated with transmission of infectious diseases such as hepatitis and HIV.

**Abuse Deterrence Studies**
Arymo ER is formulated with inactive ingredients that make the tablet more difficult to manipulate for misuse and abuse.

To evaluate the ability of Arymo ER to reduce the potential for misuse and abuse, a series of abuse-deterrent in vitro laboratory physical manipulation, chemical extraction, and syringeability studies was conducted. An oral pharmacokinetic study and an oral clinical abuse potential study were also conducted.

In vitro physical and chemical manipulation studies were performed to evaluate the ability of different methods to defeat the extended-release properties. The results of this testing demonstrated that Arymo ER tablets, in comparison to morphine sulfate extended-release tablets, have increased resistance to cutting, crushing, grinding or breaking using a variety of tools. When subjected to a liquid environment, the manipulated Arymo ER tablets form a viscous hydrogel (ie, a gelatinous mass) that resists passage through a hypodermic needle. The oral pharmacokinetic study (N=38) showed that oral ingestion of manipulated Arymo ER resulted in a higher Cmax, but similar AUC, when compared to intact Arymo ER. In addition, manipulated Arymo ER had a lower Cmax and longer Tmax than crushed morphine sulfate extended-release tablets. The oral clinical abuse potential study (N=39) demonstrated that the oral administration of manipulated Arymo ER resulted in a statistically lower mean drug liking score than the oral administration of crushed morphine sulfate extended-release tablets. However, the difference between manipulated Arymo ER and crushed morphine sulfate extended-release tablets for Take Drug Again was not statistically significant, indicating that the difference in drug liking scores was not clinically meaningful.

**Dependence**
Arymo ER should not be abruptly discontinued. If Arymo ER is abruptly discontinued in a physically dependent patient, a withdrawal syndrome may occur. Some or all of the following can characterize this syndrome: restlessness, lacrimation, rhinorrhea, yawning, perspiration, chills, myalgia, and mydriasis. Other signs and symptoms also may develop, including irritability, anxiety, backache, joint pain, weakness, abdominal cramps, insomnia, nausea, anorexia, vomiting, diarrhea, or increased blood pressure, respiratory rate, or heart rate.

Infants born to mothers physically dependent on opioids will also be physically dependent and may exhibit respiratory difficulties and withdrawal signs.

**STORAGE AND HANDLING**
Store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F). Dispense in a tight, light-resistant container.

Arymo ER is distributed by Egalet US, Inc.
for publication the final CMS discharge planning rule has not been released. Although nothing is certain, we would expect the basic tenets of the proposed rule to survive into the final product. With that caveat, we propose general recommendations that will help prepare for the new regulations.

Carefully read and understand the final rule and any interpretive guidelines. Work with your legal counsel to ensure that the institution’s interpretation is consistent across departments and reflected in policies and procedures.

Know how these changes may affect existing demonstration projects in which your institution may already be involved. Are you in a Comprehensive Care for Joint Replacement (CJR) market or participate in Bundled Payments for Care Improvement (BPCI) model? If so, these projects may serve as a resource for wider adoption of best practices. You will also want to ensure that new policies do not conflict with the demonstration guidelines.

Become educated about the IMPACT Act and begin a discussion of how relevant data on post-acute providers will be collected, analyzed, and used in practice. Think about this process from a clinical (what PAC provider will best fit my patient’s medical needs) and regulatory (are financial or other considerations being improperly used) standpoint.

Collaborate with physicians, nurses, and advisors from post-acute organizations to identify processes, functions, and training needs related to the IMPACT Act and care coordination across the continuum. The increased participation of clinical staff in the development and implementation of the discharge plan may require workflow changes related to admission and discharge procedures. Also, the clear and repeated mandates related to charting will require additional staff training and potential changes to electronic medical records.

In conclusion, the reader can be inspired by the expressed framework for health care transformation. It is the Triple Aim: Better Care for Individuals, Better Health for Populations, and Lower Per Capita Costs. Helping people make a well-informed choice for themselves is an inherently good thing that care managers can do.

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**CE I**

*Post-Acute Networks: The Discharge Planner’s Dilemma
continued from page 29*

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Q: Do CE programs expire?
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Q: Is your Website secure for dues payment?
A: ACCM uses the services of PayPal, the nation’s premier payment processing organization. No financial information is ever transmitted to ACCM.

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