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Gary S. Wolfe

Stop Workplace Bullying in Health Care

One of the highest rates of workplace bullying occurs in the health care environment. The far-reaching implications of bullying—defined as any type of repetitive abuse in which the victim of the bullying behavior suffers verbal abuse, threats, humiliating or intimidating behaviors, or behaviors by the perpetrator that interfere with his or her job performance, and are meant to place at risk the health and safety of the victim—must be actively addressed by employees and employers.

Four types of bullying are defined as:

- Direct verbal bullying is characterized by threats, insults, and name-calling.
- Indirect relational bullying is characterized by exclusionary behavior and rumor spreading.
- Cyber-bullying, the newest form of bullying, uses electronic methods (texting, email, social media) to inflict emotional distress on the target.

Retaliation uses psychological and social behaviors to cause harm. One example is conceptualized by the adage "Once they stop talking to you, they begin talking about you." This type of bullying may occur, for example, when a target is perceived as "ratting out" another employee or blamed for being "passed over" for a promotion.

Other intimidating behavior found in health care organizations may include:

- Shaming, humiliating, or spreading malicious rumors
- Insulting or slighting an individual based on race, religion, or appearance
- Throwing objects
- Physically abusing another

Why Do Individuals Bully?

Generally, a bully has an extreme need to have complete control over an individual or an environment. Additionally, the bully may have personality flaws such as an exaggerated sense of self.

Bullying usually occurs via a systematic mistreatment of an individual in which the bully:

- Sabotages a person's work
- Uses verbal abuse

Employs public humiliation (often in front of co-workers)

- Excludes or ignores the person

The impact of bullying is significant on both the individual and the employer. Bullying decreases job satisfaction among employees, decreases employee productivity, increases employee absence from work, and increases job turnover. Intimidating and disruptive behaviors can foster medical errors, contribute to poor patient satisfaction and preventable adverse outcomes, and increase the cost of care.

What Can You Do?

Everyone must raise awareness of workplace bullying and work together to get ahead of the problem. Organizations can implement these specific steps to address workplace bullying:

1. Institute a clear statement of "zero tolerance" in relation to bullying behaviors, irrespective of the role or seniority of the perpetrator.
2. Adopt an organization-wide anti-bullying policy that:
   - Identifies examples of bullying behavior
   - Outlines manager and staff responsibilities

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Bringing the 'Quadruple Aim' Into Case Management Practice

By MaryBeth Kurland, CAE, Vivian Campagna, MSN, RN-BC, CCM, *Commission for Case Manager Certification*

As case managers know, the "triple aim" approach has long been the ideal for health care delivery, with three inter-related goals of improving population health, increasing patient satisfaction, and smarter spending. But there is a fourth "aim": satisfaction for clinicians and healthcare providers.

Put together, the "quadruple aim" spans the spectrum of providing care including caring for the provider. With the added demands on clinicians and providers today, and the lack of resources available, burnout and dissatisfaction are on the rise. The symptoms include loss of enthusiasm for work, feelings of cynicism, and a low sense of personal accomplishment. The quadruple aim attempts to counteract these issues by emphasizing the satisfaction of the clinicians along with that of the patients. By focusing on the happiness of all involved, the quadruple aim supports delivery of the best possible care to patients.

For case managers, the "fourth aim" is particularly meaningful as they take on bigger caseloads and shoulder more responsibilities, such as evaluating and tracking outcomes achieved by the interdisciplinary team. The Commission for Case Manager Certification (CCMC) put the spotlight on the quadruple aim at its 2017 New World Symposium—Case Management: Expertise for the Future. Several speakers addressed the quadruple aim in sessions that were designed to inform as well as entertain, delivering the message that case managers need less stress in order to provide better patient care leading to desired outcomes.

Many of the case managers at the symposium said they intend to implement the fourth aim in their own lives and practice, as well as with their teams. They immediately saw the connection between better self-care and a higher degree of performance, with less risk of burnout.

Managing Increased Expectations

In every care setting and venue, case managers face increased expectations for achieving goals. Some, like the health goals set by the patient (i.e. the "client" receiving case management services), can be tremendously satisfying. But others, such as expectations set by administrators, can create pressure.

Consider the example of a hospital that implemented a "discharge by noon" program, which sounded very good on paper. But in practice, it fell to the case managers who were expected to ensure that this goal was achieved—despite the reality that physicians often wanted to see their patients during morning rounds before writing discharge orders. No matter that they were given ownership of the discharge by noon process, case managers could not change what the doctors did. This quickly became a recipe for frustration and mounting stress because the case managers could not meet the expectations set by others.

The solution was to escalate the issue to someone in administration who could make changes. As they advocated for themselves, case managers experienced a reduction in their stress because they were heard. This freed them to focus on the smaller incremental changes they could make, one patient at a time.

Three Tips for the Quadruple Aim

Below are three tips for how case managers can embrace the quadruple aim in their practice and their lives.

Know what's yours to change—and what needs to be escalated. As the "hub" of the interdisciplinary team, case managers face multiple responsibilities and expectations, from facilitating communicating across the team to tracking outcomes. Add to that the expectations of third-parties such as insurers and healthcare organizations. These mounting pressures can overwhelm case managers. One way to deal with that stress is to know the difference between what the case manager can change and what needs to be escalated to someone else. This distinction lets case managers reduce their frustration and find satisfaction in being "heard."

Practice mindfulness. Mindfulness has gotten a lot of attention lately, as a way to train your mind to focus on the present moment and spend less time preoccupied with unhealthy, unproductive thoughts. Mindfulness for the case

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Part 4: Case Management Society of America Issues Revised Standards of Practice—Professional Case Management Roles and Responsibilities

By Elizabeth Hogue, Esq.

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

Case managers generally perform primary functions of assessment, planning, facilitation, coordination, monitoring, evaluation, and advocacy. Collaboration and ongoing communication with clients, clients' families and caregivers, and other health professionals involved in clients' care are integral to the functions of case managers.

Recent revisions to CMSA's standards state that specific functions of case managers may include, but are not limited to, the following:

- Considering predictive modeling, screening and other data to determine whether clients may benefit from case management services
- Conducting assessments of clients' health, physical, functional behavioral, and psychological and social needs that direct development and implementation of specific plans of care
- Identifying target goals for care in collaboration with clients, clients' families and caregivers, and other members of the health care team
- Planning care interventions and needed resources with clients, families or family caregivers, providers, payors and community-based services to maximize clients' health care responses, quality, safety, cost-effective outcomes and optimal care experiences
- Facilitating communication and coordination among members of the interprofessional health care team, including involving clients in decision-making processes, in order to minimize fragmentation in services provided and prevention of unsafe care and suboptimal outcomes
- Collaborating with other health care professionals and support services providers across care settings, levels of care and professional disciplines in order to help ensure safe transitions of care
- Coordinating care interventions, referrals to specialty providers and community-based support services, consults and resources across practitioners and care settings
- Communicating continuously with clients, their families and caregivers and others involved in clients' care to help ensure that they are well-informed and current on plans of care
- Educating clients, their families and caregivers, and members of the health care team about treatment options, community resources, health insurance benefits, psychosocial and financial concerns, and case management services in order to make timely and informed decisions
- Counseling and empowering clients to solve problems by exploring options of care and alternative plans to achieve desired outcomes
- Completing notifications for and pre-authorization of services, medical necessity reviews and concurrent or

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Case managers generally perform primary functions of assessment, planning, facilitation, coordination, monitoring, evaluation, and advocacy. Collaboration and ongoing communication with clients, clients' families and caregivers, and other health professionals involved in clients' care are integral to the functions of case managers.

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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Insights on Case Management in Workers' Compensation

By Myra Keleher, DNP, RN, CDMS, CCM

Case managers in workers' compensation are often underestimated by those who aren't familiar with our important role in the industry. Our efforts to help injured workers navigate the complex health care system are sometimes viewed as simple cost-cutting measures. In reality, our sole purpose is to ensure that injured workers receive the best possible care as soon as possible to help expedite an efficient and safe return to work.

Over my 20-plus years in the industry, I have witnessed the effects of our contributions daily. From the construction worker who returns to the worksite after undergoing surgery and rehab for a repetitive stress injury, to a police officer who rejoins the force after sustaining a devastating on-duty spinal cord injury thanks to adaptive equipment—workers' comp case managers make significant impacts on the lives of injured workers.

So why are we underestimated? Perhaps it's because we're so dedicated to the welfare of those committed to our care and the complexity of our busy work schedules that we don't stop and educate others about what we do.

Essentially, when an employee is injured, the case manager's role is to assess and interpret information related to a claim and identify areas in need of intervention or support. Case managers collaborate with the worker and their family, coordinate and communicate with all providers on the care team, and provide valuable claims insights and updates to claims professionals and payers on new jurisdictional requirements, new guidelines from employers, and new risks within the workplace.

Case managers are expected to advocate for the injured worker, while also representing the interests of the employer. They must stay abreast of physician networks and ancillary providers for respective customers. They are responsible for carefully documenting each case, noting when an injured worker's treatment is following accepted guidelines or when it's fallen outside a normal course of treatment for the diagnosis.

Case managers are expected to advocate for the injured worker, while also representing the interests of the employer.

As branch manager of Genex Services' Lake Mary, FL, office, I'm responsible for day-to-day operations, as well as meeting annual performance and financial goals. I also recruit, hire, and manage a staff of 30, most of whom are telephonic nurse case managers, who work remotely.

These work-at-home positions are in high demand, as they afford nurses a great deal of independence and flexibility. Many nurses are looking to transition away from the high pressures of a hospital setting and want to move into business management.

When hiring, I primarily look for nurses with relevant certifications (eg, CCM, CDMS, CRRN, and COHN) and at least a year of experience in case management, preferably in workers' comp, but I also accept case managers who have med-surg, orthopedic, emergency department, or ICU experience.

Aside from providing telephonic case management services to the Southeast, my office also handles several national customers, which is why I manage nurses across the country. For national accounts, nurses may sit in one state, but must be licensed in multiple states and be familiar with the case management requirements in all the states for which they manage cases.

Telephonic case management is most effective when used within 90-120 days of the injury. Proactive customers get our case managers involved from the day of injury, or as early as possible. Other times, case managers are assigned cases when injured workers are forced to miss work due to their injuries. Our case managers then facilitate getting the employees back to work, either in a modified capacity or full duty.

It's a complicated job, so I work to ensure our case managers have a manageable workload and adequate administrative support. At Genex, we support

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***Myra Keleher, DNP, RN, CDMS, CCM** is Branch Manager of Case Management at Genex Services.*

Five Key Principles Case Managers Should Know About Return-to-Work Programs

By Lisa Scotton, RN, MJ, CCM, CDMS, COHN

Return-to-work (RTW) programs in the workplace are an important part of an organization's culture. These programs are designed to enable ill or injured employees to ease back into the workplace after a period of absence. Best practice RTW programs encompass all occupational or non-occupational injuries or illnesses. While RTW has always been a focus of workers' compensation case management, clinical and disability case managers are also tasked with recognizing their role in helping the individual return to optimal health and productivity.

Understanding RTW is especially important given the aging workforce, as more people stay active in their jobs beyond the traditional retirement age. Coupled with the rise in age-related chronic conditions, this demographic is creating more demand for RTW assistance and other workplace health and productivity programs.

Here are five key principles case managers should know about RTW programs:

1. **Understand the employee's functionality.** Functionality refers to activities the employee can do, not what the employee can't do. For example, an employee recovering from a fractured ankle would have an impaired ability to walk, stand and climb stairs, but would likely still be able to perform sedentary work. The case manager collaborates with the health care provider to identify activities the employee can safely do while recovering from an illness or injury—not simply how long the employee cannot work.
2. **Review the employee's essential job functions.** Essential job functions are the basic, fundamental duties of a job, which can be found in an employee's job description. This includes physical (walking, standing, lifting, etc.) and cognitive (reasoning, decision making, computing, etc.) job activities. Understanding this information is critical in order to ensure a safe and sustainable return-to-work plan.
3. **Identify potential accommodations and/or work modifications.** In many cases, a timely return to work can be facilitated when the employer can provide a reasonable accommodation. This may include adaptive equipment, such as an ergonomic keyboard or a sit/stand workstation; modified job requirements; and/or a reduction in work hours. Studies have shown that the employer's cost for an accommodation can average around $500, but in many cases, there may be no cost at all. There are benefits to both parties: An accommodation enables the employee to return to work, and the employer benefits by having a skilled employee return to work, while also reducing the direct and indirect costs of absenteeism.
4. **Know the Americans with Disabilities Act (ADA) requirements.** The Americans with Disabilities Act (ADA) is a law that prohibits discrimination against employees with disabilities, especially in the workplace. In 2009, the ADA was amended and broadened the definition of disability, thereby affording job protections to more Americans with disabilities. Disabilities are not just physical; there are also "invisible" disabilities, such as behavioral health conditions or metabolic conditions, such as diabetes. Protections under the law allow people with disabilities to retain, or return to, their jobs. For case managers, this may involve helping employers evaluate an accommodation request using the ADA interactive process.
5. **Provide information and support to managers.** The workplace practice of not allowing employees to return to work until they are "100 percent" is no longer acceptable. Supervisors and managers should be educated to overcome the fear that a recovering employee could be re-injured and an absence prolonged. The solution is having a Certified Disability Management Specialist (CDMS) or a Certified Case Manager (CCM) who is knowledgeable about return to work best practices help educate employers, while also facilitating a safe, timely and sustainable way for the employee to return to work.

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Value-based Care Leads to Shorter Lengths of Stay in Skilled Nursing Facilities:

5 Recommendations for Thorough Discharge Planning

Alissa Getts, MSN, CCM, and Dana Strauss, PT, MPT

Increase in Value-based Payment Models

The Centers for Medicare and Medicaid Services (CMS) have made efforts to contain rising costs via the Innovation Center by creating alternative payment models, which reward hospitals and health systems that control costs while improving quality of care. Since its rollout in 2013, the Bundled Payment for Care Improvement (BPCI) program, one of CMS's popular value-based reimbursement models, is now likely going to be an inescapable reality as acute hospitals and health systems are finding this program to be a favorable payment reform. Last year the Comprehensive Care for Joint Replacement (CCJR) program was the first mandatory bundle payment to be piloted in select markets in what is likely to be a series of bundled payment programs such as the Cardiac Bundle that will include Acute Myocardial Infarction (AMI) and Coronary Artery Bypass Graft (CABG). These programs are planned to be in effect on July 1, 2017, testing quality improvement and cost reduction for Medicare beneficiaries.[1] The CCJR program will also expand under current plans. While this program now only includes elective hip and knee replacements, planned expansion will cover fractured femur and hip. The cardiac bundle will be placed into hospitals in 98 metropolitan selected areas (MSAs) across the country, and the expanded CCJR will affect the same 67 MSAs that originally started the program in 2016.[1]

Value-based Payments Affect Skilled Nursing Facilities

Value-based payment models are created for the purposes of reducing Medicare spending and improving patient outcomes, partly by improving care coordination between health-care providers. As more hospital systems take on more financial risk by adopting more value based programs like BPCI and various types of Accountable Care Organizations (ACO), they will be looking at creating networks of post–acute care providers. It's in a health system's best interest to collaborate with skilled nursing facilities (SNFs) that understand the purpose of these programs and to partner with facilities that have made efforts to improve their own care coordination and patient outcomes while being more cognizant of their lengths of stay (LOS) (which affect total cost per episode for bundled programs and total cost per patient for ACOs). Research shows that patients sent to preferred facilities have LOS that are 5 to 7 days shorter than those sent to nonpreferred facilities.[2] These shorter LOS not only help value-based programs achieve their financial targets but also encourage early care planning and patient and family education.

In creating these post-acute relationships, the potential for savings is significant. Nursing home-based SNFs are Medicare's single biggest expense for post-acute care. CMS spent $28 billion on skilled nursing care in 2013, up from $13.6 billion in 2001.[2] Those SNFs who can show hospital systems that their patients will receive high-quality care and effective care coordination in an efficient time will gain additional market share. This will offset the anticipated losses that will occur because of shorter LOS and more of a push towards lower-cost alternatives such as home health or outpatient services once deemed medically appropriate. A common fear of SNFs is the inability to keep their Medicare census full because of shorter LOS and the hospital's push for a lower-cost alternative for post-acute care when planning discharges. Health care business models are shifting from volume based to value based, and SNFs stand to lose if long-standing business model has benefited by encouraging longer LOS for members who had available days to use.

During SNF utilization review (UR) meetings, the clinical team reviews each plan of care for every patient in the facility. From experience, we know the number of SNF

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days that a patient has available in their bank is one indicator of how quickly the team acted on discharge planning. Overutilization of the SNF days will occur if this practice continues. One suggestion to change this practice: instead of leading a UR by stating how many SNF days a patient has left or how can we continue to "skill" this patient, instead pose the question "what has to be done to get this patient to the next level of care?"A proactive approach to UR meetings will set the tone for all clinical staff to work together to effectively coordinate care for each patient.

Value-based Programs Prove To Be Effective

Bundled programs have been successful in saving Medicare dollars. SNF patients who participated in the orthopedic bundled program had a decrease in LOS by an average of 1.3 days compared to those patients did not participate.[3] As LOS decreases, discharge planners in SNFs play a significant role in the success of the program. The care coordination and appropriate transition time for discharge will fall on physicians, physical therapists, social workers, and care managers of these institutions.

BPCI and ACO coordinators observe that compliance of front-line staff at SNFs during this period of change is not initially high. Change in payment delivery models is inherently difficult. Coaching staff to adapt to a new mindset is a challenge for SNF leaders. Discharge planners and other members of the clinical team may not understand the benefits of value-based programs. The benefits will be better coordination for patients and appropriate utilization of their Medicare benefits, which will lead to better outcomes and fewer visits to the emergency department (ED) and hospital. For value-based payment models to be successful, all clinical disciplines need to change the way they practice. The expectation is that clinical staff physicians, nurses, rehabilitation therapists, and pharmacists will collaborate to set a positive tone for more efficient care and early discharge planning. The belief that shorter LOS will compromise care is not true when effective care coordination and quality discharge planning have been implemented.

Nurturing Compliance Among Clinical Staff

Administrators need to nurture a belief that patient care will

not be compromised by shorter LOS. As seen by experience, this is one of the biggest obstacles. Common verbiage heard by clinical staff to patients is that "because you are in a bundled or ACO program, our facility has to discharge you early." This all-too-common language makes the challenge of the discharge planning teams even harder as negative assumptions about value-based care are fertilized by these attitudes. Value payment models are created to hold the providers accountable for the quality and quantity of care that they provide. The goal is to be able to not overutilize the post-acute benefit. Quality care and optimal patient outcomes can be achieved with shorter LOS.

Recommendations for Discharge Planners to Adapt to Shorter LOS

The following are 5 ways in which care managers can modify their discharge planning process to meet the quality demands that value based payment programs are placing on SNF's.

1. **Determine an Anticipated Day of Discharge (ADOD).** It is common practice for acute inpatient facilities to use estimated discharge dates when determining the LOS for acute inpatient admission. The benefits of having an ADOD include streamlining the transition to the next level of care.4 If there is a set date when the patient will be discharged, this will allow for more comprehensive planning. Care Pathways can be developed to meet the goals in time for discharge. In hospitals, ADOD is sometimes written on the whiteboard of a patient's room. This is to set expectations with patients and family members so that they know how long the stay will be. This can be very valuable to both the patient and SNF. It allows for better communication and eliminates any surprises. Mitigating expectations of what can be accomplished during the SNF stay and setting the expectations will avoid patients thinking they will be in the SNF until they are at full previous level of function. The SNF discharge planner's role is to determine when the patient is ready for the next level of care, which is home health or outpatient therapy. It is important to remember that an ADOD is a target date, meaning that if a patient is not medically ready to go, the date can be extended. And that goes for patients who do better in a shorter time fram—their date of discharge can be moved up earlier. Physical therapy and nursing should work together when determining the ADOD because their shared input in clinical judgment and input are valuable when setting realistic goals for patients.

2. **Plan an initial "Welcome" family meeting the first few days of admission.** Three to 5 days immediately after admission, new patients should have a family/caregiver meeting with the discharge planning staff, nursing, and the rehabilitation team to discuss health care goals and anticipated discharge date. This is an opportunity for the clinical team to identify barriers, determine discharge needs, and get an accurate picture of the patient's previous level of function. This meeting will initiate communication with patients and families and keep them aware of the anticipated time frame the patient will be at the SNF. Use this opportunity to get an accurate prior level of function (PLOF) for the patient, which is important for setting a ADOD. Describing a PLOF by noting "independent" is not enough to get an accurate description. Explore the patient's concerns at home, fall history, willingness to use assistive devices, and frequency of use. The more detailed the information about previous level of function, the less chance of setting unrealistic rehabilitation goals that can prolong LOS.

3. **Make the home care referral early.** As soon as they are admitted to the SNF, identify the patients who will need home care after discharge. Patients with chronic illnesses should be flagged as potential candidates for home care. For example, elderly patients with congestive heart failure that are discharged to SNF have a higher chance of a 30-day hospital readmission than HF patients discharged to another setting (27% vs 22%).5 Referring home care services for these patients is an effective way to help reduce unnecessary readmissions after a SNF admission. Home health agencies in a bundle payment scenario are strategically positioned to best help providers such as SNFs reduce the risk of readmission for their patients.[6] Evidence suggests that through better coordination between the home health care setting and skilled nursing facilities, improving core discharge planning and transition processes can reduce the percentage of avoidable rehospitalizations. Home care agencies will be able to provide complex patients with continued education, coaching, and support for patient self-management in the home setting.

   If the SNF has the advantage of having an onsite home care coordinator/liaison, make the referral early and inform the patient that best practice is to start planning for transitioning back home when they are admitted to the SNF. By meeting a representative from the home health agency, patients can obtain the necessary information regarding home programs and be able to ask questions. The home care representative will be able to gain more knowledge about the patient, perform a

Instead of leading a UR by stating how many SNF days a patient has left or how can we continue to "skill" this patient, instead pose the question "what has to be done to get this patient to the next level of care?"

comprehensive health assessment, and give the agency a head start in planning appropriate staffing on discharge. Making early referrals to home health care agencies allows for efficient staffing of home field nurses and therapists. If an onsite home health coordinator is not available, have the agency representative call the patient/family directly. It's also important that the home care agency the patient chooses obtains proper medical records, discharge summaries, and medication reconciliation so that transition can be smooth and care continuous.

4. **Start a teaching plan for patient and caregivers on the first day of admission.** Discuss discharge planning with the patient and families as early as the first day of admission. Use every opportunity to start providing the patient information so that they will be prepared for self-care when discharged. Identify the needs of the patient at admission so that appropriate teaching can be provided before discharge. For example, does the patient have a new colostomy? Is he or she using a new inhaler for COPD? Is the patient on aspiration precautions? As the discharge coordinator, find teaching opportunities and reinforce to the front-line staff that every contact with the patient is an opportunity to teach. For example, when respiratory therapists give treatments to COPD patients, they should be educating the patient on early signs and symptoms of exacerbation. Nurses should take time during their bedside treatments to reinforce elements of the care plan before the patient is discharged. Family members should be aware of signs and symptoms to look out for that could lead to exacerbations of chronic disease, such as fluid overload for heart failure patients or shortness of breath or coughing symptoms for patients with chronic obstructive pulmonary disorder.

   When home, a patient's ability to detect symptoms early and contact the physician can prevent serious conditions and a trip to the ED. Leaving the teaching to be done the day before or same day of discharge is poor planning. Patients need reinforcement and a chance to demonstrate back when complex issues like colostomy care, medication education, basic wound care, or invasive catheter care will require self-management, even with the intermittent assistance of home health nurses at home. Bring in caregivers as early as possible to observe and repeat-demonstrate functional mobility assistance in the therapy rooms and demonstrate the level of functional assistance the patient requires to return home. Involving the family and caregivers well before discharge is crucial. Thorough education is an important component of rehospitalization prevention and achievement of better outcomes.

5. **Initiate post-discharge calls.** In October 2017, SNFs will be expected to publicly report quality metrics such as their hospital readmission rates. The pressure is now on SNFs to come up with quality initiatives to prevent unnecessary hospital readmissions. These quality metrics will be counted towards a scoring system that will determine SNF reimbursement rates from CMS. One quality initiative easily implemented is reaching out to the patients after discharge. It has been proven in various studies that timely post-discharge follow-up calls are effective in reducing near-hospital readmissions.[6] One study shows a direct correlation between the timing of the intervention and the rate of readmission; the closer the intervention to the date of discharge, the greater the reduction in number of readmissions. The study also reported that ED visits were reduced and physician office visits increased, suggesting that these follow-up calls may have encouraged patients to seek earlier assistance and reducing readmission.[7]

   Post-discharge phone calls can be made by anyone on the clinical staff. It's up to the discharge team to delegate these calls to a clinical staff member. The caller should have access to the patient's electronic medical record discharge summary. Medication review and teaching is an important element in successful transition of care. Reviewing discharge care plans, confirming if follow-up physician visits have been scheduled, and reinforcing what signs and symptoms to report to the primary physician or when to call emergency services are elements of these calls.

   Patients who have been discharged with home care services should not be excluded from follow-up calls. Don't assume that because the patient is under another service that the follow-up call is unnecessary. These calls

It's been reported that 37% of SNFs stays did not develop care plans that met requirements or did not provide services in accordance with care plans. For 31% of stays, SNFs did not meet discharge planning requirements such as providing a summary of the patient's stay, patient's status at discharge, or post-discharge plan of care to the patient.

are good opportunities to confirm that the patient had a home care visit and to be alerted about any decline in health or function that could lead to a readmission. Establishing communication with the home health agencies can also lead to better planning when a patient does have a decline at home yet may not need to go back into the hospital. Medicare beneficiaries may be able to return to the SNF for additional skilled days if medically appropriate as long as there has been appropriate follow-up.

Current Discharge Planning at the SNF Level

Effective discharge planning plays a big role in the success of value-based care. It's also simply best practice to do this, yet this is not an easy task for SNF administrators to enforce. Discharge planning in SNFs has been analyzed by The Office of Inspector General (OIG) of the US\ Department of Health and Human Services. It's been reported that 37% of SNFs stays did not develop care plans that met requirements or did not provide services in accordance with care plans. For 31% of stays, SNFs did not meet discharge planning requirements such as providing a summary of the patient's stay, patient's status at discharge, or post-discharge plan of care to the patient. Medicare paid approximately $5.1 billion for stays that did not meet these quality of care requirements.[8]

The time is now for SNFs to look at their own discharge processes and identify gaps and deficiencies to make quality improvements. The future success of their business depends on it.

Summary

The challenge in value-based care models is for SNFs to effectively manage patient care with lower LOS while meeting the expectations for higher quality outcomes. Discharge planners are at the forefront of this shift from volume-based to value-based care and these 5 recommendations are intended to help care managers be proactive. While bundle programs and ACOs can help with improvements in this area, it's the responsibility of each facility to reassess its processes and implement new ways to become leaders in the value-based world of health care. CE 1

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CE II

Workplace Bullying:

Professional Ethics Tackles a Cultural Mainstay

By Ellen Fink-Samnick, MSW, ACSW, LCSW, CCM, CRP

Introduction

The scene plays out again and again across practice settings and professional disciplines: a physician yells at a case manager not to 'bug' him about clarifying a patient's medication management regimen. A nurse case manager brags about scaring off that 'bleeding heart' social work case manager. Team members bitterly disagree during care coordination rounds, then insult each other while a family sits wide-eyed in attendance. An epidemic of bullying has invaded the care continuum with every stakeholder at risk. It compromises the quality, sanctity, and safety of patient care, while traumatizing an increasing segment of the workforce.

Definitions and Context

Several definitions are mandated to ensure a comprehensive foundation of the topic at hand. *Workplace bullying* refers to the repeated, health-harming mistreatment of one or more persons (the targets) by one or more perpetrators. It is abusive conduct that is threatening, humiliating, or intimidating, or work-interference.[1] Bullying is typically deliberate and causes negative effects on the victim. It is thought of as an attempt to control employees with behavior that is intentional, aggressive, and frequent.[2]

Several causal factors for bullying have been identified in the literature. Among these are:

- The hierarchical stratification that exists in health care settings[3]
- Traditional and outdated models of professional education[4-9]
- The gender impact[6,10,11]
- Other workplace dynamics endemic to the health and human services workforce[12,13]

The following workplace behaviors are indicative of how bullying is referred to across the literature:[2,14-16]

- Intimidation
- Harassment
- Victimization
- Aggression
- Emotional abuse
- Psychological harassment
- Maltreatment

These obstructive and disparaging actions directly impact every aspect of patient care. Managing them should be a prime area of focus for all case managers. especially with the basic objective of ethical standards and codes of professional conduct to protect the public interest (see CCMC, The Code of Professional Conduct for Case Managers and CDMS, The CDMS Code of Professional Conduct).[6,17]

In contrast, *lateral violence* is a dynamic that occurs when

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Bullying is now viewed in the context of workplace violence.

individuals, who are both victims of a situation of dominance turn on each as opposed to confronting the system, which may have oppressed them both. Whether individuals and/or groups, those involved internalize feelings such as anger and rage, then manifest those feelings through behaviors such as gossip, jealousy, putdowns, and blaming.[18] This dynamic is a common occurrence across health and behavioral health environments.

Consider the case management department dealing with attrition and retention issues—an all-too-often occurrence. As a result, case managers must work more frequently on weekends or on extended days in row. What manifests is a tougher time coping with work stress. The staff begin to project their frustration on each other as well as other colleagues. They become impatient and more irritable, with team collaboration replaced by competition and utter disintegration. Along with this scenario setting the tone for lateral violence, it equally contributes to developing negative camaraderie among the workforce, as well as poor morale.

Bullying is now viewed in the context of workplace violence.[19] Rayner and Hoel's 5 categories of workplace violence directly reflect bullying behaviors:[20]

1. Threat to professional status (public humiliation)
2. Threat to personal standing (name calling, insults, teasing)
3. Isolation (withholding information)
4. Overwork (impossible deadlines)
5. Destabilization (failing to give credit where credit is due)

Each of the described behaviors is most likely familiar to case management professionals and needs little explanation. The flagrant disrespect conveyed by threatening and insulting colleagues contributes to poor performance, plus an environment that is unsafe and ripe for consumption by a harmful practice culture. While the culture of any organization may be conducive to bullying, it (the culture) does not need further fostering. Enabling a disabled system never bodes well for any industry, particularly one tasked to render safe, accountable, and efficient care.

A series of behaviors are frequently confused with bullying. For example, consider illegal harassment and discrimination. While bullying may often create a hostile work environment, it is quite different from an organization that promotes bias or allows for an illegally hostile work environment (eg, an employer tolerating inappropriate jokes or racial slurs). Behaviors that should not be considered bullying include when[16]:

- Managers set high work standards and/or expectations for staff
- Managers hold staff accountable for performance
- Staff have differences of opinion
- When staff and managers provide constructive feedback

There is also a dramatic difference between when an individual is having a bad day and bullying behavior. The health care environment is a stressful place for every member of the workforce, especially those in case management. There are unpredictable and complex situations occurring on a consistent basis, independent of practice setting or role. New regulations, reimbursement strategies, and care delivery models make for added pressure. Becoming irritable or showing frustration due to workplace or even life stress is quite different from the disruptive behaviors identified with bullying.[16]

Evidence and Impact

The health care profession has one of the highest levels of workplace bullying.[21] A range of focused studies provide glaring evidence of the impact of the obstructionist behavior of bullying on professionals and patients alike.

Traditional Research

Research notes that as high as 38% of the United States health care workforce reports psychological harassment on the job.[22] More than 53% of student nurses have been put down by a staff nurse, with 48% of pharmacists and other health care professionals reporting experiences of verbal abuse in the workplace.[23,24] Workplace bullying is 4 times more common than sexual harassment or racial discrimination on the job.[10]

The data reinforce how bullying becomes easily accepted as the predominant workplace cultural norm. Devaluing the confidence of younger and less experienced colleagues can offer a perverse sense of gratification to those staff members who are more senior.[9] More than 72% of employers actually deny, discount, encourage, rationalize, or further defend these disruptive behaviors.[15]

FIGURE 1 MEDICAL ERROR CATEGORIES[34]

Diagnostic	• Error or delay in diagnosis • Failure to employ indicated tests • Use of outmoded tests or therapy • Failure to act on results of monitoring or testing
Treatment	• Error in performance of an operation, procedure, or test • Error in administering treatment • Error in the dose or method of using a drug • Avoidable delay in treatment or responding to an abnormal test • Inappropriate care
Preventive	• Failure to provide prophylactic treatment • Inadequate monitoring of follow-up treatment
Other	• Failure of communication • Equipment failure • Other system failure

Those who endured bullying in the workplace have reported an increasing incidence of mental health diagnoses. Post-traumatic stress disorder has been reported as high as 30% among those who have been bullied. The incidence of clinical depression resulting from a bullying event is at 49% (either new to the person or exacerbated).[1,7,25,26]

The Gender Factor

The research dealing with the gender context of workplace bullying yields concerning observations. One survey[15] found that 69% of bullies are men and 57% of targets are women. Women bullies target women from 68% to as much as 80% of cases. Ninety-five percent of women believed they were undermined by another woman in the workplace at some point in their career.[10]

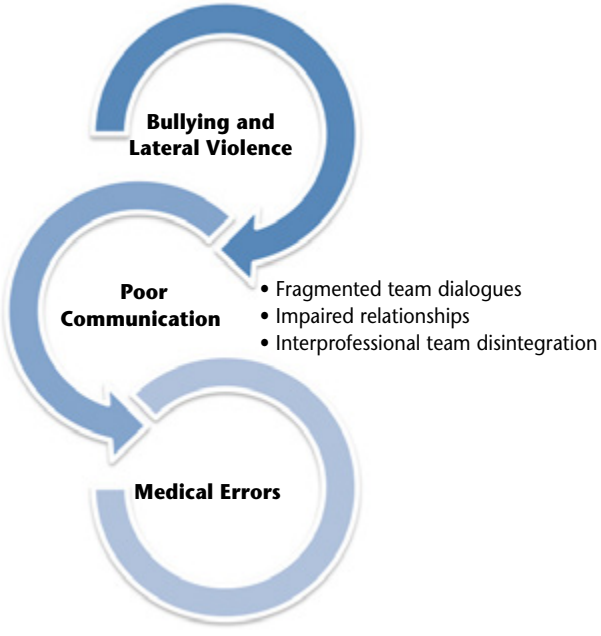
These numbers have profound significance for the case management workforce, of which a vast majority (95.2%) are women.[11,27] The 'queen bee syndrome' presents all too frequently; women who rise to success in male-dominated environments are prone to oppose the rise of other woman. As a result, these individuals who may have originally fought for their role and complained of unequal treatment perpetuate a pattern of inequity by turning on their fellow gender. They fail to nurture the next generation of women professionals—a trend bound to wreak havoc on succession planning for any case management department. Women who report to female supervisors detail more frequent symptoms of physical and psychological stress than those who work for male supervisors. In the interest of maintaining power and authority, the queen bee seeks to devalue the confidence of those perceived as potential competitors by undermining their professional standing.[10]

The Impact of Medical Errors

When professionals feel disempowered to address the dynamics of bullying, whether manifesting as insults or threats toward them or patients and families, the outcomes can and will be deadly.[19] The industry continues to reel from 2016 research that identified medical errors as the third leading cause of death in the United States.[28] Back in the 1990s, medical errors were identified as a major epidemic. Studies by the Health and Medicine Division of the National Academies of Sciences, Engineering and Medicine, (formally the Institute of Medicine) showed how medical errors contributed to the deaths of 44,000 to 98,000 people in the United States alone.[29-33]

Researchers originally divided medical error occurrences across the categories of diagnostic, treatment, preventative, and other,[34] as shown in Figure 1. Notice how *Failure of communication* appears in the 'other' category. However, even at this time, those in the industry can understand how faulty communication easily transcends the other categories. A hallmark of case management practice is clear and professional communication. Less than optimal effort

FIGURE 2 THE PROCESS OF BULLYING, POOR COMMUNICATION, AND MEDICAL ERRORS



BOX 1 **CASE SCENARIO BULLYING, POOR COMMUNICATION, AND MEDICAL ERRORS**

Tanya is a new case manager at an acute rehabilitation hospital. As a former bedside nurse on the orthopedic unit, Tanya had the reputation of being overly assertive and direct in her interactions with the interprofessional team. While somewhat daunting to less experienced staff, the physicians appreciated Tanya's ability to facilitate patient care. The director of case management felt these behaviors could be tempered and reframed to empower Tanya in her new role as a case manager. However, what started as potential strengths were quickly perceived as threats to staff, with huge leadership challenges.

A recent complaint was made to the case management director that sent Tanya into orbit. The occupational therapy coordinator complained that Tanya bullied newer therapists and over-stepped her authority. "Let' em get a thicker skin." Tanya said. "I've got no time for whiney staff challenging every treatment clarification. They don't have to like me, they just have to do as I say. My bark is nothing compared to how those physicians go off."

On one occasion, a misunderstanding occurred about a patient's therapy orders and the intensity of treatment he could endure. The patient was transferred to the facility following a motor vehicle accident. With a severe tib/fib fracture of the left leg and an external fixator still in place, the initial orders called for the patient to be non-weight bearing. However, Tanya was clear she knew better. 'I spent 10 years as an ortho nurse. These docs are extra cautious and we need to get this guy moving.' She told the therapists to do a full treatment hour with the patient, threatening them with disciplinary action. The new PT was petrified, so did as Tanya told her.

What resulted was movement of the external fixator screws and further damage to the leg. The patient was transferred back to the hospital for surgery, an extended hospitalization, and the involvement of risk management. Tanya was put on probation, running the risk of disciplinary action by Human Resources. Complaints were also filed by the patient's family with Tanya's case management certification and nursing licensure boards.

impedes care quality and contributes to otherwise avoidable medical errors, the process of which is shown in Figure 2.

Team confusion may ensue about proper treatment orders or recommendations (eg, medications, identified durable medical equipment). The patient could develop a medical complication from the miscommunication, such as a stress fracture or potentially a blood clot, with disastrous implications. Studies support this premise, with 75% of those surveyed for one investigation identifying how disruptive behaviors led to medical errors, of which almost 30% contributed to patient deaths.[35] Other reports cite the number as high as 250,000 annually.[28] In this patient-centered care climate that focuses on pursuing the 3 dimensions of performance (ie, improving health, the patient experience, and reducing cost) bullying is antithetical to the Triple, and new Quadruple, Aims.[36] Consider the case scenario in Box 1.

Ethical Implications for Case Management

Advocacy, beneficence, fidelity, justice, and nonmaleficence; case management's ethical tenets[1,17] wield a heavy hand when it comes to the context of bullying and lateral violence. In reflecting on Tanya's actions, we see that she is at risk for sanction of several ethical tenets, particularly those of advocacy, fidelity, and nonmaleficence. A major challenge exists when a case manager's practice presents as potentially more self-serving than patient centered.

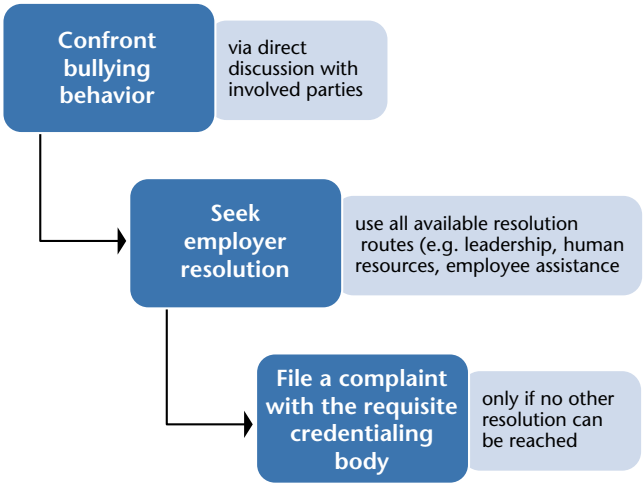
Tanya's failure to adhere to the physician's orders put her patient at extreme risk. If a case manager questions a physician's orders, there are ways to appropriately consult with involved team members as opposed to making a unilateral decision—one that potentially could be viewed as outside of the scope of practice (eg, prescribing weight-bearing status). Failing to advocate on behalf of the patient's best interests further compromised Tanya's patient's care, contributing to a medical error of grand proportions. Her unprofessional behavior toward her colleagues puts her in violation of several principles for board certified case managers, including[17]:

- Principle 1: Board-Certified Case Managers (CCMs) will place the public interest above their own at all times.
- Principle 4: Board-Certified Case Managers (CCMs) will act with integrity and fidelity with clients and others.

It can be equally questioned whether Tanya heeded case management's underlying values,[17] whereby:

- Board-Certified Case Managers (CCMs) embrace the underlying premise that when the individual(s) reaches the optimum level of wellness and functional capability, everyone benefits: the individual(s) served, their support systems, the health care delivery systems and the various reimbursement systems
- Board-Certified Case Managers (CCMs) understand that case management is guided by the ethical principles of autonomy, beneficence, nonmaleficence, justice, and fidelity
- Certificants shall respect the integrity and protect the welfare of those persons or groups with whom they are working (CDMS, The CDMS Code of Professional Conduct)

FIGURE 3 THE PROCESS OF BULLYING, POOR COMMUNICATION, AND MEDICAL ERRORS



Case managers serve a pivotal role in ensuring a smooth care coordination process, marked by the identification of a patient's unique issues and opportunities. The established standards of practice set the tone for how a case manager should manage his or her professional presence. Amid an environment fraught with what can feel like daily changes, case managers must be accountable for their own behavior, first and foremost. Tanya's actions negated several of the established guiding principles of professional case management[37] including to:

- Use a client-centric, collaborative partnership approach that is responsive to the individual client's culture, preferences, needs, and values
- Use a comprehensive, holistic, and compassionate approach to care delivery with integrates a client's medical, behavioral, social, psychological, functional and other need
- Implement evidence-based care guidelines in the care of clients, as available and applicable to the practice setting, and/or client population served
- Promote optimal client safety at the individual, organizational, and community level

Finally, Tanya's poor interactions with her colleagues reflect a profound inability to fully recognize her secondary ethical obligation.[37] The engagement and maintenance of respectful relationships with coworkers, employers, and other professionals is definitely not on her radar.

Three Steps to Address Bullying

Managing bullying situations are challenging at best. However, a number of approaches can provide case managers the confidence in their competence to address both disruptive behaviors and the persons engaging in them.

A gradient action plan offers strategic guidance with all involved parties. Three significant steps guide professional efforts to manage workplace bullying, as shown in Figure 3. In conjunction with these 3 steps, case managers should do their due diligence to:

- Take opportunities to educate and support colleagues
- Provide relevant resources to those staff impacted (eg, employee assistance programs, local therapy support)
- Advocate for change in your profession and organization
- Engage with local and national initiatives to move relevant legislation forward

BOX 1 HEALTHY WORKPLACE BILL FAQS (HEALTHY WORKPLACE BILL, 2017B)

What the HWB Does for Employers:

- Precisely defines an "abusive work environment"
- Requires proof of health harm by licensed health or mental health professionals
- Protects conscientious employers from vicarious liability risk when internal correction and prevention mechanisms are in effect
- Gives employers the reason to terminate or sanction offenders
- Requires plaintiffs to use private attorneys
- Plugs the gaps in current state and federal civil rights protections

What the HWB Does for Workers

- Provides an avenue for legal redress for health harming cruelty at work
- Allows a victim to sue the bully as an individual
- Holds the employer accountable
- Seeks restoration of lost wages and benefits
- Compels employers to prevent and correct future instances
- Supports those in 'at will' situations who fear retribution

What the HWB Does Not Do

- Involve state agencies to enforce any provisions of the law
- Incur costs for adopting states
- Require plaintiffs to be members of protected status groups
- Use the term "workplace bullying"

Legislation

At the time of this writing there continues to be no federal legislation to address workplace bullying in the United States. There has been robust advocacy by professional associations and regulatory entities through the writing of practice standards, guidelines, and position statements to address workplace incivility and safety.[37-41]

Over the years there has been action by more than half of the states to move formal legislation forward to address workplace bullying.[42] However, the most promising effort to date is the Healthy Workplace Bill (HWB).[43,44] HWB is a template of legislation that has passed 32 legislatures between the United States and Canada. A detailing of the bill's benefits appears in Box 2, with an updated map of legislation progress available at http://healthyworkplacebill.org.

Conclusion

Human interaction is at the heart of the health care industry, whether physical or behavioral health. How case managers engage and establish rapport can define the success or failure of their efforts, whether dealing with patients, providers, practitioners, or other stakeholders. Bullying not only impedes the quality of these relationships, but puts all involved at unnecessary risk for harm. Case management can serve a pivotal role in overturning a dangerous workplace culture that allows bullying, plus in being staunch advocates to foster relevant legislative change. **CE II**

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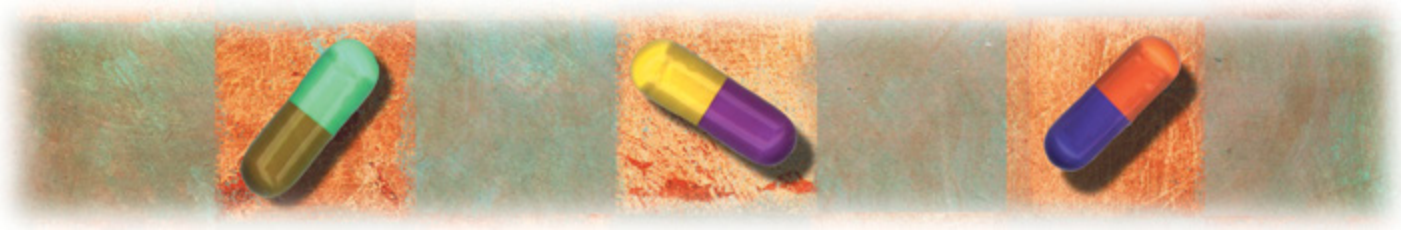
PharmaFacts for Case Managers



Zejula (niraparib) capsules, for oral use

INDICATIONS AND USAGE

Zejula is indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.

DOSAGE AND ADMINISTRATION

Recommended Dosage

The recommended dose of Zejula as monotherapy is 300 mg (three 100 mg capsules) taken orally once daily.

Instruct patients to take their dose of Zejula at approximately the same time each day. Each capsule should be swallowed whole. Zejula may be taken with or without food. Bedtime administration may be a potential method for managing nausea.

Patients should start treatment with Zejula no later than 8 weeks after their most recent platinum- containing regimen.

Zejula treatment should be continued until disease progression or unacceptable toxicity.

In the case of a missed dose of Zejula, instruct patients to take their next dose at its regularly scheduled time. If a patient vomits or misses a dose of Zejula, an additional dose should not be taken.

Dose Adjustments for Adverse Reactions

To manage adverse reactions, consider interruption of treatment, dose reduction, or dose discontinuation. The recommended dose modifications for adverse reactions are listed in Tables 1, 2 and 3.

DOSAGE FORMS AND STRENGTHS

100 mg capsule having a white body with "100 mg" printed in black ink, and a purple cap with "Niraparib" printed in white ink.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Myelodysplastic Syndrome/Acute Myeloid Leukemia

Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML), including cases with fatal outcome, have been reported in patients who received Zejula. In Trial 1 (NOVA), MDS/AML occurred in 5 out of 367 (1.4%) of patients who received Zejula and in 2 out of 179 (1.1%) patients who received placebo. Overall, MDS/AML has been reported in 7 out of 751 (0.9%) patients treated with Zejula in clinical studies.

The duration of Zejula treatment in patients prior to developing MDS/AML varied from <1 month to 2 years. All patients had received previous chemotherapy with platinum and some had also received other DNA damaging agents and radiotherapy. Discontinue Zejula if MDS/AML is confirmed.

Bone Marrow Suppression

Hematologic adverse reactions (thrombocytopenia, anemia and neutropenia) have been reported in patients treated with Zejula. Grade ≥3 thrombocytopenia, anemia and neutropenia were reported, respectively, in 29%, 25%, and 20% of patients receiving Zejula. Discontinuation due to thrombocytopenia, anemia, and neutropenia occurred, respectively, in 3%, 1%, and 2% of patients. Do not start Zejula until patients have recovered from hematological toxicity caused by previous chemotherapy (≤ Grade 1). Monitor

TABLE 1

Recommended Dose Adjustments

Dose level	Dose
Starting Dose	300 mg/day (three 100 mg capsules)
First Dose Reduction	200 mg/day (two 100 mg capsules)
Second Dose Reduction	100 mg/day* (one 100 mg capsule)

*If further dose reduction below 100 mg/day is required, discontinue ZEJULA.

TABLE 2

Dose modifications for non-hematologic adverse reactions

Non-hematologic CTCAE* ≥ Grade 3 adverse reaction where prophylaxis is not considered feasible or adverse reaction persists despite treatment	• Withhold Zejula for a maximum of 28 days or until resolution of adverse reaction. • Resume Zejula at a reduced dose per Table 1. Up to 2 dose reductions are permitted.
CTCAE ≥ Grade 3 treatment-related adverse reaction lasting more than 28 days while patient is administered Zejula 100 mg/day	Discontinue medication.

*CTCAE=Common Terminology Criteria for Adverse Events

TABLE 3

Dose modifications for hematologic adverse reactions

Monitor complete blood counts weekly for the first month, monthly for the next 11 months of treatment and periodically after this time.	
Platelet count <100,000/μL	First occurrence: • Withhold Zejula for a maximum of 28 days and monitor blood counts weekly until platelet counts return to ≥100,000/μL. • Resume Zejula at same or reduced dose per Table 1. • If platelet count is <75,000/μL, resume at a reduced dose.
	Second occurrence: • Withhold Zejula for a maximum of 28 days and monitor blood counts weekly until platelet counts return to ≥100,000/μL. • Resume Zejula at a reduced dose per Table 1. • Discontinue Zejula if the platelet count has not returned to acceptable levels within 28 days of the dose interruption period, or if the patient has already undergone dose reduction to 100 mg once daily.*
Neutrophil <1,000/μL or Hemoglobin <8 g/dL	• Withhold Zejula for a maximum of 28 days and monitor blood counts weekly until neutrophil counts return to ≥1,500/μL or hemoglobin returns to ≥9 g/dL. • Resume Zejula at a reduced dose per Table 1. • Discontinue Zejula if neutrophils and/or hemoglobin have not returned to acceptable levels within 28 days of the dose interruption period, or if the patient has already undergone dose reduction to 100 mg once daily.*
Hematologic adverse reaction requiring transfusion	• For patients with platelet count ≤10,000/μL, platelettransfusion should be considered. If there are other risk factors such as co-administration of anticoagulation or antiplatelet drugs, consider interrupting these drugs and/or transfusion at a higher platelet count. • Resume Zejula at a reduced dose.

*If myelodysplastic syndrome or acute myeloid leukemia (MDS/AML) is confirmed, discontinue ZEJULA

complete blood counts weekly for the first month, monthly for the next 11 months of treatment, and periodically after this time. If hematological toxicities do not resolve within 28 days following interruption, discontinue Zejula, and refer the patient to a hematologist for further investigations, including bone marrow analysis and blood sample for cytogenetics

Cardiovascular Effects

Hypertension and hypertensive crisis have been reported in patients treated with Zejula. Grade 3–4 hypertension occurred in 9% of Zejula treated patients compared to 2% of placebo treated patients in Trial 1. Discontinuation due to hypertension occurred in <1% of patients.

Monitor blood pressure and heart rate monthly for the first year and periodically thereafter during treatment with Zejula. Closely monitor patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension. Medically manage hypertension with antihypertensive medications and adjustment of the Zejula dose, if necessary .

Embryo-Fetal Toxicity

Based on its mechanism of action, Zejula can cause fetal harm when administered to a pregnant woman. Zejula has the potential to cause teratogenicity and/or embryo-fetal death since niraparib is genotoxic and targets actively dividing cells in animals and patients (e.g., bone marrow) . Due to the potential risk to a fetus based on its mechanism of action, animal developmental and reproductive toxicology studies were not conducted with niraparib.

Apprise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for 6 months after the last dose of Zejula

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The safety of Zejula monotherapy 300 mg once daily has been studied in 367 patients with platinum-sensitive recurrent ovarian, fallopian tube, and primary peritoneal cancer in Trial 1 (NOVA). Adverse reactions in Trial 1 led to dose reduction or interruption in 69% of patients, most frequently from thrombocytopenia (41%) and anemia (20%). The permanent discontinuation rate due to adverse reactions in Trial 1 was 15%. The median exposure to Zejula in these patients was 250 days. Table 4 shows lab changes.

CLINICAL STUDIES

Trial 1 (NOVA) was a double-blind, placebo-controlled trial in which patients (n=553) with platinum- sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer were randomized 2:1 to Zejula 300 mg orally daily or matched placebo within 8 weeks of the last therapy. All patients had received at least two prior platinum-containing regimens and were in response (complete or partial) to their most recent platinum-based regimen.

TABLE 4

Abnormal Laboratory Findings in ≥25% of Patients Receiving ZEJULA

	Grades 1-4		Grades 3-4	
	Zejula N=367 (%)	Placebo N= 179 (%)	Zejula N= 367 (%)	Placebo N= 179 (%)
Decrease in hemoglobin	85	56	25	0.5
Decrease in platelet count	72	21	35	0.5
Decrease in WBC count	66	37	7	0.7
Decrease in absolute neutrophil count	53	25	21	2
Increase in AST	36	23	1	0
Increase in ALT	28	15	1	2

N=number of patients; WBC=white blood cells; ALT=Alanine aminotransferase; AST=Aspartate aminotransferase

Randomization was stratified by time to progression after the penultimate platinum therapy (6 to <12 months and ≥12 months); use of bevacizumab in conjunction with the penultimate or last platinum regimen (yes/no); and best response during the most recent platinum regimen (complete response and partial response). Eligible patients were assigned to one of two cohorts based on the results of the BRACAnalysis CDx. Patients with deleterious or suspected deleterious germline BRCA mutations (gBRCAm) were assigned to the germline BRCA mutated (gBRCAmut) cohort (n=203), and those without germline BRCA mutations were assigned to the non-gBRCAmut cohort (n=350).

The major efficacy outcome measure, PFS (progression-free survival), was determined primarily by central independent assessment per RECIST (Response Evaluation Criteria in Solid Tumors, version 1.1). In some cases, criteria other than RECIST, such as clinical signs and symptoms and increasing CA-125, were also applied.

The median age of patients ranged from 57–64 years among patients treated with Zejula and 58-67 years among patients treated with placebo. Eighty-six percent of all patients were white. Sixty-seven percent of patients receiving Zejula and 69% of patients receiving placebo had an ECOG of 0 at study baseline. Approximately 40% of patients were enrolled in the U.S. or Canada and 51% of all patients were in complete response to most recent platinum-based regimen, with 39% on both arms with an interval of 6-12 months since the penultimate platinum regimen. Twenty-six percent of those treated with Zejula and 31% treated with placebo had received prior bevacizumab therapy.

Approximately 40% of patients had 3 or more lines of treatment.

The trial demonstrated a statistically significant improvement in PFS for patients randomized to Zejula as compared with placebo in the gBRCAmut cohort and the non-gBRCAmut cohort.
At the time of the PFS analysis, limited overall survival data were available with 17% deaths across the two cohorts.

Manufactured for: TESARO, Inc.

Symproic (naldemedine) tablets, for oral use, C-II

INDICATIONS AND USAGE

Symproic is indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain.

DOSAGE AND ADMINISTRATION

Administration

- Alteration of analgesic dosing regimen prior to initiating Symproic is not required.
- Patients receiving opioids for less than 4 weeks may be less responsive to SYMPROIC
- Discontinue Symproic if treatment with the opioid pain medication is also discontinued.

Adult Dosage

The recommended dosage of Symproic is 0.2 mg orally once daily with or without food.

DOSAGE FORMS AND STRENGTHS

Tablets: 0.2 mg naldemedine; supplied as yellow, round, film-coated, debossed with Shionogi above the identifier code 222 on one side and 0.2 on the other side.

CONTRAINDICATIONS

Symproic is contraindicated in:

- Patients with known or suspected gastrointestinal obstruction and patients at increased risk of recurrent obstruction, due to the potential for gastrointestinal perforation.
- Patients with a history of a hypersensitivity reaction to naldemedine. Reactions have included bronchospasm and rash

WARNINGS AND PRECAUTIONS

Gastrointestinal Perforation

Cases of gastrointestinal perforation have been reported with use of another peripherally acting opioid antagonist in patients with

conditions that may be associated with localized or diffuse reduction of structural integrity in the wall of the gastrointestinal tract (eg, peptic ulcer disease, Ogilvie's syndrome, diverticular disease, infiltrative gastrointestinal tract malignancies, or peritoneal metastases). Take into account the overall risk-benefit profile when using Symproic in patients with these conditions or other conditions which might result in impaired integrity of the gastrointestinal tract wall (eg, Crohn's disease). Monitor for the development of severe, persistent, or worsening abdominal pain; discontinue Symproic in patients who develop this symptom

Opioid Withdrawal

Clusters of symptoms consistent with opioid withdrawal, including hyperhidrosis, chills, increased lacrimation, hot flush/flushing, pyrexia, sneezing, feeling cold, abdominal pain, diarrhea, nausea, and vomiting have occurred in patients treated with Symproic

Patients having disruptions to the blood-brain barrier may be at increased risk for opioid withdrawal or reduced analgesia. Take into account the overall risk-benefit profile when using Symproic in such patients. Monitor for symptoms of opioid withdrawal in such patients.

ADVERSE REACTIONS

Serious and important adverse reactions described elsewhere in labeling include:

- Gastrointestinal perforation
- Opioid withdrawal

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The data described below reflect exposure to Symproic in 1163 patients in clinical trials, including 487 patients with exposures greater than six months and 203 patients with exposures of 12 months.

The following safety data are derived from three double-blind, placebo-controlled trials in patients with OIC and chronic non-cancer pain: two 12-week studies (Studies 1 and 2) and one 52-week study (Study 3).

In Studies 1 and 2, patients on laxatives were required to discontinue their use prior to study enrollment. All patients were restricted to bisacodyl rescue treatment during the study. In Study 3, approximately 60% of patients in both treatment groups were on` a laxative regimen at baseline; patients were allowed to continue using their laxative regimen throughout the study duration. The safety profile of Symproic relative to placebo was similar regardless of laxative use.

Common adverse reactions occurring in at least 2% of patients receiving Symproic and at an incidence greater than placebo included abdominal pain (8%-11%), diarrhea (7%), nausea (4%-6%), gastroenteritis (2%-3%), and vomiting (3%) across the three studies.

Adverse reactions up to 12 months in Study 3 are similar to those listed in Tables 1 and 2 (diarrhea: 11% vs. 5%, abdominal pain: 8% vs. 3%, and nausea: 8% vs. 6% for Symproic and placebo, respectively).

Opioid Withdrawal

In Studies 1, 2 and 3, adverse reactions consistent with opioid withdrawal were based on investigator assessment and adjudicated based upon the occurrence of at least 3 adverse reactions potentially related to opioid withdrawal with onset of a constellation of those symptoms occurring on the same day or within one day of each other.

Adverse reactions of possible opioid withdrawal could include non-gastrointestinal (GI) symptoms (e.g., hyperhidrosis, hot flush or flushing, chills, tremor, tachycardia, anxiety, agitation, yawning, rhinorrhea, increased lacrimation, sneezing, feeling cold, and pyrexia), GI symptoms (e.g., vomiting, diarrhea, or abdominal pain), or both GI and non-GI symptoms.

In pooled Studies 1 and 2, the incidence of adverse reactions of opioid withdrawal was 1% (8/542) for Symproic and 1% (3/546) for placebo. In Study 3 (52-week data), the incidence was 3% (20/621) for Symproic and 1% (9/619) for placebo. Most Symproic treated subjects experienced nearly equal incidence of GI only or both GI and non-GI symptoms.

Less Common Adverse Reactions:

Two patients developed symptoms of hypersensitivity following a single dose of SYMPROIC. One patient reported bronchospasm and another rash.

DRUG INTERACTIONS

Table 1 includes drugs with clinically important drug interactions with Symproic and instructions for preventing or managing the interaction.

DRUG ABUSE AND DEPENDENCE

Controlled Substance

Symproic contains naldemedine, a Schedule II controlled substance.

CLINICAL STUDIES

Symproic was evaluated in two replicate, 12-week, randomized, double-blind, placebo-controlled trials (Study 1 and Study 2) in which Symproic was used without laxatives in patients with OIC and chronic non-cancer pain.

Patients receiving a stable opioid morphine equivalent daily dose of at least 30 mg for at least 4 weeks before enrollment and self-reported OIC were eligible for clinical trial participation. Patients with evidence of significant structural abnormalities of the GI tract were not enrolled in these trials.

In Studies 1 and 2, patients had to either be not using laxatives or willing to discontinue laxative use at the time of screening and willing to use only the provided rescue laxatives during the screening and treatment periods.

TABLE 1

Clinically Relevant Interactions Affecting Naldemedine When Co-Administered with Other Drugs

STRONG CYP3A INDUCERS (e.g., rifampin, carbamazepine, phenytoin, St. John's Wort)	
Clinical Impact	Significant decrease in plasma naldemedine concentrations, which may reduce efficacy
Intervention	Avoid use of Symproic with strong CYP3A inducers.
OTHER OPIOID ANTAGONISTS	
Clinical Impact	Potential for additive effect of opioid receptor antagonism and increased risk of opioid withdrawal.
Intervention	Avoid use of Symproic with another opioid antagonist.
MODERATE (e.g., fluconazole, atazanavir, aprepitant, diltiazem, erythromycin) AND STRONG (eg, itraconazole, ketoconazole, clarithromycin, ritonavir, saquinavir) CYP3A INHIBITORS	
Clinical Impact	Increase in plasma naldemedine concentrations
Intervention	Monitor for potential naldemedine-related adverse reactions
P-GLYCOPROTEIN (P-GP) Inhibitors (e.g., amiodarone, captopril, cyclosporine, quercetin, quinidine, verapamil)	
Clinical Impact	Increase in plasma naldemedine concentrations
Intervention	Monitor for potential naldemedine-related adverse reactions

In Studies 1 and 2, OIC was confirmed through a two-week run in period and was defined as no more than 4 spontaneous bowel movements (SBMs) total over 14 consecutive days and less than 3 SBMs in a given week with at least 25% of the SBMs associated with one or more of the following conditions: (1) straining; (2) hard or lumpy stools; (3) having a sensation of incomplete evacuation; and (4) having a sensation of anorectal obstruction/blockage.

An SBM was defined as a bowel movement (BM) without rescue laxative taken within the past 24 hours. Patients with no BMs over the 7 consecutive days prior to and during the 2 week screening period or patients who have never taken laxatives were excluded.

In the screening and treatment periods, bisacodyl was used as rescue laxative if patients had not had a BM for 72 hours and were allowed one-time use of an enema, if after 24 hours of taking bisacodyl they still had not had a BM.

A total of 547 patients in Study 1 and 553 patients in Study 2 were randomized in a 1:1 ratio to receive Symproic 0.2 mg once daily or placebo for 12 weeks. Study medication was administered without regard to meals.

The mean age of subjects in Studies 1 and 2 was 54 years; 59% were women; and 80% were white. The most common types of pain in Studies 1 and 2 were back or neck pain (61%). The mean baseline number of SBMs was 1.3 and 1.2 per week for Studies 1 and 2, respectively.

Prior to enrollment, patients were using their current opioid for a mean duration of approximately 5 years. A wide range of types of opioids were used. The mean baseline opioid morphine equivalent daily dosage was 132 mg and 121 mg per day for Studies 1 and 2, respectively.

The efficacy of Symproic was assessed in Studies 1 and 2 using a responder analysis. A responder was defined as a patient who had at least 3 SBMs per week and a change from baseline of at least 1 SBM per week for at least 9 out of the 12 weeks and 3 out of the last 4 weeks in Studies 1 and 2.

The responder rates in Studies 1 and 2 are shown in Table 2.

HOW SUPPLIED/STORAGE AND HANDLING

Symproic is supplied as 0.2 mg naldemedine tablets in a bottle of 90 tablets

Store Symproic in light resistant container at 20 to 25°C (68 to 77°F); excursions permitted to 15 to 30°C (59 to 86°F)

Symproic is a trademark of the Shionogi group.

TABLE 2

Efficacy Responder Rates in Studies 1 and 2 in Patients with OIC and Chronic Non-Cancer Pain

	Study 1			Study 2		
	SYMPROIC 0.2 mg once daily (N=273)	Placebo (N=272)	Treatment Difference [95% CI]	SYMPROIC 0.2 mg once daily (N=276)	Placebo (N=274)	Treatment Difference [95% CI]
Responder#	130 (48%)	94 (35%)	13% [5%, 21%]	145 (53%)	92 (34%)	19% [11%, 27%]
p value*			0.0020			<0.0001

#The primary endpoint was defined as a patient who had at least 3 SBMs per week and a change from baseline of at least 1 SBM per week for at least 9 out of the 12 study weeks and 3 out of the last 4 weeks.

CI=Confidence Interval

*Cochran-Mantel-Haenszel test adjusted for opioid dose strata (30 to100 mg; greater than 100 mg)

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J Am Coll Cardiol. 2017 Apr 4;69(13):1707-1714. doi: 10.1016/j.jacc.2017.01.038.

The benefit of donor-recipient matching for patients undergoing heart transplantation.

Nguyen VP, Mahr C, Mokadam NA, Pal J, Smith JW, Dardas TF.

BACKGROUND: Heart transplant volumes are not matching growing demand, and donor heart use may be decreasing. OBJECTIVES: This study sought to investigate the benefit of heart transplantation compared with waiting while accounting for the estimated risk of a given donor-recipient match. METHODS: This study identified 28,548 heart transplant candidates in the Organ Procurement and Transplant Network between July 2006 and December 2015. Donor-recipient match quality was estimated from the donor risk index. A time-dependent covariate Cox model was used to determine the effect of donor-recipient match quality on the likelihood of a composite outcome while waiting for a transplant or after transplantation. The composite outcome was death or delisting as too ill. RESULTS: Donor and recipient risk estimates were inversely related to the candidate urgency. Net benefit from heart transplantation was evident across all estimates of donor-recipient status 1A and 1B candidates: status 1A (lowest-risk quartile hazard ratio [HR]: 0.37; 95% confidence interval [CI]: 0.31 to 0.43; highest-risk quartile HR: 0.52; 95% CI: 0.44 to 0.61) and status 1B candidates (lowest-risk quartile HR: 0.41; 95% CI: 0.36 to 0.47; highest-risk quartile HR: 0.66; 95% CI: 0.58 to 0.74). Status 2 candidates showed a benefit from heart transplantation; however, survival benefit was delayed. For the highest-risk donor-recipient matches, a net benefit of transplantation occurred immediately for status 1A candidates, after 12 months for status 1B candidates, and after 3 years for status 2 candidates. CONCLUSIONS: This study demonstrated a survival benefit of heart transplantation across all ranges of estimated donor-recipient match risk for status 1A and status 1B candidates. Donor heart acceptance should be the favored strategy for these candidates. The benefit of transplantation for status 2 candidates was less apparent and dependent on estimated donor-recipient match risk, suggesting that a measure of donor-recipient match quality may be useful when considering the immediate benefit of heart transplantation for status 2 candidates in stable condition.

Eur J Gastroenterol Hepatol. 2017 Mar 24. doi: 10.1097/MEG.0000000000000871. [Epub ahead of print]

Clinical efficacy and tolerability of direct-acting antivirals in elderly patients with chronic hepatitis C.

Sherigar JM, Gayam V, Khan A, et al.

BACKGROUND: There is a lack of evidence-based data on aged patients with newer direct-acting antivirals (DAAs) and with shorter duration of treatment regimens involving DAAs with or without ribavirin (RBV) and pegylated interferon (Peg IFN). PATIENTS AND METHODS: Medical records of 240 patients treated with DAAs with or without Peg IFN and RBV between January 2013 and July 2015 were retrospectively analyzed. Patients were divided into two groups: patients aged 65 years and older (N=84) and patients aged younger than 65 years (N=156). Pretreatment baseline patient characteristics, treatment efficacy, factors affecting sustained virologic response at 12 weeks after treatment, and adverse reactions were compared between the groups.

RESULTS: No statistically significant difference was observed with end of treatment response (98.8 vs. 98%, P=0.667) and sustained virologic response at 12 weeks after treatment (93.1 vs. 94.1%, P=0.767) between patients aged 65 and older and those younger than 65 years of age. Fatigue was the most common adverse event recorded (32.5%), followed by anemia (19.6%), leukopenia (11.7%), thrombocytopenia (10%), skin rash (8.3%), and headache (7.9%). The RBV dose was reduced in eight (8%) patients and four patients discontinued the RBV treatment because of severe anemia. RBV dose reduction or discontinuation did not reach statistical significance (P=0.913). Increased fibrosis, cirrhosis, aspartate aminotransferase, alanine aminotransferase, hemoglobin, and platelet levels seem to affect the sustained virologic response in the elderly. Twelve (6.28%) patients failed to respond to treatment and the failure rate was not significant (P=0.767) between the

groups. CONCLUSION: DAAs with or without IFN and RBV in the standard recommended 12 or 24-week treatment regimens are effective, well tolerated, and may be safely extended to elderly patients infected with chronic hepatitis C.

Am J Surg. 2016 Dec;212(6):1063-1067. doi: 10.1016/j.amjsurg.2016.08.017. Epub 2016 Sep 28.

Transanal endoscopic microsurgery and transanal minimally invasive surgery: is one technique superior?

Melin AA, Kalaskar S, Taylor L, Thompson JS, Ternent C, Langenfeld SJ.

BACKGROUND: Transanal endoscopic microsurgery (TEM) and transanal minimally invasive surgery (TAMIS) have been shown to improve the quality of transanal resections, allowing for improved visibility and access to the proximal rectum. This study compares the short-term outcomes between TEM and TAMIS among experienced colorectal surgeons. METHOD: A retrospective review was conducted for TEM and TAMIS performed from 2012 to 2015 by local colorectal surgeons. Baseline patient demographics, operative variables, pathology results, and short-term outcomes were assessed. RESULTS: Sixty-nine patients were identified (40 TEM and 29 TAMIS). Patient demographics, tumor characteristics, operative variables, margin status, and postoperative complications were similar for both. Volume of resection was higher for TAMIS ($P < .001$). Lymph node retrieval was achieved in 17.2% of TAMIS cases compared with 0% of TEM ($P = .01$). CONCLUSIONS: TAMIS appears to have equivalent indications and outcomes compared with TEM. TAMIS is associated with larger specimens and more frequent presence of mesorectal lymph nodes.

BMJ. 2016 Sep 6;354:i4482. doi: 10.1136/bmj.i4482.

Atrial fibrillation and risks of cardiovascular disease, renal disease, and death: systematic review and meta-analysis.

Odutayo A, Wong CX, Hsiao AJ, et al.

OBJECTIVE: To quantify the association between atrial fibrillation and cardiovascular disease, renal disease, and death. DESIGN: Systematic review and meta-analysis. DATA SOURCES: Medline and Embase. ELIGIBILITY CRITERIA: Cohort studies examining the association between atrial fibrillation and cardiovascular disease, renal disease, and death. Two reviewers independently extracted study characteristics and the relative risk of outcomes associated with atrial fibrillation: specifically, all cause mortality, cardiovascular mortality, major cardiovascular events, any stroke, ischaemic stroke, haemorrhagic stroke, ischaemic heart disease, sudden cardiac death, congestive heart failure, chronic kidney disease, and peripheral arterial disease. Estimates were pooled with inverse variance weighted random effects meta-analysis. RESULTS: 104 eligible cohort studies involving 9 686 513 participants (587 867 with atrial fibrillation) were identified. Atrial fibrillation was associated with an increased risk of all cause mortality (relative risk 1.46, 95% confidence interval 1.39 to 1.54), cardiovascular mortality (2.03, 1.79 to 2.30), major cardiovascular events (1.96, 1.53 to 2.51), stroke (2.42, 2.17 to 2.71), ischaemic stroke (2.33, 1.84 to 2.94), ischaemic heart disease (1.61, 1.38 to 1.87), sudden cardiac death (1.88, 1.36 to 2.60), heart failure (4.99, 3.04 to 8.22), chronic kidney disease (1.64, 1.41 to 1.91), and peripheral arterial disease (1.31, 1.19 to 1.45) but not haemorrhagic stroke (2.00, 0.67 to 5.96). Among the outcomes examined, the highest absolute risk increase was for heart failure. Associations between atrial fibrillation and included outcomes were broadly consistent across subgroups and in sensitivity analyses. CONCLUSIONS: Atrial fibrillation is associated with an increased risk of death and an increased risk of cardiovascular and renal disease. Interventions aimed at reducing outcomes beyond stroke are warranted in patients with atrial fibrillation.

AIDS. 2017 Mar 18. doi: 10.1097/QAD.0000000000001458. [Epub ahead of print]

Impact of opioid substitution therapy on the HIV prevention benefit of antiretroviral therapy for people who inject drugs.

Mukandavire C, Low A, Mburu G, et al.

OBJECTIVE: A recent meta-analysis suggested that opioid substitution therapy (OST) increased uptake of anti-retroviral treatment (ART) and HIV viral suppression. We modelled whether OST could improve the HIV prevention benefit achieved by ART amongst people who inject drugs (PWID). METHODS: We modelled how introducing OST could improve the coverage of ART across a PWID population for different baseline ART coverage levels. Using existing data on how yearly HIV-transmission risk is related to HIV plasma viral load, changes in the level of viral suppression across the population were used to project the relative reduction in yearly HIV-transmission risk achieved by ART, with or without OST, compared to if there was no ART - defined here

as the prevention effectiveness of ART. RESULTS: Due to OST use increasing the chance of being on ART and achieving viral suppression if on ART, the prevention effectiveness of ART for PWID on OST (compared to PWID not on OST) increases by 44%, 31% or 20% for a low (20%), moderate (40%) or high (60%) baseline ART coverage, respectively. Improvements in the population-level prevention effectiveness of ART are also achieved across all PWID, compared to if OST was not introduced. For instance, if OST is introduced at 40% coverage, the population-level prevention effectiveness of ART could increase by 27%, 20% or 13% for a low (20%), moderate (40%) or high (60%) baseline ART coverage, respectively. CONCLUSIONS: OST could markedly improve the HIV prevention benefit of ART; supporting strategies that aim to concurrently scale-up OST with ART.

Ann Thorac Surg. 2016 Jul;102(1):102-8. doi: 10.1016/j.athoracsur.2016.01.019. Epub 2016 Apr 9.

Outcomes in patients bridged with univentricular and biventricular devices in the modern era of heart transplantation.

Grimm JC, Sciortino CM, Magruder JT, et al.

BACKGROUND: Biventricular support before orthotopic heart transplantation (OHT) has been shown to adversely affect short- and long-term outcomes, but the comparative effect of support type is largely unknown. This study determined the comparative effect of univentricular and biventricular support on survival in bridged patients after OHT. METHODS: The United Network of Organ Sharing database was queried for adult patients bridged to OHT with a univentricular (left ventricular assist device [LVAD]), biventricular (biventricular assist device [BiVAD]), or total artificial heart ([TAH]) device between 2004 and 2012. Unconditional and conditional survivals were compared with the Kaplan-Meier method. Cox proportional hazards regression models were constructed to determine the risk-adjusted influence of support type on death. RESULTS: Of the 4,177 patients identified, 3,457 (20.4%), 575 (3.4%), and 145 (0.9%) were bridged with an LVAD, BiVAD, and TAH, respectively. Unadjusted 30-day, 1-year, and 5-year estimated survival was greater in LVAD patients than in the BiVAD and TAH cohorts. After risk-adjustment, BiVAD and TAH were associated with an increased risk of death at all time points. Unadjusted and adjusted 5-year survival, conditional on 1-year survival, was worse, however, in only TAH patients. CONCLUSIONS: Patients with biventricular failure bridged to OHT with a TAH or BiVAD experience worse short- and long-term survival comparison with those with an LVAD. This difference is most likely due to an increase in early death and depends on the type of BiVAD device implanted.

Am J Cardiol. 2017 Mar 1. pii: S0002-9149(17)30191-1. doi: 10.1016/j.amjcard.2017.02.005. [Epub ahead of print]

Mortality risk stratification in Fontan patients who underwent heart transplantation.

Berg CJ, Bauer BS, Hageman A, Aboulhosn JA, Reardon LC.

The number of patients who require orthotopic heart transplantation (OHT) for failing Fontan physiology continues to grow; however, the methods and tools to evaluate risk of OHT are limited. This study aimed to identify a set of preoperative variables and characteristics that were associated with a greater risk of postoperative mortality in patients who received OHT for failing Fontan physiology. Thirty-six Fontan patients were identified as having undergone OHT at University of California-Los Angeles Medical Center from 1991 to 2014. Data were collected retrospectively and analyzed. The primary end point was designated as postoperative mortality. After an average follow-up time of 3.5 years, 17 (44%) patients suffered postoperative mortality. Patient characteristics including (1) age <18 years at the time of OHT, (2) Fontan-OHT interval of <10 years, (3) systemic ventricular ejection fraction <20%, (4) moderate-to-severe atrioventricular valve insufficiency, (5) an elevated Model of End-stage Liver Disease, eXcluding INR score, or (6) need for advanced mechanical support before surgery were associated with an increased incidence of postoperative mortality. Using these risk factors, we present a theoretical framework to stratify risk of postoperative death in failing Fontan patients after OHT. In conclusion, a method such as this may aid in the transplantation evaluation and listing process of patients with failing Fontan physiology.

Hypertension. 2017 Mar 27. pii: HYPERTENSIONAHA.117.09182. doi: 10.1161/HYPERTENSIONAHA.117.09182. [Epub ahead of print]

Age at first childbirth and hypertension in postmenopausal women.

Park S.

Whether age at first childbirth has an effect on hypertension incidence is unclear. The objectives of this study were to

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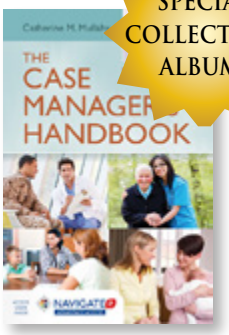

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examine the relationship between age at first childbirth and hypertension and to examine whether degree of obesity, measured as body mass index, mediates age at first childbirth-related hypertension in postmenopausal women. This study analyzed 4779 postmenopausal women data from the Korea National Health and Nutrition Examination Survey 2010 to 2012. Logistic regression analyses were used to investigate relationship between age at first childbirth and hypertension. Mediation analysis was performed to examine the contribution of body mass index to age at first childbirth-related hypertension. Mean of participants' age at first childbirth and current age were 23.8 and 63.4 years, respectively. The prevalence of hypertension was 51.1%. Age at first childbirth was significantly associated with the prevalence of hypertension (odds ratio, 0.963; 95% confidence interval, 0.930-0.998; P=0.036). Women with age at first childbirth ≤19 years had significantly higher risk of hypertension (odds ratio, 1.61; 95% confidence interval, 1.17-2.23; P=0.004) compared with those >19 years. Multivariable-adjusted prevalence of hypertension was significantly lower in women who delivered the first infant at 20 to 24 (45.5%), 25 to 29 (46.1%), and ≥30 (39.9%) years compared with those at ≤19 years (58.4%). Body mass index completely mediated age at first childbirth-hypertension relationship (indirect effect: odds ratio, 0.992; 95% confidence interval, 0.987-0.998; P=0.008). Age at first childbirth was significantly associated with hypertension in postmenopausal women. Body mass index mediated the effects of age at first childbirth on hypertension.

Am J Surg. 2016 Dec;212(6):1175-1182. doi: 10.1016/j.amjsurg.2016.09.017. Epub 2016 Sep 29.

Comparison of pulmonary function tests and perioperative outcomes after robotic-assisted pulmonary lobectomy vs segmentectomy.

Echavarria MF, Cheng AM, Velez-Cubian FO, et al.

BACKGROUND: Lobectomy is standard treatment for early-stage lung cancer, but sublobar resection remains debated. We compared outcomes after robotic-assisted video-assisted thoracoscopic (R-VATS) segmentectomy vs lobectomy. METHODS: We retrospectively analyzed data from 251 consecutive patients who underwent R-VATS lobectomy (n = 208) or segmentectomy (n = 43) by a single surgeon over 36 months. Pulmonary function tests and perioperative outcomes were compared using Chi-squared test, unpaired Student t test, or Kruskal-Wallis test, with significance at P ≤ .05. RESULTS: Intraoperative complications were not significantly different, but median operative times were longer for R-VATS segmentectomies (P < .01). Postoperative complications were not significantly different, except for increased rates of pneumothorax after chest tube removal (P = .032) and of effusions or empyema (P = .011) after R-VATS segmentectomies. Predicted changes for forced expiratory volume in 1 second and diffusion constant of the lung for carbon monoxide are significantly less after R-VATS segmentectomy (P < .001). CONCLUSIONS: R-VATS segmentectomy should be considered as an alternative to lobectomy for conserving lung function in respiratory-compromised lung cancer patients, although oncologic efficacy remains undetermined.

Transplantation. 2017 Mar 28. doi: 10.1097/TP.0000000000001752. [Epub ahead of print]

Wait time of <6 and >18 months predicts hepatocellular carcinoma recurrence after liver transplantation: proposing a wait time "sweet spot."

Mehta N, Heimbach J, Lee D, et al.

BACKGROUND: It has been postulated that short wait time before liver transplant (LT) for hepatocellular carcinoma (HCC) results in the inclusion of tumors with aggressive biology, but prolonged wait time could result in a shift to more aggressive tumor behavior. We therefore test the hypothesis that a wait time "sweet spot" exists with a lower risk for HCC recurrence compared to the other 2 extremes. METHODS: This multi-center study included 911 patients from 3 LT centers with short, medium and long wait times (median of 4, 7, and 13 months, respectively) who received MELD exception listing for HCC from 2002-2012. RESULTS: Wait time, defined as time from initial HCC diagnosis to LT, was <6 months in 32.4%, 6-18 months in 53.7%, and >18 months in 13.9%. Waitlist dropout was observed in 18.4% at a median of 11.3 months. Probability of HCC recurrence at 1 and 5 years were 6.4% and 15.5% with wait time <6 or >18 months (n=343) versus 4.5% and 9.8% with wait time of 6-18 months (n=397), respectively (p=0.049). When only pre-LT factors were considered, wait time <6 or >18 months (HR 1.6, p=0.043) and AFP >400 at HCC diagnosis (HR 3.0, p<0.001) predicted HCC recurrence in multivariable analysis. CONCLUSION: This large multi-center study provides evidence of an association between very short (<6 months) or very long (>18 months) wait times and an increased risk for HCC recurrence post-LT. The so-called "sweet spot" of 6-18 months should be the target to minimize HCC recurrence.

NEW GUIDELINES FOR CHILDHOOD OBESITY

"Pediatric Obesity—Assessment, Treatment, and Prevention: An Endocrine Society Clinical Practice Guideline," was published in *The Journal of Clinical Endocrinology & Metabolism (JCEM)*. The guideline is co-sponsored by the European Society of Endocrinology and the Pediatric Endocrine Society.

Children and teenagers are diagnosed as overweight when BMI is between the 85th and 95th percentile for their age and sex. Obesity is categorized as a BMI greater than or equal to the 95th percentile for their age and sex. Extreme obesity is identified as a BMI greater than or equal to 120% of the 95th percentile.

Recommendations include:

- Children or teens with a BMI greater than or equal to the 85th percentile should be evaluated for related conditions, such as metabolic syndrome and diabetes.
- Youth evaluated for obesity do not require measurement of fasting insulin values, as these values have no diagnostic value.
- Obese children and teens do not require routine laboratory evaluations for endocrine disorders that can cause obesity unless their height or growth rate is less than expected based on age and pubertal stage.
- Specific genetic testing is indicated in early onset obesity (before 5 years of age), cases of hyperphagia, other clinical findings of genetic obesity syndromes, or a family history of extreme obesity. Approximately 7% of children with extreme obesity may have rare chromosomal abnormalities or genetic mutations. ■

Thymus Removal Effective Treatment for Myasthenia Gravis

Study results from the Randomized Trial of Thymectomy in Myasthenia Gravis compared patients who received a thymectomy plus prednisone to a group who received only prednisone. Those who received surgery plus prednisone had an overall reduction in muscle weakness and required lower daily doses of prednisone, 44 mg versus 60 mg for those taking prednisone alone. Results were published in the *New England Journal of Medicine*. In addition, visit this video summarizing the key findings here. The NIH says the trial has provided strong support for thymectomy—a result that's been many years in coming. ■

Kaiser Health News Reports on Dozens of Cancer Drugs with Little Efficacy

Improving survival is the goal of most cancer drugs. However, the FDA's efforts to move oncology drugs through the approval process more quickly has provided patients with expensive drugs that have shown little ability to improve survival. In fact, cancer treatment has changed very little over the past 10 years. According to a study in *JAMA Otolaryngology—Head & Neck Surgery*, the 72 cancer therapies approved between 2002 and 2014 increased cancer survival by only 2.1 months over older drugs. Meanwhile the cost of the new drugs averages $171,000 per year per patient. For more on this topic see Kaiser Health News. ■

LOW LUNG CANCER SCREENING RATES AMONG THOSE WHO SMOKE

Just 3.3% of eligible smokers surveyed said they had received a low-dose computed tomography scan in the past year to check for lung cancer. That was in 2010. In 2015, the percentage had inched up to 3.9%, or 262,700 people out of 6.8 million who were eligible. The analysis of data from the National Health Interview Survey, a large, ongoing in-person federal survey conducted by the National Center for Health Statistics, was performed by researchers at the American Cancer Society and published online in *JAMA Oncology*. ■

Screen Hospice Caregivers Early and Often to Prevent Depression and Anxiety

More than 34 million people in the U.S. care for terminally ill loved ones, but few resources are available to help them navigate the challenges they encounter.

A study at the University of Missouri School of Medicine found that nearly 25% of caregivers were moderately or severely depressed and nearly 33% had moderate or severe anxiety. The researchers recommend that health providers remember to treat the whole family, providing ongoing screening to family caregivers to identify early signs of depression and anxiety. Researchers found that younger caregivers were more likely to be depressed or anxious and that caregivers who are married and caring for a family member with a diagnosis other than cancer, such as Alzheimer's disease, had higher levels of depression. ■

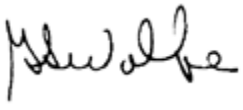
Stop Workplace Bullying in Health Care *continued from page 2*

- Provides tiered response strategies aimed at early intervention and informal resolution
- Provides clear and confidential grievance, investigation, and disciplinary procedures
- Requires any steps taken in relation to complaints of bullying to be documented
- Protects staff who report bullying or cooperate in investigatory processes

3. Implement, review, and monitor the policy
4. Train all staff, clinical and non-clinical, to assist in the recognition and resolution of issues related to bullying
   - Include information about bullying in the organization's orientation program
   - Provide additional training to managers and supervisors that enables them to identify and deal with problem behavior at an early stage
5. Ensure appropriate support internal and external mechanisms are available to assist victims of bullying
6. Establish structures that encourage patient feedback to management, thereby providing an additional external source of surveillance in relation to problem behaviors

Everyone needs to stand up and do the right thing to stop workplace bullying. As certified case managers who adhere to the Code of Conduct, you are obligated to take action.

Read "Workplace Bullying: Professional Ethics Tackles a Cultural Mainstay" published in this issue of *CareManagement*.



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ACCM: Improving Case Management Practice through Education

Insights on Case Management in Workers' Compensation *continued from page 8*

the development of our nurses both in terms of opportunities for advancement and continuing education. Every year, we offer approximately 50 free CEUs to nurses internal to our organization.

Continuing education is also important to keep up with this challenging field, which is always changing. Aging baby boomers and the growing incidence of obesity present new comorbidities and increased injury risk and severity. We strive to stay at the forefront of developments to help facilitate the best-possible results.

What's exciting is the plethora of emerging solutions to assist in our jobs. For example, with the proliferation of sophisticated case management software, smartphones, tablet computers, and video conferencing, there are more tools than ever at our disposal.

The potential applications in workers' compensation are endless. Case managers are leveraging telehealth to better coordinate treatment and ancillary services, improve discharge planning from hospitals, and help educate injured workers about tapering off opioid prescriptions. In short, it's a great time to be a case manager in workers' comp. CM

Bringing the 'Quadruple Aim' Into Case Management Practice *continued from page 4*

manager can reap benefits, personally and professionally, by distinguishing between what needs attention now and what is beyond the case manager's control, or hasn't materialized as yet. Being in the moment (calming your mind with deep breaths, walking around the block, etc.) can introduce healthier, more mindful habits.

Put yourself first. This is a hard one for most people, and especially those in "helpful professions" such as nursing and social work, which are two of the disciplines of practicing case managers. Putting yourself first doesn't mean you ignore the needs of others. But case managers must recognize that, unless they take care of themselves first, they will be unable to provide care for others.

The quadruple aim comes at a beneficial time for case managers: the healthcare arena continues to undergo changes, while the aging of the population increases the number of complex cases. Focusing on the wellbeing and satisfaction of all involved can lead to better care and improved population health. CM

Five Key Principles Case Managers Should Know About Return-to-Work Programs *continued from page 9*

RTW programs have changed how disability is viewed in the workplace. The more case managers understand about RTW programs, the more they can support the individual in returning to optimal health and productivity. CDMSs and CCMs who are specialists in this area have the expertise to initiate the conversation.

Click here for more information about the CDMS certification. CM

Post-Acute Networks: The Discharge Planner's Dilemma *continued from page 21*

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Part 4: Case Management Society of America Issues Revised Standards of Practice—Professional Case Management: Roles and Responsibilities *continued from page 6*

retrospective communications based on payors' requirements, and utilization management procedures
- Ensuring appropriate allocation, use and coordination of services and resources while striving to improve safety and quality of care, and maintaining cost effectiveness
- Identifying and addressing barriers to care and clients' engagement in their own health
- Assisting clients to achieve safe care transitions
- Promoting self-advocacy by clients, independence and self-determination, and provision of client-centered and culturally appropriate care
- Advocating for both clients and payors to facilitate positive outcomes except, when a conflict arises, the needs of clients must be the "number one priority"
- Evaluating the effectiveness of plans of care, resource allocation and service provision while applying outcome measures reflective of organization policies and expectations, accreditation standards and regulatory requirements

Engaging in performance improvement activities to improve clients' access to timely care and services, and enhancing the achievement of goals and desired outcomes

Based on the above description of the roles and responsibilities of case managers, it is clear that they play a crucial role in the health care delivery system. CM

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