CareManagement

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HIV/AIDS:
Thoughts on the Pandemic

This year, the world marked the 35th anniversary of the first published reports of what would come to be known as HIV/AIDS. This disease has wrought enormous suffering and devastation and caused more than 35 million deaths. Yet today, thanks to remarkable achievements in biomedical science and public health, we have the tools to build a better future for individuals living with HIV and for those at risk of infection. I am hopeful that new approaches currently under exploration could expedite the end of the HIV/AIDS pandemic.

The greatest scientific accomplishment in HIV research has been the development of effective treatments that suppress the virus and prolong the lives of those living with HIV. Over time, scientists have refined and optimized antiretroviral therapy, delivering safer, more effective drugs that are easier to take. Today, a person living with HIV on antiretroviral therapy can expect to live a nearly normal lifespan.

Antiretroviral therapy has been transformational for both individuals and communities. Large studies conducted in diverse settings, from US cities to African villages, have demonstrated the power of treatment to preserve the health of those living with HIV. Additionally, studies have proven that when an individual living with HIV is on antiretroviral therapy and the virus is durably suppressed, the risk that he or she will sexually transmit the virus is negligible. Research also has repeatedly demonstrated that HIV incidence diminishes when HIV testing is aggressively implemented, individuals with HIV infection are linked to treatment, and support is provided to keep them in care. The power of treatment as prevention cannot be underestimated in helping to achieve global targets to dramatically reduce new infections and improve the health of those already living with HIV.

While preventing new infections is essential, it remains critical that the 36.7 million people living with HIV globally benefit from cutting-edge science. Today's treatments are lifesaving, yet people living with HIV still suffer from higher rates of chronic disease than their uninfected counterparts. Science has made remarkable strides in preventing the transmission of HIV from mother to infant during pregnancy, birth, and breastfeeding.

Some sobering facts:

- Half of the people infected worldwide will receive treatment for HIV/AIDS.
- Some 1.1 million people died of AIDS last year.
- Forty percent of people infected with HIV are undiagnosed.

In the United States, approximately 1.9 million people are estimated to have been infected with HIV, including over 698,000 who have already died; today, 1.2 million people are living with HIV, 1 in 8 don't know it. Young people were the most likely to be unaware of their infection. Among people aged 13 to 24, an estimated 51% (31,300) of those living with HIV didn't know.

The response to the US epidemic has yielded numerous successes, but challenges remain:

- From 2005 to 2014, the annual number of new HIV diagnoses declined 19%. In 2015, 35,513 individuals were diagnosed with HIV.
- Gay and bisexual men, particularly young African American gay and bisexual men, are most affected. Among all gay and bisexual men, trends have varied by race and over time.

From 2005 to 2014:

- Among white gay and bisexual men,

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More Social Workers Seeking Board Certification as Case Managers

By Jane Harkey, RN-BC, MSW, CCM, *Chair, Commission for Case Manager Certification (CCMC)*

Social workers have always been eligible to take the Certified Case Manager (CCM®) certification examination administered by the Commission for Case Manager Certification (CCMC). Today, however, we are seeing greater interest among social workers in becoming board-certified case managers[1]—a trend we see as exciting for the case management field and for the health care industry.

As previously announced, a partnership between CCMC and the National Association of Social Workers (NASW) has made it easier for social workers to sit for the CCM® exam. Under an agreement between the two organizations, social workers who qualify for the NASW case management credential may also pre-qualify to take the CCMC certification examination at no additional fee. (For details, contact the NASW Credentialing Center at Credentialing.nasw@socialworkers.org.)

CCM certification applies broadly across multiple disciplines, including nursing, social work, and other allied health fields. Currently 6% of CCMs are social workers, a percentage that has been rising. (About 89% of CCMs come from nursing backgrounds.)

For more than a century, there has been close alignment between social work and case management. In fact, public health social workers were among the first case managers to provide case management services in the early 20th century. Social work and case management remain closely tied: A 2004 NASW study of licensed social workers found that case management was a component of most social workers' jobs, and that a significant number of social workers reported spending more than half of their time engaged in it.

A 2004 NASW study of licensed social workers found that case management was a component of most social workers' jobs, and that a significant number of social workers reported spending more than half of their time engaged in it.

Another commonality between social work and case management is the close link between behavioral health and physical health; indeed, the two are inseparable. As research shows, most adults with a behavioral health disorder have at least one medical condition, and about one-third of those with a medical condition have a co-morbid mental health condition. The link between physical and mental health also underscores the importance of taking a holistic, person-centered approach—one that is embraced by both case management and social work.

As more social workers consider pursuing case management certification, it's important to expose misperceptions or myths about case management. First, it is not an entry level position—a perception that may exist because the term "case manager" is sometimes used indiscriminately, and not referring to a board-certified case manager who is an experienced practitioner in health and human services.

A recent CCMC trend survey shows that 67% of CCMs have nine or more years of case management experience; 25% supervise others, and 67% have specialty training. Compensation for CCMs also underscores that this is a job for experienced professionals: The median salary ranges between $75,000 and $80,000 per year, and 40% of board-certified case managers report salaries above $80,000. Half of those in executive positions report earning more than $100,000 a year.

Today more than ever, social workers are finding a place under the broad umbrella of case management, and are pursuing board certification to distinguish themselves as possessing the skills and expertise to meet the challenges of 21st century health and human services. CM

Jane Harkey, RN-BC, MSW, CCM, *is the Chair of the Commission for Case Manager Certification (CCMC), the first and largest nationally accredited organization that certifies case managers. Currently, more than 40,000 case managers hold the CCM certification (see www.ccmcertification.org). Ms. Harkey is also a geriatric case manager, based in New Jersey.*

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Case Management Society of America (CMSA) Issues Revised Standards of Practice:

Identification of Care Needs and Opportunities

By Elizabeth Hogue, Esq.

CMSA decided to revise the Standards again this year to emphasize the professional nature of the practice and role of case managers as an integral and necessary component of the health care delivery system.

The Case Management Society of America (CMSA) recently issued revised Standards of Practice for Case Management. The Standards were first published in 1995, and were also revised in 2002 and 2010. The general purpose of the Standards is to identify important knowledge and skills for case managers. These Standards are applicable in all practice settings.

CMSA decided to revise the Standards again this year to emphasize the professional nature of the practice and role of case managers as an integral and necessary component of the health care delivery system. These standards likely apply to all case managers regardless of practice setting or whether they are certified case managers.

After identifying and assessing clients, the next step in the professional case management process is identification of care needs and opportunities that may benefit from case management interventions. Case managers must demonstrate compliance with this standard through the following activities:

- Document agreement among clients, clients' families, other caregivers and other providers and organizations regarding care needs and opportunities identified by case managers
- Document identification of opportunities for effective intervention, such as:
  - –Lack of established, evidence-based plans of care with specific goals
  - –Over-utilization or under-utilization of services and resources
  - –Use of multiple providers and/or agencies
  - –Lack of integrated care
  - –Use of inappropriate services or levels of care
  - –Lack of primary providers or any providers
  - –No-adherence to case management plans of care that may be associated with low reading levels, low health literacy and/or numeracy, low health activation levels, and language and communication barriers
  - –Lack of education or understanding of disease processes, current conditions, prescribed medications, substance use and abuse, and social determinants of health
  - –Lack of ongoing evaluation of clients' medical, cognitive and behavioral, social and functional limitations
  - –Lack of support from clients' families and other caregivers, especially when under stress
  - –Financial barriers to adherence of case management plans of care
  - –Determination of patterns of care or behavior that may be associated with increased severity of conditions
  - –Compromised client safety
  - –Inappropriate discharge or delay from other levels of care
  - –High cost injuries or illnesses
  - –Complications related to medical, psychosocial or functional conditions or needs
  - –Frequent transitions between care settings and/or providers
  - –Poor or lack of coordination of care between settings and/or providers

This activity of care management alone demonstrates the complexity of provision of professional case management services. Collaboration with other providers will assist case managers to meet this standard. CM

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

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Supporting Millennials in the Workforce

By Ed Quick, MA, MBA, CDMS CRC

In today's multigenerational workforce, the youngest and often newest employees may be the ones reporting the most stress and anxiety in their lives. For disability management specialists and other workforce managers, this raises the question of how to address the needs of Millennials, while promoting stay-at-work strategies and individual habits to maintain productivity and bolster employees' coping skills.

Work/life stresses, including difficulty maintaining integration between the two, are often experienced by Millennials. This phenomenon has been observed by certified disability management specialists (CDMSs) and has been captured in data by the American Psychological Association (APA). An APA survey found that Millennials report above-average stress levels at 5.5 (on a 10-point scale), followed closely by Gen Xers at 5.4. Baby boomers reported below-average stress levels at 4.5.

The APA survey also found that Millennials are the most likely of all generations to report stress levels increasing over the previous year, as well as experiencing more loneliness and isolation due to stress, compared to other generations. Furthermore, CDMSs have observed:

Millennials often struggle with how to cope with work demands after leaving college and no longer having many of their life stresses (especially financial) managed at least in part by or with their parents.

Millennials may find themselves working in unfamiliar or unexpected work environments or roles; for example, they may have demanding jobs even at the entry level.

Millennials are the most likely of all generations to report stress levels increasing over the previous year, as well as experiencing more loneliness and isolation due to stress.

Millennials tend to be more open and willing to share their emotions and their experiences of stress, such as with co-workers and supervisors.

Millennials may ask for time off without being aware of the policies and programs that govern such absences and what may be required to qualify for those programs; for example, they may not be aware of the ongoing requirements to maintain their eligibility or qualifications for paid time off (PTO).

These observed tendencies among Millennials are not meant to criticize younger workers or compare them unfavorably with others. Rather, the objective here is to help educate disability managers who work closely with Millennials and their employers, whether as part of a broader employee population or as colleagues who are new to teams or departments. Whatever the context in which disability managers encounter these younger workers, they need to be sensitive to Millennials' needs and their tendency to have higher levels of stress and expectations.

Offering support is crucial—as is educating Millennials and others about the policies and programs that apply to mental and emotional health. For example, an employee who requests time off because he/she is "so stressed out," may not be aware of PTO eligibility. Preventing misunderstandings of how their benefits work can help ameliorate Millennials' stresses.

For example, employees with mental health diagnoses are typically covered by their employer's health benefits. An employee who needs support with work/life integration or other stresses may be referred to the Employee Assistance Program (EAP), if one is offered by the employer. Or the company may have social workers or other support personnel available to aid employees.

To be most effective, EAPs and similar initiatives should stress the importance of employees staying on the job. As CDMSs, we understand the benefit to employees when work remains part of their day-to-day life. Removing individuals from the work environment while a physical or mental health issue is treated may undermine longer-term success and be counterproductive in helping employees learn to manage stress.

Another consideration for CDMSs is determining the source of the

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Ed Quick, MA, MBA, CDMS CRC, *is a Commissioner with the Commission for Case Manager Certification (CCMC), which administers the CDMS certification. He has more than 15 years of experience in disability and workforce management with Fortune 100 companies, and currently works as a global senior benefits manager.*

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Alternative Payment Models Transform Health Care: An Overview for Case Managers and Discussion of How to Address Patient Questions

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

The Center for Medicare and Medicaid Services (CMS) Innovation Center, a creation of the Affordable Care Act, has initiated new payment models that are transforming the way health care is delivered across the country.[1] The most familiar ones are Accountable Care Organizations (ACOs), Bundled Payment Care Improvement (BPCI), and Comprehensive Joint Replacement (CJR) programs. These programs reduce risk to the payor (CMS) and increase risk to hospitals, primary care physicians (ACO) and specialists (BCPI and CJR).

It is important that case managers and those involved in discharge planning understand how these models work and how they can improve the quality of care in a cost-effective way. Patients will have questions as they hear rumors and read information in the media about Medicare's new initiatives, and this may bring cause for concern. When patients ask about how their health care is changing, case managers should respond clearly and effectively as the clinical and cost-containment success of these new programs partially rely on early engagement in the acute care setting.

Alissa Getts, RN, MSN, CCM is the Team Lead and Post-Acute Care Manager, and Dana Strauss, PT, MPT, is a population-health Post-Acute Care Navigator at Valley Hospital, Ridgefield, New Jersey.

This article will help case managers understand the three common value-based payment models, the modification of their practices and information on how to answer patients' questions. Under these CMS alternative payment models, there is a built-in incentive to adopt a new, more proactive approach to care coordination and discharge planning.

The Institute for Healthcare Improvement (IHI) states that "common language is key," and understanding the goals and direction of the health care system is fundamental to communicating a shared vision.[2] The discharge planners have become essential advocates of these value-based programs and leaders in the mission toward their success.

Value-based programs like these alternative payment models have the potential to affect patients, case managers, health systems, and post-acute care providers including skilled nursing facilities (SNFs) and home health agencies (HHA). These programs have common goals but vary in several ways. The concepts will be explained to help care managers gain a working knowledge of the information.

A Guide to Popular Alternative Payment Models

BPCI: Bundled Payment Care: Improvement models are retrospective payment programs in which each participant manages patients through acute and post-acute episodes of care and offer options regarding financial risk.[3] Providers agree on a set fee for payment for the entire care episode, which could be anywhere from 30 to 90 days. This set fee includes costs for post-acute care providers as well as financial penalties for any readmissions that occur within the episodic period.

Initial reimbursements are handled like fee-for-service, but Medicare looks back at all the claims data and performs reconciliation of spent Medicare dollars versus expected spending for that diagnosis-related group (DRG). If expenses go over the agreed amount, the providers have to pay back the money in the overspend. Providers also seek to benefit from spending under the expected total cost for the episode by splitting the savings with Medicare. There are other monetary incentives for providers if they stay within the bundled payment agreement. This program also does the following: (1) it forces a more thorough discussion between case management and other practitioners in acute care regarding the optimal discharge post-acute setting, and (2) it encourages the acute and post-acute worlds (including SNFs, home health companies, outpatient clinics) to collaborate more and be accountable for patient outcomes and Medicare dollars spent.

Accountable Care Organizations (ACOs) a.k.a Medicare Shared Savings Program (MSSP): An ACO is a group of local physicians and providers collaborating to provide coordinated

One way the ACO reaches its goals is by improved provider collaboration along the continuum of care settings, also known as transitional care.

care to a population of patients. A savings or a loss in spending, based on a budgeted amount during a time period, determines whether a provider receives money back in their portion of the savings incurred or owes money because too much has been spent.[4] Quality metrics and outcomes are tracked to determine whether care was provided efficiently (low-cost, high-quality outcomes). This program is designed to create patient-centered care. Patient medical information is shared among the providers to prevent duplication of services and increase medication safety and compliance. One way the ACO reaches its goals is by improved provider collaboration along the continuum of care settings, also known as transitional care. Some may try to describe being in an ACO as similar to being in an HMO. Being in an ACO does not mean your Medicare benefits change. In an HMO, beneficiaries have to receive care from a network of providers to be covered. In an ACO, patients have the right to choose their providers, and benefits are not affected by going to a provider outside the ACO.[5]

Comprehensive Joint Replacement Program (CJR): Out of the success of the BCPI program came a mandate in 67 metropolitan markets for value-based bundled payments for total hip and knee replacements, which was estimated to provide Medicare with a cost savings of $153 million dollars within [5] years. The goal is improving direct care coordination between acute care hospitals and post-acute, and home health providers and preoperative programs. Only hospitals can initiate episodes (unlike the choices provided by BCPI of different models), and gainsharing with surgeons will still be allowed up to 50% percent above the surgeon's fee.[6]

The CJR model is not as complex as the bundle or ACO programs, as it is an incentivized structure rewarding hospitals, not physicians. The CJR rewards the hospitals for successfully coordinating post-acute care appropriately and cost effectively. Most patient care provided in the CJR program does not occur in hospitals. The amount of reconciliation monies at stake in the CJR program is smaller than in the bundle programs.[3]

Case Manager's Essential Role in the Program's Success

By understanding the different payment models case managers can see the essential role they play because discharge planning is a critical piece of the cost containment pie. Post-acute care is a major driver of cost for Medicare, and, therefore, under these models there is a significant focus on reforming the utilization of these services.[7] Patients must be guided during their acute stay to choose the best option for their post-acute destination. Hospitals that have implemented these alternative payment models have created specialized roles like Post-Acute Care Navigators or ACO Transitional Care Coordinators for the sole purpose of ensuring that the right patients are going to the right places for the right levels of care.

Until value-based care came into play, hospitals were motivated simply to efficiently discharge patients to adhere to Medicare's length-of-stay guidelines. It has not been common practice for case managers to steer or navigate patients to selected post-acute care facilities based on data-driven insights and collaboration strategies between acute and post-acute care providers. Accurately assessing the best discharge disposition for patients now takes on greater importance, as lower-cost levels of care, like home health and outpatient services, can meet the needs of patients effectively. Performing comprehensive assessments using basic case management skills can be effective when determining appropriate discharge dispositions.

Since the optimal outcome is discharging patients back to the community where they can self-manage their care (often with the help of their support system), case managers should aim to help their patients achieve this as soon as they are medically and physically able. Effective discharge planning for patients who may seem to have a decline in function or had prolonged hospital stay requires a thorough physical therapy evaluation, including prior level of function and physical therapy (PT) prognosis for functional progress. Early PT intervention is best for these patients. Case managers sometimes may feel that if a patient is unsteady, it is safer for the patient to go to rehab than home. However, research has shown that patients who had knee surgery and go home for therapy do just as well as patients who have gone to inpatient rehab facilities.[8]

Patients often enter the hospital unaware of these alternative payment models, and it is important to keep them informed.

Home Therapy Versus Rehab Facility?

Understanding the purpose of and how each payment model works brings awareness of episode costs to case managers and others involved in discharge planning—where the patient goes for post-acute care greatly affects these costs. Careful discharge planning is crucial to the success of these programs. After comprehensive discharge planning assessments and PT evaluation have been made, case managers should always first ask themselves, "What could deter this patient from returning directly home?" Case managers cannot rely solely on physician referrals or patient and families that suggest rehab after discharge simply because this had occurred in the past. The new payment models will force case managers to work towards taking down discharge barriers to home and setting goals with the care team to reduce preventable risk factors that could lead to unwanted readmissions or poor outcomes.[9] Case managers should get in the habit of considering home as the first choice for discharge, and then factor in higher levels of care (SNF, rehab facility) when the home environment does not seem feasible for the patient.

Know Your Post-Acute Care Network "Preferred Partners"

Administering bundle, CJR, or ACO programs will mean that hospitals will identify high-quality, cost-efficient post-acute care providers and develop collaborative relationships to further improve outcomes. Data from 2012 show that the average acute care facility discharged patients to an estimated 39 different SNFs.10 Routinely discharging patients to a large number of post-acute care facilities with varying quality makes it nearly impossible to coordinate care and follow the patient's progress after discharge.[7] Hospital systems need to invest in the development of post-acute care networks that meet the needs of their population(s).[7] It was not common practice for case managers to steer patients towards a selected rehab facility. They would present a list of providers in the area and rely on the patient and family to make the decision. The alternative payment programs do not take away the patient's right of choice. This information may get misinterpreted as the bundle or ACO programs are being discussed, especially when patients hear about "preferred partners." Case managers must inform their patients of the benefits of selecting a partnered facility, yet they should always reinforce that the patient's right to choose remains.

Keeping Patients Informed

Patients often enter the hospital unaware of these alternative payment models, and it is important to keep them informed. Patients' lack of understanding of their participation in ACO and/or bundle programs can cause anxiety if not explained in a way they can understand. Case managers can alleviate fears by delivering information about alternative payment models in a way that patients understand. This helps patients take part in their own care planning and be involved in the decision-making regarding discharge planning. Informed case managers equipped with thorough knowledge can answer common questions from patients and families with ease.

Common Patient Questions

1. **Do I have to choose one of the preferred providers for my rehab?"**

   Choice has always been paramount in traditional Medicare, and alternative payment models do not change that. What has changed are incentives to gather standardized information about all the post-acute providers and offer that information to patients to help them make an informed decision. Medicare encourages narrowing networks based on performance. As long as all facilities are examined the same way, health systems can choose how they will be evaluated. This is what should be shared with the patient.

2. **"I would like to go to rehab after my knee replacement, but I was told I would only be in the facility about 5 to 7 days. I read on the CMS website that I have 20 days covered at 100%. Can I use the 20 days?"**

   The ultimate determination of length of stay in a rehab is what is needed to transition to the next level of care—what is medically necessary. In the case of a SNF, the providers look at your ability to return home to continue your therapy after your surgery when determining a discharge date. Like at the hospital, a SNF admission also needs to meet CMS criteria to be covered.

3. **"What makes the 'preferred' facilities the best choice?"**

   A sample answer is: The partner facilities that have collaborated with the hospital are working to improve communication and plan your care to make transitioning from one

care setting to another as seamless as possible. The health system has selected facilities that demonstrate high-quality standards and outcomes. This is important because the programs described will provide coordinators that will continue to oversee your care for a period of time after discharge. Having a partnership with these post-acute care providers will help streamline communication, improve medication reconciliation, and achieve better outcomes for you.

4. **"My doctor is in an ACO. What does that mean for me?"**

   A sample answer might be: Wherever you are in the health care system, a health care professional will keep an eye out for you to make sure you are receiving the right care and you understand that care. The ACO is making sure your chosen providers are giving you the care that meets your health care goals and helps coordinate your care in challenging times. You will have a care coordinator who can help you make the necessary follow-up appointments, answer medication questions, and reach out to your physician if needed. An ACO provides a teamwork approach to ensuring you have the best care possible and that you have access to all eligible resources if problems arise. Being part of the ACO means that all physicians handling your care have access to your medical records so they can see what other physicians have prescribed for you. This will make it easier for your primary care physician and specialists to plan your care.

5. **"I don't want people calling me at home. Do I have to be in the program?"**

   The health care team might explain: The hospital has participated in these value-based initiatives to work with the government health programs to improve overall health care and reduce unnecessary costs These programs have shown to be successful when there is a focus on coordination and communication with the patient. You cannot opt out of a bundle program because that is what the hospital has agreed to use as their reimbursement method. You have a choice to not receive regular follow-up phone calls; however, for patients, this feature can be a benefit and provides patients a point person to be their advocates, get answers to troubling questions, and assist them with other health care resources.

Summary

Presently the paradigm is shifting to value-based care from the fee-for-service model that the health care industry has been accustomed to. Case managers must understand that the key to the success of these models is careful discharge planning and risk mitigation. Case managers serve key roles by educating patients, looking beyond the walls of the hospital for best patient care, and facilitating a team decision for discharge planning. Optimal transitional care requires multiple disciplines to work together, including hospital, SNF, and home health—the case manager is the link among them. Understanding how these new programs work and their goals is the first step to becoming a leader in care transformation and health care improvement. CE 1

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How Case Managers Are Addressing America's Health Literacy Problem

By Catherine M. Mullahy, RN, BS, CRRN, CCM

An independent study commissioned by iTriage, an Aetna-owned health technology firm whose mission is to leverage digital tools to "simplify health care for healthier lives," reflects what many health care providers already knew. There's an epidemic of poor health literacy among many Americans. The iTriage study surveyed 1000 adults and found that only 18% were "proficient" in health literacy, 36% were rated as "intermediate," 29% as "basic," and 17% as "below basic." While this sample is small, other studies over the past decade also point to a serious health literacy problem.

As far back as 2003, a National Assessment of Adult Health Literacy (NAAL) identified 36% of adults as having serious limitations in their health literacy skills. That's more than 77 million people who would be challenged to perform what the NAAL deemed common health tasks such as following their prescription directions. For health care providers and professionals, plan sponsors, insurers and government agencies, the implications of a health-illiterate population are many. They include poorer health care outcomes, increased incidence of preventable hospital visits and admissions, higher rates of emergency services, higher costs of care, and inefficient use of resources. These are all areas in which case managers can make a significant difference by assuming an elevated role in addressing their patients' health literacy deficiencies. After all, health literacy is part of the core principles of the Commission for Case Manager Certification (placing public interest above their own and respecting the rights and inherent dignity of all clients), the codes of autonomy and beneficence of the Certification of Disability Management Specialist, and the codes of service and social justice of the National Association of Social Workers (Box 1). Improving health literacy requires a better understanding of the problem and methods for helping to solve it.

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What Is Health Literacy?

Solving the problems starts with having a basic understanding of how we define health literacy. On its website, the federal government states:

> *Health literacy is the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.*

A further explanation indicates the factors on which achieving health literacy is dependent. These include the communications skills of lay persons and professionals; their knowledge of health topics, culture, and the demands of both health care and public health systems; and their knowledge of a specific situation. Health literacy is a critical factor in a patient's ability to navigate our health system (ie, find appropriate service providers and complete forms), provide personal health history, engage in self- and chronic disease management, and understand probability and risk factors. There is also a numerical

BOX 1 **CODES OF ETHICS**

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

component to health literacy in that patients must be able to comprehend matters like calculating cholesterol and blood sugar levels, medication measurements, nutrition labels, premiums, copays and deductibles. Finally, health literacy also encompasses a patient's knowledge of various health topics (eg, heart health, nutrition, causes of certain common chronic diseases like obesity and diabetes, the effect of one's lifestyle on health, etc). Without a basic health literacy foundation, a patient's health can be placed in grave jeopardy. The problem of health literacy is not a simple one, however, as there are many factors which contribute to its prevalence.

Factors Driving Health Literacy Problems

Health literacy problems stem from many factors. Our nation's high school dropout rate is 30%, according to data from the Editorial Projects in Education Research Center's Cities in Crisis report. Given the complexities involved in health care, from medical terminology to rapidly changing technologies and convoluted health insurance plans, it is not difficult to understand why individuals without a basic high school education would have health literacy problems. Then there is our nation's increasing multiculturalism, which increases language and cultural challenges that interfere with health literacy. The NAAL's study bears evidence to this. When looking at health literacy among whites and Hispanics, the proportion of adults who had "basic" or "below basic" health literacy skills was 28% of white adults vs 65% of Hispanic adults. Age is also a factor with those over 65 years of age having poorer health literacy than those under 65. That said, the iTriage study found that more than one-third of

Further, while many professionals may believe they are communicating effectively, patient feedback and the number of patients who are not complying with their treatment plans would suggest otherwise.

18- to 24-year-olds have "below basic" health literacy.

Consider also the way health information is communicated. People are bombarded with all sorts of medical information coming from numerous sources—some reputable and others not. From evidence-based clinical information to medical educational content and anecdotal information from other people, it can be very confusing even for well-educated, English-speaking individuals, let alone for those whose English is a second language or a language in which they are not proficient. Then, there are medical product and pharmaceutical advertisements coming at us from all sides—our newspapers, magazines, and television sets. Even if health care professionals made every effort to help their patients fully understand their medical condition, prescriptions, costs of care, etc, we have yet another factor contributing to the health literacy problem. It is that many health care professionals simply do not have enough time in their schedules to sit with a patient and his or her family to make certain that they have a full grasp of their health situation. Further, while many professionals may believe they are communicating effectively, patient feedback and the number of patients who are not complying with their treatment plans would suggest otherwise. Let's also not forget that being sick is an emotionally charged experience. Suffering a medical emergency, getting a diagnosis of a life-threatening disease, or having a chronic medical condition takes an emotional toll on a patient and his or her family. This emotion can get in the way of their being able to objectively listen and comprehend the health information being provided. All of these factors are not lost on the federal government, which has undertaken various initiatives directed at improving health literacy in America.

Initiatives to Improve Health Literacy

The US Department of Health & Human Services' Office of Disease Prevention and Health Promotion issued a brief titled, "America's Health Literacy: Why We Need Accessible Health Information." In the brief, the organization calls for making health information more accessible and usable, educating health professionals on how to communicate better, prioritizing health literacy improvements, and integrating cultural and linguistic components in health information materials. The National Institutes of Health (NIH) also has issued information to help physicians and other health professionals learn how to clearly communicate with their patients. Under its motto of "Health Literacy: *Saves Lives. Saves Time. Saves Money,"* the NIH has delineated what should be the goals of a successful health information encounter. For instance,

- Providers should offer a clear understanding of what to do to improve one's health, why it is being done, and precisely how to do it.
- Providers should confirm that the patient has an understanding of what was conveyed by using the "teach back" method (ie, wherein the patient is asked to repeat the information back to the professional to ensure a full understanding).

In addition to the NAAL, US Department of Health & Human Services, and NIH, the National Academies of Sciences, Engineering, and Medicine held a public workshop to tackle the health literacy problem. The organization issued a Workshop Summary 2016 for its "Integrating Health Literacy, Cultural Competence, and Language Access Services," revealing its discussion points for the workshop, including the skills and competencies needed for effective health professional-to-patient communications; interventions and strategies for integrating health literacy, cultural competency, and language services; and the different perspectives of the various constituents such as health providers, patients and families, and payers.

Case Managers on the Frontline of Health Literacy

For their part, case managers can be vital patient advocates helping patients to obtain, process and understand basic health information and services; make appropriate health care decisions; navigate health care systems, and access the best care—all core principles of our professions (Box 1). These measure require critical observation of patients

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To prevent a decline in a patient's health and/or a serious consequence due to a health literacy problem and its ramifications, case managers should thoroughly evaluate their patients' understanding before, during, and after health care information and/or services are provided.

and an assessment of what they do or don't understand. There are specific red flags that signal low health literacy, including:

- Patient frequently misses appointments.
- Patient provides incomplete patient registration forms.
- Patient does not comply with medication.
- Patient is unable to name medications orz explain their purpose or dosage.
- Patient identifies pills by looking at them rather than reading the labels.
- Patient is unable to give coherent, sequential history.
- Patient asks few questions.
- Patient does not follow through on tests or referrals.

To prevent a decline in a patient's health and/or a serious consequence due to a health literacy problem and its ramifications, case managers should thoroughly evaluate their patients' understanding before, during, and after health care information and/or services are provided. It's important that case managers acknowledge cultural differences, be respectful of them, and be diligent in making sure that these differences are not interfering with the patient's comprehension of their medical situation. Case managers should limit the number of messages conveyed, keep their language plain and straightforward, and focus on actions that should be taken. For example, instead of saying, "Swallow that pill," say, "Take that pill." Use the word "fats" not "lipids," "belly" not "abdomen," and "harmful" not "adverse." Wherever possible, it is helpful to patients and their families if instructions are supplemented with visuals. Apply the "teach-back" method mentioned previously, asking patients to restate what you have explained to them in their own words to make sure they have a good understanding. Demonstrate and draw pictures so that patients and their families can better understand their medical condition and/or procedure.

Create a Safe Environment for Patients and Family

Case managers also can help promote health literacy in their patients by creating a "safe" environment for patients and their family members to ask questions, and share what they know and don't know, or are afraid to ask. Often, patients feel vulnerable and may be hesitant to express their lack of understanding. Case managers can help encourage them and assuage patients' insecurity by citing examples of experiences encountered with other patients so that the individual knows that he or she is not alone. This helps open the door to better communication and health literacy. Patients are always well served by communication that features many open-ended questions. This allows patients to answer without being led and enables case managers to better gauge their patients' understanding of the health information being conveyed. Where language barriers exist, engaging a medically trained interpreter is essential in promoting health literacy. Patients too are a wealth of insight, and case managers can learn much from them in this area. For patients, allowing them to communicate their questions or concerns such as, "Tell me what's wrong," "What do I need to do and why?" and "What are the benefits for me?" will help promote better health literacy.

By focusing on the patient in this way, case managers can help effect steady improvement in the health literacy of their patients. CE II

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PharmaFacts for Case Managers

Soliqua™ 100/33 (insulin glargine and lixisenatide injection), for subcutaneous use

Indications and Usage

Soliqua 100/33 is a combination of a long-acting human insulin analog with a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus inadequately controlled on basal insulin (less than 60 units daily) or lixisenatide.

Limitations of Use

- Has not been studied in patients with a history of unexplained pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Not recommended for use in combination with any other product containing lixisenatide or another GLP-1 receptor agonist.
- Not for treatment of type 1 diabetes mellitus or diabetic ketoacidosis.
- Not recommended for use in patients with gastroparesis.
- Has not been studied in combination with prandial insulin.

Dosage and Administration

- Discontinue therapy with lixisenatide or basal insulin prior to initiation of Soliqua 100/33.
- In patients inadequately controlled on less than 30 units of basal insulin or on lixisenatide, the starting dosage is 15 units (15 units insulin glargine/5 mcg lixisenatide) given subcutaneously once daily.
- In patients inadequately controlled on 30 to 60 units of basal insulin, the starting dosage is 30 units (30 units insulin glargine/10 mcg lixisenatide) given subcutaneously once daily.
- Inject once a day within the hour prior to the first meal of the day.
- Maximum daily dosage is 60 units (60 units of insulin glargine and 20 mcg of lixisenatide).
- Soliqua 100/33 Pen delivers doses from 15 to 60 units with each injection.
- Use alternative antidiabetic products if patients require a Soliqua 100/33 daily dosage below 15 units or over 60 units
- See Full Prescribing Information for titration recommendations.
- Inject subcutaneously in thigh, upper arm, or abdomen.
- Do not administer intravenously, intramuscularly, or by an infusion pump.
- Do not dilute or mix with any other insulin products or solutions.

Important Administration Instructions

- The Soliqua 100/33 prefilled pen is for single-patient use only
- Train patients on proper use and injection technique before initiating Soliqua 100/33.
- Always check the Soliqua 100/33 label before administration
- Visually inspect for particulate matter and discoloration prior to administration. Only use Soliqua 100/33 if the solution is clear and colorless to almost colorless.
- Inject Soliqua 100/33 subcutaneously into the abdominal area, thigh, or upper arm.
- Rotate injection sites within the same region from one injection to the next to reduce the risk of lipodystrophy
- Do NOTadminister intravenously, intramuscularly, or via an insulin pump.
- Do NOT dilute or mix Soliqua 100/33 with any other insulin or solution.
- Do NOT split the dose of Soliqua 100/33.

Dosage Forms and Strengths

Injection: 100 units of insulin glargine per mL and 33 mcg of lixisenatide per mL in a 3 mL single-patient use pen.

Contraindications

- During episodes of hypoglycemia
- Hypersensitivity to Soliqua 100/33 either of the active drug substances (insulin glargine or lixisenatide), or any of its excipients. Hypersensitivity reactions including anaphylaxis have occurred with both lixisenatide and insulin glargine

Warnings and Precautions

- Anaphylaxis and serious hypersensitivity reactions: can occur with either of the components in Soliqua 100/33. Instruct patients to discontinue if a reaction occurs and promptly seek medical attention.
- Pancreatitis: Discontinue promptly if pancreatitis is suspected. Do not restart if pancreatitis is confirmed.
- Never share a Soliqua 100/33 prefilled pen between patients, even if the needle is changed.
- Hyperglycemia or hypoglycemia with changes in Soliqua 100/33 regimen: Carry out under close medical supervision.

- Overdose due to Medication errors: Soliqua 100/33 contains two drugs. Instruct patients to always check the label before each injection since accidental mix-ups with insulin-containing products can occur. Do not exceed the maximum dose or use with other GLP-1 receptor agonists.
- Hypoglycemia: May be life-threatening. Increase frequency of glucose monitoring with changes to: insulin dosage, coadministered glucose lowering medications, meal pattern, physical activity; and in patients with renal or hepatic impairment and hypoglycemia unawareness.
- Acute Kidney Injury: Monitor renal function in patients with renal impairment and in patients with severe GI adverse reactions. Use is not recommended in patients with end-stage renal disease
- Immunogenicity: Patients may develop antibodies to insulin glargine and lixisenatide. If there is worsening glycemic control or failure to achieve targeted glycemic control, significant injection-site reactions or allergic reactions, alternative antidiabetic therapy should be considered.
- Hypokalemia: May be life-threatening. Monitor potassium levels in patients at risk of hypokalemia and treat if indicated.
- Fluid retention and heart failure with use of thiazolidinediones (TZDs): Observe for signs and symptoms of heart failure; consider dosage reduction or discontinuation if heart failure occurs.
- Macrovascular Outcomes: Clinical studies have not shown macrovascular risk reduction with Soliqua 100/33.

Adverse Reactions

Adverse reactions commonly associated with Soliqua 100/33 include hypoglycemia, allergic reactions, nausea, nasopharyngitis, diarrhea, upper respiratory tract infection, headache.

Drug Interactions

- Drugs that affect glucose metabolism: Adjustment of Soliqua 100/33 dosage may be needed; closely monitor blood glucose.
- Antiadrenergic Drugs (e.g., beta-blockers, clonidine, guanethidine, and reserpine): Hypoglycemia signs and symptoms may be reduced.
- Effects of delayed gastric emptying on oral medications: Lixisenatide delays gastric emptying which may impact absorption of concomitantly administered oral medications. Oral contraceptives and other medications such as antibiotics and acetaminophen should be taken at least 1 hour prior to Soliqua 100/33 administration or 11 hours after.

Use in Specific Populations

- Pregnancy: Soliqua 100/33 should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Clinical Studies

A total of 736 patients with type 2 diabetes participated in a randomized, 30-week, active-controlled, open-label, 2-treatment arm, parallel-group, multicenter study to evaluate the efficacy and safety of Soliqua 100/33 compared to insulin glargine 100 units/mL.

Patients screened had type 2 diabetes were treated with basal insulin for at least 6 months, receiving a stable daily dose of between 15 and 40 units alone or combined with 1 or 2 oral antidiabetic drugs (OADs) (metformin, sulfonylurea, glinide, SGLT-2 inhibitor or a DPP-4 inhibitor), had an HbA1c between 7.5% and 10% and a FPG less than or equal to 180 mg/dL or 200 mg/dL depending on their previous antidiabetic treatment.

This type 2 diabetes population had the following characteristics: Mean age was 60 years, 46.7% were male, 91.7% were Caucasian, 5.2% were Black or African American and 17.9% were Hispanic. At screening the mean duration of diabetes was approximately 12 years, the mean BMI was approximately 31 kg/m^2, mean eGFR was 80.6 mL/min/1.73 m^2 and 86.1% of patients had an eGFR ≥60 mL/min.

After screening, eligible patients (n=1018) entered a 6-week run-in phase where patients remained on or were switched to insulin glargine 100 units/mL, if they were treated with another basal insulin, and had their insulin glargine dose titrated/stabilized while continuing metformin (if previously taken). The mean HbA1c decreased during run-in period from 8.5 to 8.1%. Any other OADs were discontinued.

At the end of the run-in period, patients with an HbA1c between 7% and 10%, FPG ≤140 mg/dL and insulin glargine daily dose of 20 to 50 units (mean of 35 units), were randomized to either Soliqua 100/33 (n=367) or insulin glargine 100 units/mL (n=369).

Soliqua 100/33 and insulin glargine were to be titrated weekly to target a fasting plasma glucose goal of <100 mg/dL. The mean dose of insulin glargine at baseline was 35 units. The maximum dose of insulin glargine allowed in the trial was 60 units (insulin dose cap) in both groups. The targeted fasting plasma glucose goal was achieved in 33% of patients in both groups at 30 weeks.

At Week 30, there was a reduction in HbA1c from baseline of -1.1% for Soliqua 100/33 and –0.6% for insulin glargine (100 units/mL). The mean difference (95% CI) in HbA1c reduction between Soliqua 100/33 and insulin glargine was -0.5 [-0.6, -0.4] and statistically significant. The trial was designed to show the contribution of the GLP-1 component to glycemic lowering and the insulin glargine dose and the dosing algorithm was selected to isolate the effect of the GLP-1 component. At the end of the trial, the doses of insulin glargine were equivalent between treatment groups. The mean final dose of Soliqua 100/33 and insulin glargine at week 30 was 46.7 units (for Soliqua 100/33: 46.7 units insulin glargine/15.6 mcg lixisenatide). The difference in effect observed in the trial may not necessarily reflect the effect that will be observed in the care setting where alternative insulin glargine dosage can be used.

Storage

Prior to first use, Soliqua 100/33 pen should be stored in a refrigerator, 36°F–46°F (2°C–8°C). Do not freeze. Protect from light.

Discard after the expiration date printed on the label.

Soliqua 100/33 should not be stored in the freezer and should not be allowed to freeze. Discard Soliqua 100/33 if it has been frozen.

After first use, store at room temperature below 86°F (30°C). Replace the pen cap after each use to protect from light.

Discard pen 14 days after first use.

Always remove the needle after each injection and store the Soliqua 100/33 pen without a needle attached. This prevents contamination and/or infection, or leakage of the Soliqua 100/33 pen, and will ensure accurate dosing. Always use a new needle for each injection to prevent contamination.

Soliqua 100/33 is manufactured by sanofi-aventis.

Exondys 51

Indications and Usage

Exondys 51 is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping. This indication is approved under accelerated approval based on an increase in dystrophin in skeletal muscle observed in some patients treated with Exondys 51. A clinical benefit of Exondys 51 has not been established. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.

Dosage and Administration

Dosing Information

The recommended dose of Exondys 51 is 30 milligrams per kilogram administered once weekly as a 35 to 60 minute intravenous infusion.

If a dose of Exondys 51 is missed, it may be administered as soon as possible after the scheduled time.

Preparation Instructions

Exondys 51 is supplied in single-dose vials as a preservative-free concentrated solution that requires dilution prior to administration. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Use aseptic technique.

a. Calculate the total dose of Exondys 51 to be administered based on the patient's weight and the recommended dose of 30 milligrams per kilogram. Determine the volume of Exondys 51 needed and the correct number of vials to supply the full calculated dose.
b. Allow vials to warm to room temperature. Mix the contents of each vial by gently inverting 2 or 3 times. Do not shake.
c. Visually inspect each vial of Exondys 51. Exondys 51 is a clear, colorless solution that may have some opalescence. Do not use if the solution in the vials is discolored or particulate matter is present.
d. With a syringe fitted with a 21-gauge or smaller non-coring needle, withdraw the calculated volume of Exondys 51 from the appropriate number of vials.
e. Dilute the withdrawn Exondys 51 in 0.9% Sodium Chloride Injection, USP, to make a total volume of 100-150 mL. Visually inspect the diluted solution for particulates.
f. Exondys 51 contains no preservatives and should be administered immediately after dilution. Complete infusion of diluted Exondys 51 solution within 4 hours of dilution. If immediate use is not possible, the diluted solution may be stored for up to 4 hours at 2°C to 8°C (36°F to 46°F). Do not freeze. Discard unused Exondys 51.

Administration Instructions

Application of a topical anesthetic cream to the infusion site prior to administration of Exondys 51 may be considered.

Exondys 51 is administered via intravenous infusion. Flush the intravenous access line with 0.9% Sodium Chloride Injection, USP, prior to and after infusion.

Infuse the diluted Exondys 51 solution over 35 to 60 minutes. Do not mix other medications with Exondys 51 or infuse other medications concomitantly via the same intravenous access line.

Dosage Forms and Strengths

Exondys 51 is a clear and colorless solution that may have some opalescence, and is available as follows:

- Injection: 100 mg/2 mL (50 mg/mL) solution in a single-dose vial
- Injection: 500 mg/10 mL (50 mg/mL) solution in a single-dose vial

Contraindications

None.

Adverse Reactions

Clinical Trials Experience

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

In the Exondys 51 clinical development program, 107 patients received at least one intravenous dose of Exondys 51, ranging between 0.5 mg/kg (0.017 times the recommended dosage) and 50 mg/kg (1.7 times the recommended dosage). All patients were male and had genetically confirmed Duchenne muscular dystrophy. Age at study entry was 4 to 19 years. Most (89%) patients were Caucasian.

Exondys 51 was studied in a double-blind, placebo-controlled study for 24 weeks (Study 1), followed by an open-label extension (Study 2). In Study 1, 12 patients were randomized to receive weekly intravenous infusions of Exondys 51 (n=8) or placebo (n=4) for 24 weeks.

All 12 patients continued in Study 2 and received open-label Exondys 51 weekly for up to 208 weeks.

In Study 1, 4 patients received placebo, 4 patients received Exondys 51 30 mg/kg, and 4 patients received Exondys 51 50 mg/kg (1.7 times the recommended dosage). In Study 2, 6 patients received Exondys 51 30 mg/kg/week and 6 patients received Exondys 51 50 mg/kg/week.

Adverse reactions that occurred in 2 or more patients who received Exondys 51 and were more frequent than in the placebo group in Study 1 are presented in Table 1 (the 30 and 50 mg/kg groups are pooled). Because of the small numbers of patients, these represent crude frequencies that may not reflect the frequencies observed in practice. The 50 mg/kg once weekly dosing regimen of Exondys 51 is not recommended [see Dosage and Administration (2.1)].

The most common adverse reactions were balance disorder and vomiting.

In the 88 patients who received ≥30 mg/kg/week of Exondys 51 for up to 208 weeks in clinical studies, the following events were reported in ≥10% of patients and occurred more frequently than on the same dose in Study 1: vomiting, contusion, excoriation, arthralgia, rash, catheter site pain, and upper respiratory tract infection. There have been reports of transient erythema, facial flushing, and elevated temperature occurring on days of Exondys 51 infusion.

Use in Specific Populations

Pregnancy

There are no human or animal data available to assess the use of Exondys 51 during pregnancy. In the U.S. general population, major birth defects occur in 2% to 4% and miscarriage occurs in 15% to 20% of clinically recognized pregnancies.

Lactation

There are no human or animal data to assess the effect of Exondys 51 on milk production, the presence of eteplirsen in milk, or the effects of Exondys 51 on the breastfed infant.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Exondys 51 and any potential adverse effects on the breastfed infant from Exondys 51 or from the underlying maternal condition.

Pediatric Use

Exondys 51 is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping, including pediatric patients

Intravenous administration of eteplirsen (0, 100, 300, or 900 mg/kg) to juvenile male rats once weekly for 10 weeks beginning on postnatal day 14 resulted in renal tubular necrosis at the highest dose tested and decreased bone densitometry parameters (mineral density, mineral content, area) at all doses. The kidney findings were associated with clinical pathology changes (increased serum urea nitrogen and creatinine, decreased urine creatinine clearance). No effects were observed on the male reproductive system, neurobehavioral development, or immune function. An overall no-effect dose was not identified. Plasma eteplirsen exposure (AUC) at the lowest dose tested (100 mg/kg) was similar to that in humans at the recommended human dose (30 mg/kg).

Geriatric Use

DMD is largely a disease of children and young adults; therefore, there is no geriatric experience with Exondys 51.

Patients with Renal or Hepatic Impairment

Exondys 51 has not been studied in patients with renal or hepatic impairment.

Clinical Studies

Exondys 51 was evaluated in three clinical studies in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping.

In Study 1, patients were randomized to receive weekly infusions of Exondys 51 (30 mg/kg, n=4); Exondys 51 (50 mg/kg, n=4), or placebo (n=4) for 24 weeks. The primary endpoint was dystrophin production; a clinical outcome measure, the 6-minute walk test (6MWT), was also assessed. The 6MWT measures the distance that a patient can walk on a flat, hard surface in a period of 6 minutes. Patients had a mean age of 9.4 years, a mean 6-minute walk distance (6MWD) at baseline of 363 meters, and were on a stable dose of corticosteroids for at least 6 months. There was no significant difference in change in 6MWD between patients treated with Exondys 51 and those treated with placebo.

All 12 patients who participated in Study 1 continued treatment with open-label Exondys 51 weekly for an additional 4 years in Study 2. The 4 patients who had been randomized to placebo were re-randomized 1:1 to Exondys 30 or 50 mg/kg/week such that there were 6 patients on each dose. Patients who participated in Study 2 were compared to an external control group. The primary clinical efficacy outcome measure was the 6MWT. Eleven patients in Study 2 had a muscle biopsy after 180 weeks of treatment with Exondys 51, which was analyzed for dystrophin protein level by Western blot. Study 2 failed to provide evidence of a clinical benefit of Exondys 51 compared to the external control group. The average dystrophin protein level after 180 weeks of treatment with Exondys 51 was 0.93% of the dystrophin level in healthy subjects. Because of insufficient information on dystrophin protein levels before treatment with Exondys 51 in Study 1, it is not possible to estimate dystrophin production in response to Exondys 51 in Study 1.

In Study 3, 13 patients were treated with open-label Exondys 51 (30 mg/kg) weekly for 48 weeks and had a muscle biopsy at baseline and after 48 weeks of treatment. Patients had a mean age of 8.9 years and were on a stable dose of corticosteroids for at least 6 months. Dystrophin levels in muscle tissue were assessed

continues on page 30

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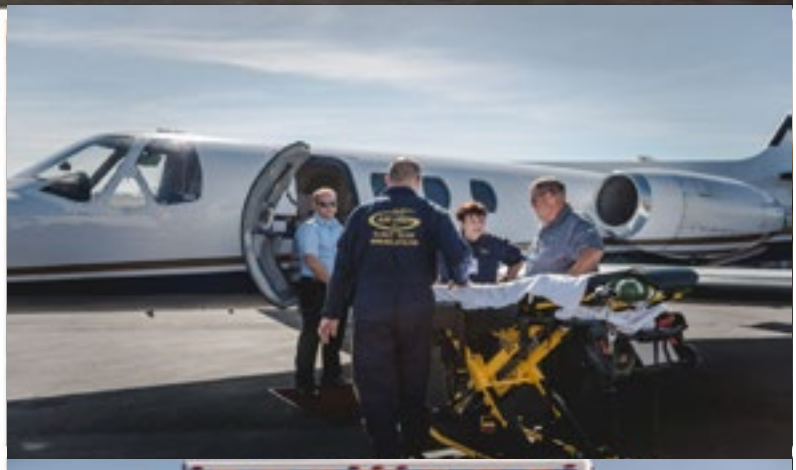

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Circulation. 2016 Nov 23. pii: CIRCULATIONAHA.116.023361. [Epub ahead of print]

Heart failure stages among older adults in the community: the Atherosclerosis Risk in Communities Study.

Shah AM, Claggett B, Loehr LR, et al.

BACKGROUND: Although HF disproportionately affects older adults, little data exist regarding the prevalence of American College of Cardiology/American Heart Association heart failure (HF) stages among older individuals in the community. Additionally, the role of contemporary measures of longitudinal strain (LS) and diastolic dysfunction in defining HF stages is unclear. METHODS: HF stages were classified in 6,118 participants in the Atherosclerosis Risk in Communities study (age 67 - 91 years) at the fifth study visit as follows: stage A (asymptomatic with HF risk factors but no cardiac structural or functional abnormalities), B (asymptomatic with structural abnormalities, defined as left ventricular hypertrophy, dilation or dysfunction, or significant valvular disease), C1 (clinical HF without prior hospitalization), and C2 (clinical HF with prior hospitalization). RESULTS: Using the traditional definitions of HF stages, only 5% of examined participants were free of HF risk factors or structural heart disease (Stage 0), 52% were categorized as Stage A, 30% Stage B, 7% Stage C1, and 6% Stage C2. Worse HF stage was associated with a greater risk of incident HF hospitalization or death at a median follow-up of 608 days. LVEF was preserved in 77% and 65% in Stages C1 and C2 respectively. Incorporation of LS and diastolic dysfunction into the Stage B definition reclassified 14% of the sample from Stage A to B and improved the net reclassification index (p=0.028) and integrated discrimination index (p=0.016). Abnormal LV structure, systolic function (based on LVEF and LS), and diastolic function (based on e', E/e', and left atrial volume index) were each independently and additively associated with risk of incident HF hospitalization or death in Stage A and B participants. CONCLUSIONS: The majority of older adults in the community are at risk for HF (Stages A or B), appreciably more compared to previous reports in younger community-based samples. LVEF is robustly preserved in at least two-thirds of older adults with prevalent HF (Stage C), highlighting the burden of HFpEF in the elderly. LV diastolic function and LS provide incremental prognostic value beyond conventional measures of LV structure and LVEF in identifying persons at risk for HF hospitalization or death.

AIDS Res Hum Retroviruses. 2016 Nov 21. [Epub ahead of print]

Lower frailty is associated with successful cognitive aging among older adults with HIV.

Wallace LM, Ferrara M, Brothers TD, et al.

BACKGROUND: Aging with HIV poses unique and complex challenges, including avoidance of neurocognitive disorder. Our objective here is to identify the prevalence and predictors of successful cognitive aging (SCA) in sample of older adults with HIV. METHODS: One hundred three HIV-infected individuals aged 50 and older were recruited from the Modena HIV Metabolic Clinic in Italy. Participants were treated with combination antiretroviral therapy (cART) for at least one year and had suppressed plasma HIV viral load. SCA was defined as the absence of neurocognitive impairment (as defined by deficits in tasks of episodic learning, information processing speed, executive function, and motor skills) depression, and functional impairment (instrumental activities of daily living). In cross-sectional analyses odds of SCA were assessed in relation to HIV-related clinical data, HIV-Associated Non-AIDS (HANA) conditions, multimorbidity (≥2 HANA conditions), and frailty. A frailty index was calculated as the number of deficits present out of 37 health variables. RESULTS: SCA was identified in 38.8% of participants. Despite no differences in average chronologic age between groups, SCA participants had significantly fewer HANA conditions, a lower frailty index, and were less likely to have hypertension. Additionally, hypertension (OR=0.40, p=0.04), multimorbidity (OR=0.35, p=0.05), and frailty (OR=0.64, p=0.04 were significantly associated with odds of SCA. CONCLUSIONS: Frailty is associated with the likelihood of successful cognitive aging in people living with HIV. This defines an opportunity to apply knowledge from geriatric population research to people aging with HIV to better appreciate the complexity of their health status.

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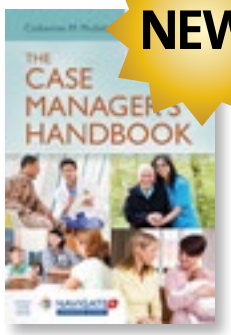

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HIV Med. 2016 Nov 9. doi: 10.1111/hiv.12442. [Epub ahead of print]

Alcohol and dietary factors associate with gut integrity and inflammation in HIV-infected adults.

Webel AR, Sattar A, Funderburg NT, et al.

OBJECTIVES: HIV-infected adults have heightened monocyte activation and inflammation, at least partially as a consequence of altered gut integrity. The role of dietary factors in microbial translocation and inflammation and their downstream effect on markers of cardiovascular disease (CVD) have not been explored. Our purpose was to describe the longitudinal dietary patterns of HIV-infected adults, and to examine the relationship between dietary intake, gut integrity, inflammation and subclinical markers of CVD in HIV-infected adults. METHODS: We conducted a secondary analysis of 147 HIV-infected participants in a 96-week randomized clinical trial of rosuvastatin as primary CVD prevention. Dietary intake was assessed using dietary recall; plasma gut integrity, monocyte activation and inflammation markers were measured using an enzyme-linked immunosorbent assay (ELISA); and CVD risk was assessed using carotid ultrasound and the coronary artery calcium score. Linear mixed models were used to analyse longitudinally measured biomarkers. RESULTS: The median age was 45 years and 78% of patients were male. At baseline, participants consumed a mean (standard deviation) of 108 (70) g of fat daily, 19 (15.6) g of fibre, 266 (186) g of carbohydrates and 15.6 (5.9) g of protein; 45% of the sample consumed alcohol. Over time, alcohol consumption was associated with several markers of gut integrity and inflammation (all $P < 0.05$). CONCLUSIONS: HIV-infected adults in a contemporary, high-resource setting have poor dietary patterns. Alcohol use was associated with worse gut integrity and increased inflammation, while other aspects of diet (fibre, carbohydrates and fat) were not. These data add to growing evidence illustrating the need for a better understanding of the effect of lifestyle factors on comorbidities in HIV-infected adults.

J Am Soc Hypertens. 2016 Oct 28. pii: S1933-1711(16)30549-6. doi: 10.1016/j.jash.2016.10.005. [Epub ahead of print]

Total antihypertensive therapeutic intensity score and its relationship to blood pressure reduction.

Levy PD, Willock RJ, Burla M, et al.

Predicting blood pressure (BP) response to antihypertensive therapy is challenging. The therapeutic intensity score (TIS) is a summary measure that accounts for the number of medications and the relative doses a patient received, but its relationship to BP change and its utility as a method to project dosing equivalence has not been reported. We conducted a prospective, single center, randomized controlled trial to compare the effects of Joint National Committee (JNC) 7 compliant treatment with more intensive (<120/80 mm Hg) BP goals on left ventricular structure and function in hypertensive patients with echocardiographically determined subclinical heart disease who were treated over a 12-month period. For this preplanned subanalysis, we sought to compare changes in BP over time with changes in TIS. Antihypertensive therapy was open label. TIS and BP were determined at 3-month intervals with titration of medication doses as needed to achieve targeted BP. Mixed linear models defined antihypertensive medication TIS as an independent variable and change in systolic BP as an outcome measure, while controlling for gender, age, baseline BP, and treatment group. A total of 123 patients (mean age 49.4 ± 8.2 years; 66% female; 95.1% African-American) were enrolled and 88 completed the protocol. For each single point increase in total antihypertensive TIS, a 14.5 (95% confidence interval: 11.5, 17.4) mm Hg decrease in systolic BP was noted (15.5 [95% confidence interval: 13.0, 18.0] mm Hg for those who completed the trial). Total TIS is a viable indicator of the anticipated BP-lowering effect associated with antihypertensive therapy.

BMC Gastroenterol. 2016;16(1):137.

Long-term outcomes of liver transplantation in patients with hepatitis C infection are not affected by HCV positivity of a donor.

Stepanova M, Sayiner M, de Avila L, Younoszai Z, Racila A, Younossi ZM.

BACKGROUND: The use of HCV-positive livers for HCV-positive recipients is becoming more common. Our aim is to evaluate long-term outcomes in liver transplant recipients transplanted with HCV antibody-positive organs. METHODS: From the Scientific Registry of Transplant Recipients (1995-2013), we selected all adult liver transplant recipients with HCV, and cross-sectionally compared long-term graft loss and mortality rates between those who were transplanted from HCV antibody-positive (HCV+) vs. HCV antibody-negative donors. RESULTS: We included 33,668 HCV+ liver transplant recipients (54.0 ± 7.7 years old, 74.1% male, 71.0% white, 23.6% with liver malignancy). Of those, 5.7% (N = 1930) were transplanted from HCV+ donors; the proportion gradually increased from 2.9% in 1995 to 9.4% in 2013. Patients who were transplanted from HCV+ positive donors were more likely to be discharged alive after transplantation (95.4% vs. 93.9%, p = 0.006), but this difference was completely

accounted for by a greater proportion of HCV+ donors in more recent study years (p = 0.10 after adjustment for the transplant year). After transplantation, both mortality in HCV patients transplanted from HCV+ donors (12.5% in 1 year, 24.2% in 3 years, 33.0% in 5 years) and the graft loss rate (2.2% in 1 year, 4.8% in 3 years, 7.5% in 5 years) were similar to those in HCV patients transplanted from HCV-negative donors (all p > 0.05). CONCLUSIONS: Over the past two decades, the use of HCV+ organs for liver transplantation has tripled. Despite this, the long-term outcomes of HCV+ liver transplant recipients transplanted from HCV+ donors were not different from those who were transplanted with HCV-negative organs.

Am J Kidney Dis. 2016 Nov 20. pii: S0272-6386(16)30556-X. doi: 10.1053/j.ajkd.2016.08.038. [Epub ahead of print]

Referral for kidney transplantation and indicators of quality of dialysis care: a cross-sectional study.

Plantinga LC, Pastan SO, Wilk AS, et al.

BACKGROUND: Dialysis facility performance measures to improve access to kidney transplantation are being considered. Referral of patients for kidney transplantation evaluation by the dialysis facility is one potential indicator, but limited data exist to evaluate whether referral is associated with existing dialysis facility quality indicators. STUDY DESIGN: Cross-sectional study. SETTING & PARTICIPANTS: 12,926 incident (July 2005 to September 2011) adult (aged 18-69 years) patients treated at 241 dialysis facilities with complete quality indicator information from US national registry data linked to transplantation referral data from all 3 Georgia kidney transplantation centers. FACTORS: Facility performance on dialysis quality indicators (high, intermediate, and low tertiles). OUTCOME: Percentages of patients referred within 1 year of dialysis therapy initiation at dialysis facility. RESULTS: Overall, a median of 25.4% of patients were referred for kidney transplantation within 1 year of dialysis therapy initiation. Higher facility-level referral was associated with better performance with respect to standardized transplantation ratio (high, 28.6%; intermediate, 25.1%; and low, 22.9%; P=0.001) and percentage waitlisted (high, 30.7%; intermediate, 26.8%; and low, 19.2%; P<0.001). Facility-level referral was not associated with indicators of quality of care associated with dialysis therapy initiation, including percentage of incident patients being informed of transplantation options. For most non-transplantation-related indicators of high-quality care, including those capturing mortality, morbidity, and anemia management, better performance was not associated with higher facility-level transplantation referral. LIMITATIONS: Potential ecologic fallacy and residual confounding. CONCLUSIONS: Transplantation referral among patients at dialysis facilities does not appear to be associated with overall quality of dialysis care at the facility. Quality indicators related to kidney transplantation were positively associated with, but not entirely correspondent with, higher percentages of patients referred for kidney transplantation evaluation from dialysis facilities. These results suggest that facility-level referral, which is within the control of the dialysis facility, may provide information about the quality of dialysis care beyond current indicators.

Cancer. 2016 Nov 22. doi: 10.1002/cncr.30424. [Epub ahead of print]

Clinical and genetic determinants of ovarian metastases from colorectal cancer.

Ganesh K, Shah RH, Vakiani E, et al.

BACKGROUND: Ovarian metastases from colorectal cancer (OM-CRC) often are unresponsive to chemotherapy and are associated with poor survival. To the authors' knowledge, the clinicopathologic and genomic predictors of OM-CRC are poorly characterized and optimal clinical management remains unclear. METHODS: Women with a histopathological diagnosis of OM-CRC who were treated at Memorial Sloan Kettering Cancer Center from 1999 to 2015 were identified. Next-generation somatic mutation profiling (Memorial Sloan Kettering-Integrated Mutation Profiling of Actionable Cancer Targets [MSK-IMPACT]) was performed on 38 OM-CRC cases, including 21 matched tumor pairs/trios. Regression models were used to analyze variables associated with progression-free survival and overall survival (OS). RESULTS: Kirsten Rat Sarcoma Viral Oncogene Homolog (KRAS), SMAD family member 4 (SMAD4), and neurotrophic receptor tyrosine kinase 1 (NTRK1) mutations were more frequent in cases of OM-CRC than in instances of CRC occurring without OM. SMAD4 and lysine methyltransferase 2D (KMT2D) mutations were associated with reduced OS. Matched multisite tumor sequencing did not identify OM-specific genomic alterations. Of the 195 patients who underwent oophorectomy for OM-CRC (median age, 49 years with a progression-free survival of 9.4 months and an OS of 23 months from oophorectomy), 76% had extraovarian metastasis (EOM). In multivariable analysis, residual disease after surgery (R2 resection) was associated with worse survival. Patients with EOM were less likely to achieve R0/R1 surgical resection status (complete macroscopic resection without clinical/radiological evidence of disease) (48% vs 94%). However, if R0/R1 resection status was achieved, both patients with (35.9 months vs 12 months) and without (43.2 months vs 14.5 months)

EOM were found to have better OS. Among 114 patients with R0/R1 resection status, 23 (20%) had no disease recurrence, including 10 patients (9%) with > 3 years of follow-up. CONCLUSIONS: Loss-of-function alterations in SMAD4 are frequent and predictive of worse survival in patients with OM-CRC. Similar to oligometastatic CRC to the lung or liver, surgical resection of OM-CRC is associated with a better outcome only if all macroscopic metastatic disease is resected.

BMJ. 2016;355:i5719. doi: 10.1136/bmj.i5719.

Management of mild hypertension in adults.

Viera AJ, Hawes EM.

Elevated blood pressure is a common risk factor for cardiovascular disease and affects one in three adults. Blood pressure lowering drugs substantially reduce the risk of stroke, coronary heart disease, heart failure, and premature death, but most clinical trials showing benefits have primarily included patients with moderate to severe hypertension, known cardiovascular disease, or elevated risk of cardiovascular disease. The benefits of treating mild hypertension in patients without cardiovascular disease are less clear, but recent meta-analyses offer some insights. Pooled data from trials that include a large percentage of participants with mild hypertension show significant reductions in stroke, death from cardiovascular disease, and total mortality. Meta-analyses comparing lower blood pressure targets also suggest a benefit of treating patients with mild hypertension, although net benefits are greater for patients at higher absolute levels of cardiovascular disease risk. Before starting drug treatment, most patients should have out-of-office monitoring to confirm hypertension. Lifestyle modifications for reducing blood pressure are appropriate for all patients and may be recommended while delaying drug treatment for those at lower absolute levels of cardiovascular disease risk. Patient level control of blood pressure is supported by home monitoring and by once daily, low cost drug. Control of blood pressure for a population of patients is enhanced by system level interventions such as registries, implementation of evidence based protocols, drug titration visits, and performance metrics.

Transplantation. 2016;100(12):2640-2647.

Improving national results in liver transplantation using grafts from donation after cardiac death donors.

Croome KP, Lee DD, Keaveny AP, Taner CB.

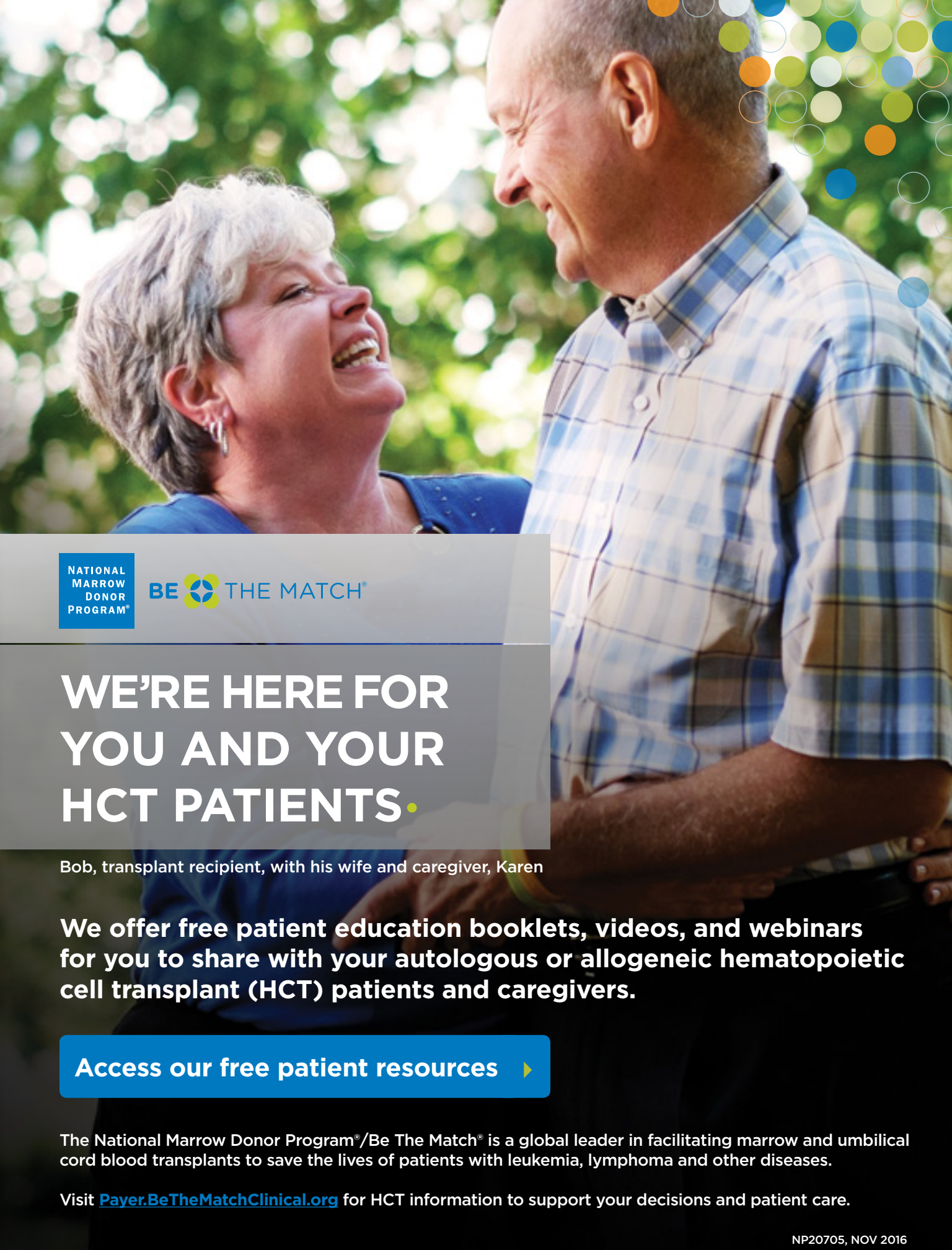
BACKGROUND: Published reports describing the national experience with liver grafts from donation after cardiac death (DCD) donors have resulted in reservations with their widespread utilization. The present study aimed to investigate if temporal improvements in outcomes have been observed on a national level and to determine if donor and recipient selection have been modified in a fashion consistent with published data on DCD use in liver transplantation (LT). METHODS: Patients undergoing DCD LT between 2003 and 2014 were obtained from the United Network of Organ Sharing Standard Transplant Analysis and Research file and divided into 3 equal eras based on the date of DCD LT: era 1 (2003-2006), era 2 (2007-2010), and era 3 (2011-2014). RESULTS: Improvement in graft survival was seen between era 1 and era 2 (P = 0.001) and between era 2 and era 3 (P < 0.001). Concurrently, an increase in the proportion of patients with hepatocellular carcinoma and a decrease in critically ill patients, retransplant recipients, donor age, warm ischemia time greater than 30 minutes and cold ischemic time also occurred over the same period. On multivariate analysis, significant predictors of graft survival included: recipient age, biologic MELD score, recipient on ventilator, recipient hepatitis C virus + serology, donor age and cold ischemic time. In addition, even after adjustment for all of the aforementioned variables, both era 2 (hazard ratio, 0.81; confidence interval, 0.69-0.94; P = 0.007), and era 3 (hazard ratio, 0.61; confidence interval, 0.5-0.73; P < 0.001) had a protective effect compared to era 1. CONCLUSIONS: The national outcomes for DCD LT have improved over the last 12 years. This change was associated with modifications in both recipient and donor selection. Furthermore, an era effect was observed, even after adjustment for all recipient and donor variables on multivariate analysis.

Ann Rheum Dis. 2016 Nov 11. pii: annrheumdis-2016-209954. doi: 10.1136/annrheumdis-2016-209954. [Epub ahead of print]

Risk of diabetes mellitus associated with disease-modifying antirheumatic drugs and statins in rheumatoid arthritis.

Ozen G, Pedro S, Holmqvist ME, Avery M, Wolfe F, Michaud K.

OBJECTIVE: To investigate the rate of incident diabetes mellitus (DM) in patients with rheumatoid arthritis (RA) and the impact of disease-modifying antirheumatic drug (DMARD) and statin treatments. METHODS: We studied patients with RA and ≥1 year participation in the National Data Bank for Rheumatic Diseases without baseline DM from 2000 through 2014. DM was determined by self-report or initiating DM medication. DMARDs were categorised into four mutually exclusive groups: (1) methotrexate monotherapy (reference); (2) any abatacept with or without synthetic DMARDs (3) any other DMARDs with methotrexate; (4) all other DMARDs without methotrexate; along with separate statin, glucocorticoid and hydroxychloroquine (yes/no) variables.



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NP20705, NOV 2016

HIV/AIDS: Thoughts on the Pandemic *continued from page 2*

diagnoses dropped steadily, declining 18% overall.

- Among Hispanic/Latino gay and bisexual men, diagnoses rose by 24%.
- Although diagnoses among African American gay and bisexual men increased 22%, they have leveled off in the past 5 years, increasing less than 1% since 2010.
- Young African American gay and bisexual men (aged 13 to 24) experienced an 87% increase in diagnoses. But since 2010, diagnoses have declined 2%.
- Diagnoses among all women declined 40%, and among African American women, diagnoses declined 42%.
- Among all heterosexuals, diagnoses declined 35%, and among people who inject drugs, diagnoses declined 63%.

Heterosexuals and people who inject drugs also continue to be affected by HIV. In 2015:

- Heterosexual contact accounted for 24% (9,339) of HIV diagnoses.
- Women accounted for 19% (7,402) of HIV diagnoses. Diagnoses among women are primarily attributed to heterosexual contact (86%, or 6,391) or injection drug use (13%, or 980).
- Six percent (2,392) of HIV diagnoses in the United States were attributed to injection drug use (IDU) and another 3% (1,202) to male-to-male sexual contact and IDU.

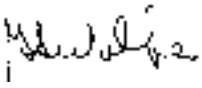
African Americans continue to experience the greatest burden of HIV compared to other races and ethnicities. Hispanics/Latinos are also disproportionately affected by HIV. In 2015:

- African Americans represented 12% of the US population, but accounted for 45% (17,670) of HIV diagnoses.
- Hispanics/Latinos represented about 18% of the US population, but accounted for 24% (9,290) of HIV diagnoses.

Where you live can impact your risk of becoming infected with HIV. On average, the risk of becoming infected with HIV is 1 in 99. However, the risk is greater is you live in the South and along the East Coast. The 10 top cities with the highest new infection rates are: Baton Rouge, LA (44.7 people per 100,000); Miami, FL (42.8); New Orleans, LA (36.9); Jackson, MS (32.2); Orlando, FL (28.8); Memphis, TN (27.6); Atlanta, GA (25.9); Columbia, SC (25.6); Jacksonville, FL (25.1); Baltimore, MD (24.3).

I commemorate the lives lost and communities devastated by HIV/AIDS. I also celebrate those lives that have been saved and the courageous individuals who have brought hope and healing to those living with and affected by this disease. But the work is not done. The efforts bring hope that an end to the HIV/AIDS pandemic is achievable.

Education and testing is the key. What are you doing to end this pandemic?



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ACCM: Improving Case Management Practice through Education

Supporting Millennials in the Workforce *continued from page 8*

employee's stress. If the root cause is a conflict between the employee and his/her boss or with co-workers, this is a human resources issue that should be addressed as such. Often these matters can be resolved by providing training, education, and other resources to both the employee and manager on how to communicate with each other, manage work and delivery expectations, and reinforce the overall culture of the organization. But if the underlying issue is some variation of work/life stress, CDMSs can be instrumental in helping employees, and in particular Millennials, to access the appropriate programs, such as an EAP.

The objective is to help employees, regardless of their roles in the organization, learn new skills to help them manage stress and cope with the fluidity and complexity of today's work/life integration. For Millennials experiencing stress, these skills can help them remain productive, engaged, and connected with others—now and in the future. CM

PharmaFacts for Case Managers

continued from page 22

by Western blot. In the 12 patients with evaluable results, the pre-treatment dystrophin level was 0.16% ± 0.12% (mean ± standard deviation) of the dystrophin level in a healthy subject and 0.44% ± 0.43% after 48 weeks of treatment with Exondys 51 ($p < 0.05$). The median increase after 48 weeks was 0.1%.

How Supplied/Storage and Handling

Exondys 51 injection is supplied in single-dose vials. The solution is clear and colorless, and may have some opalescence.

- Single-dose vials containing 100 mg/2 mL (50 mg/mL) eteplirsen
- Single-dose vials containing 500 mg/10 mL (50 mg/mL) eteplirsen

Store Exondys 51 at 2°C to 8°C (36°F to 46°F). Do not freeze. Protect from light and store Exondys 51 in the original carton until ready for use.

Exondys 51 is manufactured for Sarepta Therapeutics, Inc., Cambridge, MA

REUTERS POLL SAYS AMERICANS WANT TRUMP TO FOCUS ON HEALTH CARE FIRST

The poll was conducted online from November 9 to 14, 2016 and responded to by 1,782 American adults. Twenty-one percent of Americans indicate that health care is the first priority over jobs (at 16%) and immigration at (14%). The Washington Post published an FAQ about potential changes to health care under a Trump administration.

HEALTH CARE HACKERS WORKING OVERTIME

According to research by the Healthcare Information and Management Systems Society (HIMSS), 39 providers and payers have spent nearly $52.5 million in court settlement payments for privacy and security violations under HIPPA since 2008. In 2016, more than 86 hacking incidents that affected more than 11 million individuals were reported. HIMSS is calling for the creation of a national chief information security officer.

Help Patients Learn About Medicare's New Rules

Kaiser Health News has published a Consumer's Guide to Medicare's New Rules on Doctor Pay that can be share with patients so they better understand the quality initiatives that will guide payments to doctors under Medicare

CMS Makes Sharing Data for Quality Payment Program Easier

A new web-based tool allows clinicians to automatically share electronic data for the Medicare Quality Payment Program. The application program interface (API) is publicly available.

BEST HOSPITAL IT DEPARTMENTS

HealthcareITNews has published a report on hospitals that are excelling in technologies from chatbots that mine social media to wearables to trendy tools like sensing devices, speech recognition, and virtual visits.

Do Viruses Target Men and Women Differently?

New research from Royal Holloway University, published today in Nature Communications, has shown that viral infections can evolve to affect men and women differently and become more virulent in men.

Researchers from the School of Biological Sciences at Royal Holloway looked at the virus HTLV-1, which can cause leukaemia in infected individuals. Infected women tend to develop leukaemia less often than men when there is more mother-to-child transmission. Mortality due to infectious diseases is often higher among men than women, but this has historically been attributed to differences in the immune system of each sex.

"It has already been established that men and women react to illness differently, but evidence shows that viruses themselves have evolved to affect the sexes differently. Viruses may be evolving to be less dangerous to women, looking to preserve the female population. The reason why these illnesses are less virulent in women is that the virus wants to be passed from mother to child, either through breastfeeding, or just through giving birth," stated researchers. Read the full paper, The Evolution of Sex-specific Virulence in Infectious Diseases.

Racial Disparities Continue in Breast Cancer Mortality Rates

Despite declining death rates for breast cancer patients across the board (1.9% decline from 2010 to 2014), older black women are more likely to die of breast cancer than white women. Both black and white women have the same risk, but black women are 41% more likely to die of the disease. The Centers for Disease Prevention and Control (CDC) cites calorie-dense foods, lack of exercise, and increasing obesity rates as possible reasons. Access to care continues to be a major factor: 40% to 50% of black women get less than optimal care for breast cancer, including mammography screening and treatment.

BILINGUAL NURSES IMPROVE PATIENT SAFETY

The demand for nurses who are bilingual is increasing as at least 21% of the US population speaks a language other than English. Misunderstandings in the delivery of health care information abounds among those with low literacy and those whose native language is not English. One organization, the nonprofit Chicago Bilingual Nurse Consortium, is working to bridge the gap by helping foreign-born nurses become licenses. At South Mountain Community College in Arizona, the Bilingual Nursing Fellowship Program supports bilingual students who are in danger of dropping out of nursing school to help boost the workforce.

New PhD Program in Healthcare Quality and Safety

Northwestern Universy Feinberg School of Medicine in Chicago, Illinois, has started a doctoral program for senior and mid-career clinicians and others working in health care.

IBM MERA To Help Aging Population

IBM and Rice University are developing a robot called IBM MERA, a prototype multi-purpose eldercare robot, to help aging populations. The robot is a Watson-enabled application designed to help the elderly and their caregivers. IBM Research also has plans to work with Sole Cooperativa, an independent healthcare provider in Italy, to equip senior housing with sensors to monitor day-to-day activities of its residents.

The IBM MERA prototype was created with students and faculty from Rice University's departments of Electrical and Computer Engineering and Psychology. It will be used to help study innovative ways of measuring an individual's vital signs, such as heart rate, heart rate variability and respiratory rate; answer basic health-related questions; and determine if an individual has fallen by reading the results of an accelerometer.

State of Predictive Analytics in US Healthcare

Results of a roundtable discussion on predictive analytics, held in Philadelphia in August 2016 is available for download.

Doctors' Medicare Prescribing Costs Fueled by Hepatitis C Drugs

The number of presribers who edged over the $5 million mark for prescriptions increased tenfold from 41 in 2011 to 514 in 2015. Those exceeding $10 million in drug prescription costs went from 2 to 70 in the same time period. At the top of the spending list were Harvoni or Sovaldi, drugs to cure hepatitis C. Other pricey drugs to treat cancer, multiple sclerosis, and rheumatoid arthritis were high on the list.

DECLINE IN DEMENTIA PREVALENCE

A new study finds that the prevalence of dementia has fallen sharply in recent years, most likely as a result of Americans' rising educational levels and better heart health, which are both closely related to brain health.

Dementia rates in people over age 65 fell from 11.6 percent in 2000 to 8.8 percent in 2012, a decline of 24 percent, according to a study of more than 21,000 people across the country published Monday in *JAMA Internal Medicine*.

Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health

The Surgeon General has released his report, which outlines, in part, the growing epidemic of opioid addiction in the US.

Facing Addiction co-founder Greg Williams penned this *Huffington Post* blog. A guide on conversation about the epidemic has been published as has a video of the Surgeon General and friends discussing the problem.

Alleviating Loneliness Aids Recovery in Hospitalized Older Patients

An NPR report shows that loneliness can be a problem for older people, especially when they're in the hospital. Their children may have moved away. Spouses and friends may themselves be too frail to visit. So a California hospital is providing volunteer companions in the geriatric unit.

Loneliness is a legitimate medical issue. There are a number of studies linking loneliness and social isolation in old people to poorer health and earlier death, including one published earlier in *JAMA Psychiatry* associating loneliness, social isolation, and brain changes typical in Alzheimer's.

Potential Therapy for Brain Swelling During Concussion

A team of biomedical engineering researchers at the University of Arkansas have identified a cause of fluid swelling of the brain, or cellular edema, that occurs during a concussion.

The researchers discovered that pre-treating the cells with an existing, FDA-approved drug used for epilepsy and altitude sickness reduces the expression of a specific protein that causes swelling.

Their findings were published in a recent issue of *Nature's Scientific Reports*.

"Our study found that mild traumatic brain injury resulted in increased expression of a protein called aquaporin-4, which caused a massive cellular influx of fluid, leading to increased astrocyte cell volume and injury," said Kartik Balachandran, assistant professor of biomedical engineering. "We then worked with a drug called acetazolamide. Our results showed that acetazolamide minimized cell swelling and injury, suggesting a therapeutic role for this drug in reducing the detrimental effects of concussions." ■

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LITSCAN FOR CASE MANAGERS

continued from page 24

Time-varying Cox proportional hazard models were used to adjust for age, sex, socioeconomic status, comorbidities, body mass index and RA severity measures. RESULTS: During a median (IQR) 4.6 (2.5-8.8) years of follow-up in 13 669 patients with RA, 1139 incident DM cases were observed. The standardised incidence ratio (95% CI) of DM in patients with RA (1.37, (1.29 to 1.45)) was increased compared with US adult population. Adjusted HR (95% CI) for DM were 0.67 (0.57 to 0.80) for hydroxychloroquine, 0.52 (0.31 to 0.89) for abatacept (compared with methotrexate monotherapy), 1.31 (1.15 to 1.49) for glucocorticoids and 1.56 (1.36 to 1.78) for statins. Other synthetic/biological DMARDs were not associated with any risk change. Concomitant use of glucocorticoids did not alter DM risk reduction with hydroxychloroquine (HR 0.69 (0.51 to 0.93)). CONCLUSIONS: In RA, incidence of DM is increased. Hydroxychloroquine and abatacept were associated with decreased risk of DM, and glucocorticoids and statins with increased risk.

Allergy. 2016 Nov 22. doi: 10.1111/all.13090. [Epub ahead of print]

The burden of non-adherence among adults with asthma: A role for shared decision making.

Pollard S, Bansback N, FitzGerld JM, Bryan S.

A shared approach to decision making framework has been suggested for chronic disease management especially where multiple treatment options exist. Shared decision making (SDM) requires that both physicians and patients are actively engaged in the decision-making process, including information exchange; expressing treatment preferences; as well as agreement over the final treatment decision. Although SDM appears well supported by patients, practitioners and policy makers alike, the current challenge is to determine how best to make SDM a reality in everyday clinical practice. Within the context of asthma, adherence rates are poor and are linked to outcomes such as reduced asthma control, increased symptoms, health care expenditures, and lower patient quality of life. It has been suggested that SDM can improve treatment adherence, and that ignoring patients' personal goals and preferences may result in reduced rates of adherence. Furthermore, understanding predictors of poor treatment adherence is a necessary step toward developing effective strategies to improve the patient reported and clinically important outcomes. Here we describe why a shared approach to treatment decision making for asthma has the potential to be an effective tool for improving adherence, with associated clinical and patient-related outcomes. In addition, we explore insights into the reasons why SDM has not been implemented into routine clinical practice.

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