

CareManagement

OFFICIAL JOURNAL OF THE ACADEMY OF CERTIFIED CASE MANAGERS

Vol. 16, No. 1 FEBRUARY/MARCH 2010

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Gary S. Wolfe

Health Care Reform: *Continued*

The United States provides some of the best medical care in the world, yet a growing body of evidence indicates the system falls short. This is not new information for a case manager. Case managers on a regular basis see the short falls in the health care system. Many of these short falls have created the need and demand for case management. Although national health spending is significantly higher than the average rate of other industrialized countries, the United States is the only such country that fails to guarantee universal health insurance. Today, health care coverage is deteriorating, leaving millions without affordable access to preventive and essential health care. The quality of care is highly variable and delivered by a system that too often is poorly coordinated, driving up costs, and putting patients at risk. With rising costs straining family, business, and public budgets; deteriorating access to care; and variable quality; improving health care performance is a matter of national urgency.

Since The Commonwealth Fund started issuing National and State Scorecards measuring the US health system, things have gotten worse. Published in July 2008, the second *National Scorecard, Why Not the Best? Results from the National Scorecard on U.S. Health System Performance, 2008*, rates US health system performance on 37 core indicators for a score of 65 out of 100, a slight decline from the 2006 score of 67. The report demonstrates that access to health care declined significantly during this period and that health system efficiency remains low. However, selected quality metrics have shown improvement. Overall, the 2008 Scorecard indicates that despite pockets of progress, the US health system continues to operate far below the performance of leading nations, delivery systems, states, and regions.

Some of the strategies to improve our

ailing health care system should include:

- Extending comprehensive, affordable, and seamless insurance coverage to all
- Aligning incentives to reward high-quality, efficient care
- Organizing the health system to achieve accountable, coordinated care
- Investing in public reporting, evidence-based medicine, and the infrastructure necessary to deliver the best care
- Exploring creation of a national entity that sets goals for health system performance and priorities for improvement, monitors performance, and recommends practices and policies

Hopefully these strategies will be incorporated into the National Health Care Reform Package currently under consideration by the Congress.

Health care reform will impact case management. How, remains to be seen. What are you doing right NOW to encourage and aid reform? Here are some things you can think about doing:

- Talk to your elected officials about the problems you encounter in health care and what possible solutions are.
- Encourage wellness with all your patients, friends, and family. This includes better nutrition, regular exercise, preventive medical checkups, and adherence to medical treatment plans.
- Encourage your employer to offer cost-effective benefits for plan members.
- Be well informed.

As we start a new decade, let's be part of the solution in addressing the problems in health care delivery.

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ACCM: Improving Case Management Practice through Education

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Vol. 16, No 1, February/March 2010.

CareManagement (ISSN #1531-037X) is published six times a year, February, April, June, August, October, and December, and its contents are copyrighted by Mason Medical Communications Inc., 256 Post Road East, Suite 204, Westport, CT 06880-3617; Tel: 203-454-1333; Fax: 203-227-9495.

Subscription rates: US: \$80 per year (six issues), Canada: \$135 per year; foreign: \$150 per year. Individual copies: US: \$15; Canada & foreign: \$25. Domestic institutional rates: \$125 per year.

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CareManagement is indexed in the CINAHL® Database and Cumulative Index to Nursing & Allied Health Literature™ Print Index and in RNDex.™

Being in a Caring Profession Doesn't Mean We Can't—and Shouldn't—Care for Ourselves

By **Ellen Fink-Samnack LCSW, CCM, CRC**, Commissioner, Commission for Case Manager Certification (CCMC)

Does this sound familiar? Being tired, stressed out, and burned out is an occupational hazard that comes with being a health and human services professional. Long shifts with few or no breaks are part of the territory. Anyone who says differently is looking at this world through rose-colored glasses.

Then here is the wake-up call. The time has come to stop the self-talk that perpetuates the self-fulfilling prophesy that has turned health and human services into martyrdom. Unless we are willing to change our attitudes and behaviors, the unhealthy culture of practice that has been created will continue. In other words, we must advocate for ourselves just as we advocate for others.

For many of us in caring professions, self-care is viewed as anathema to what we do. We tell ourselves that the needs of the client/patient always come first. We cannot possibly give our own needs priority or even equal rank with the needs of our clients/patients. As noble as it sounds, this attitude is now threatening the quality of case management

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and care management services that we deliver. Unless we put more attention on ourselves, our interventions will suffer, if for no other reason than the fact that burned-out and stressed-out practitioners will leave the profession in droves.

Change in behavior starts with awareness, acknowledging the rippling impact of our choices on ourselves, our colleagues, our professional environment, our longevity in our chosen field, our career satisfaction, and, ultimately, the quality of interventions and services

Being in a helping profession does not make us helpless! We can adapt and change our behaviors, even in subtle but significant ways.

we provide to the valued consumers of our services. Being in a helping profession does not make us helpless! We can adapt and change our behaviors, even in subtle but significant ways.

Lucille was a health and human services professional with 20 years in the practice. Day in and day out, she worked with children and families, until she was on the verge of burning out. One day, she realized that she had a choice. Instead of focusing only on those things she “had” to do—which admittedly were the reasons she got into the field in the first place—Lucille gave herself permission to explore those things she always wanted to do. She began writing professional articles and submitted a proposal to present at a conference, which was accepted. Suddenly, she was reengaged in her profession, with activities that

challenged her intellectually and refreshed her emotionally. She continues to provide services to her patients/clients, but with a greater sense of being in control of her profession, instead of the other way around.

For others, it is taking a yoga class or learning how to meditate, enjoying music or walking in nature. It may mean a stricter boundary between work time and personal time in order to rejuvenate. In ways large and small, self-care can become a priority. The choice, however, is up to each of us.

John was in a new management role with a large staff of health and human services professionals. The environment had become toxic, taking a heavy toll on the staff. In

order to implement changes that would make the workplace healthier, improve job satisfaction, and elevate the quality of services, John turned to his staff. They were given free rein to suggest how work should be done. Sadly, all the staff could envision was the status quo. Even though they admitted their dissatisfaction and unhappiness, they were stuck in the box and couldn't get out.

It is far too easy to place the blame on “the industry” and much tougher to roll up our sleeves to make the necessary changes. Adopting new attitudes and behaviors takes effort, and so we gravitate to the familiar, even when it is dissatisfactory.

The truth is there will always be challenges: managed care, the economy, budget cuts, shifts in priorities and organizational goals, frustrations with

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A Sign of the Times: Helping Employees to Stay Productive While Dealing With Stress

By Lisa Scotton, RN, CDMS, COHN, CCM, CPDM, *Commissioner*

Workforce cutbacks and an uncertain economy that is still recovering from the recession have added to the stress felt by employees—particularly those who now find themselves being more productive than ever. Not only are many employees doing their own jobs, they are also taking on some or all of the responsibilities that had been handled by others who have been laid off.

Presumably, these employees are the “cream of the crop”—the individuals who have the knowledge, experience, and proven ability to get the job done. For employers, keeping these employees productive is imperative. The reality, however, is that workplace stresses—particularly when coupled with personal and financial concerns—can impact a person’s health, wellness, and productivity. These worries escalate further when employees are afraid they could lose their jobs.

For those of us in disability management, occupational health, and related disciplines, our challenge becomes helping employees to access the resources they need to deal with the work and life stresses they are facing. Communication, which is always necessary for effective workplace programs, becomes crucial.

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An Employee Assistance Program (EAP) can be very helpful. However, EAPs typically have low utilization rates, which may reflect a lack of understanding about the program by employees, particularly about whether information is kept strictly confidential. Companies that offer an EAP must communicate it broadly and frequently to employees to make the program anonymous and accessible. Put up posters in the lunchroom or break room. Feature the EAP

For those of us in disability management, occupational health, and related disciplines, our challenge becomes helping employees to access the resources they need to deal with the work and life stresses they are facing.

in the employee newsletter or on the employee Website. Let employees know the type of help that is available, from sessions with a counselor to assistance arranging childcare and eldercare.

Education programs are also helpful for managers as well as employees. For managers, training sessions could focus on the impact of economic and workplace stress on their direct reports—as well as on the managers, themselves. For employees, stress management techniques can be offered in lunch-and-learn programs or with tips and advice in a newsletter or on a Website.

The link between stress and workplace productivity becomes even more apparent when dealing with return-to-work (RTW) and stay-at-work cases. In these situations, the disability manager, occupational health nurse, or other

professional must address a specific health issue that could impact a person’s ability to perform his or her regular tasks. In addition to physical challenges, professionals must also be aware of the red flags that indicate an employee is allowing workplace stress and fears to influence his or her decisions.

For example, a long-time employee who becomes injured—whether on or off the job—may seek to return to work faster than is medically feasible out of

fear that, when the next round of cutbacks is made, he could be let go. Even when such concerns are unfounded, their impact on an employee’s state of mind is very real.

If an employee’s physical health requires a gradual

resumption of duties, a transition schedule should be put in place; for example, half-days the first week or a six-hour work day. Another way to promote a successful RTW without overtaxing the employee is to resume work on a Thursday. Instead of having an employee come back on a Monday and face a long, first week back at work, she can start the preceding Thursday. After two days on the job, the employee then has the weekend to rest and recuperate.

Professionals in disability management and occupational health also need to be on alert for employees who need support staying at work because of a physical condition. Rather than put in for sick leave or short-term disability because a chronic condition or an existing injury has flared up, an employee

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ASPIRE to Excellence: Take a Leap Toward Patient-centered Care in 2010

By **Christine M. MacDonell**, *Managing Director of Medical Rehabilitation and International Aging Services*

We at CARF hope that all of you had peaceful and happy holidays. As in every January, things settle down after the holiday activities, people are re-energized, and adventures begin anew! Every year in January, CARF publishes their new standards manuals that reflect the previous year's work. Now some may say that doesn't reenergize but...

In 2010 there are the new home and community services standards that cross over all areas that CARF accredits. In a previous column we highlighted these new standards for you. The development of these standards and the subsequent field review brought forth great ideas that were incorporated into a variety of sections in our standards. One that bears discussion is a standard that is now found in our ASPIRE to Excellence section under leadership. If any organization or individual were seeking accreditation in our case management standards, this standard would apply.

As case managers, you are very "person centered." Your model is to listen and to be able to respond to and include the person you are working with in appropriate decision making—no matter what area of their life you are addressing. It is very easy for the terms

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"person centered" or "person directed" to be bantered about without thinking about the actualization of the words.

The new standard states the following:

A person-centered philosophy is demonstrated by leadership and personnel, guides service delivery, and is communicated to stakeholders in an understandable manner.

As case managers you are aware through your work that using person-centered approaches results in changed lives for many individuals with diverse

A person-centered philosophy is demonstrated by leadership and personnel, guides service delivery, and is communicated to stakeholders in an understandable manner.

disabilities and for their families. Individuals report fewer unmet needs, more community connections, more satisfying living situations and relationships, and enhanced vocational opportunities.¹

Case managers, as well as all professionals delivering care, need to be exposed and trained in the various approaches of person-centered delivery of services. Many individuals receiving services are only familiar with professionals leading meetings and groups and making decisions. They are hesitant to direct their own care. A person-centered philosophy does not happen automatically. It is developed, evolves, and changes as necessary—and, as with any change, it needs to be endorsed and driven by leaders. However, the day-to-day implementation and use of

the philosophy are done by the front-line individuals. For the philosophy to be used and implemented, training, education, role playing, and a feedback structure from both staff and individuals being served need to be in place.

To begin, individuals receiving services need to understand and appreciate their role and the variety of approaches that can be taken in person-centered delivery of services. It should be evident that there is an orientation

for the person to understand that he or she will be an active participant in the decision-making process of care. The information about your services should be clear and understandable, including how you will use these approaches. The person

needs to be comfortable with the process and accept his or her role. As a case manager, you will work with the person to decide what supports if any might be necessary to increase the knowledge and comfort of the person. Each individual and family/support system you work with will react and respond to these approaches in their own unique way. Some will become active participants and relish the person-centered approach. Others will require your encouragement, support, and ongoing direction to establish their role in person-centered care.

As a case manager, your unique talents and skills in communication, collaboration, identification of, and making resources available are all

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What Case Managers/Discharge Planners Need to Know About Private-duty Home Care Services

By Elizabeth E. Hogue, Esq.

Is it appropriate to offer patients and their families the option to pay privately for home care services?

That's a question some discharge planners and case managers ask or may be confused about.

In order to be appropriate for home health or hospice services paid for by any payer, including the Medicare Program, patients must either be able to care for themselves or they must have a primary caregiver. Patients' family members or others may be willing to fulfill this role on a voluntary basis. If not, discharge planners and case managers should offer patients and their family members the option to pay privately for a primary caregiver who can meet the patient's needs between visits from professional staff from home health agencies and hospices. These types of services may be referred to by post-acute providers as "private-duty home care services."

The option to pay for private-duty home care services should be offered to all patients who cannot care for themselves and who have no voluntary primary caregivers. Patients who can care for themselves or have voluntary primary caregivers may also wish to contract for additional assistance, so discharge planners and case managers should offer this option to all patients who may benefit from these services.

Discharge planners and case managers may be reluctant to offer these services to patients and their families because of the cost of such services. They may also erroneously conclude that patients and their families cannot

afford these services. But it's wrong to jump to conclusions about who can afford these services. Instead, private-duty home care services should be offered to every patient and family who may benefit from them. This conclusion is consistent with legal and ethical requirements that govern the practice of case management.

Offer private-duty home care services to all patients who may benefit from them.

From a legal point of view, discharge planners and case managers who work in hospitals must comply with Conditions of Participation (COPs) that govern hospitals. Specifically, discharge planners and case managers are required to develop appropriate discharge plans, if necessary, for all patients. Development of appropriate discharge plans undoubtedly includes private-duty home care services for patients who may benefit from them.

In addition, the Case Management Society of America (CMSA) has published national standards of care for case managers. They are likely to apply to all case managers and discharge planners, regardless of whether they are certified as case managers, because they are practicing as case managers.

These standards make it clear that case managers have a duty to advocate on behalf of patients. As advocates for patients, discharge planners and case managers have an obligation to make

sure that patients understand all of the options available to them, including the option to pay privately for home care services.

Case managers and discharge planners also have an ethical obligation to inform patients about the availability of private-duty services. Autonomy is an important ethical principle applicable to the practice of case management and discharge planning. This ethical principle generally requires case managers to provide information to patients so that they can make informed choices.

Patients cannot make choices about the care they wish to receive unless they have information about all services available, including private-duty services. Therefore, you as a case manager or discharge planner have a clear ethical obligation to provide information about private-duty home care services to all patients who may benefit from them.

Patients are in the drivers' seat when it comes to decisions about their care, but they cannot make appropriate choices unless they have information about all of the types of care available to them. This is why it is so important for discharge planners and case managers to make sure that patients have information about private-duty home care services. **CM**

Elizabeth E. Hogue is a health care attorney and consultant in Washington, DC. To obtain more information about fraud and abuse issues in a book entitled Preventing Fraud and Abuse, send a check for \$30.00 made out to Elizabeth E. Hogue, Esq., to Fulfillment, 107 Guilford, Summerville, SC 29483.

Improving the End-of-Life Experience for Hospice Patients from a Case Manager Perspective: Disruptive Issues and How to Address Them

By Kevin T. Bain, PharmD, MPH

There are many approaches to the end-of-life experience, and each patient and health care provider approaches this experience uniquely. Hospices approach the end-of-life experience from an interdisciplinary team (IDT)-oriented perspective, providing expert medical, emotional, psychosocial, and spiritual support services expressly tailored to meet the needs of not only patients but also caregivers (family members or other loved ones responsible for taking care of patients).¹ Case managers, usually nurses, are essential members of the IDT, working in concert with physicians and other team members to provide an end-of-life experience that is consistent with the needs of patients and caregivers. There are several issues that have the potential to disrupt this experience. This article discusses these issues and how case managers can address these issues from the perspectives of pre- and post-hospice enrollment.

Issues Potentially Disrupting the End-of-Life Experience

Reimbursement Rates May be Insufficient to Cover the Costs of Hospice Care

Hospice care is an elected benefit covered under Medicare (Part A), Medicaid, and most managed care or private insurance plans.² The Medicare Hospice Benefit (MHB) is the predominant source of payment for hospice care in the United States; in 2007, the MHB

covered 87% of hospice patient days, whereas the remaining 13% were covered by a variety of other payers.³ More than 90% of hospices have been certified by the Centers for Medicare & Medicaid Services (CMS) to file for reimbursement for their services under the MHB.² Under the MHB, patients and caregivers are entitled to a multitude of services that include case management, such as regular home care visits by nurses; physician services; social work services; home health aide and homemaker services; counseling services; durable medical equipment and medical supplies; therapies related to the terminal illness; certain physical, occupational, and speech therapy services; short-term inpatient care, including respite care, and short-term continuous care at home; bereavement services for caregivers for 12 months; and any covered medically necessary and rational services as identified by the IDT.^{4,5}

Hospice care is paid for on a per diem basis, such that the hospice bills Medicare for each day a patient is enrolled in the MHB, regardless of the amount of services provided on a given day.^{3,6} Because patients require differing intensities of care during their end-of-life experience, the MHB provides patients and caregivers four levels of care to meet their needs: (1) routine home care, (2) continuous home care, (3) general inpatient care, or (4) inpatient respite care.⁷ Routine home care

comprises the vast majority (95.9%) of hospice patient days.² For the 2008/2009 fiscal year, the hospice per diem rate for routine home care was \$139.97 per patient day.³

The hospice per diem rate for each level of care is adjusted annually based on the Hospital Market Basket Index.⁶ The fiscal year 2009/2010 rates increased by approximately 2.1% of the 2008/2009 rates, such that the hospice per diem rate for routine home care for the 2009/2010 fiscal year is \$142.91.⁶ Although the reimbursement rates have increased annually over the last several years, with the advent of costly palliative therapies like chemotherapy and radiation, the average cost to hospices has risen much faster than the rates.⁷ Most hospices in the United States are small in size (median average daily census in 2008 was 60.3 patients²) and, based on economies of scale, may not have the ability to provide these therapies,^{8,9} especially because Medicare does not provide additional payments beyond the fixed reimbursement rates. As a result, patients who elect to continue these therapies may be excluded from hospice enrollment or be enrolled in hospice after these therapies have been discontinued, typically closer to death. Medicare data suggest that a significant percentage—up to 33%—of cancer patients receive chemotherapy in their last 6 months of life, including a sizable percentage (9%) in their last month.¹⁰ ►

The growth in the percentage of patients receiving hospice care for a short time is of concern to hospices and payers because short hospice length of service—especially to the extent that it may be due to avoidably late enrollment—may cause needless suffering for patients and caregivers and have adverse economic consequences for payers.

The amount a hospice can be paid by Medicare in a given fiscal year is limited by a cap allotted by Medicare.³ If the amount received by a hospice is greater than the cap, then the hospice must pay the CMS back the difference.³ A hospice is likely to exceed the cap when it enrolls a disproportionately large number of patients with long hospice lengths of service. Although the number of US hospices exceeding the cap has historically been low, a small but growing number of hospices have exceeded the cap since 2004.⁴ As a result, many hospices have adopted tighter enrollment policies, which may inadvertently shorten hospice length of service for some patients.

Growing Prevalence of Short Hospice Length of Service

Since the first hospice opened in 1974, the number of hospices has risen rapidly. For 2008, the National Hospice and Palliative Care Organization (NHPCO) estimated that there were approximately 4,850 hospices located in the United States, District of Columbia, Puerto Rico, Guam, and US Virgin Islands.² The rapid rise in the number of hospices correlates with the continuous rise (nearly 10% annually) in the number of patients utilizing hospice care.³ According to the NHPCO, an estimated 1.45 million patients utilized hospice care in 2008,² a 13-fold increase in 20 years.³ By this estimate, 38.5% of

all deaths in the United States in 2008 occurred under the care of a hospice.²

Although the provision and utilization of hospice care in the United States has grown markedly over the last decades, the length of time patients are served remains relatively short, according to the NHPCO. In 2008, the median length of service was 21.3 days, meaning that half of hospice patients received care for less than 3 weeks.² The percentage of patients served by hospices for 7 days or less was 35.4%.² This reflects a 4.6% increase from 2007, when 30.8% of patients had what is considered a short hospice length of service.

The growth in the percentage of patients receiving hospice care for a short time is of concern to hospices and payers because short hospice length of service—especially to the extent that it may be due to avoidably late enrollment—may cause needless suffering for patients and caregivers and have adverse economic consequences for payers.¹¹ Short hospice length of service may mean that patients and caregivers have been unable to optimally benefit from a desirable end-of-life experience because, in large part, their hospice has had inadequate time to learn their needs and develop a plan of care to meet their needs.¹¹ Short hospice length of service might also mean that patients have received costly and possibly unnecessarily aggressive medical care for an excessively long period before enrollment in hospice.¹¹ The evidence suggests that enrolling patients earlier, especially those otherwise destined to have a short hospice length of service, might improve the end-of-life

experience for patients and caregivers and also prove cost effective.¹¹⁻¹³

Insufficient Discussions About End-of-life Decisions

Patients nearing the end of life need support in understanding and making decisions about the choices available to help them maximize their end-of-life experience. Research shows that the conventional health care system often fails to provide sufficient discussions about end-of-life decisions, such as using advance directives and hospice care, despite the important role patients and caregivers have in these decisions.¹⁴⁻¹⁷ In the absence of documented end-of-life decisions, aggressive medical care is provided by default, often contrary to the needs of patients.¹⁸⁻²⁰ Aggressive medical care at the end of life, such as mechanical ventilator use and resuscitation, is associated with worse quality of life for patients,^{17,21} more difficult bereavement adjustment for caregivers,¹⁷ and higher health care costs for payers.^{18,22} To the contrary, sufficient discussions about end-of-life decisions is associated with less aggressive medical care near death and earlier hospice enrollment, which is associated with longer hospice length of service and better quality of life,¹⁷ as well as lower health care costs.^{21,23,24}

How Case Managers Can Address the Issues

Pre-hospice Enrollment

A considerable proportion of patients are not enrolled in hospice until they are very close to death, in large part because of late referrals. If patients were

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If patients were referred to hospice earlier and if efforts were directed to reducing the percentages of patients enrolled with especially short hospice length of service, it might be possible to improve the end-of-life experience for patients and caregivers while reducing the use of superfluous resources and expenditures for health care.

referred to hospice earlier and if efforts were directed to reducing the percentages of patients enrolled with especially short hospice length of service, it might be possible to improve the end-of-life experience for patients and caregivers while reducing the use of superfluous resources and expenditures for health care. Because referrals to hospice are typically facilitated by physicians, to address this issue, case managers need to focus on finding complimentary means for facilitating referrals.

One way to do this from the pre-hospice enrollment perspective is through greater use of non-hospice palliative care services by case managers in the acute care setting. Research shows that integrating case management and palliative care services is a feasible and effective way to improve the quality of care for patients.²⁵ Research also shows that use of hospital-based palliative care services leads to more timely patient referral to hospice,²⁶ is associated with greater satisfaction among patients and caregivers with their care experience and communication by the IDT,^{26,27} and is associated with significant cost savings compared with usual care.^{26,28,29} These data suggest that opportunities are available to integrate case management and hospital-based palliative care services to support earlier referrals to hospice.

Another way to do this from the pre-hospice enrollment perspective is through medication management by case managers in the acute care setting. A substantial proportion of case managers' responsibilities at hospital discharge consists of reviewing medication

plans with patients³⁰ and performing medication reconciliation, which involves the accurate transfer of medication information across the continuum of care.³¹ Opportunities are available for case managers to incorporate discussions about discontinuing costly and possibly unnecessarily aggressive medical care with patients, caregivers, and members of the IDT before discharge and enrollment in hospice.

Post-hospice Enrollment

Although many of the issues previously addressed are intimately linked to decision making before hospice enrollment, if efforts were directed to reducing feelings of abandonment, it might be possible to improve the end-of-life experience for patients and caregivers after hospice enrollment. Despite the professed importance of nonabandonment to hospice care, research shows that patients and caregivers sometimes feel abandoned by their health care providers around the time of death.^{15,32,33} Research also shows that before death, abandonment feelings are related to loss of continuity between patients and health care providers and at the time of death or after, abandonment feelings resulted from lack of closure for patients and caregivers.³³ Because abandonment reflects different needs occurring at different times in the end-of-life experience,³³ to address this issue, case managers need to focus on developing both continuity and closure strategies.

One way case managers can achieve continuity from the post-hospice enrollment perspective is by maintaining contact with patients and caregivers throughout their end-of-life experience. Another


way to do this is by assuring patients and caregivers that the case manager will continue to be available as death approaches and thereafter.³³ One way case managers can achieve closure from the post-hospice enrollment perspective is by anticipating and disclosing the probable last visit with patients and caregivers before death. Another way to do this is by contacting caregivers after death.³³

Conclusions

Case managers are committed to improving the end-of-life experience and expanding access to hospice care in the United States with the goal of greatly enhancing quality of life for patients and caregivers. However, there are several issues that have the potential to disrupt the end-of-life experience for Americans, including delayed access to hospice care. It is especially important, therefore, that case managers develop strategies to address these issues. This article focused on issues case managers have more control over, such as supporting earlier referrals to hospice and reducing feelings of abandonment. Addressing other issues may hinge on health care reform, such as changes to the MHB that strategically align reimbursement for hospice care with the needs of patients and caregivers. **CEU**

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Case Managers: On the Front Line

By **R. Blake Chaffee, PhD**, and **Kristin Musch, RN, C, CCM**

Case managers are among the front-line caregivers who have the opportunity to recognize those suffering from behavioral health issues related to military combat.

This continuing education article explores some of the latest research (see “Important Research Helps Define, Treat PTSD”) related to returning veterans, the potential barriers that may interfere with them seeking services, information on how to identify a veteran or family member who may be experiencing some problems related to combat, and available resources.

The current conflicts in Iraq and Afghanistan, Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF), have been ongoing for more than 6 and 8 years, respectively. Throughout that time, soldiers, Marines, sailors, and airman, have deployed to both theaters of operations, some multiple times.

Male or female, married or single, they leave behind loved ones who must also deal with separation, uncertainties, and loss.

Deployment to these war zones is unique in several respects for military members and their families. Notably, this is the first time in history when the United States has fought an extended conflict with an all-volunteer force. The size of the all-volunteer force has meant that these are the first conflicts in which repeat deployments have become rou-

tine. Before 2001, military women had rarely experienced ground combat. These and other factors present major new challenges for military families.

According to the National Center for PTSD, experts think that post-traumatic stress disorder (PTSD) occurs in about 6% to 11% of OEF veterans and 12% to 20% of OIF veterans.¹

Barriers to Care

Perceived barriers to accessing mental health care often prevent affected combat veterans from seeking the care they need.

The leading research about these barriers and the mental health problems suffered by soldiers and Marines on combat duty in Iraq and Afghanistan is a study led by Charles W. Hoge, MD, published July 1, 2004, in the *New England Journal of Medicine*.²

This research was the catalyst for follow-up studies and policy changes. Many subsequent articles and studies cite this investigation as the definitive research conducted on returning combat veterans from these conflicts. Hoge and co-authors concluded:²

Our findings indicate that among the study groups there was a significant risk of mental health problems and that the subjects reported important barriers to receiving mental health services, particularly the perception of stigma among those most in need of such care.

The Hoge study found numerous barriers (Box 1) among those who met

BOX 1

Perceived Barriers to Care

- 65% I would be seen as weak
- 63% My unit leadership might treat me differently
- 59% Members of my unit might have less confidence in me
- 55% There would be difficulty getting time off work for treatment
- 51% My leaders would blame me for the problem
- 50% It would harm my career
- 45% It is difficult to schedule an appointment
- 41% It would be too embarrassing
- 38% I don't trust mental health professionals
- 25% Mental health care costs too much money
- 25% Mental health care doesn't work
- 22% I don't know where to get help
- 18% I don't have adequate transportation

screening criteria for a mental health disorder.²

The researchers also found that only a small percentage of study participants who met the screening criteria for a mental disorder reported seeking help from any mental health professional:² ►

The researchers also found that only a small percentage of study participants who met the screening criteria for a mental disorder reported seeking help from any mental health professional.

- Army respondents after deployment to Afghanistan: 13%
- Army respondents after deployment to Iraq: 27%
- Marine respondents after deployment to Iraq: 21%

In other words, those most in need of care are not likely to seek it.

In a proactive effort to identify Service members experiencing behavioral health issues, the government developed the Post-Deployment Health Assessment (PDHA) and the Post-Deployment Health Reassessment (PDHRA) tools. All Service members returning from deployment are screened using the PDHA on their return and again 3 to 6 months following their return using the PDHRA. This procedure was specifically developed to accommodate the fact that adjustment difficulties and symptoms of post-traumatic stress may not be present immediately on return but may develop over time. Subsequent research supports this process.³

Military Culture

Mild-to-moderate mental disorders are managed by both military members and civilians as a matter of course in everyday life, treated or untreated, with vary-

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Kristin Musch has been working with the West Region TRICARE contract for almost 13 years. Initially a behavioral health case manager, she now is responsible for educating internal staff members, beneficiaries, and providers regarding behavioral health-related topics and initiatives.

ing degrees of disruption and success. Membership in a military unit, however, involves a level of scrutiny and visibility that is rarely seen in civilian employment.

Koffman notes the importance of unit integrity and esprit des corps as factors contributing to the relatively low rate of combat stress casualties in Operation Desert Storm.⁴

Hoge and colleagues² report concerns about losing the confidence of unit members and being treated differently by unit leadership as elements of the stigma surrounding behavioral health consultation.

Both of these concerns indicate the importance of unit cohesion to the individual Service member. Being seen as a stable, reliable, trustworthy member of the unit may be as essential to the success of the individual as it is to the unit. As Hoge notes,⁵ mental disorders are often associated with behavioral problems that are not conducive to military service.

Symptoms of mental disorders such as fatigue, memory problems/forgetfulness, indecision, irritability, and impulsiveness can certainly undermine a Service member's reputation as a stable, reliable, trustworthy unit member and can be mistaken as a "bad attitude" by unit members and leadership.

While research on the actual attitudes of active duty service members (ADSMs) toward mental illness is sparse, the concerns expressed by the soldiers and Marines studied by Hoge and colleagues indicate that being identified as in need of behavioral health services is to be avoided.² More research is clearly necessary to fully understand how this perception develops and the specific factors that sustain it within the military

lifestyle and culture.

Career concern and loss of unit and leadership confidence appear to be at the core of behavioral health stigma.² As with any human organization, attitudes toward mental illness among members of the military are certainly not monolithic and may differ from those expressed in official policy. The reticence of soldiers and Marines to be identified as in need of behavioral health services may reflect an adaptive posture to the current military environment in which they function. Disclosing mental health symptoms or disorders may be perfectly acceptable and encouraged by their current unit and leadership, but that disclosure becomes part of their permanent record available to future leadership whose attitudes are unknown.

Coincidentally, military leadership is faced with the challenge of recruiting, selecting, and assigning military personnel to myriad administrative, industrial, and operational roles, many of which cannot be adequately performed by anyone whose performance might be impaired by a physical or mental disorder. Lack of disclosure of any such condition presents a potentially dangerous situation for the organization and the individual.

Unique Needs of Guard, Reserve

A 2007 study by Milliken, Auchterlonie, and Hoge⁶ found that 6.2% of ADSMs and 6.6% of National Guard and Reserve (Reserve Component) members reported three or more symptoms on the PTSD screening questions in the PDHA compared with 9.1% of ADSMs and 14.3% of Reserve Component members on the PDHRA.

Reserve Component members might be at greater risk than ADSMs of developing symptoms of post-traumatic stress several months after returning from deployment.

These findings suggest that Reserve Component members might be at greater risk of developing symptoms of post-traumatic stress several months after returning from deployment. The authors suggest that the difference may be due to differences in social support available to ADSMs and Reserve Component members.⁶

ADSMs typically return with their unit to the military installation from which they deployed and tend to reside either on the installation or close by in the civilian community. ADSMs then have access to all of the medical and psychosocial support services available on the installation as well as the community of their peers, many of whom have also been deployed. Their families have continued access to such social support throughout deployment.

Reserve Component members, in contrast, can reside anywhere in a much larger area surrounding the National Guard armory or Reserve Center where they drill, and armories and Reserve Centers do not offer many of the support services available to ADSMs and their family members on military installations. In fact, Reserve Component members and their families may be the only military family in their community. This means that few, if any, of their neighbors, friends, and schoolmates share the common experience of having a family member deployed.

The Role of Providers

Healthcare providers and case managers who manage patients with physical ailments are often the first caregivers to see these men and women and are on the first line of defense to help their patients make the decision to seek treatment.

But civilian health providers may not always be aware of the symptoms and treatment for combat stress and PTSD or how patients with these problems may present in their medical practice. Because of their concern about the stigma associated with mental health issues, Service members are generally more likely to prefer to be seen in the

BOX 2

Typical Presentation of Mental Health Issues Among Service Members

- Complaints of insomnia or nightmares
- Night sweats
- Problems relating to a spouse or other close family member
- Feelings of disconnection from family and friends
- Increased use of alcohol or other drugs
- Risky sexual practices
- Aggressive driving
- Suicidal ideation and gestures

primary care clinic than the mental health clinic. They are more likely to focus on physiologic complaints such as insomnia, fatigue, appetite changes, or unexplained somatic symptoms.

It is helpful if healthcare providers ask their patients whether they or a family member have recently been deployed to a combat zone and how they've been adjusting since their return. Service members who have been deployed should be evaluated with particular attention to the physical

symptoms associated with post-traumatic stress, including sleep disturbance and hypervigilance.

The most common mental health issues related to combat are PTSD, anxiety, depression, and substance abuse. A typical presentation may include complaints of insomnia or nightmares, night sweats, problems relating to a spouse or other close family members, feelings of disconnection from family and friends, or an increase in use of alcohol or other drugs (Box 2). There are also health-threatening behaviors associated with exposure to traumatic events including risky sexual practices, aggressive driving, as well as suicidal ideation and gestures. Any suspicion of suicidal ideation must be assessed immediately.

Oftentimes, the patient can continue to be managed within the general medical practice. Providing educational materials to patients and their family can be very helpful and may assure them that they are not alone in their experiences. The National Center for PTSD recommends that if a referral to a mental health consultant is necessary, this recommendation should be discussed with the patient.⁷ It is important to ask the patient at the next visit if he or she followed through with that referral.

Help From Home Program

In an effort to help address the behavioral health needs of those patients it serves, TriWest Healthcare Alliance developed and produced *Help From Home*, an aggressive multichannel education and information resource program. TriWest's goal was to identify and provide 24/7 access to the best resources for military families. ►

Help From Home tackles the stigma issue of perceived weakness in seeking treatment and narrows the support gap that Guard and Reserve members experience.

The program tackles the stigma issue of perceived weakness in seeking treatment and narrows the support gap that Guard and Reserve members experience. TriWest’s program does this by:

- Presenting “psychological health” as analogous to physical health and fitness
- Selecting and qualifying/vetting evidence-based information
- Directing users to military and community resources
- Educating civilian providers about deployment-related health concerns
- Providing support services to family members of deployed service members
- Offering information via several modalities, thus allowing service members and their families to obtain information anonymously, if they choose

Elements of the TriWest program include:

- **The Behavioral Health Web Portal** (www.triwest.com/bh) that was developed using a “stepped-care” model. A “stepped-care” model provides a continuum of information and services. This allows Web visitors to find the level of information they are seeking from a list of frequently asked questions to more in-depth information from books, videos, and other Web links on their chosen topic. The information on the Web portal has been vetted, ensuring evidence-based information that is targeted to the needs of those members that TriWest serves in 21 western states. This resource allows TRICARE beneficiaries to access deployment healthcare information 24 hours a day 7 days a week. The portal is also a clinical resource tool for civilian primary care and behav-

Important Research Helps Define, Treat PTSD

PTSD is becoming more prevalent among those serving in combat areas, and the increasing need to understand this disorder has led to a number of relevant studies.

These studies, conducted with returning Service members, contribute the following findings:

- 69.3% of returning Service members report no emotional distress or traumatic brain injury (TBI).⁸
- Of soldiers who reported a high rate of PTSD symptoms on the PDHA, 49.4% of National Guard and Army Reserve soldiers and 59.2% of active soldiers reported symptomatic improvement by the time of the PDHRA approximately 6 months later. However, more than twice as many new cases were identified among soldiers who did not have a high PTSD score initially on the PDHA.⁶
- The percentage of soldiers and Marines who report symptoms of mental disorders increases as the number of combat deployments increases.⁹
- Confidence in leadership is a mitigating factor in emotional distress reported. Units with high combat exposure and high confidence in their leadership reported fewer symptoms than units with low combat exposure and low confidence in their leadership.¹⁰
- PTSD patients are 6 times more likely to attempt suicide than the general population.¹¹
- While the studies differ considerably, these findings provide a basis for understanding the concept of behavioral health stigma in the military community.

It is useful to note that stigma surrounding behavioral health consultation is by no means unique to the military. Kessler¹² reported that 23% of men and 17% of women reported stigma as a barrier to seeking behavioral health services in the general population. Dingfelder¹³ reports previous survey results of the percentage of Americans reporting they are definitely or probably unwilling to have a person with mental illness:

Move next door	38%
Spend an evening socializing with you	56%
Make friends with you	33%
Work closely with you	58%
Marry into your family	68%

A behavioral health crisis line (1-888-284-3743) is in operation 24 hours a day, 7 days a week, and is accredited by the American Association of Suicidology. The hotline averages more than 20,000 contacts per month.

ioral health providers. It provides links to clinically based Web sites, practice guidelines, clinical assessment tools, and treatment resources.

The Help From Home program includes a two-disc DVD providing discreet deployment support for service members and their families to view in the privacy of their own homes. The goal of the DVD is for service members and their families to learn how to recognize symptoms of combat stress, understand the necessity of early treatment, pinpoint available resources, and gain the confidence to seek treatment and make an educated decision to seek specialized help. The DVD set is available at no charge and can be ordered or viewed from TriWest's Web site, www.triwest.com/bh.

A behavioral health crisis line (1-888-284-3743) is in operation 24 hours a day, 7 days a week, and is accredited by the American Association of Suicidology. The hotline averages more than 20,000 contacts per month.

- **TRICARE Assistance Program (TRIAP)** is a new program available for ADSMs and their families. This program encourages early intervention to address issues, which if ignored, may contribute to more serious problems. Licensed counselors are available 24/7/365 for confidential counseling via chat or Web-based video about common challenges experienced by returning service members. This counseling is confidential and nonreportable, unless there is a danger to the patient or others. Typical topics of discussion include marital issues, parenting issues, handling

stress and anxiety, overcoming conflicts at work, improving communication, and more. This service can be accessed from a person's home through the TriWest Web site at www.triwest.com or by calling 1-888-TRIWEST (1-888-874-9388).

Be Part of the Solution

In the ideal military, Service members would willingly acknowledge their physical and mental disabilities, secure in the knowledge that their skills and abilities are sufficiently valuable to win them challenging and rewarding career opportunities after receiving effective treatment. The ideal may not be achievable, but approximating it more closely may be realistic and beneficial to force readiness and retention.

The next person you see professionally may be one of the thousands who need solutions. By understanding how combat affects service members and their families, recognizing a pattern of problems, and knowing where to go for available resources, case managers can be a vital part of the healthcare team.

CEU

Exam starts on page 16

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Exam 1

Case Managers: On the Front Line

1. According to the National Center for PTSD, post-traumatic stress disorder occurs in what percentage of OIF veterans?
 - a. 1%–6%
 - b. 12%–20%
 - c. 20%–50%
 - d. 50%–70%
2. According to a 1999 study by Kessler et al, patients with PTSD are _____ times more likely to attempt suicide than the general population.
 - a. 5
 - b. 6
 - c. 10
 - d. 30
3. Symptoms of PTSD and other combat-related mental disorders always occur in the first 3 months postdeployment.
 - a. True
 - b. False
4. Results from the PDHA and PDHRA indicate that Reserve members may be at greater risk of developing PTSD than Active Duty Service Members.
 - a. True
 - b. False
5. Stigma surrounding behavioral health consultation is unique to the military.
 - a. True
 - b. False
6. According to the Hoge study of 2004, concerns that Service members report as barriers to seeking behavioral health care include all but:
 - a. They fear they would be seen as weak.
 - b. They fear leadership might treat them differently.
 - c. They fear they will be discharged from the military.
 - d. They fear their career may be negatively impacted.
7. Service members often first seek care from the primary care physician, complaining specifically of psychological problems.
 - a. True
 - b. False
8. The most common mental health issues related to combat include all except:
 - a. PTSD
 - b. Depression
 - c. Substance abuse
 - d. Bipolar disorder
9. The PDHRA is an assessment that is done approximately 6 months after the PDHA.
 - a. True
 - b. False
10. Most Service members who experience behavioral health problems after deployment seek behavioral health services.
 - a. True
 - b. False

Exam 2

Improving the End-of-Life Experience for Hospice Patients from a Case Manager Perspective: Disruptive Issues and How to Address Them

1. Case managers are essential members of the interdisciplinary team working in concert with physicians and other team members to provide an end-of-life experience that is consistent with the needs of patients and caregivers.
 - a. True
 - b. False
2. In 2007, the Medicare Hospice Benefit covered _____ of hospice patient days.
 - a. 70%
 - b. 75%
 - c. 87%
 - d. 92%
3. Under the Medicare Hospice Benefit, patients and caregivers are entitled to a multitude of services including:
 - a. Case management
 - b. Regular home visits
 - c. Physician services
 - d. Social work services
 - e. All of the above
4. The Medicare Hospice Benefit provides the following levels of care:
 - a. Routine home care
 - b. Continuous home care
 - c. General inpatient care
 - d. Inpatient respite care
 - e. All of the above
5. By estimate, what percentage of deaths occurred under the care of a hospice?
 - a. 27%
 - b. 33.5%
 - c. 38.5%
 - d. 42.3%
6. Enrolling patients shortly before they die can contribute to the following:
 - a. Needless suffering
 - b. Adverse economic consequences for payers
 - c. Inability to obtain optimal benefit
 - d. Receipt of costly and possible unnecessarily aggressive medical care
 - e. All of the above
7. Patients nearing the end of life need support in understanding and making decisions about choices available to help them maximize their end-of-life experience.
 - a. True
 - b. False
8. Aggressive medical care at the end of life is associated with:
 - a. Worse quality of life for patients
 - b. More difficult bereavement adjustment for caregivers
 - c. Higher health care costs of payers
 - d. All of the above
9. If patients were enrolled in hospice sooner, it might be possible to improve their end-of-life experience.
 - a. True
 - b. False
10. Before death, abandonment feelings are related to loss of continuity between patients and health care providers, resulting in lack of closure for patients and caregivers. The case manager needs to focus on developing both continuity and closure strategies.
 - a. True
 - b. False

The answer sheet for these tests must be received by May 31, 2010. Expired exams cannot be returned. Faxed exams cannot be accepted. You may submit one or both exams; credits will be granted accordingly.

CareManagement, Vol. 16, No. 1
February/March 2010

Exam 1: Case Managers: On the Front Line

This educational manuscript has been approved for 2 hours of CCM and CDMS education credit by The Commission for Case Manager Certification and the Certification of Disability Management Specialists Commission. Provider #00059431.

Answers: Please indicate your answer by filling in the letter:

1. ____ 2. ____ 3. ____ 4. ____ 5. ____ 6. ____ 7. ____ 8. ____ 9. ____ 10. ____

Exam 2: Improving the End-of-Life Experience for Hospice Patients from a Case Manager Perspective: Disruptive Issues and How to Address Them

This educational manuscript has been approved for 2 hours of CCM and CDMS education credit by The Commission for Case Manager Certification and the Certification of Disability Management Specialists Commission. Provider #00059431.

Answers : Please indicate your answer by filling in the letter:

1. ____ 2. ____ 3. ____ 4. ____ 5. ____ 6. ____ 7. ____ 8. ____ 9. ____ 10. ____

Continuing Education Program Evaluation

Please indicate your rating by circling the appropriate number using a scale of 1 (low) to 5 (high).

1. How well did the program meet the learning objectives?
2. Was this home study format an effective way to present this material?
3. Was the content current to case management practice?
4. Information presented could be applied to own practice?

	Exam 1:					Exam 2:				
	1	2	3	4	5	1	2	3	4	5
1. How well did the program meet the learning objectives?	1	2	3	4	5	1	2	3	4	5
2. Was this home study format an effective way to present this material?	1	2	3	4	5	1	2	3	4	5
3. Was the content current to case management practice?	1	2	3	4	5	1	2	3	4	5
4. Information presented could be applied to own practice?	1	2	3	4	5	1	2	3	4	5

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Ann Intern Med. 2010 Jan 5;152(1):18-25.

Association of antiretroviral therapy adherence and health care costs.

Nachega JB, Leisegang R, Bishai D, et al.

Background: Antiretroviral therapy (ART) adherence predicts HIV disease progression and survival, but its effect on direct health care costs is unclear. **OBJECTIVE:** To determine the effect of ART adherence on direct health care costs among adults in a resource-limited setting. **DESIGN:** Cohort study. **SETTING:** Aid for AIDS, a private-sector disease management program in South Africa. **PATIENTS:** 6833 HIV-infected adults who started ART between August 6, 2000, and April 30, 2006. **MEASUREMENTS:** Monthly direct health care costs authorized by Aid for AIDS were averaged over all months. Pharmacy claim adherence, expressed as a percentage, was categorized into quartiles, from 1 (lowest) to 4 (highest). Effects of covariates on monthly total costs were assessed with a 2-step model with logit for probability of nonzero costs and a generalized linear model (GLM). **RESULTS:** Total mean monthly costs were \$370 (SD, \$644). Mean monthly costs of ART were \$32 (SD, \$18); hospitalizations, \$151 (SD, \$436); consultations, \$76 (SD, \$66); investigations, \$37 (SD, \$50); and non-ART medications, \$53 (SD, \$180). Total mean monthly costs ranged from \$313 (SD, \$598) for quartile 4 to \$376 (SD, \$657) for quartile 1. Hospitalization costs increased from 29% to 51% of total costs as adherence decreased. In the GLM 2-step model, moving from adherence quartile 1 to quartile 2, 3, or 4 increased the probability of having nonzero total monthly costs by 0.078, 0.15, and 0.21 percentage point, respectively ($P < 0.001$). For patients with nonzero costs, increasing adherence from quartile 1 to quartile 2, 3, or 4 decreased total monthly costs by \$70, \$133, and \$192, respectively ($P < 0.001$). Moving from adherence quartiles 1 to 4 had the highest decrease in net overall median monthly health care costs (-\$85 [interquartile range, -\$116 to -\$41]). **LIMITATIONS:** Indirect health care costs were not included. Experience may not reflect that of public HIV/AIDS programs. **CONCLU-**

SION: High ART adherence was associated with lower mean monthly direct health care costs, particularly reduced hospitalization costs, in this South African HIV cohort.

Johns Hopkins Bloomberg School of Public Health, Baltimore, MD

Clin Infect Dis. 2010 Feb 1;50(3):426-436.

Epidemiology of hepatitis B virus infection in a US cohort of HIV-infected individuals during the past 20 years.

Chun HM, Fieberg AM, Hullsiek KH, et al.

Background: The epidemiologic trends of hepatitis B virus (HBV) infection in HIV-infected patients over the past 20 years are largely unknown. **METHODS:** Prevalence and risk factors for HBV infection overall, at the time of HIV infection, and after HIV infection were examined in an ongoing observational HIV cohort study. Risk factors for HBV infection at the time of diagnosis of HIV infection were evaluated using logistic regression, and risk of incident HBV infection after diagnosis of HIV infection was evaluated using Cox proportional hazards models. **RESULTS:** Of the 2769 evaluable participants, 1078 (39%) had HBV infection, of whom 117 (11%) had chronic HBV infection. The yearly cross-sectional prevalence of HBV infection decreased from a peak of 49% in 1995 to 36% in 2008. The prevalence of HBV infection at the time of diagnosis of HIV infection decreased during 1989-2008 from 34% to 9%. The incidence of HBV infection after diagnosis of HIV infection decreased from 4.0 cases per 100 person-years during the pre-highly active antiretroviral therapy (HAART) era to 1.1 cases per 100 person-years during the HAART era; however, this incidence remained unchanged during 2000-2008, with >20% of HBV infections occurring after HIV infection being chronic. Decreased risk of HBV infection after diagnosis of HIV infection was associated with higher CD4 cell count and the use of HBV-active HAART. Receipt of 1 dose of HBV vaccine was not associated with reduced risk of HBV infection after diagnosis of HIV infection. **CONCLUSIONS:** Although the burden of HBV

infection overall is slowly decreasing among HIV-infected individuals, the persistent rate of HBV infection after diagnosis of HIV infection raises concern that more-effective prevention strategies may be needed to significantly reduce the prevalence of HBV infection in this patient population.

Naval Health Research Center and Naval Medical Center San Diego, San Diego, CA

Hepatology. 2009 Nov 13.

Effectiveness of hepatitis C treatment with pegylated interferon and ribavirin in urban minority patients.

Feuerstadt P, Bunim AL, Garcia H, et al.

Randomized controlled trials of hepatitis C virus (HCV) therapy with pegylated interferon and ribavirin have demonstrated sustained viral response rates (SVRs) of 54%-63% (efficacy). Treatment results in clinical practice (effectiveness) may not be equivalent. The goal of this study was to assess the effectiveness of HCV treatment with pegylated interferon and ribavirin in a treatment-naïve, human immunodeficiency virus (HIV)-negative, United States urban population with many ethnic minority patients. We evaluated 2370 outpatients for HCV therapy from 2001 to 2006 in the Faculty Practice of the Albert Einstein College of Medicine or the attending-supervised Montefiore Medical Center Liver Clinic. Care was supervised by one experienced physician under conditions of everyday clinical practice, and appropriate ancillary resources were made available to all patients. Two hundred fifty-five patients were treated with a mean age of 50 years (60% male, 40% female; 58% Hispanic, 20% African American, 9% Caucasian, 13% other; 68% genotype 1, the remainder genotypes 2 or 3). Patients had at least one liver biopsy. Intention-to-treat analysis (ITT) showed SVR in 14% of genotype 1 patients and 37% in genotype 2/3 patients ($P < 0.001$). SVR was significantly higher in faculty practice (27%) than in clinic patients (15%) by intention-to-treat ($P = 0.01$) but not per-protocol analysis (46% faculty practice, 34% clinic). 3.3% of 1,656 treatment-naïve, HIV antibody-negative individuals ultimately achieved SVR. Current HCV therapies may sometimes be unavailable to, inappropriate for, and ineffective in United States urban patients. Treatment with pegylated interferon and ribavirin was less effective in this population than is implied by multinational phase III controlled trials. New strategies are needed to care for such patients.

Division of Gastroenterology, Department of Medicine, Montefiore Medical Center, The Albert Einstein College of Medicine, Bronx, NY

Transplantation. 2009 Oct 15;88(7):884-890.

Liver retransplantation of more than two grafts for recurrent failure.

Akpinar E, Selvaggi G, Levi D, et al.

Background: Transplantation of more than two livers for recurring graft failure has not been specifically addressed in the literature. **METHODS:** A retrospective analysis was conducted from a total of 2527 overall liver transplants at our institution. Main indications for multiple retransplant included primary nonfunction, chronic rejection, hepatic artery thrombosis, and recurrent disease. **RESULTS:** We identified 39 patients who received more than two grafts (32 received 3 grafts, 5 received 4 grafts, and 2 received 5 grafts). All patients required interposition arterial grafts from the aorta and hepatojejunostomy for the biliary reconstruction. Seventeen patients are still alive at last follow-up. Perioperative mortality rates after 3rd, 4th, and 5th liver graft were 25%, 14%, and 50%, respectively. Patient and graft survival rates were 72% and 56% at 1 year, respectively. Median length of stay was 27 days and median graft survival was 2.9 years. **CONCLUSIONS:** Selection of patients and a significant use of available resources are some of the important factors that clinicians need to take into account when dealing with multiple retransplantations. With such conditions, however, liver retransplantation of more than two grafts can be a life-saving procedure.

Miami Transplant Institute, University of Miami Miller School of Medicine, Miami, FL

Circulation. 2009 Nov 3;120(18):1814-1821. Epub 2009 Oct 19.

Tobacco smoke exposure in either the donor or recipient before transplantation accelerates cardiac allograft rejection, vascular inflammation, and graft loss.

Khanna AK, Xu J, Uber PA, Burke AP, Baquet C, Mehra MR.

Background: Tobacco exposure in cardiac transplant recipients, before and after transplantation, may increase the risk of cardiac allograft vasculopathy and allograft loss, but no direct evidence for this phenomenon is forthcoming. In this experimental study, we investigated early consequences of tobacco smoke exposure in cardiac transplant donors and recipients with an emphasis on alloinflammatory mediators of graft outcome. **METHODS AND RESULTS:** Using heterotopic rat cardiac transplantation, we tested the effects of donor or

recipient tobacco smoke exposure in 6 groups of animals (rat heterotopic cardiac transplantation) as follows: tobacco-naïve allogeneic rejecting controls (n=6), tobacco-naïve nonrejecting controls (n=3; killed on day 5 to simulate survival times of tobacco-treated animals), isografts (n=3), both donor and recipient rats exposed to tobacco smoke (n=4), only donor rats exposed to tobacco smoke (n=7), and only recipient rats exposed to tobacco smoke (n=6). Polymerase chain reaction studies of tissue and peripheral (systemic) protein expression were performed to evaluate inflammatory (tumor necrosis factor-alpha, interferon-gamma, interleukin-6) and alloimmune (interleukin-1 receptor 2, programmed cell death-1, and stromal cell-derived factor-1) pathways, as was histological analysis of the cardiac allografts. Our experiments reveal that pretransplantation tobacco exposure in donors and/or recipients results in heightened systemic inflammation and increased oxidative stress, reduces posttransplantation cardiac allograft survival by 33% to 57%, and increases intragraft inflammation (tumor necrosis factor-alpha, interferon-gamma, interleukin-6) and alloimmune activation (CD3, interleukin-1 receptor 2, programmed cell death-1, and stromal cell-derived factor-1) with consequent myocardial and vascular destruction. **CONCLUSIONS:** These sentinel findings confirm that tobacco smoke exposure in either donors or recipients leads to accelerated allograft rejection, vascular inflammation, and graft loss. Molecular pathways that intersect as arbiters in this phenomenon include instigation of alloimmune activation associated with tobacco smoke-induced inflammation.

Division of Cardiology, University of Maryland School of Medicine, Baltimore, MD

Am J Hypertens. 2009 Dec 31.

Additive interaction of metabolic syndrome and chronic kidney disease on cardiac hypertrophy, and risk of cardiovascular disease in hypertension.

Iwashima Y, Horio T, Kamide K, et al.

Background: Recent epidemiologic analyses have demonstrated a link between the metabolic syndrome (MetS) and chronic kidney disease (CKD). We examined the association between MetS, CKD, and left ventricular hypertrophy (LVH), and prospectively investigated the predictive value of the combination of MetS and CKD for cardiovascular disease (CVD) in essential hypertension. **METHODS:** A total of 1160 essential hypertensive patients (mean age 63 years, 53% male) underwent clinical evaluation, laboratory testing, and Doppler echocardiography, and were monitored for a mean

follow-up of 4.8 years. **RESULTS:** At baseline, total subjects were divided into four groups according to the presence/absence of MetS and/or CKD, and, compared to the group without MetS and CKD [MetS(-)/CKD(-)]; those with MetS and CKD [MetS(+)/CKD(+)] had a multivariate-adjusted odds ratio of 2.40 (95% confidence interval [CI] 1.66-3.48) for LVH. During the follow-up period, 172 subjects developed CVD. Multiple Cox regression analysis including LV mass index (LVMI) showed that the presence of MetS as well as that of CKD were each independent predictors of CVD (hazard ratio 1.90 for MetS, 1.82 for CKD). We then divided the total subjects into four groups, and found that, compared to the MetS(-)/CKD(-) group, multivariate-adjusted HR for the MetS(+)/CKD(+) group was 3.58 (95% CI 2.14-5.95). **CONCLUSIONS:** Our findings suggest that, in essential hypertension, the combination of MetS and CKD is a strong risk for LVH as well as a strong and independent predictor of subsequent CVD. These findings highlight the clinical importance of the concomitance of MetS and CKD in essential hypertension.

Division of Hypertension and Nephrology, Department of Medicine, National Cardiovascular Center, Osaka, Japan

Curr Opin Nephrol Hypertens. 2010 Jan 5.

Essential hypertension and risk of nephropathy: a reappraisal.

Murea M, Freedman BI.

PURPOSE OF REVIEW: Treating mild-to-moderate essential hypertension in nondiabetic African Americans fails to halt nephropathy progression, whereas hypertension control slows nephropathy progression in European Americans. The pathogenesis of these disparate renal syndromes is reviewed. **RECENT FINDINGS:** The nonmuscle myosin heavy chain 9 gene (MYH9) is associated with a spectrum of kidney diseases in African Americans, including idiopathic focal global glomerulosclerosis historically attributed to hypertension, idiopathic focal segmental glomerulosclerosis, and the collapsing variant of focal segmental glomerulosclerosis (HIV-associated nephropathy [HIVAN]). Risk variants in MYH9 likely contribute to the failure of hypertension control to slow progressive kidney disease in nondiabetic African Americans. **SUMMARY:** Early and intensive hypertension control fails to halt progression of 'hypertensive nephropathy' in African Americans. Genetic analyses in patients with essential hypertension and nephropathy attributed to hypertension, focal segmental glomerulosclerosis and HIVAN reveal that MYH9

gene polymorphisms are associated with a spectrum of kidney diseases in this ethnic group. Mild to moderate hypertension may cause nephropathy in European Americans with intrarenal vascular disease improved by the treatment of hypertension, hyperlipidemia and smoking cessation.

Department of Internal Medicine, Section on Nephrology, Wake Forest University School of Medicine, Winston-Salem, NC

Arch Surg. 2009 Nov;144(11):1013-1020.

Comment in: *Arch Surg.* 2009 Nov;144(11):1020.

Identification of specific quality improvement opportunities for the elderly undergoing gastrointestinal surgery

Bentrem DJ, Cohen ME, Hynes DM, Ko CY, Bilimoria KY.

HYPOTHESIS: Specific complications occur more frequently in elderly patients undergoing major gastrointestinal (GI) tract operations that may represent opportunities for quality improvement. **DESIGN:** Retrospective cohort study. **SETTING:** One hundred twenty-one hospitals participating in American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP). **PATIENTS:** Using the ACS-NSQIP participant use file (2005-2006), patients undergoing upper gastrointestinal tract (n = 4115), hepatobiliary or pancreatic (n = 3364), and colorectal (n = 17,268) operations at 121 hospitals were examined. **MAIN OUTCOME MEASURES:** Risk-adjusted 30-day outcomes were assessed using regression modeling adjusting for patient characteristics, comorbidities, and surgical procedures. The elderly were defined as those older than 75 years. **RESULTS:** Between January 1, 2005, and December 31, 2006, a total of 54,747 patients who underwent major GI tract operations were identified from the ACS-NSQIP data file. In the elderly, overall perioperative morbidity was 1.2 to 2 times higher and mortality was 2.9 to 6.7 times higher than in younger patients after adjusting for differences in preoperative comorbidities. Irrespective of procedure type, the elderly were significantly more likely to experience cardiac (acute myocardial infarction and cardiac arrest), pulmonary (pneumonia, pulmonary embolism, and respiratory failure), and urologic (urinary tract infection and renal failure) complications. However, surgical site infections, postoperative bleeding events, deep venous thromboses, and rates of return to the operating room did not differ significantly by age. **CONCLUSIONS:** Morbidity and mortality are markedly higher in older patients. Quality measures for the elderly currently address only myocardial infarction, surgical site infection, and deep

venous thrombosis. If care for the elderly is to be improved, quality improvement initiatives need to be expanded to include postoperative pulmonary and renal complications.

Department of Surgery, Feinberg School of Medicine, Northwestern University, Chicago, IL

Carcinogenesis. 2009 Dec 31.

Dietary quercetin, quercetin-gene interaction, metabolic gene expression in lung tissue, and lung cancer risk.

Lam TK, Rotunno M, Lubin JH, et al.

Epidemiological and mechanistic evidence on the association of quercetin-rich food intake with lung cancer risk and carcinogenesis are inconclusive. We investigated the role of dietary quercetin and the interaction between quercetin and P450 and GST polymorphisms on lung cancer risk in 1822 incident lung cancer cases and 1991 frequency matched controls from the Environment And Genetics in Lung cancer Etiology (EAGLE) study. In non-tumor lung tissue from 38 adenocarcinoma patients, we assessed the correlation between quercetin intake and mRNA expression of the same P450 and GST metabolic genes. Multivariate odds-ratios (ORs) and 95% confidence intervals (CIs) for sex-specific quintiles of intake were calculated using unconditional logistic regression adjusting for putative risk factors. Frequent intake of quercetin-rich foods was inversely associated with lung cancer risk (OR = 0.49; 95% CI = 0.37-0.67; P trend < 0.001), and did not differ by P450 or GST genotypes, gender, or histological subtypes. The association was stronger in subjects who smoked > 20 cigarettes per day (OR = 0.35; 95% CI = 0.19-0.66; P trend = 0.003). Based on a 2-sample t-test, we compared gene expression and high-versus-low consumption of quercetin-rich foods and observed an overall up-regulation of GSTM1, GSTM2, GSTT2, and GSTP1 as well as a down-regulation of specific P450 genes (P values < 0.05, adjusted for age and smoking status). In conclusion, we observed an inverse association of quercetin-rich food with lung cancer risk and identified a possible mechanism of quercetin-related changes in the expression of genes involved in the metabolism of tobacco-carcinogens in humans. Our findings suggest an interplay between quercetin intake, tobacco smoking, and lung cancer risk. Further research on this relationship is warranted.

Cancer Prevention Fellowship Program, Office of Preventive Oncology, National Cancer Institute, National Institutes of Health (NIH), DHHS, Bethesda, MD

PharmaFacts for Case Managers



New Approvals

Kapidex (dexlansoprazole)

The US Food and Drug Administration (FDA) has approved Kapidex (dexlansoprazole) delayed-release capsules for the once-daily, oral treatment of heartburn associated with symptomatic nonerosive gastroesophageal reflux disease (GERD), the healing of erosive esophagitis (EE), and the maintenance of healed EE. Kapidex (30 mg and 60 mg) is the first proton pump inhibitor (PPI) with a dual delayed-release (DDR) formulation designed to provide two separate releases of medication.

PPIs work by reducing acid production by turning off many of the acid pumps in the stomach. Kapidex contains two types of enteric-coated granules, resulting in a concentration-time profile with two distinct peaks: the first peak occurs 1 to 2 hours after administration, followed by a second peak within 4 to 5 hours. In addition, Kapidex can be taken regardless of when food is consumed.

The approval was based on global studies conducted in 20 countries evaluating approximately 6000 patients with erosive and nonerosive GERD. Two identically designed, double-blind, 8-week, randomized, controlled trials (RCTs) compared treatment with Kapidex to treatment with lansoprazole in patients with EE. Kapidex (60 mg) produced high overall healing rates at week 8 when compared with lansoprazole 30 mg (87% and 85%, respectively, in the first study; and 85% and 79%, respectively, in the second study) and was generally well tolerated.

Data from a 6-month maintenance of healed EE study demonstrated that patients treated with Kapidex 30 mg experienced consistently high overall maintenance of healed EE and heartburn relief versus patients on placebo.

In a 4-week trial in patients who identified heartburn as their primary GERD symptom and did not have esophageal erosions, Kapidex demonstrated a statistically significant greater percent of days (median rates) with heartburn-free 24-hour periods over placebo.

Kapidex is contraindicated in patients with known hypersensi-

tivity to any component of the formulation. Symptomatic response with Kapidex does not preclude the presence of gastric malignancy. The most commonly reported treatment-emergent adverse reactions ($\geq 2\%$): diarrhea, abdominal pain, nausea, upper respiratory tract infection, vomiting, and flatulence. Kapidex should not be co-administered with atazanavir. Kapidex may interfere with the absorption of drugs for which gastric pH is important for bioavailability (eg, ampicillin esters, digoxin, iron salts, ketoconazole). Patients taking concomitant warfarin may require monitoring for increases in international normalized ratio (INR) and prothrombin time.

RiaSTAP (human fibrinogen concentrate)

RiaSTAP is the first and only treatment approved by the FDA for acute bleeding episodes in patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia. RiaSTAP is not indicated to treat dysfibrinogenemia.

Fibrinogen, also called Factor I, is a protein needed to form a blood clot. Fibrinogen levels in plasma determine the potential clotting ability and activity in the body. Diminished concentrations of fibrinogen limit the body's ability to form a clot. Certain fibrinogen levels usually indicate normal blood clotting ability, though in rare instances a person can have a normal quantity of fibrinogen that does not function as needed.

Symptoms of congenital fibrinogen deficiency include excessive bleeding following injury, bruising, bleeding of the umbilical cord at birth and from the site of the umbilical stump in a newborn, spontaneous bleeding and bone, joint or tissue hemorrhage. To determine fibrinogen levels and confirm a diagnosis, blood coagulation testing is needed.

RiaSTAP is a purified fibrinogen concentrate indicated for the treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia. RiaSTAP is not indicated for dysfibrinogenemia. RiaSTAP is contraindicated in individuals who have had severe immediate hypersensitivity reactions, including anaphylaxis to RiaSTAP or its components.



Physicians should monitor patients for early signs of allergic or hypersensitivity reactions and if necessary, discontinue administration and institute appropriate treatment. Thrombotic events have been reported in patients receiving RiaSTAP. Physicians should weigh the benefits of administration versus the risks of thrombosis.

RiaSTAP is made from pooled human plasma. Products made from human plasma may contain infectious agents (eg, viruses and theoretically the Creutzfeldt-Jakob disease agent [CJD] that can cause disease). The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and by a process demonstrated to inactivate and/or remove certain viruses during manufacturing. Despite these measures, such products may still potentially transmit disease. There is also the possibility that unknown infectious agents may be present in such products.

The most serious adverse reactions that have been reported in clinical studies or through postmarketing surveillance following RiaSTAP treatment are allergic-anaphylactic reactions and thromboembolic episodes, including myocardial infarction, pulmonary embolism, deep vein thrombosis and arterial thrombosis. The most common adverse reactions that have been reported in clinical studies or through postmarketing surveillance following RiaSTAP treatment are allergic reactions and generalized reactions such as chills, fever, nausea and vomiting. There are no human or animal data regarding use in pregnancy. In children, shorter half-life and faster clearance have been observed.

RiaSTAP is for intravenous use only and must be reconstituted before use. It must be administered under physician supervision.

Savella (milnacipran HCL)

The FDA has approved Savella, a selective serotonin and norepinephrine dual reuptake inhibitor (SNRI) for the management of fibromyalgia, a chronic condition characterized by widespread pain and decreased physical function.

Although the exact mechanism by which Savella improves the symptoms of fibromyalgia is unknown, some researchers believe that abnormalities in certain brain neurotransmitters may be central to fibromyalgia. Savella blocks the reuptake of both norepinephrine and serotonin, with greater selectivity for the inhibition of norepinephrine reuptake in vitro. This may be the mechanism by which Savella acts to improve the symptoms of fibromyalgia.

The clinical development program for Savella was unique in its use of a composite responder analysis as the primary endpoint. This endpoint required individual patients to demonstrate concurrent improvement in multiple validated measures, including pain (visual analog scale), patient global assessment (patient global

impression of change), and physical function (Short Form-36 Physical Component Summary).

The efficacy of Savella was established in two US pivotal Phase III clinical trials involving 2084 treated patients (1460 Savella; 624 placebo), which showed that Savella demonstrated clinically significant improvements compared with placebo in treating fibromyalgia. The first study was 6 months in duration and the second study was 3 months in duration. In both studies, a greater proportion of patients in the Savella treatment arms (100 mg/day and 200 mg/day) as compared with placebo treatment, at 3 months, experienced at least a 30% reduction in pain from baseline and also rated themselves as “very much improved” or “much improved” based on the patient global assessment. In addition, a greater proportion of patients treated with Savella as compared with placebo treatment met the criteria for a treatment response as measured by concurrent improvements in pain, physical function, and patient global assessment. In both studies, some patients who rated themselves as globally “much” or “very much” improved experienced a decrease in pain as early as week 1 of treatment with a stable dose of Savella that persisted throughout these studies.

The most frequently occurring adverse reaction was nausea. Other common adverse reactions reported in these clinical trials were constipation, hot flush, hyperhidrosis, vomiting, palpitations, heart rate increased, dry mouth and hypertension. Most adverse reactions reported were mild to moderate. Savella is contraindicated in patients taking monoamine oxidase inhibitors (MAOIs) concomitantly or within 14 days of discontinuing treatment of an MAOI or in patients with uncontrolled narrow-angle glaucoma. Development of a potentially life-threatening serotonin syndrome may occur with agents that inhibit serotonin reuptake, including Savella, particularly with concomitant use of serotonergic drugs (including triptans and tramadol) and with drugs that impair metabolism of serotonin (including MAOIs). The concomitant use of Savella with serotonin precursors is not recommended.

Blood pressure and heart rate should be monitored prior to initiating treatment with Savella and periodically throughout treatment. SNRIs, including Savella, have been associated with reports of increases in blood pressure and heart rate. Pre-existing hypertension, tachyarrhythmias, and other cardiac diseases should be treated before starting therapy with Savella. Savella should be used with caution in patients with significant hypertension or cardiac disease. For patients who experience a sustained increase in blood pressure or heart rate while receiving Savella, either dose reduction or discontinuation should be considered. Savella should be prescribed with caution in patients with a history of a seizure disorder, mania, or controlled narrow-angle glaucoma.

Savella has been associated with mild elevations of ALT and AST. Rarely, fulminant hepatitis has been reported in patients ►



treated with milnacipran. Savella should be discontinued in patients who develop jaundice or other evidence of liver dysfunction and should not be resumed unless another cause can be established.

Degarelix

Degarelix, an injectable gonadotropin-releasing hormone (GnRH) receptor antagonist, received FDA approval for use in patients with advanced prostate cancer. Potential trade names are still under review with the FDA.

Phase III studies showed that degarelix is at least as effective as leuprolide (Lupron Depot) in sustaining castrate levels or lower of testosterone, and had a statistically significant faster reduction of testosterone. At Day 3 of treatment, 96% of degarelix patients achieved castrate levels of testosterone, compared with 0% receiving leuprolide. By Day 14, 99% of degarelix patients achieved castrate levels of testosterone, compared with 18% receiving leuprolide.

In the clinical trial, prostate-specific antigen (PSA) levels were also monitored as a secondary endpoint. PSA levels were lowered by 64% two weeks after administration of degarelix, 85% after one month, 95% after three months, and remained suppressed throughout the 1 year of treatment. These PSA results should be interpreted with caution because of the heterogeneity of the patient population studied. No evidence has shown that the rapidity of PSA decline is related to a clinical benefit.

Prostate cancer is known to grow in the presence of testosterone. Suppression of testosterone has been a treatment goal for advanced prostate cancer for many years. Surgical castration was the standard method of reducing testosterone from the 1940s until the mid-1980s when the earliest forms of medical castration, luteinizing hormone releasing hormone (LHRH) agonists, were introduced.

Overall, the most commonly observed adverse reactions during degarelix therapy included injection site reactions (eg, pain, erythema, swelling or induration), hot flushes, increased weight, fatigue, and increases in serum levels of transaminases and gamma-glutamyltransferase (GGT). Ninety-nine percent of these observed adverse reactions were grade 1 or 2 (mild to moderate). Specifically relating to the injection site adverse reactions, most were transient, of mild to moderate intensity, occurred primarily with the starting dose and led to few discontinuations (< 1%). Grade 3 (severe) injection site reactions occurred in 2% or less of patients receiving degarelix. Degarelix is contraindicated in patients with known hypersensitivity to degarelix or to any of the product components. Degarelix is not indicated in women or pediatric patients. Long-term androgen deprivation therapy pro-

longs the QT interval. Physicians should consider whether the benefits of androgen deprivation therapy outweigh the potential risks in patients with congenital long QT syndrome, electrolyte abnormalities, or congestive heart failure and in patients taking Class IA (eg, quinidine, procainamide) or Class III (eg, amiodarone, sotalol) antiarrhythmic medications.

Zolpimist (zolpidem tartrate)

Zolpimist (zolpidem tartrate) 5 mg and 10 mg Oral Spray received FDA approval for the short-term treatment of insomnia characterized by difficulties with sleep initiation. Zolpimist contains zolpidem tartrate, the same active ingredient as Ambien, the world's leading sedative hypnotic for the treatment of insomnia.

NovaDel submitted its Zolpimist application using the FDA's 505(b)(2) process based on data from two randomized, open-label, dose-ranging studies comparing Zolpimist with Ambien tablets in young and elderly healthy volunteers. Both studies compared the pharmacokinetics and safety of comparable doses of zolpidem administered as an oral spray versus tablets. The pharmacokinetic profiles were assessed by the maximum drug concentration (C_{max}) and total exposure to drug (area-under-the-curve/AUC_{0-inf}). The speed of drug absorption and level of sedation were also assessed in these studies. The results demonstrated bioequivalence between Zolpimist and Ambien. Also included in the submission were data from process validation and registration stability batches produced at the intended commercial manufacturing facility.

Because of its rapid onset of action, patients should take Zolpimist immediately before bedtime and be prepared to get a full night's sleep (7-8 hours). Patients should use extreme care in or avoid engaging in activities requiring full alertness such as driving or operating hazardous machinery the morning after taking any sleep medication. Patient must avoid alcohol.

Complex behaviors such as somnambulism (sleepwalking), including driving or eating while not fully awake, with amnesia for the event, as well as cases of severe allergic reactions have been reported in patients who have taken a sedative hypnotic. Patients reporting such events should contact their physician immediately, discontinue use, and not be rechallenged. Prolonged usage of a sedative hypnotic should be avoided without first consulting a physician.

Patients experiencing unusual changes in thinking or behavior, or if sleep problems persist, should see their physician as these may be indicative of another medical condition.

Sedative hypnotics are nonnarcotic; however, they do have some risk of dependency. The most commonly observed side effects in controlled clinical trials were headache, somnolence and dizziness.



Trilipix (fenofibric acid)

The FDA approved Trilipix (fenofibric acid) delayed-release capsules for use along with diet to help lower triglycerides and LDL cholesterol, and to raise HDL cholesterol in patients with lipid problems. Trilipix is the first and only fibrate to be approved for use in combination with a statin. In certain patients, treatment guidelines recommend the combination of a fibrate with a statin to further improve lipid levels. Trilipix has not been shown to prevent heart disease or heart attack.

The FDA's approval of Trilipix was based on the largest clinical trial program to date designed to evaluate the efficacy and safety of a fibrate in combination with various statins. The efficacy and safety of Trilipix in combination with the three most commonly prescribed statins—rosuvastatin, atorvastatin, and simvastatin—was evaluated in three randomized, multicenter, double-blind, controlled, 12-week Phase III studies, totaling 2698 patients with mixed dyslipidemia. Patients included in the studies had multiple lipid problems, with an LDL > 130 mg/dL, triglycerides > 150 mg/dL, and HDL less than 40 mg/dL for men and less than 50 mg/dL for women. A total of 1911 patients who completed one of the 12-week studies subsequently enrolled in a 52-week long-term, open-label extension study. The Phase III combination studies all met their primary endpoints.

Combination therapy significantly improved HDL and triglycerides compared to statin therapy alone, and significantly improved LDL compared to Trilipix alone. All of the combinations and the statins had clinically meaningful reductions in LDL.

Trilipix should not be taken by people with liver, gallbladder, or severe kidney disease, nursing mothers, or those allergic to any product ingredient. Unexplained muscle pain, tenderness, or weakness may be a sign of a serious side effect and should be reported to a healthcare provider right away. Rarely, muscle-related problems can cause kidney damage. These side effects may be increased when Trilipix is used with a statin. Patients should tell their healthcare provider about all the medicines they take to help avoid serious side effects. Blood tests may be performed before and during treatment with Trilipix. Patients should contact their healthcare provider if they experience abdominal pain, nausea or vomiting while taking Trilipix. These may be signs of inflammation of the gallbladder or pancreas. Women who are pregnant should not take statins and should talk with their healthcare provider about Trilipix if they are pregnant or may become pregnant.

The most common side effects with Trilipix include headache, heartburn, nausea, muscle aches and increases in muscle or liver enzymes that are measured by blood tests.

New Indications

Velcade (bortezomib)

The FDA approved a supplemental new drug application (sNDA) for Velcade, which expands the label to include long-term (median follow-up 36.7 months) overall survival (OS) data from the landmark VISTA trial and provides specific dosing recommendations for patients with hepatic impairment. The VISTA trial examined the use of Velcade-based therapy in patients with previously untreated multiple myeloma (MM).

The VISTA trial is the largest Phase III registration study to report long-term overall survival in previously untreated multiple myeloma patients. This multicenter, international 682-patient clinical trial compared Velcade, melphalan, and prednisone (VcMP) to melphalan, and prednisone (MP) in patients with previously untreated MM who were not eligible for stem cell transplantation. In the original interim analysis of the VISTA data, the VcMP arm demonstrated a statistically significant improvement above the MP arm in time-to-disease progression (24 months vs 17 months), complete response (35% vs 5%), response rate (69% vs 34%), progression-free survival (18.3 months vs 14 months), and OS (hazard ratio [HR] 0.61) compared to the MP arm. The updated results presented at ASH included the following facts:

- There was a 35% reduced risk of death in the VcMP arm, compared with the MP arm (HR = 0.65, P = 0.0008).
- The median survival was not reached in the VcMP arm, while the median OS in the MP arm was 43.1 months.
- The safety profile of Velcade in combination with MP was consistent with the known safety profiles of both Velcade and MP.

In VISTA, the most commonly reported adverse events for Velcade in combination with MP vs MP, respectively, were thrombocytopenia (52% vs 47%), neutropenia (49% vs 46%), nausea (48% vs 28%), peripheral neuropathy (47% vs 5%), diarrhea (46% vs 17%), anemia (43% vs 55%), constipation (37% vs 16%), neuralgia (36% vs 1%), leukopenia (33% vs 30%), vomiting (33% vs 16%), pyrexia (29% vs 19%), fatigue (29% vs 26%), lymphopenia (24% vs 17%), anorexia (23% vs 10%), asthenia (21% vs 18%), cough (21% vs 13%), insomnia (20% vs 13%), edema peripheral (20% vs 10%), rash (19% vs 7%), back pain (17% vs 18%), pneumonia (16% vs 11%), dizziness (16% vs 11%), dyspnea (15% vs 13%), headache (14% vs 10%), pain in extremity (14% vs 9%), abdominal pain (14% vs 7%), paresthesia (13% vs 4%), herpes zoster (13% vs 4%), bronchitis (13% vs 8%), hypokalemia (13% vs 7%), hypertension (13% vs 7%), abdominal pain upper (12% vs 9%), hypotension (12% vs 3%), dyspepsia (11% vs 7%), nasopharyngitis (11% vs 8%), bone pain (11% vs 10%), arthralgia (11% vs 15%) and pruritus (10% vs 5%).

CARDIAC CARE NOT IMPROVED BY PUBLIC REPORTING OF HOSPITAL REPORT CARDS

TORONTO, Ontario—A Canadian study in the November 18 issue of *JAMA* demonstrated that public reporting of hospital quality improvement report cards had no effect on 11 of the 12 indicators of care for acute myocardial infarction (MI) and no effect on 5 of the 6 indicators of care for chronic heart failure. The study by Tu and colleagues was the first large, randomized trial to evaluate the effectiveness of public report cards on improving performance.

As part of the study, sample charts from 81 Ontario hospitals from 1999 to 2001 were reviewed, and hospitals were randomly chosen to receive either early

feedback on performance before results were publicly reported or delayed feedback at the same time results were released to the media. Follow-up performance data from 2004 to 2005 were obtained for the same cardiac conditions at the 81 hospitals. Of the hospitals who received early feedback with the initial report cards, 73% changed order sets and clinical pathways or care maps. Yet there was no significant change in performance between this group and the group who received delayed feedback.

The only two indicators that improved with early feedback were greater use of fibrinolytic therapy for

MI patients before transfer to a coronary unit and greater use of angiotensin-converting enzyme (ACE) inhibitor or angiotensin-receptor blocker therapy for patients with left ventricular dysfunction.

The authors stated that the findings “suggest that public release of hospital-specific performance data may not be a particularly effective system-wide intervention for measurably improving processes of care” for either of these conditions. They added that “more frequent and timely feedback of publicly released report cards on a regular basis might have been more effective.” ■

Post-CABG Depression Improved by Phone-delivered Team Care

PITTSBURGH, PA—The mental and physical functioning of patients with postsurgical depression following coronary artery bypass grafting (CABG) improved dramatically with use of a collaborative-care intervention by a nurse care manager delivered by telephone, report researchers in the November 16 issue of *JAMA*.

Benefits began within 2 months of surgery and continued through 8 months of follow-up. Half of the 150 patients who received the intervention reported a 50% or more reduction in mood symptoms, compared with 30% of patients who received usual post-CABG care.

The care manager followed evidence-based treatment protocols, provided education and taught self-management techniques, actively involved primary care physicians through regular

exchanges of real-time information, proactively monitored treatment responses and suggested adjustments when indicated, and facilitated co-management or transfer of care to local mental health specialists when patients did not respond to treatment, had clinically complicated cases, or were referred by the primary care physician.

A total of 2485 post-CABG patients were initially screened; 302 with moderate depression participated in the study. Half the patients received the intervention and half received usual care. A group of 151 post-CABG patients without depression were also followed.

The nurse care manager contacted patients by phone in 15- to 45-minute sessions, providing education about depression and its effect on cardiovascular disease. Antidepressant therapy was

initiated or adjusted by the care manager through the patient's primary care provider. Patients' mental and physical health was closely monitored with the 36-item Short-Form health survey (SF-36), physical functioning was measured using the Duke Activity Status Index, and mood systems were rated with the Hamilton Rating Scale for Depression. Care managers reported weekly to a study psychiatrist and internist.

Men showed a significantly better response to the intervention than did women with a nearly 6-point rise on the SF-36; 61% of men reported a 50% improvement in depression symptoms compared with 38% of women who reported the same. The authors noted that the gender difference indicates the patient population that is likely to benefit most from such an intervention. ■

SURVIVAL IN PANCREATIC CANCER IMPROVED 30% WITH ADJUVANT THERAPY

Adjuvant chemoradiotherapy improves median survival of patients with resectable pancreatic cancer by 30% over surgery alone, according to data analyzed from a population-based cancer registry of nearly 3000 patients, reported in the January issue of *Archives of Surgery*. About half of the patients (51.9%) did not receive chemotherapy or chemoradiotherapy. Approximately 25.0% of the patients underwent chemoradiotherapy, and 10.0% received chemotherapy alone. Patients treated with surgery only had a significantly lower ($P < 0.001$) median overall survival of 12.6 months compared

with patients who received chemotherapy or radiation preoperatively (19.9 months) or postoperatively (17.0 months). Other factors positively affecting survival were age younger than 40 years and receiving treatment at a teaching facility vs a non-teaching facility or a high-volume center over a low-volume center. Race, ethnicity, and abstention from alcohol and tobacco did not positively influence survival.

Missing from the study, however, was information on cancer stage in more than 50% of patients, margin status, and information on the type or duration of adjuvant therapy. ■

Prenatal and Infancy Nurse Visits May Keep Girls Out of Jail

Among a population of mostly young, unmarried, and low socioeconomic women (85%), prenatal and infancy in-home visits by nurses appears to have affected the chances that their daughters would end up in jail. Only 10% of girls whose mothers had been visited by nurses while pregnant and after giving birth had been arrested by age 19 compared with 30% of those in a comparison group. Families in the study were recruited between April 1978 and September 1980 when the mothers attended antepartum clinics or obstetricians' offices. Similar results among did not occur among boys born to these mothers. The researchers concluded, in the January issue of *Archives of Pediatric and Adolescent Medicine*, that their findings suggest that the program "has the potential to produce lasting changes in criminal offending trajectories, early childbearing, and economic outcomes for girls born to low-resource mothers." Further studies are planned to better understand the lack of effect on boys. ■

TENS for Diabetic Neuropathy, Not Lower Back Pain

According to a meta-analysis reported in *Neurology* (December 2009 issue), transcutaneous electrical nerve stimulation (TENS) is not recommended to treat chronic low back pain but should be considered for reducing pain from diabetic neuropathy. Among the 11 clinical trials

that compared TENS to placebo or another therapy for relief of painful neurologic disorders, TENS was shown not to be effective for lower back pain (Level A evidence) but was considered to have possible benefit for the relief of diabetic neuropathy (Level B evidence). ■

High-Tech Approach to Portion Control Aids Kids

The Mandometer is a scale that weighs food on the plate atop it. Its small attached computer displays a real-time graph showing how much food has been removed from the plate compared to a target line, and a voice prompts the eater to eat faster or slower when the curves separate too much. Researchers at a hospital-based obesity clinic in Bristol,

England, tested the Mandometer's effectiveness on the eating habits of newly referred patients, aged 9 to 17. The 106 children were randomized to receive standard dietary and exercise advice and support from a research nurse, dietitian, and clinician—either with or without mealtime feedback from the Mandometer device. After 24 months of use, the BMI

standard deviation score, the primary endpoint, dropped by 0.24 more with use of the device than with standard care alone ($P < 0.001$). Eating speed fell by 11% over 12 months among those patients who used the device compared with a 4% gain among those receiving the standard treatment arm. Results were reported in the January issue of *BMJ*. ■

Being in a Caring Profession Doesn't Mean We Can't—and Shouldn't—Care for Ourselves *continued from page 3*

other professions, and turf battles over best practice models versus best care for patients/clients.... The only constant is change. Therefore, we must own our part of the problem in order to become part of the solution.

Look at what you have already done or what can be done (or perhaps is being done) within your agency, department, or organization to empower individuals and teams. Are you on board? Have you implemented a positive change in your own attitude

and behavior? If not, why not? The time has come to embrace the change.

If we as health and human services professionals make a commitment to share our thoughts and perspectives with at least one other person, eventually we will create a new culture of practice for ourselves and for the next generation of our workforce. This begins by acknowledging the individual value and priority of our own needs as readily as we do the needs of our clients.

The choice is ours. We can see ourselves as helpless victims of our profession, other professions, or the organizations where we work, or we can look at the situation through a different

lens. If you think this means rose-colored glasses, then try them on! Look at the possibilities of what you can do to recognize and elevate your self-care. Even a small change can be a significant first step. **CM**

The Commission for Case Manager

Certification is the first and largest nationally accredited organization that certifies case managers. The CCMC is a nonprofit, volunteer organization that oversees the process of case manager certification with its CCM credential. CCMC is positioned as the most active and prestigious certification organization supporting the case management industry. For more information, visit www.ccmcertification.org.

A Sign of the Times: Helping Employees to Stay Productive While Dealing With Stress *continued from page 4*

may try to "tough it out." This sets up a health risk for the employee, which may turn into lost productivity if the person's condition worsens.

A transitional assignment elsewhere in the company, however, may allow the employee to heal. Let's take an example: Fred, a long-time employee, asks the on-site occupational health nurse for ibuprofen because of a sore shoulder. Two days later, Fred is back with the same complaint. When the occupational health nurse inquires again, Fred admits that he has been told by his doctor that he needs rotator cuff surgery, but he doesn't want to take the time off now to

have it done. The longer Fred stays in his current job, however, the more he aggravates the condition, which is the result of a preexisting nonoccupational injury.

The occupational health nurse can help Fred to explore alternate work or light duty temporarily to stop aggravating the shoulder injury. Fred is still on the job, contributing his knowledge and experience, but instead of being in a physically demanding job on the production line, he is working in quality control. After the surgery, Fred returns temporarily to the light-duty assignment as he heals. His time off work is far less than if Fred had caused further injury to his shoulder.

Employee health is always essential to workplace productivity. In these current times, we must appreciate that wellness is impacted by more than just

physical conditions. Stresses at home and on the job—from financial worries to fear of being laid off—can affect employee health and undermine productivity. Professionals who work closely with the workforce can help with education, resources, and support, providing assistance that employees need to stay healthy—and on the job. **CM**

The CDMS Commission is the only independent, nationally accredited organization that certifies disability management specialists. Each year the Commission honors a company or organization for demonstrating leadership in disability management. For more information about the CDMS Commission, its Certified Disability Management Specialist Credential, or the annual QLA award, please see the commission Website at www.cdms.org.

ASPIRE to Excellence: Take a Leap Toward Patient-centered Care in 2010 *continued from page 5*

approaches to be carried over to the person. Case management in its coordination, facilitation, and advocacy work offers to persons served a systematic approach to needed services. From the beginning, if the person served has successful engagement, involvement, and ability to make decisions and understand his or her role in collabora-

tion with the case manager, the direct results of services will be seen as useful and an enhancing part of the delivery of services.

Whether you seek accreditation or not, the evidence demonstrates that person-centered delivery of services enhances results. Take a moment at the beginning of this new decade to reflect on your practice and how the people you serve are partners in their care. If you believe patient-centered care is an area in which you or your facility can

make improvements, please contact us to assist with resources to help you start down this path. The new 2010 CARF Medical Rehabilitation Manual can be ordered online at www.carf.org at the bookstore. **CM**

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Vol. 16, No. 1 2010. *CareManagement* (ISSN #1531-037X) is published six times a year, February, April, June, August, October and December and its contents copyrighted by Mason Medical Communications, Inc., 256 Post Road East, Suite 204, Westport, CT 06880-3617; Tel: 203-454-1333; Fax: 203-227-9495.

Periodicals postage paid at Westport, CT and additional mailing offices.
POSTMASTER: Send changes of address to *CareManagement*, PO Box 210, Greens Farms, CT 06838-0210.

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