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INSIDE THIS ISSUE

Suffering

Gary S. Wolfe

Suffering is something that everyone experiences. You cannot go through life without some suffering. Suffering is an unpleasant experience or a threat of harm or pain. Suffering is the negative aspect of the affective phenomena. The opposite of suffering is happiness or joy. Suffering can be categorized in many ways: physical, mental, emotional, social, spiritual, and psychological.

Suffering occurs in many ways and in different situations. As a case manager, I think of suffering in the lives of my patients. They suffer because of a disease, illness, or injury. They may suffer because of emotions: a relationship gone badly; the loss of a loved one; a separation or move. They may suffer because they can no longer perform the work they loved. They may suffer because of declining health and they can no longer do the things they enjoy. Suffering consumes a person's life. The intensity of suffering changes: from no suffering to high-intensity suffering depending on the situation and where a person is on the continuum of suffering.

Epicurus, an ancient Greek philosopher as well as the founder of the school of philosophy called Epicureanism, taught that the purpose of philosophy was to attain a happy, tranquil life, characterized by peace and freedom from pain and self-sufficiency surrounded by friends. I argue that this is not reality because everyone suffers going through life.

Disease, illness, and injury contribute to suffering. The health care field addresses suffering in many ways through such subfields as medicine, psychology, alternative medicine, public health, and specialist providers. Approaches to suffering remain problematic, however. This is partly true because most health care providers are never educated about how to help the person suffering. Typically, health care providers are taught to treat symptoms, disease, or injury, but the treatment of and approach to suffering are left out. Sometimes the thought is to fix the primary problem to relieve the suffering or make it fade. As case managers, we frequently see that doesn't really work.

David Brooks, journalist, suggests that suffering can produce a benefit. Brooks suggests that suffering helps us look at ourselves closely. We learn things about ourselves that we can control and things we cannot control. Brooks cites the example of Franklin Roosevelt who learned from living with polio to have deeper empathy for the world around him.

Although everyone likes happiness, we are formed by suffering.

What can case managers do about suffering in their patients? In this issue, we publish Ethical Considerations in Patients Who Are Suffering by Michael J. Demoratz, PhD, LCSW, CCM. This article will give you a blueprint for understanding the types of suffering and how to access and approach suffering in your patients.

We at the Academy of Certified Case Managers are all suffering over the unexpected death on September 22, 2016, of Patrice Sminkey, the CEO of the Commission for Case Manager Certification (CCMC). Patrice joined CCMC in 2010, having spent her entire career in the health care sector. A registered nurse, she had a rich background in home health and infusion services, chronic disease management, and business development. She brought energy and a keen focus on advocating for the professional case manager. Patrice had many notable achievements during her tenure at CCMC. She will be missed. But, as we suffer, we recognize that we have grown better because of her.

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ACCM: Improving Case Management Practice through Education

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Education and Information: Preparing the Case Managers for the Future

By MaryBeth Kurland, *Chief Operations Officer, Commission for Case Manager Certification (CCMC)*

Without question, more is being expected of case managers today. In the post–health care reform era, greater emphasis is being placed on accountability and transparency in care delivery. Case management, care coordination, and care transitions are all seen as vital strategies to achieve desired outcomes—as defined by the "triple aims" of improving the experience of care, achieving better health of individuals and populations, and reducing the per capita cost of care.

As more tasks and responsibilities are placed on case managers, the issue becomes how these valued professionals can best be prepared for demanding roles in delivering patient-centered care. The education of case managers is a significant concern, given that the majority of these professionals learn on the job. As the Commission for Case Manager Certification (CCMC) found in its most recent role and function study, nearly nine of out ten case managers surveyed said they gained the knowledge and skills they needed through on-the-job experience.

Educating ourselves and contributing to the knowledge of others is a value shared by many case managers. The CCMC see it as part of our work to advance the ongoing education and training of both board-certified case managers and professional case managers. To further that mission, the Commission offers several resources. Here are some highlights:

- CMLearning Network—created by the Commission to advance knowledge and expand learning opportunities. The CMLearning Network offers Issue Briefs, certification preparation workshops, and the Case Management Body of Knowledge® web-based learning platform.
- Case Management Body of Knowledge®—a comprehensive online resource based on a clearly defined knowledge framework for the field of case management. The CMBOK contains essential information about what a case manager needs to know and be able to do effectively and competently for the primary benefit of consumers of health care services and their support systems.
- Webinars—a host of topics are featured live and then archived in our Webinar Library. Among our recent topics (available in the library) are: The Triple Aim for Case Management—Population Health; Trends and Challenges—Case Managers Tackle the Opioid Epidemic; and the Latest on Patient Privacy Rights—Consumers and Electronic Access to Health Data.
- New World Symposium—educational workshops, expert speakers, informative panels, the latest insights about case management, and multiple opportunities for earning CEs. The theme of this year's symposium is "Case Management: Expertise for the Future." The symposium will be held January 26–28, 2017, at the Gaylord Texan Resort & Convention Center in Dallas.This is a dynamic time in health care and within case management. Professional case managers (and, in particular, those who are board certified) are key members of interdisciplinary teams in acute, subacute, primary care/accountable care organizations, and other care delivery settings. In addition, the field of practice is expanding across multiple disciplines, not only nursing and social work, but also rehabilitation, mental health counseling, occupational therapy, pharmacy, and more. As we come together, we learn from each other and share knowledge that contributes to competence and confidence among professional case managers.

The Commission would like to acknowledge that our expansion of educational resources was part of the vision of our late CEO, Patrice Sminkey, who died unexpectedly on September 22, 2016. Patrice infused our organization with energy and passion to advocate for professional case managers. Patrice touched so many people within the Commission, among its partners, and across case management and the broader field of health and human services. Her loss is deeply felt, and her legacy lives on in our commitment to advance case management practice. CM

***MaryBeth Kurland** is the Chief Operations Officer of the Commission for Case Manager Certification (CCMC), the first and oldest nationally accredited organization that certifies case managers (www.ccmcertification.org). To date, nearly 60,000 case managers have earned the Certified Case Manager (CCM®) credential, and more than 40,000 board-certified case managers are in practice today.*

In Memoriam, Patrice Sminkey,

CEO, Commission for Case Manager Certification
September 22, 2016

PATRICE V. SMINKEY, RN, infused the Commission for Case Manager Certification (CCMC®) with energy and a keen focus on our mission to advocate for professional case manager excellence. The Board of Commissioners joins with hundreds of volunteers and the more than 40,000 board-certified case managers who grieve the loss of our colleague, leader, and friend.

Patrice spent her entire career in the health care sector. Soon after attaining her licensure as a registered nurse, she was supervising others in the growing home health and infusion services sectors. Patrice's management skills and magnetic personality led to increasingly more responsible leadership roles. She came to the Commission from URAC, a health care accreditation organization, where she served as the senior director of business development. Prior to her work at URAC, she served as senior vice president of operations and client management at Patient InfoSystems (Rochester, NY), which specialized in management of chronic disease programs and services.

This combination of clinical and health care business savvy made Patrice the perfect fit for CCMC leadership as CEO in 2010. She hit the ground running. Early on, she brought the exam application and renewal process in-house; she supported this by developing an exceptional customer service team. Patrice was always about strong connections. Her efforts behind the scenes—to improve processes like PACE, for example—made our organization not only more efficient, but also more agile and responsive to Certified Case Managers (CCM®s) and certification candidates.

As the Affordable Care Act was just beginning implementation, it was critical for the Commission to quickly build awareness of the role and function of the professional case manager within this new context. CCMC also needed to develop a suite of robust education and professional development tools to support an informed, relevant, and expanding case manager workforce. Notable CCMC achievements during Patrice's tenure included

- Nearly doubling the ranks of board-certified CCMs, which now number more than 40,000
- Launching and maintaining ongoing content expansion of the CCMC Case Management Body of Knowledge® online learning tool, now used by thousands of new and experienced case managers
- Creating and implementing the CMLearning Network®, including the annual webinar series, associated issue briefs, and videos
- Establishing the CCMC New World Symposium™, the Commission's conference that was created to build community, engender collaboration, and boost professional development
- Formation of a formal collaboration with the National Association of Social Workers (NASW) related to CCM certification for health care social workers

Patrice's natural ebullience and admirable character struck a chord with many, and helped CCMC to recruit and nurture a strong volunteer community. She enjoyed a productive, positive relationship with the Commission's board and contributed mightily to our shared work to build CCMC's resources.

There may be no better way to honor Patrice Sminkey and her many accomplishments on behalf of case managers than with our renewed commitment to case management and the Commission's path forward.

How to Ensure Proper Use of EHR Features and Capabilities: Copy and Paste, Copy Forward and Cut and Paste

By Elizabeth Hogue, Esq.

In June, 2016, the Centers for Medicare and Medicaid Services (CMS) issued a publication entitled "Ensuring Proper Use of Electronic Health Record Features and Capabilities." The publication includes a decision table intended to help providers use common features of electronic health records (EHRs) appropriately. CMS first addressed the use of the copy and paste, copy forward and cut and paste features of EHRs.

The copy and paste feature allows users to use the content of another entry and to select information from an original or previous source to reproduce in another location. The copy forward capability replicates all or some information from a previous note to a current note, while the cut and paste feature removes documentation from the original location and places it in another location.

The use of these features raises a number of program integrity issues. Copy and paste can, for example, lead to redundant and inaccurate information in EHRs. The authorship of documentation may be unclear since it cannot be tracked to the original source.

In addition, such documentation lacks information specific to individual patients necessary to support services rendered to each patient. This lack of specificity can, in turn, affect the quality of care and can cause improper payments due to:

- False information about services provided to patients
- Coding from old or outdated information that may lead to "upcoding"

The use of these features raises a number of program integrity issues. Copy and paste can, for example, lead to redundant and inaccurate information in EHRs.

Recommendations to help ensure appropriate use of these features include:

- Develop and implement a policy governing the use of these features that balances efficiencies against the potential for inaccurate, fraudulent, and/or unmanageable documentation.
- Policies applicable to the use of these features should require practitioners to modify copied information to develop patient-specific content that is related to current visits and/or services.
- Policies governing the use of these features should also require proper notation and clear attribution of copied information.
- Providers should also monitor and audit the use of these features in the audit log. EHR systems should be enabled to record the method of each data entry, i.e., copy and paste or direct text entry, in order to enhance auditing capabilities.

According to CMS, best practices with regard to the use of these features include:

- Ensure that practitioners recognize documentation of each patient encounter as a stand-alone document.
- Documentation must reflect the level of services actually delivered and meet the requirements of various payor sources for billing and reimbursement.
- Validate each entry that is not authored by the user, including the name, date, time and source of information. Systems may be designed to routinely provide validation.
- Prohibit the use of the cut and paste feature, since it removes original source documentation.

The use of EHR has become essential to many providers, but resulting efficiencies may bring new problems and liabilities, if the features and capabilities of EHR are improperly used. CM

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

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CDMS Update:
Disability Management and the Care Continuum

By Stan Scioscia, MEd, CDMS

As we consider the health and wellness of individuals today, we cannot overlook the context of the work environment. For many individuals, the desire to return to work after an illness or injury, whether occupational or nonoccupational, is a primary goal that should also be addressed as part of the care plan.

Case managers, who come from a variety of clinical backgrounds, may not be aware of the resources that can be tapped when advocating for the ill/injured individual or for a family member who requires ongoing care. One important resource is the job protection offered by the Family and Medical Leave Act (FMLA). FMLA entitles eligible employees of employers covered by the law to take unpaid, job-protected leave for a variety of specific family and medical reasons, with the continuation of group health insurance. In addition, several states have similar legislation that provides job protection for employees who are affected by a health issue or who must care for a family member. In some instances, states offer paid family leave (PFL).

Case managers and care managers need not have in-depth expertise in employee leave legislation such as FMLA. But they should know where to go to tap this expertise—such as a certified disability management specialist (CDMS), who has the requisite knowledge and experience in helping people impacted by disability.

Disability managers and disability specialists are schooled in federal and state laws that protect people who are affected by disability. In addition, CDMSs in particular often work closely with employers on return-to-work (RTW) or stay-at-work (SAW) programs that allow people to return to or remain in the workplace after an injury or illness—even before that person is "100 percent." As research shows, returning to work as soon as medically feasible, as approved by treating physicians, can help people recover faster and retain an important connection to the workplace.

For many individuals, the desire to return to work after an illness or injury, whether occupational or nonoccupational, is a primary goal that should also be addressed as part of the care plan.

Disability management resources are more important than ever, given the aging of the population and the likelihood of people staying in the workforce longer, beyond the age typically associated with retirement. Therefore, a care plan that addresses a person's comprehensive health goals should also consider the impact of health on employment (and vice versa). For the case manager who is dedicated to meeting the needs of the whole person, the importance and satisfaction of having productive work cannot be minimized or overlooked.

At the same time, disability management specialists understand that they, too, are part of the care continuum. While many may define the continuum as acute care, sub-acute care (such as that delivered in a skilled nursing facility), and care delivered in the community, the continuum doesn't stop there. The care continuum extends into the workplace, given the important links between health and the individual's ability to be productive in their lives, including at work.

The more aware we become of our specializations, the better we can work together and collaborate with our fellow professionals. With an interdisciplinary approach, we bring to bear our own knowledge and expertise for a common goal: advocating for and serving the needs of the individual. A person caring for an elderly parent or an ill child may need the job protection offered by the FMLA. Or the individual may be ill or injured and require care and treatment on an ongoing basis. When we work together, we become more effective in meeting the needs of the individual. CM

Stan Scioscia, M.Ed, CDMS, *is a past chair of the former Certification of Disability Management Specialists Commission, and is now a board member of the Commission for Case Manager Certification (CCMC). CCMC owns and administers the Certified Disability Management Specialist (CDMS) certification.*

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CE 1

Benefits of Informatics for Case Managers

By Elizabeth A. Dailey MBA, HCM, MSN, RN; David A. Zaworski MSN, RN; Katherine A. Fetter MSN, RN, EMT-P

Introduction

Current health care movements, including the rising cost of health care and the momentum towards primary prevention strategies, place case managers in a unique position to translate information systems into practice. The US Department of Health and Human Services[1] identifies the use of health information technology (HIT) and communication approaches as important initiatives to improve health equity, improve health outcomes, and promote care quality. Emerging trends in health care necessitate the need for reliable systems that will facilitate the delivery of safe quality patient care. As Internet usage has become routine across the United States, many technology-savvy consumers rely on it to manage diet and fitness needs, research and evaluate symptoms and health conditions, and shop for care providers. The need for accurate, consistent systems across the United States will assist case managers in meeting the unique goals of their patients.

Because case managers work in a variety of settings, including public health settings, acute care settings, and outpatient clinics, they must be on the forefront of the emerging technological advancements that will promote consistency in care and standardization in assessment tools and resources. In addition, the processes of assessment, planning, implementing, and evaluating patient care can be critically enriched with information systems that translate knowledge and data into technological systems. These developments encourage consistency among providers and organizations as well as facilitate the case manager's attempts to pursue and secure resources.

Elizabeth A. Dailey MBA, HCM, MSN, RN; ***David A. Zaworski,*** *and* ***Katherine A. Fetter*** *are faculty members at Chamberlain College of Nursing in Medina, OH.*

Background

Case managers have long been recognized as experts in their field and essential contributors to the interdisciplinary team. Case managers advocate, empower, educate, and support people in the effort to increase health literacy, promote access to health services, and improve health-related outcomes.[2] Case management has traditionally been used for care coordination with an emphasis on meeting the needs of vulnerable patient populations with chronic vulnerabilities and illnesses.[3] While the goal of case management has not changed, the tools and resources available have become substantial. Case managers have a responsibility to understand the unique aspects of the technological resources available and their relationship to the health care environment. Therefore, the case manager must be prepared to employ elements of computer science and information science to pilot multifaceted information systems to foster continuity of care and optimal patient outcomes.

Informatics and telehealth are considered broad terms that refer to the use of technology for the monitoring of health, disease management, health promotion, access to evidence, research, and other medical data.[4] Simply communicating or relaying information over the telephone is a form of telecommunication. Informatics blends computer science, technology, and information science, which enables the case manager to assemble and manage data, knowledge, and information.[5]

From privacy concerns to funding issues, using technology to care for people is a multidimensional endeavor that requires consideration of where funds are allocated and how information is managed and disclosed. Kellermann and Jones[6] described the distinction between implementation and the effective utilization of these systems in current practice. The authors spoke of difficulty in using the systems rather than the ability to analyze data obtained as a concern for systems choice and implementation. The costs of the systems need to be compared to the benefits that can be realized over time. Clinical decision-support systems (CDSS) and computerized physician order entry systems can reduce errors caused by drug interactions, transcription errors, and can assist in monitoring lab/procedure results, which will help to greatly reducing the costs associated with therapies and extended stays and treatments associated with these potential errors.

The rise of informatics in health care has been associated with a simultaneous rise in concern regarding the confidentiality of the information and potential for unwanted disclosure. As more researchers and hospital systems are using data mining techniques, there is fear that confidential information may be released within or gleaned from the data being used. Who has access

Case management information systems are used to identify trends in treatment modalities and patterns in the provision of care, and to monitor the availability and use of resources to provide support in decision making and treatment in a cost-effective manner.

to electronic medical records (EMR), electronic health records (EHR), and the data obtained from them remains a concern for many health consumers. Case managers can strive to decrease privacy concerns by providing education and support as appropriate to patients and families.

It is important to address the various sociocultural issues that have arisen as a result of the massive amounts of knowledge available on the Internet. Case managers must emphasize the significance of avoiding disparities related to access and ensure that people from other cultures and linguistically diverse backgrounds are not disadvantaged in the care they receive based on their lack of access to or understanding of health-related technologies. The case manager can foster an increased understanding of informatics and electronic health tools by asking direct questions to help recognize a patient's level of knowledge. Providing anticipatory guidance and support to patients related to their electronic care options can help reduce hospital readmissions, foster better self-management of various chronic illnesses, facilitate open communication, and promote patient engagement.[7]

Implementation

Just like learning a new language can be challenging, understanding the various elements related to knowledge management and computer science can also be frustrating. To bridge the gap between the translation of knowledge into the practice setting, many strategies can be used. Effken[8] described the need for an effective and comprehensive approach to the design and implementation of technology-based systems that specifically addresses the needs of case managers. Case managers must be involved in the creation, design, and implementation of systems that directly impact the care they provide. The financial aspect of any prospective changes must be closely evaluated in addition to the possible impact of the changes to the case manager's workflow.

Case management information systems are used to identify trends in treatment modalities and patterns in the provision of care, and to monitor the availability and use of resources to provide support in decision making and treatment in a cost-effective manner.[9] These systems include telemedicine, health information networks, decision and resource support tools, electronic charting systems, and various Internet and mobile communication tools. For the case manager, use of real time information at the touch of a screen can facilitate scheduling appointments, notification of multiple providers regarding patient updates, trend analysis, creation of predictive models, and better management of the high-risk patient's care.[10] The information that can be gathered through informatics can ensure medication reconciliation is the same since discharge. Patients have their questions and concerns answered, and case managers can track patients' conditions to ensure they are not declining toward a state that would require additional hospitalizations.

Provider portals and electronic charting systems are able to consolidate a patient's entire medical record and group information into various categories, which supports cost-effective decision making and treatment. Whether the case manager is in a hospital setting or on the road, staying connected provides the ability to prioritize and manage care in response to the patient's unique health care needs along the illness-wellness continuum.

Disease prevention and health promotion are important aspects of the care case managers provide. According to Edelman and Mandle,[11] health promotion initiatives assist individuals in altering their lifestyle and moving towards a state of wellness. Reaching a state of peak health involves implementing case management strategies focused on prevention, education, and support. Core competencies for the case manager in the primary prevention realm involve general health teaching and support in collaboration with the interdisciplinary team. Secondary prevention strategies include scheduling early diagnostic testing, thereby facilitating prompt treatment. Tertiary prevention strategies include providing education, support, and coordinating the resources necessary to return patients to their highest level of functioning.

Many innovative strategies have been developed that enable case managers to focus on prevention and partner with patients to help them reach their goals. In Cleveland, Ohio, case managers benefited from a $75,000 grant to the Cleveland Clinic's Stephanie Tubbs Jones Health Center from the Verizon Foundation to aid in the utilization of wireless technology.[12] The Affordable Care Act (ACA) has generated change

Further research is needed to ensure that data transmitted in the field are relayed to the proper storage sites either via web links, uploads, or satellites without interference or fear of data breaches.

in terms of the cost, availability, and organization of health care in the United States. Further, the Health Information Technology for Economic and Clinical Health (HITECH) Act enacted in 2011 provides financial incentives for physicians and health care organizations for the meaningful use of technology to stimulate patient's health learning and adopt electronic health record and charting systems.[13]

Conclusion

Case managers manage multiple patients with multiple unique issues. They are tasked with providing the most up-to-date data to the health care teams, giving high-quality care, and all the while, being cost effective. For these reasons and many more well beyond this article, the use of technological advancements related to the acquisition, distribution, and storing of information have provided case managers the opportunity to manage these current expectations. No longer can the health care system use cost or training as an excuse to avoid using informatics and telehealth applications. The complexity of patient care warrants the use of informatics.

Informatics is imperative to the successful trending of data, timely responses to providers, access to a provider in real time, and information transfer back and forth between patient and provider. Despite all the possible positives that can be stated about the use of informatics in case management, there remain concerns that need further research.

Further research is needed to ensure that data transmitted in the field are relayed to the proper storage sites either via web links, uploads, or satellites without interference or fear of data breaches. Additionally, discussion and research needs to be conducted to determine what can be done using this technology when a patient moves from one geographical location in a state to another. Should there be a standardized state database for this information or should this information be sent to another case manager in record form? If a state database is the appropriate approach, who then is responsible for the storage, security, and cost of management of these data?

Finally, a centralized database of funding should be developed to assist case management. When hospitals, insurance companies, and state or local entities are looking for help with acquisition, distribution, and storage systems, it should not take years to find appropriate funding. Despite the need for some further research in different areas, these technologies will allow timely, effective acquisition of data, while enabling the provision of cost-effective care. **CE 1**

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CE II

Ethical Considerations in Patients Who Are Suffering

By Michael J. Demoratz, PhD, LCSW, CCM

Are you suffering? This is a difficult, perhaps the most difficult, question we may ever ask—especially to someone who actually appears to be suffering. The implication is that if we ask, we might also need to be prepared to offer a solution to the problem. Hesitating to ask, or not asking at all, may mean we are unsure of being able to offer a solution or insecure about exploring the nature of suffering. Maybe we just don't know. Encouraging the conversation for all the parties involved should be a key feature of your assessment as a case manager. Ethically speaking, case managers are required by their Standards of Practice to do so (see Box 1 for Code of Ethics of CCMC, CDMS, and NASW).

After nearly 40 years of addressing better pain management at end of life, I have seen that we no longer have a problem asking if someone is in pain. Even families are now coached to ask about pain regularly. Since pain seems to have a clearer path to resolution, and there are many different types of pain medications that exist and in a step-ladder pattern can be used for more and more severe levels of the pain being experienced. When we ask our patient the question we want to know severity: "Tell me on a scale of 1–10" or "Select a face that tells me how you feel inside." We want to know where: "Show me where it hurts." We want to know the quality of the pain: "Describe the intensity. Is it dull, sharp, or shooting?" All of these questions are being asked to guide us in ameliorating pain. All that is required on the part of the patient is truthfulness and accuracy when being asked.

Michael J. Demoratz, *PhD, LCSW, CCM, is senior case manager at AMADA Concierge Care.*

Assessing Suffering

Suffering, however, is much harder to assess than pain. Suffering occurs on many levels. Some of these levels may be known to the patient, but there are other levels that may require you to develop a first degree (level) of trust or rapport with the patient to ensure truthfulness and safety. Treating suffering still requires an assessment with careful observation and questions of patients and those close to them. Simply asking the question, "Are you suffering?" implies the one asking might also have the answer. Put simply, would you ask someone if they were thirsty if you have nothing to offer them to drink?

Suffering and the nature of suffering are crucial aspects, arguably the most crucial, for case managers to understand and be able to assist with the assessment. Why suffering? Recently, California became the 5th state to address and pass legislation to allow Physician Aid in Dying (PAD). Clearly, the issue is an emotionally charged one, and strong positions supporting and opposing these laws are well-articulated in the literature by very thoughtful professionals with experience in working with people with serious or life-limiting illness. This article will not address the issue of PAD from either a positive or negative position. Instead, the passage of this piece of legislation and the apparent need for it begs us to explore the underlying cause(s) and the person's needs. Therefore, a PAD request could be the basis for a better exploration, and eventually a better understanding, of the nature of suffering and those caring for these very special patients. Clearly, these individuals are suffering—because they tell us so. It is strongly believed by individuals on both sides of the issue that a request for PAD may in fact be the result of untreated suffering. The first question in response to a request for PAD should be "Are you suffering?" The follow-up question is, "What in your condition has changed that this is now coming to light?"

The Nature of Suffering

A great deal has been written over the past few years about the nature of suffering, how suffering manifests itself,

Although depression is common in individuals with a life-limiting illness or condition, it is important not to assume that the only treatment is adding a medication. Sometimes, talking is the best medicine.

and how an individual responds to the progression of their condition. The first step in understanding suffering is to know the various levels in which it occurs. In his groundbreaking work, *The Nature of Suffering and the Goals of Medicine,* Eric Cassell, MD, addressed the 4 levels of suffering that occur—physical, psychological, social, and spiritual. Each level presents differently and needs to be assessed so that treatments can be provided to address each effectively.

Physical Suffering

The primary level, physical suffering, is perhaps the easiest to ascertain. Patients know the physical manifestations, the symptoms: pain, nausea, diarrhea, fatigue, to name a few. Each one of the physical symptoms may have a different solution. Patients who are familiar with their pain level may have self-identified and treated the symptom at some time during their illness with success. The only clear difference is the intensity of the pain and the fear that it is unremitting or untreatable with what they might see as standard care. If in the past, for example, an aspirin or some other over-the-counter medicine might have been capable of addressing their pain, they might not believe or accept that they are now ready for something stronger.

Sometimes, patients will not complain of pain or another symptom because they may see the level of the symptom as an acceptable one. Patients who are asked, "are you in pain?" might state, "of course I have pain; I have cancer!" My very own mother made this statement nearly 15 years ago to my question about the pain she was experiencing during cancer treatment. In a clear example of the shoemaker's shoe-less children, my mother hid the nature of her pain and suffering so as not to burden her well-loved, end-of-life subject matter expert son. Closer inspection with her physician revealed that her pain was unrelated to her primary cancer but associated with a secondary symptom of critically low hemoglobin. It was totally treatable, by the way. Family relationships aside, without a level of trust that there might be a stronger medicine to address the pain or another reason for it, our patients many, many times, like my mother, will be silent and not express any concern.

Pain has been addressed in the literature and the subject of thousands of articles and presentations to professional audiences as the 5th vital sign—We Must Assess Pain. It is unacceptable to not do so routinely. One of the challenges that has been part of this discussion over the past 40 years is the issue of tolerance and addiction. Patients, many of whom have been brought up to detest the notion of recreational drugs, may fear addiction, may even raise this as a real concern, stating so to their health care providers. "I don't want to get hooked." Some health care providers who are unfamiliar with good pain management treatments might even foster some of the same concerns. Clearly, the issue of tolerance is a real one. Patients may need greater amounts of medication over time because their bodies acclimate to the doses given. They might also need to be switched to stronger medications to address pain more effectively. At no point in time should a patient with clearly identifiable, clinically assessed pain be allowed to think they are becoming addicted to the medication. The mention of the word could reinforce the negative connotation that somehow they are responsible for their pain and that addressing it with greater levels of medication is a result of something they don't have control over. The pain experienced is a direct result of their serious medical condition, whether it is an injury, inflammation, or some other cause that is not behaviorally based.

Psychological

The next level in which suffering occurs is in the psychological realm. This too has certain acceptable and identifiable markers—depression and anxiety. The challenge for the health care worker is to verify and not assume that one is depressed without asking the question. Which question? Well perhaps start with "you appear a little down today; how are you feeling?" versus asking "are you depressed?" Although depression is common in individuals with a life-limiting illness or condition, it is important not to assume that the only treatment is adding a medication. Sometimes, talking is the best medicine. Adding a medication to treat sadness, appearing to many as depression (in their assessment), can be problematic for seniors with greater sensitivity to medications—sometimes very problematic, with the direct result that the patient often suffers more and not less than the condition presents. In addition, the negative side effects of

most antidepressants and antianxiety medications are prevalent for most people. The good news is that having a targeted conversation with a very ill person is something you can do. It shows you care and allows you to better understand the nature of suffering for the person sitting or lying before you. Betty Ferrell and Nessa Coyle in their book The Nature of Suffering and the Goals of Nursing Care outlined the value of these conversations while sitting with a patient and family. Simply asking a few questions or making a few comments that gently open the door to a more meaningful conversation can reveal much about the concerns that matter most for the person you are treating. Conveying genuine caring and concern for the experience your patient is having and being able to empathize and relate as one human to another, allows you to help your patient with what matters most to them.

When we come upon someone who appears anxious, the first concern might be to ensure that it is not a physical symptom, for example shortness of breath, that is causing them to be anxious. Shortness of breath is not a behavioral health concern. It may be caused by retention of excess fluids, impacting their ability to breathe. Certainly, there may be an underlying diagnosis that will reveal to you that a physical symptom is the culprit, but don't assume that their anxiety will go away with the inclusion of mental health support. There are numerous medications and treatments to address depression and anxiety. Therefore, evaluation and assessment of the root causes is invaluable. We should never just assume that "of course they have depression and anxiety; they are facing the end of their life." Patients facing the end of life can benefit from the kindness you exhibit by showing

BOX 1 CODES OF ETHICS

CDMS	The fundamental spirit of caring and respect with which the Code is written is based upon five principles of ethical behavior. These include autonomy, beneficence, nonmaleficence, justice, and fidelity, as defined below: • Autonomy: To honor the right to make individual decisions. • Beneficence: To do good to others. Nonmaleficence: To do no harm to others. • Justice: To act or treat justly or fairly. • Fidelity: To adhere to fact or detail. See the entire CDMS Code of Professional Conduct
NASW	The mission of the social work profession is rooted in a set of core values. These core values, embraced by social workers throughout the profession's history, are the foundation of social work's unique purpose and perspective: • Service • Social justice • Dignity and worth of the person • Importance of human relationships • Integrity • Competence See the entire NASW Code of Ethics
CCMC	Principles • Board-Certified Case Managers (CCMs) will place the public interest above their own at all times. • Board-Certified Case Managers (CCMs) will respect the rights and inherent dignity of all of their clients. • Board-Certified Case Managers (CCMs) will always maintain objectivity in their relationships with clients. • Board-Certified Case Managers (CCMs) will act with integrity and fidelity with clients and others. • Board-Certified Case Managers (CCMs) will maintain their competency at a level that ensures their clients will receive the highest quality of service. • Board-Certified Case Managers (CCMs) will honor the integrity of the CCM designation and adhere to the requirements for its use. • Board-Certified Case Managers (CCMs) will obey all laws and regulations. • Board-Certified Case Managers (CCMs) will help maintain the integrity of the Code, by responding to requests for public comments to review and revise the code, thus helping ensure its consistency with current practice. • Because case management exists in an environment that may look to it to solve or resolve various problems in the health care delivery and payor systems, case managers may often confront ethical dilemmas. Case managers must abide by the Code as well as by the professional code of ethics for their specific professional discipline for guidance and support in the resolution of these conflicts. See the entire CCMC Code of Professional Conduct

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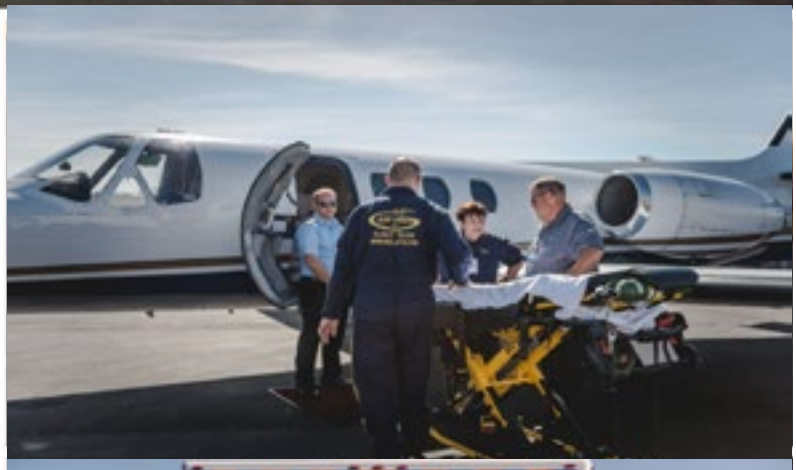

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The final level of suffering, and perhaps the most challenging of all, is in the spiritual realm. Hopelessness lives here.

your concern. Stated simply, ask the question, "You appear sad or anxious. How can I help you?"

Social

Suffering occurs at the social level from the moment a diagnosis of a serious or life-limiting diagnosis is made. Patients will pick and choose who they share this information with or if they share it at all. Some will go for weeks or months, if not years, before revealing the truth inside—unless, of course, the physical manifestations are forced on them to confirm a question by a caring individual. The circle of those invited to share this truth may be quite small at first: a spouse, a parent, an adult child, or a close friend may be the only ones who know. These individuals may suffer too. They may imagine and project a greater manifestation of suffering than the person actually experiencing the illness feels. Many times, it is silence that creates added suffering for the person and those invited into the circle. As their disease or condition progresses, the value of including others in the conversation for emotional support and assistance can be great. "If you don't tell me, I don't ask. I don't ask, I can't help"… becomes the concern at this level. Professionals with a mental health or behavioral health background best assess this level of suffering. Certainly others on the team can identify this level of suffering especially if they understand the importance of encouraging a referral to an individual or group for therapy or counseling. Groups can help with emotional support and targeted educational materials to address the concerns that typically arise with their condition.

Isolation breeds a greater level of social suffering—especially those who suffer in silence. The numbers of patients benefitting from peer group experience is vast. Nearly every condition has a group and even subgroups within to address this sense of isolation and the nuanced experiences of the attendees. These can be in-person, online, or by phone and are often described as life-saving by participants. Remember most support groups have separate groups for family caregivers, focusing on their specific needs and concerns. Individual and group support can be small or large, free or fee-based. Finding a support group can be done online via a disease-specific website or by picking up the phone.

Spiritual

The final level of suffering, and perhaps the most challenging of all, is in the spiritual realm. Hopelessness lives here. It has been said that it is unlikely, if not impossible, to have hope without a belief in something greater than yourself. This may reveal itself using religiously inspired terms, or referring to the Dieties: God, Jesus, Buddha, and Mohammad or Vishnu. For some, it may be less about religion and more about the relationship with what each individual might describe as a higher authority: a doctor, family member, or even dog could serve in the role. Your comfort or lack of comfort with the spiritual aspects of a patient's outward expression will be sensed by them, and conversation can be facilitated or stifled as a result. Being open and inclusive will garner support and trust in any referral you make on their behalf.

Unfortunately, in our mostly secular medical environments, we may limit our spiritual assessment of an individual to the simple question "Do you have a religious affiliation?" This is usually ascertained on admission to a hospital or other institution or organization, and the person asking has limited training in this area. The question once asked and recorded may never be addressed again unless the organization has a spiritual component as part of its' service offering.

Hospice programs, for example, routinely offer chaplain services to every person admitted under their care. Their approach is nondenominational in nature. If patients defer the service, the staff offering a chaplain will advise the patient and family that chaplains can be added at any time. If a specific faith perspective is sought, the chaplain can assist in obtaining special rites or sacraments: Last Rites by a priest, for example, could be found using the chaplain's assistance, as could a Rabbi for the Kiddush, or an Imam to lead prayers. Hospitals too now recognize the value a trained chaplain can bring to patients when addressing end-of-life goals and preferences.

Thich Nhat Hanh in the book *No Mud, No Lotus* addresses this from a Buddhist perspective that others might also agree with. Without suffering, happiness does not exist, since one can be aware of happiness simply because they know and have experienced

suffering. The concept of happiness as the absence of suffering allows the one suffering to know the difference, and with this knowledge, suffer less.

Addressing spiritual distress, or existential suffering, takes a skilled practitioner, one willing to walk the path with a patient and their family. There may arise the resurfacing of old issues related to family secrets, past transgressions, or internal wounds caused or experienced by the person facing the end of his or her life. Some patients may hide issues of pain or suffering as they feel the experience will serve as penance for the past issue. Some cultures may even see suffering as a badge of courage that cleanses them for the afterlife. Anticipatory losses for patients at this level include the lost opportunity to heal the relationship from the past. This level of suffering can be more significant than the other levels since it plays into the legacy of what the afflicted has left behind (peace or wreckage).

The need for forgiveness is a paramount feature for this level of suffering—forgiving or asking for forgiveness are both important. Chaplains with training and experience in end-of-life, hospice, and palliative care can gently explore these issues as they arise. Remember, these issues may be buried deeply. It is not likely that a patient will share something of this nature on first meeting. Ongoing involvement of a chaplain will allow the potential for these conversations to take place. Patients may only share issues like this once trust is established, and even then only to someone they feel will be able to help them. Sometimes, patients may request a spiritual advisor to address existential suffering. When patients make this type of request, it is important to address it quickly. Significant spiritual growth can occur for someone burdened with guilt over an old issue and a tremendous sense of relief, inspired by the right professional, can be as significant as finding the right dose of medication to make someone pain-free.

Conclusion

Addressing the four areas where suffering can occur is important for a good patient assessment. Especially true for patients facing an end-of-life process, the need for exploration of these areas will drive treatment decisions as well.

As the Silver Tsunami of baby boomer seniors crashes on the doorsteps of health care institutions, the multitudes arriving at the feet of providers in unbelievable numbers will demand that care be different. We will be pressured, more now than ever, to deal with the issue of patient suffering and the importance of good medical care in addressing this promptly. We all have an idea of what suffering looks like, feels like, and even smells like. We may project these issues onto others knowingly or unknowingly and ascribe them when there are none or when they clearly exist. Retrospectively, suffering may become amplified after the death (Oh, she suffered so much!) since it may have been an overarching theme of the illness or condition and very memorable … and not in a good way.

We can do better. Patients suffer because we don't ask them better questions. It is vital that we know that suffering is much more than pain and physical symptoms. Patients may feel they are a burden, and if the area of suffering is not addressed, their care may be burdensome to them and family. Patients' choices will reflect our expertise conveyed or our incompetence delivered.

At the end of the day, it's all about suffering and its control. Atul Gawande, MD in his book Being Mortal perhaps said it best—"Assisted living is far harder than assisted death." Patients need health care professionals to support them, advocate for them, care for them, talk with them, and educate them. If we do this effectively, the need for PAD will be very limited and mostly unnecessary.

What are you doing to proactively address suffering on all four levels? Remember, this is hard work, but we are a resilient people. Being comfortable with uncomfortable conversations will show patients and families your willingness to walk the difficult path that lies ahead. The time is now. The Centers for Medicare & Medicaid's recent inclusion of a payment mechanism for end-of-life conversations is a clear start down this path for a cultural shift. Your empathic response to patients suffering will be felt if you've done the work too. Know your value and the value of your team members.

Remember, if you find yourself standing before the patient who is suffering, there is a good chance you've been invited into a sacred circle. Be prepared to talk to your patients and please ask them, "Are you suffering?" And if they say so, ask, "How can I help you?" Then be prepared to gently walk with them along this journey. You will find that the rewards are life changing for you both. **CE II**

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PharmaFacts for Case Managers

Yosprala

INDICATIONS AND USE

Yosprala, a combination of aspirin and omeprazole, is indicated for patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin-associated gastric ulcers.

The aspirin component of Yosprala is indicated for

- Reducing the combined risk of death and nonfatal stroke in patients who have had ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli
- Reducing the combined risk of death and nonfatal MI in patients with a previous MI or unstable angina pectoris
- Reducing the combined risk of MI and sudden death in patients with chronic stable angina pectoris
- Use in patients who have undergone revascularization procedures (coronary artery bypass graft [CABG] or percutaneous transluminal coronary angioplasty [PTCA]) when there is a pre-existing condition for which aspirin is already indicated.

The omeprazole component of Yosprala is indicated for decreasing the risk of developing aspirin-associated gastric ulcers in patients at risk for developing aspirin-associated gastric ulcers due to age (≥ 55) or documented history of gastric ulcers.

Limitations of Use

- Yosprala contains a delayed-release formulation of aspirin and it is not for use as the initial dose of aspirin therapy during onset of acute coronary syndrome or acute MI, or before percutaneous coronary intervention (PCI), for which immediate-release aspirin therapy is appropriate
- Yosprala has not been shown to reduce the risk of gastrointestinal bleeding due to aspirin
- Yosprala is not interchangeable with the individual components of aspirin and omeprazole

Dosage and Administration

- Patients should take one tablet daily.
- Yosprala is available in combinations that contain 81 mg or 325 mg of aspirin. Generally, 81 mg of aspirin has been accepted as an effective dose for secondary cardiovascular prevention. Providers should consider the need for 325 mg and refer to current clinical practice guidelines.
- Patients should take Yosprala once daily at least 60 minutes before a meal.
- The tablets are to be swallowed whole with liquid. Do not split, chew, crush, or dissolve the tablet.
- Use the lowest effective dose of Yosprala based on the individual patient's treatment goals and to avoid potential dose dependent adverse reactions including bleeding.
- If a dose of Yosprala is missed, advise patients to take it as soon as it is remembered. If it is almost time for the next dose, skip the missed dose. Take the next dose at the regular time. Patients should not take 2 doses at the same time unless advised by their doctor.
- Do not stop taking Yosprala suddenly as this could increase the risk of heart attack or stroke.

Dosage Forms and Strengths

- Oval, blue-green, film-coated, delayed-release tablets for oral administration containing either
- 81 mg delayed-release aspirin and 40 mg immediate-release omeprazole, printed with 81/40, or
- 325 mg delayed-release aspirin and 40 mg immediate-release omeprazole, printed with 325/40.

Contraindications

Yosprala is contraindicated in

- Patients with known allergy to aspirin and other nonsteroidal anti-inflammatory drug products (NSAIDs) and in patients with the syndrome of asthma, rhinitis, and nasal polyps. Aspirin may cause severe urticaria, angioedema, or bronchospasm (asthma)
- Pediatric patients with suspected viral infections, with or without fever, because of the risk of Reye's syndrome with concomitant use of aspirin in certain viral illnesses
- Patients with known hypersensitivity to aspirin, omeprazole, substituted benzimidazoles, or to any of the excipients in the formulation
- Proton pump inhibitor (PPI)–containing products, including Yosprala, are contraindicated in patients receiving rilpivirine-containing products.

Warnings and Precautions

Coagulation Abnormalities

Even low doses of aspirin can inhibit platelet function leading to

an increase in bleeding time. This can adversely affect patients with inherited (hemophilia) or acquired (liver disease or vitamin K deficiency) bleeding disorders. Monitor patients for signs of increased bleeding.

Gastrointestinal Adverse Reactions
Aspirin is associated with serious gastrointestinal (GI) adverse reactions, including inflammation, bleeding ulceration and perforation of the upper and lower GI tract. Other adverse reactions with aspirin include stomach pain, heartburn, nausea, and vomiting.

Serious GI adverse reactions reported in the clinical trials of Yosprala were gastric ulcer hemorrhage in one of the 521 patients treated with Yosprala and duodenal ulcer hemorrhage in one of the 524 patients treated with enteric-coated aspirin. In addition, there were two cases of intestinal hemorrhage, one in each treatment group, and one patient treated with Yosprala experienced obstruction of the small bowel.

Although minor upper GI symptoms, such as dyspepsia, are common and can occur anytime during therapy, monitor patients for signs of ulceration and bleeding, even in the absence of previous GI symptoms. Inform patients about the signs and symptoms of GI adverse reactions. If active and clinically significant bleeding from any source occurs in patients receiving Yosprala, discontinue treatment.

Bleeding Risk with Use of Alcohol
Counsel patients who consume three or more alcoholic drinks every day about the bleeding risks involved with chronic, heavy alcohol use while taking Yosprala.

Interaction with Clopidogrel
Avoid concomitant use of Yosprala with clopidogrel. Clopidogrel is a prodrug. Inhibition of platelet aggregation by clopidogrel is entirely due to an active metabolite. The metabolism of clopidogrel to its active metabolite can be impaired by use with concomitant medications, such as omeprazole, that interfere with CYP2C19 activity. Co-administration of clopidogrel with 80 mg omeprazole reduces the pharmacological activity of clopidogrel, even when administered 12 hours apart. When using Yosprala, consider alternative anti-platelet therapy.

Interaction with Ticagrelor
Maintenance doses of aspirin above 100 mg reduce the effectiveness of ticagrelor in preventing thrombotic cardiovascular events. Avoid concomitant use of ticagrelor with the 325 mg/40 mg tablet strength of Yosprala.

Renal Failure
Avoid Yosprala in patients with severe renal failure (glomerular filtration rate less than 10 mL/minute). Regular use of aspirin is associated in a dose-dependent manner with an increased risk of chronic renal failure. Aspirin use decreases glomerular filtration rate and renal blood flow especially with patients with pre-existing renal disease. .

Presence of Gastric Malignancy
In adults, response to gastric symptoms with Yosprala does not preclude the presence of gastric malignancy. Consider additional gastrointestinal follow-up and diagnostic testing in adult patients who experience gastric symptoms during treatment with Yosprala or have a symptomatic relapse after completing treatment. In older patients, also consider an endoscopy.

Acute Interstitial Nephritis
Acute interstitial nephritis has been observed in patients taking PPIs including omeprazole. Acute interstitial nephritis may occur at any point during PPI therapy and is generally attributed to an idiopathic hypersensitivity reaction. Discontinue Yosprala if acute interstitial nephritis develops

Clostridium difficile-associated Diarrhea
Published observational studies suggest that PPI-containing therapy like Yosprala may be associated with an increased risk of Clostridium difficile-associated diarrhea (CDAD), especially in hospitalized patients. This diagnosis should be considered for diarrhea that does not improve.

Use the lowest dose and shortest duration of Yosprala appropriate to the condition being treated.

Bone Fracture
Several published observational studies suggest that PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine. The risk of fracture was increased in patients who received high-dose, defined as multiple daily doses, and long- term PPI therapy (a year or longer). Use the lowest dose and shortest duration of Yosprala therapy appropriate to the condition being treated. Manage patients at risk for osteoporosis- related fractures according to established treatment guidelines

Cutaneous and Systemic Lupus Erythematosus
Cutaneous lupus erythematosus (CLE) and systemic lupus erythematosus (SLE) have been reported in patients taking PPIs, including omeprazole. These events have occurred as both new onset and an exacerbation of existing autoimmune disease. The majority of PPI-induced lupus erythematous cases were CLE.

The most common form of CLE reported in patients treated with PPIs was subacute CLE (SCLE). Onset of CLE occurred up to 2 years after continuous drug therapy (range from 1 to 104 weeks). CLE occurred primarily in older patients, although cases were reported in patients as young as 7 months of age. Generally, positive antinuclear antibodies (ANA) and histological findings were observed, consistent with a diagnosis of CLE. Organ involvement was not typically seen. Complete recovery generally has occurred within 12 weeks after discontinuation of the drug.

Systemic lupus erythematosus (SLE) is less commonly reported than CLE in patients receiving PPIs. PPI associated SLE is usually milder than non-drug induced SLE. Onset of SLE typically occurred within 30 days after initiating PPI treatment, but some cases occurred days or years after initiating treatment. SLE occurred primarily in older patients, although cases also occurred in young adults. The majority of patients presented with rash; however, arthralgia and cytopenia were also reported. Antibody testing for lupus, including ANA and antihistone antibodies, may be positive. Clinical signs and symptoms of SLE associated with PPI use were usually reversible once the PPI was discontinued.

Clinical symptoms generally resolved within 8 weeks. Elevated serological test results may take longer to resolve than clinical manifestations.

Avoid administration of PPIs for longer than medically indicated. If signs or symptoms consistent with CLE or SLE are noted in patients receiving Yosprala, discontinue the drug and refer the patient to the appropriate specialist for evaluation. Most patients improve with discontinuation of the PPI alone in 4 to 12 weeks.

Hepatic Impairment
Long-term moderate to high doses of aspirin may result in elevations in serum ALT levels. These abnormalities resolve rapidly with discontinuation of aspirin. The hepatotoxicity of aspirin is usually mild and asymptomatic. Bilirubin elevations are usually mild or absent. Systemic exposure to omeprazole is increased in patients with hepatic impairment. Avoid Yosprala in patients with any degree of hepatic impairments.

Cyanocobalamin (Vitamin B-12) Deficiency
Daily treatment with any acid-suppressing medications over a long period of time (e.g., longer than 3 years) may lead to malabsorption of cyanocobalamin (vitamin B-12) caused by hypo- or achlorhydria. Rare reports of cyanocobalamin deficiency occurring with acid-suppressing therapy have been reported in the literature. This diagnosis should be considered if clinical symptoms consistent with cyanocobalamin deficiency are observed in patients treated with Yosprala.

Hypomagnesemia
Hypomagnesemia, symptomatic and asymptomatic, has been reported rarely in patients treated with PPIs for at least three months, in most cases after a year of therapy. Serious adverse events include tetany, arrhythmias, and seizures. In most patients, treatment of hypomagnesemia required magnesium replacement and discontinuation of the PPI. For patients expected to be on prolonged treatment or who take Yosprala with medications such as digoxin or drugs that may cause hypomagnesemia (e.g., diuretics), consider monitoring magnesium levels prior to initiation of Yosprala and periodically during treatment

Reduced Effect of Omeprazole with St. John's Wort or Rifampin
Drugs which induce the CYP2C19 or CYP3A4 (such as St. John's Wort or rifampin) can substantially decrease concentrations of omeprazole. Avoid concomitant use of Yosprala with St. John's Wort or rifampin

Interactions with Diagnostic Investigations for Neuroendocrine Tumors
Serum chromogranin A (CgA) levels increase secondary to omeprazole-induced decreases in gastric acidity. The increased CgA level may cause false positive results in diagnostic interventions for neuroendocrine tumors. Temporarily discontinue treatment with Yosprala at least 14 days before assessing CgA levels and consider repeating the test if initial CgA levels are high. If serial tests are performed (e.g., for monitoring), the same commercial laboratory should be used for testing, as reference ranges between tests may vary

Interaction with Methotrexate
Literature suggests that concomitant use of PPIs with methotrexate (primarily at high dose) may elevate and prolong serum levels of methotrexate and/or its metabolite, possibly leading to methotrexate toxicities. In high-dose methotrexate administration, a temporary withdrawal of Yosprala may be considered in some patients.

Premature Closure of Fetal Ductus Arteriosus
NSAIDs including aspirin, may cause premature closure of the fetal ductus arteriosus. Avoid use of NSAIDs, including Yosprala, in pregnant women starting at 30 weeks of gestation (third trimester).
Abnormal Laboratory Tests
Aspirin has been associated with elevated hepatic enzymes, blood urea nitrogen and serum creatinine, hyperkalemia, proteinuria, and prolonged bleeding time.

Adverse Reactions
Clinical Studies Experience
Yosprala 325 mg/40 mg was studied primarily in two randomized, double-blind controlled clinical trials (n=524) of 6 months' duration. Adverse reactions that occurred in >2% of patients in the Yosprala arm and were more common than in the control arm were gastritis, nausea, diarrhea, gastric polyps, and noncardiac chest pain.

In Study 1 and Study 2 combined, 7% of patients taking Yosprala discontinued due to adverse reactions compared to 11% of patients taking EC-aspirin alone. The most common reasons for discontinuations due to adverse reactions in the Yosprala treatment group were upper abdominal pain (<1%, n=2), diarrhea (<1%, n=2) and dyspepsia (<1%, n=2).

Less Common Adverse Reactions
In Yosprala-treated patients in the clinical trials there were 2 patients with upper GI bleeding (gastric or duodenal) and 2 patients with lower GI bleeding (hematochezia and large intestinal hemorrhage) and one additional patient experienced obstruction in the small bowel.

How Supplied and Stored
Yosprala (aspirin 81 mg/omeprazole 40 mg) and (aspirin 325 mg/

continues on page 24

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omeprazole 40 mg) delayed-release tablets are oval, blue-green, film-coated tablets printed with 81/40 and 325/40 respectively in black ink. Yosprala tablets are packaged in high density polyethylene (HDPE) bottles with desiccants and are supplied as:

Storage: Store at 25°C (77°F); excursions permitted to 15–30°C (59 to 86°F) [see USP Controlled Room Temperature]. Store in the original container with desiccant and keep the bottle tightly closed to protect from moisture. Dispense in a tight container if package is subdivided.

Yosprala is manufactured by Aralez Pharmaceuticals US Inc.

Erelzi (etanercept-szzs) injection, for subcutaneous use

Indications

Rheumatoid Arthritis

Erelzi is indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (RA). Erelzi can be initiated in combination with methotrexate (MTX) or used alone.

Polyarticular Juvenile Idiopathic Arthritis

Erelzi is indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients ages 2 and older.

Psoriatic Arthritis

Erelzi is indicated for reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis (PsA). Erelzi can be used in combination with methotrexate (MTX) in patients who do not respond adequately to MTX alone.

Ankylosing Spondylitis

Erelzi is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis (AS).

Plaque Psoriasis

Erelziv is indicated for the treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy.

Dosage and Administration

Erelzi is administered by subcutaneous injection.

Adult patients with RA, AS, or PsA should take 50 mg weekly. For adults with PsO, the starting dose is 50 mg twice weekly for 3 months followed by 50 mg weekly for maintenance. Pediatric patients who weigh 63 kg or more should receive 50 mg weekly for treatment of juvenile idiopathic arthritis.

Note: There is no dosage form for Erelzi that allows weight-based dosing for pediatric patients below 63 kg.

Dosage Forms and Strengths

Erelzi is a clear and colorless to slightly yellow solution available as:

Injection: 25 mg/0.5 mL and 50 mg/mL solution in a single-dose prefilled syringe with BD UltraSafe Passive™ Needle Guard

Injection: 50 mg/mL solution in a single-dose prefilled Sensoready® Pen

Contraindications

Erelzi should not be administered to patients with sepsis.

Warnings and Precautions

WARNINGS: SERIOUS INFECTIONS AND MALIGNANCIES

SERIOUS INFECTIONS

Patients treated with etanercept products are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients treated with etanercept products who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Erelzi should be discontinued if a patient develops a serious infection or sepsis. Reported infections include:

- Active tuberculosis, including reactivation of latent tuberculosis. Patients with tuberculosis have frequently presented with disseminated or extrapulmonary disease. Patients should be tested for latent tuberculosis before Erelzi use and during therapy. Treatment for latent infection should be initiated prior to Erelzi use.
- Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Empiric anti-fungal therapy should be considered in patients at risk for invasive fungal infections who develop severe systemic illness.
- Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.

The risks and benefits of treatment with Erelzi should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection.

Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with Erelzi, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

MALIGNANCIES

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including etanercept products.

Adverse Reactions

Across clinical studies and postmarketing experience, the most serious adverse reactions with etanercept were infections, neurologic events, CHF, and hematologic events. The most common adverse reactions with etanercept were infections and injection site reactions.

How Supplied/Storage and Handling

Administration of one 50 mg Erelzi prefilled syringe with BD UltraSafe Passive Needle Guard or one Erelzi Sensoready Pen provides a dose equivalent to two 25 mg Erelzi prefilled syringes with BD UltraSafe Passive Needle Guard.

Erelzi Single-dose Prefilled Syringe with BD UltraSafe Passive Needle Guard and Erelzi Single-dose Prefilled Sensoready Pen

Each Erelzi (etanercept-szzs) Injection single-dose prefilled syringe with BD UltraSafe Passive Needle Guard and Erelzi single-dose pre-filled Sensoready Pen contains clear and colorless to slightly yellow solution containing 25 mg/0.5 mL or 50 mg/mL of etanercept-szzs in a single-dose syringe with a 27-gauge, ½-inch needle.

Erelzi should be refrigerated at 36°F to 46°F (2°C to 8°C). Do not use Erelzi beyond the expiration date stamped on the carton or barrel label. DO NOT SHAKE. Store Erelzi in the original carton to protect from light or physical damage.

For convenience, storage of individual syringes or Sensoready Pens at room temperature between 68°F to 77°F (20°C to 25°C) for a maximum single period of 28 days is permissible, with protection from light and sources of heat. Once a syringe or Sensoready Pen has been stored at room temperature, it should not be placed back into the refrigerator. If not used within 28 days at room temperature, the syringe or Sensoready Pens should be discarded. Do not store Erelziin extreme heat or cold. DO NOT FREEZE. Keep out of the reach of children.

Erelzi is manufactured by Sandoz, Inc.

Sustol (granisetron) extended-release injection, for subcutaneous use

Indications and Use

Sustol is indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens.

Dosage and Administration

Important Administration Instructions

- For subcutaneous injection only.
- Sustol is intended for administration by a health care provider.
- Sustol is supplied as a refrigerated kit consisting of a single-dose, pre-filled, sterile syringe, a special thin walled 18 Ga 5/8" administration needle, two syringe warming pouches, and a Point Lok® needle protection device. See the Sustol Instructions for Use included in the kit for complete administration instructions with illustrations.
- Do not substitute non-kit components for any of the components from the kit for administration.

Preparation

1. At least 60 minutes before administration, remove the Sustol kit from refrigeration.
2. Unpack the kit to allow the Sustol syringe and all other contents to warm to room temperature.
3. Activate one of the syringe warming pouches, and wrap the Sustol syringe in the warming pouch for 5 to 6 minutes to warm Sustol to body temperature.
4. Before administration, inspect the Sustol syringe visually for particulate matter and discoloration. Note that the syringe is amber colored glass. Sustol should not be administered if particulate matter or discoloration is observed, the tip cap is missing or has been tampered with, or if the Luer fitting is missing or dislodged.

Administration

1. Use standard aseptic technique when performing the injection.
2. Administer Sustol as a single subcutaneous injection in the skin of the back of the upper arm or in the skin of the abdomen at least one inch away from the umbilicus. Avoid injecting Sustol anywhere the skin is burned, hardened, inflamed, swollen, or otherwise compromised. Topical anesthetic may be used at the injection site prior to administration of SUSTOL.
3. Due to the viscosity of SUSTOL, the time required for injection is greater than most medications administered subcutaneously. Sustol requires a slow, sustained injection which may take up to 20 to 30 seconds. Pressing the plunger harder will NOT expel Sustol faster.

Recommended Dosage

The recommended dosage of Sustol is 10 mg administered subcutaneously. Administer Sustol in combination with dexamethasone at least 30 minutes before the initiation of MEC or AC combination chemotherapy. Administer Sustol on Day 1 of chemotherapy and not more frequently than once every 7 days because of the extended-release properties of the formulation.

For patients receiving MEC, the recommended dexamethasone dosage is 8 mg intravenously on Day 1. For patients receiving AC combination chemotherapy regimens, the recommended dexamethasone dosage is 20 mg intravenously on Day 1, followed by 8 mg orally, twice a day, on Days 2, 3 and 4.

If Sustol is administered with an NK1 receptor antagonist, see the prescribing information of the NK1 receptor antagonist for the recommended dexamethasone dosage.

continues on page 36

LITSCAN FOR CASE MANAGERS

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

Eur J Heart Fail. 2016 Sep 21. doi: 10.1002/ejhf.633. [Epub ahead of print]

Heart failure outcomes in clinical trials of glucose-lowering agents in patients with diabetes.

Fitchett DH, Udell JA, Inzucchi SE.

Diabetes is a major risk factor for heart failure (HF). Patients with diabetes have a high incidence of both clinical HF and subclinical LV dysfunction. Although intensive glucose lowering does not appear to impact on HF outcomes, the choice of glucose-lowering agents plays an important role in the development of HF and related cardiovascular outcomes. Whilst metformin and insulin appear to have little impact on HF progression, the role of sulphonylurea agents in this patient population remains uncertain. Thiazolidinediones (TZDs) are associated with a significant risk of HF progression and are best avoided in patients at risk. The incretin-based therapies (GLP agonists and DPP-4 inhibitors) are generally not associated with any HF interaction. However, a small increase in HF admissions was observed with the DPP-4 inhibitor saxagliptin. The GLP-1 agonist liraglutide was recently shown to reduce cardiovascular and all-cause mortality, yet hospitalization for HF was not significantly reduced. The SGLT2 inhibitor empagliflozin was shown to reduce HF admissions and cardiovascular mortality in patients with prior cardiovascular disease including HF. These recent data showing improved outcomes with a glucose-lowering category provide a novel strategy to improve survival and reduce morbidity in diabetic patients at high cardiovascular disease risk.

J Acquir Immune Defic Syndr. 2016 Sep 19. [Epub ahead of print]

Active referral of children of HIV-positive adults reveals high prevalence of undiagnosed HIV.

Wagner AD, Wachira CM, Njuguna IN, et al.

OBJECTIVES: Few routine systems exist to test older, asymptomatic children for HIV. Testing all children in the population has high uptake but is inefficient, while testing only symptomatic children increases efficiency but misses opportunities to optimize outcomes. Testing children of HIV-infected adults in care may efficiently identify previously undiagnosed HIV-infected children before symptomatic disease. METHODS: HIV-infected parents in HIV care in Nairobi, Kenya were systematically asked about their children's HIV status and testing history. Adults with untested children <12 years old were actively referred and offered the choice of pediatric HIV testing at home or clinic. Testing uptake and HIV prevalence were determined, as were bottlenecks in pediatric HIV testing cascade. RESULTS: Of 10,426 HIV-infected adults interviewed, 8,287 reported having children, of whom 3,477 (42%) had children of unknown HIV status, and 611 (7%) had children <12 years of unknown HIV status. Following implementation of active referral, the rate of pediatric HIV testing increased 3.8-fold from 3.5 to 13.6 children tested per month, (RR: 3.8, 95%CI: 2.3-6.1). Of 611 eligible adults, 279 (48%) accepted referral and were screened, and 74 (14%) adults completed testing of 1 or more children. HIV prevalence among 108 tested children was 7.4% and median age was 8 years (IQR: 2-11); one child was symptomatic at testing. CONCLUSIONS: Referring HIV-infected parents in care to have their children tested revealed many untested children and significantly increased the rate of pediatric testing; prevalence of HIV was high. However, despite increases in pediatric testing, most adults did not complete testing of their children.

MMWR Morb Mortal Wkly Rep. 2016;65(37):1004-1007. doi: 10.15585/mmwr.mm6537a4.

Unmet needs for ancillary services among men who have sex with men and who are receiving HIV medical care—United States, 2013-2014.

DeGroote NP, Korhonen LC, Shouse RL, Valleroy LA, Bradley H.

Gay, bisexual, and other men who have sex with men (MSM) are disproportionately affected by human immunodeficiency virus (HIV) in the United States (1). Ancillary services, defined as services that support retention in HIV medical care and assist with day-to-day living, can improve the health of HIV-infected MSM and help them achieve viral suppression (2). To assess the unmet needs for ancillary services among MSM receiving outpatient HIV medical care during 2013-2014, CDC used data from the Medical

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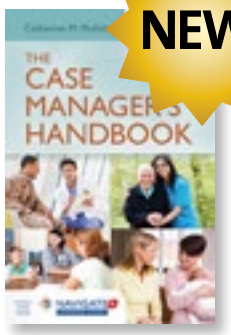

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Monitoring Project (MMP), a surveillance system designed to assess clinical and behavioral characteristics of adults receiving HIV care, to obtain nationally representative estimates of, and identify reasons for, unmet needs (3). Based on self-reported needs of persons responding to the MMP survey, the most prevalent unmet needs were for non-HIV medical care services: approximately 23% had an unmet need for dental care, and 19% had an unmet need for eye or vision care. Unmet needs were most prevalent among young, non-Hispanic black, and Hispanic/Latino MSM. State and local health departments, community-based organizations, and health care providers might improve the health of MSM living with HIV by promoting access to ancillary services using strategies that increase patient awareness of how to obtain these services, especially among young, non-Hispanic black, and Hispanic/Latino MSM.

Nephrol Dial Transplant. 2016 Sep 20. pii: gfw325. [Epub ahead of print]

Albuminuria and masked uncontrolled hypertension in chronic kidney disease.

Agarwal R.

BACKGROUND: Masked uncontrolled hypertension (MUCH) is associated with greater target organ damage such as left ventricular hypertrophy, increased arterial stiffness and albuminuria. Whether MUCH independently associates with greater cardiovascular end-organ damage or kidney damage is unclear. The objective of this study was to assess the strength of the relationship of MUCH (awake ambulatory blood pressure ≥135/85 mmHg and clinic blood pressure <140/90 mmHg) with target organ damage. METHODS: In a cross-sectional study at a veterans' administration medical center, clinically normotensive veterans without chronic kidney disease (CKD) (n = 29) and 287 patients with CKD and controlled hypertension (CH, n = 193), MUCH (n = 67) and uncontrolled hypertension (UCH, n = 27) had evaluation of target organ damage. Target organ damage was measured by echocardiography [left ventricular mass index (LVMI)], arterial ultrasonography [aortic pulse wave velocity (PWV)] and 24-h urine collection [albuminuria (urine albumin to creatinine ratio)] in all participants. RESULTS:

Compared to that of controls, LVMI was higher by 21.8 g/m2 (CI, 4.0-39.7 g/m2) in CH, 27.9 (CI, 8-47.8) in MUCH and 39.5 (CI, 15.7-63.2) in UCH (P < 0.01 for group differences, P < 0.01 for linear trend). Although differences persisted after adjustment for age, sex and race, they lost significance after adjustments for cardiovascular risk factors and their treatment. Compared to that of controls, PWV was different among CH, MUCH and UCH (P = 0.04 for group differences, P = 0.02 for linear trend). However, differences lost significance after adjustments for age, sex and race. Compared to that of controls, log2 UACR was higher by 2.40 mg/mg (CI, 1.28-3.52) in CH, 4.94 (CI, 3.70-6.18) in MUCH and 6.01 (CI, 4.49-7.53) in UCH (P < 0.0001 for group difference, P < 0.0001 for linear trend). Differences persisted after adjustment for age, sex and race, cardiovascular risk factors and their treatment and cardiovascular disease (P < 0.0001 for group difference, P < 0.0001 for linear trend). CONCLUSIONS: MUCH is more strongly related to albuminuria compared with cardiovascular damage as assessed by left ventricular mass and PWV. A graded and an independent relationship of blood pressure classification status with albuminuria is consistent with the hypothesis that renal mechanisms may be more important than cardiovascular disease in mediating the pathogenesis of MUCH.

Ann Thorac Surg. 2016 Sep 9. pii: S0003-4975(16)30738-X. doi: 10.1016/j.athoracsur.2016.06.031. [Epub ahead of print]

Patient preferences in treatment choices for early-stage lung cancer.

Tong BC, Wallace S, Hartwig MG, D'Amico TA, Huber JC.

BACKGROUND: Decision-making for lung cancer treatment can be complex because it involves both provider recommendations based on the patient's clinical condition and patient preferences. This study describes the relative importance of several considerations in lung cancer treatment from the patient's perspective. METHODS: A conjoint preference experiment began by asking respondents to imagine that they had just been diagnosed with lung cancer. Respondents then chose among procedures that differed regarding treatment modalities, the potential for treatment-related complications, the likelihood of recurrence, provider case volume, and distance needed to travel for treatment. Conjoint analysis derived relative weights for these attributes. RESULTS: A total of 225 responses were analyzed. Respondents were most willing to accept minimally invasive operations for treatment of their hypothetical lung cancer, followed by stereotactic body radiation therapy (SBRT); they were least willing to accept thoracotomy. Treatment type and risk of recurrence were the most important attributes from the conjoint experiment (each with a relative weight of 0.23), followed by provider volume (relative weight of 0.21), risk of major complications (relative weight of 0.18), and distance needed to travel for treatment (relative weight of 0.15). Procedural and treatment preferences did not vary with demographics, self-reported health status, or familiarity with the procedures. CONCLUSIONS: Survey respondents preferred minimally invasive operations over SBRT or thoracotomy for treatment of early-stage non-small cell lung cancer. Treatment modality and risk of cancer recurrence were the most important

factors associated with treatment preferences. Provider experience outweighed the potential need to travel for lung cancer treatment.

Clin Nephrol. 2016;86(10):165-174. doi: 10.5414/CN108796.

Vitamin D levels, vitamin D supplementation, and prognosis in patients with chronic kidney disease.

Namir Y, Cohen MJ, Haviv YS, Slotki I, Shavit L.

BACKGROUND: Vitamin D (Vit D) deficiency plays a central role in the pathogenesis of chronic kidney disease (CKD) complications, both skeletal and nonskeletal. The purpose of this study was to examine whether 25(OH)D levels and supplementation with oral cholecalciferol (Vitamin D3 (Vit D3)) are associated with morbidity and mortality among patients with significant CKD. METHODS: CKD patients attending the nephrology clinic at Shaare Zedek Medical Center between July 1, 2008 and January 31, 2012, tested at least twice for 25(OH)D levels, were enrolled. Primary endpoints included death, end-stage renal disease (ESRD) requiring start of dialysis, a rise of at least 50% in serum creatinine, or composite endpoints of the above. RESULTS: A total of 516 patients were studied, of whom 178, 257, and 81 patients had baseline vitamin D levels < 5 ng/mL, 15 - 30 ng/mL, and > 30 ng/mL, respectively. We found an association between baseline 25(OH)D level below 15 ng/mL and renal outcomes (start of dialysis or a rise of at least 50% in serum creatinine) in both crude and multivariate analyses (hazard ratio (HR) 3.17, 95% CI 1.12 - 8.94). Vit D3 supplementation demonstrated beneficial effects on combined renal outcomes and death in univariate analyses (p = 0.02). Moreover, an increment of 10 ng/mL in 25(OH)D levels was associated with a 25% reduction in mortality (HR 0.755 (95% CI 0.54 - 1.00), in crude but not adjusted analyses. CONCLUSIONS: Significant Vit D deficiency in CKD can serve as a biological marker indicating patients in whom adverse renal outcomes can be anticipated. Moreover, Vit D3 supplementation and rise of serum 25(OH)D levels may have beneficial influence on hard renal outcomes.

Clin Transplant. 2016 Sep 20. doi: 10.1111/ctr.12848. [Epub ahead of print]

A clinical tool to risk stratify potential kidney transplant recipients and predict severe adverse events.

Nygaard RM, Sirany AM, Wyman EA, et al.

Preoperative risk assessment of potential kidney transplant recipients often fails to adequately balance risk related to underlying comorbidities with the beneficial impact of kidney transplantation. We sought to develop a simple scoring system based on factors known at the time of patient assessment for placement on the waitlist to predict likelihood of severe adverse events one year post-transplant. The tool includes four components: age, cardiopulmonary factors, functional status, and metabolic factors. Pre-transplant factors strongly associated with severe adverse events include: diabetic (OR 3.76, p<0.001), coronary artery disease (OR 3.45, p<0.001), history of CABG/PCI (OR 3.1, p=0.001), and peripheral vascular disease (OR 2.74, p=0.008).The score was evaluated by calculation of concordance index. The C statistic of 0.74 for the risk stratification group was considered good discrimination in the validation cohort (N=127) compared to the development cohort (N=368). The pre-transplant risk group was highly predictive of severe adverse events (OR 2.36, p<0.001). Patients stratified into the above average risk group were 4 times more likely to experience severe adverse events compared to average risk patients; while patients in the high risk group were nearly 11 times more likely to experience severe adverse events. The pre-transplant risk stratification tool is a simple scoring scheme using easily obtained preoperative characteristics that can meaningfully stratify patients in terms of post-transplant risk and may ultimately guide patient selection and inform the counseling of potential kidney transplant recipients.

Ann Surg. 2016 Sep 14. [Epub ahead of print]

Association among blood transfusion, sepsis, and decreased long-term survival after colon cancer resection.

Aquina CT, Blumberg N, Becerra AZ, et al.

OBJECTIVE: To investigate the potential additive effects of blood transfusion and sepsis on colon cancer disease-specific survival, cardiovascular disease-specific survival, and overall survival after colon cancer surgery. BACKGROUND: Perioperative blood transfusions are associated with infectious complications and increased risk of cancer recurrence through systemic inflammatory effects. Furthermore, recent studies have suggested an association among sepsis, subsequent systemic inflammation, and adverse cardiovascular outcomes. However, no study has investigated the association among transfusion, sepsis, and disease-specific survival in postoperative patients. METHODS: The New York State Cancer Registry and Statewide Planning and Research Cooperative System were queried for stage I to III colon cancer resections from 2004 to 2011. Propensity-adjusted survival analyses assessed the association of perioperative allogeneic blood transfusion, sepsis, and 5-year colon cancer disease-specific survival, cardiovascular disease-specific survival, and overall survival. RESULTS: Among 24,230

patients, 29% received a transfusion and 4% developed sepsis. After risk adjustment, transfusion and sepsis were associated with worse colon cancer disease-specific survival [(+)transfusion: hazard ratio (HR) 1.19, 95% confidence interval (CI) 1.09-1.30; (+)sepsis: HR 1.84, 95% CI 1.44-2.35; (+)transfusion/(+)sepsis: HR 2.27, 95% CI 1.87-2.76], cardiovascular disease-specific survival [(+) transfusion: HR 1.18, 95% CI 1.04-1.33; (+)sepsis: HR 1.63, 95% CI 1.14-2.31; (+)transfusion/(+)sepsis: HR 2.04, 95% CI 1.58-2.63], and overall survival [(+)transfusion: HR 1.21, 95% CI 1.14-1.29; (+)sepsis: HR 1.76, 95% CI 1.48-2.09; (+)transfusion/(+) sepsis: HR 2.36, 95% CI 2.07-2.68] relative to (-)transfusion/(-) sepsis. Additional analyses suggested an additive effect with those who both received a blood transfusion and developed sepsis having even worse survival. CONCLUSIONS: Perioperative blood transfusions are associated with shorter survival, independent of sepsis, after colon cancer resection. However, receiving a transfusion and developing sepsis has an additive effect and is associated with even worse survival. Restrictive perioperative transfusion practices are a possible strategy to reduce sepsis rates and improve survival after colon cancer surgery.

Ann Surg. 2016 Sep 9. [Epub ahead of print]

National Quality Forum Colon Cancer Quality Metric Performance: how are hospitals measuring up?

Mason MC, Chang GJ, Petersen LA, et al.

OBJECTIVE: To evaluate the impact of care at high-performing hospitals on the National Quality Forum (NQF) colon cancer metrics. BACKGROUND: The NQF endorses evaluating ≥12 lymph nodes (LNs), adjuvant chemotherapy (AC) for stage III patients, and AC within 4 months of diagnosis as colon cancer quality indicators. Data on hospital-level metric performance and the association with survival are unclear. METHODS: Retrospective cohort study of 218,186 patients with resected stage I to III colon cancer in the National Cancer Data Base (2004-2012). High-performing hospitals (>75% achievement) were identified by the proportion of patients achieving each measure. The association between hospital performance and survival was evaluated using Cox shared frailty modeling. RESULTS: Only hospital LN performance improved (15.8% in 2004 vs 80.7% in 2012; trend test, P < 0.001), with 45.9% of hospitals performing well on all 3 measures concurrently in the most recent study year. Overall, 5-year survival was 75.0%, 72.3%, 72.5%, and 69.5% for those treated at hospitals with high performance on 3, 2, 1, and 0 metrics, respectively (log-rank, P < 0.001). Care at hospitals with high metric performance was associated with lower risk of death in a dose-response fashion [0 metrics, reference; 1, hazard ratio (HR) 0.96 (0.89-1.03); 2, HR 0.92 (0.87-0.98); 3, HR 0.85 (0.80-0.90); 2 vs 1, HR 0.96 (0.91-1.01); 3 vs 1, HR 0.89 (0.84-0.93); 3 vs 2, HR 0.95 (0.89-0.95)]. Performance on metrics in combination was associated with lower risk of death [LN+AC, HR 0.86 (0.78-0.95); AC+timely AC, HR 0.92 (0.87-0.98); LN+AC+timely AC, HR 0.85 (0.80-0.90)], whereas individual measures were not [LN, HR 0.95 (0.88-1.04); AC, HR 0.95 (0.87-1.05)]. CONCLUSIONS: Less than half of hospitals perform well on these NQF colon cancer metrics concurrently, and high performance on individual measures is not associated with improved survival. Quality improvement efforts should shift focus from individual measures to defining composite measures encompassing the overall multimodal care pathway and capturing successful transitions from one care modality to another.

J Pediatr. 2016 Sep 14. pii: S0022-3476(16)30727-2. doi: 10.1016/j.jpeds.2016.08.045. [Epub ahead of print]

Childhood irritable bowel syndrome characteristics are related to both sex and pubertal development.

Chumpitazi BP, Weidler EM, Czyzewski DI, et al.

OBJECTIVE: To determine the relationship of both pubertal development and sex to childhood irritable bowel syndrome (IBS) clinical characteristics including gastrointestinal symptoms (eg, abdominal pain) and psychological factors. STUDY DESIGN: Cross-sectional study with children ages 7-17 years (n = 143) with a pediatric Rome III IBS diagnosis recruited from both primary and tertiary clinics between January 2009 and January 2014. Subjects completed 14-day prospective pain and stool diaries, as well as validated questionnaires assessing several psychological factors (somatization, depression, anxiety) and Tanner stage. Stool form ratings were completed using the Bristol Stool Form Scale. RESULTS: Girls with higher Tanner scores (more mature pubertal development) had both decreased pain severity and pain interference; in contrast, boys with higher Tanner scores had both increasing pain severity (β = 0.40, P = .02) and pain interference (β = 0.16, P = .02). Girls (vs boys), irrespective of pubertal status, had both increased somatic complaints (P = .005) and a higher percentage (P = .01) of hard (Bristol Stool Form Scale type 1 or 2) stools. Pubertal status and sex did not significantly relate to IBS subtype, pain frequency, stooling frequency, anxiety, or depression. CONCLUSIONS: In children with IBS, both pubertal development and/or sex are associated with abdominal pain severity, stool form, and somatization. These differences provide insight into the role of pubertal maturation during the transition from childhood to adult IBS.

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The Associated Press: Millions Leaving Government Insurance Money On the Table?

Millions of Americans who bought individual health insurance outside the Affordable Care Act's public exchanges may be leaving money on the table if they skip those marketplaces again in picking 2017 coverage, a new report says. The Department of Health and Human Services estimates that 2.5 million people who bought so-called off-exchange coverage for this year might have income levels that qualify them for tax credits to help pay the premium. ■

Artificial Pancreas for Type 1 Diabetes Approved

The US Food and Drug Administration approved the first automated insulin delivery system—a so-called "artificial pancreas"—for people with type 1 diabetes. "This first-of-its-kind technology can provide people with type 1 diabetes greater freedom to live their lives without having to consistently and manually monitor baseline glucose levels and administer insulin," Dr. Jeffrey Shuren, director of the FDA's Center for Devices and Radiological Health, said in an agency news release.

The device—Medtronic's MiniMed 670G—is what's known as a hybrid closed-loop system. That means it monitors blood sugar and then delivers necessary background (also known as basal) insulin doses. The device will also shut off when blood sugar levels drop too low. However, this device isn't yet a fully automated artificial pancreas. People with type 1 diabetes will still need to figure out how many carbohydrates are in their food, and enter that information into the system, the agency noted.

Medtronic said the new device will be available by Spring 2017. The FDA approval is currently only for people aged 14 and older. The company is now conducting clinical trials with the device in younger patients. ■

RISK OF OPIOID ADDICTION

Young adults in the United States are more likely to become addicted to prescription opioids than they were in years past. And they're more likely to use heroin, too, a new study says. A review of federal data found the odds of becoming dependent on opioids like Vicodin and Percocet increased 37% percent among 18- to 25-year-olds between 2002 and 2014. The study was conducted by researchers from Columbia University's Mailman School of Public Health in New York City. A grim picture emerged among slightly older adults, too: Risk of an opioid use disorder more than doubled among 26- to 34-year-olds, increasing from 11% to 24%, the study found. ■

The Wall Street Journal: FDA Warns On Hepatitis C Drugs

The Food and Drug Administration is warning about the risk of reactivation of hepatitis B among patients who have had that disease and who are taking some prominent and expensive newer medicines for hepatitis C. The federal agency said it is requiring a so-called black-box warning in the labels for at least nine brand-name direct-acting antiviral drugs, including Sovaldi and Harvoni from Gilead Sciences Inc., Viekira Pak from AbbVie Inc. and Zepatier from Merck & Co. ■

ZIKA AND GUILLAIN-BARRE SYNDROME

Guillain-Barré syndrome (GBS) is an uncommon sickness of the nervous system in which a person's own immune system damages the nerve cells, causing muscle weakness, and sometimes, paralysis.

Several countries that have experienced Zika outbreaks recently have reported increases in people who have Guillain-Barré syndrome (GBS).

Current CDC research suggests that GBS is strongly associated with Zika; however, only a small proportion of people with recent Zika virus infection get GBS.

CDC is continuing to investigate the link between GBS and Zika to learn more. ■

Botox for Urinary Incontinence in Woman

For women with bladder incontinence who haven't been helped by medications or other therapies, Botox injections may help control leakage better than an implanted nerve stimulation device, a new study suggests. However, both treatments are effective, according to doctors who treat the condition. In a head-to-head comparison, women given Botox saw their number of daily urgency incontinent episodes decrease by four, on average, compared to three for women who received the implant, called InterStim. Botox patients also said they had a greater reduction in symptoms and were more satisfied with the treatment, the researchers said. More can be read about the study in the *Journal of the American Medical Association*. ■

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PharmaFacts for Case Managers

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Dosage Adjustment in Renal Impairment
In patients with moderate renal impairment (creatinine clearance of 30 to 59 mL/min), administer Sustol on Day 1 of chemotherapy and not more frequently than once every 14 days. Avoid Sustol in patients with severe renal impairment (creatinine clearance of less than 30 mL/min).

Dosage Forms and Strengths
Sustol is supplied as a clear, colorless to slightly yellow, viscous liquid and is available as an:

Extended-Release Injection: 10 mg/0.4 mL in a single-dose pre-filled syringe.

Adverse Reactions
Adverse reactions that occurred to last 3% of patients who were treated with Sustol 10 mg before and during chemotherapy in Studies 1 and 2 were injection-site reactions, constipation, fatigue, headache, diarrhea, abdominal pain, insomnia, dyspepsia, dizziness, asthenia, and gastroesophageal reflux.

Clinical Studies
In a randomized, multicenter, double-blind, parallel group study of 733 cancer patients who were receiving moderately emetogenic (MEC) or anthracycline plus cyclophosphamide (AC) combination chemotherapy, a single 10 mg subcutaneous dose of Sustol was found to be noninferiors to a single 0.25 mg intravenous dose of palonosetron hydrochloride.

How Supplied/Storage and Handling
Sustol extended-release injection is supplied in cartons of 6 kits (NDC 47426-101-06); single dose kit (NDC 47426-101-01) contains:

- One sterile single-dose amber colored glass syringe which contains 10 mg granisetron/0.4 mL
- One sterile 18 Ga 5/8" special thin walled administration needle
- Two sodium acetate syringe warming pouches
- One Point Lok needle protection device

Storage
Store Sustol in the refrigerator at 2°C to 8°C (36°F to 46°F). Sustol can be placed back in the refrigerator after being kept at room temperature. Sustol can remain at room temperature for up to a maximum of 7 days.

Protect from light. Do not freeze.

Sustol is manufactured by Heron Therapeutics. 

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application on next page

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