CareManagement

JOURNAL OF THE COMMISSION FOR CASE MANAGER CERTIFICATION | THE CASE MANAGEMENT SOCIETY OF AMERICA | THE ACADEMY OF CERTIFIED CASE MANAGERS

Vol. 23, No. 6 December 2017/January 2018

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Gary S. Wolfe

HIV Infection in the United States in 2017

In the United States, the first cases of HIV infection/AIDS were reported in a cluster of homosexual men with no known cause of impaired immunity who had symptoms of *Pneumocystis carinii* pneumonia (PCP), a rare opportunistic infection that was known to occur in people with compromised immune systems. Soon thereafter, an unexpected number of homosexual men developed a previously rare skin cancer called Kaposi's sarcoma (KS), and many more cases of PCP and KS emerged. After the Centers for Disease Control and Prevention (CDC) was alerted, a CDC task force was formed to monitor the outbreak.

In 1983, two separate research groups led by Robert Gallo and Luc Montagnier declared that a novel retrovirus may have been infecting AIDS patients, and both researchers published their findings in the same issue of the journal *Science*. Gallo claimed that a virus that his group had isolated from a person with AIDS was strikingly similar in shape to other human T-lymphotropic viruses (HTLVs) that his group had been the first to isolate. Gallo's group called their newly isolated virus HTLV-III. At the same time, Montagnier's group isolated a virus from an individual who presented with swelling of the lymph nodes of the neck and physical weakness, two characteristic symptoms of AIDS. Contradicting the report from Gallo's group, Montagnier and his colleagues showed that core proteins of this virus were immunologically different from those of HTLV-I. Montagnier's group named their isolated virus lymphadenopathy-associated virus (LAV). These two viruses turned out to be the same virus, and in 1986 LAV and HTLV-III were renamed HIV. Thus began what we now know to be one of the world's worst pandemics.

Although there is no cure or vaccine for HIV infection, remarkable strides have been made in its treatment. Although HIV infection was not originally treatable, the discovery of antiretroviral therapy currently enables HIV infection to be treated as a chronic disease in patients who have access to treatment and who achieve durable virologic suppression.

Current facts about HIV infection/AIDS:

- An estimated 1.2 million adults and adolescents in the United States were living with HIV infection in 2013.
- 13% of those living with HIV infection don't know it.
- African Americans/blacks are disproportionately affected by HIV infection in the United States. This group accounted for 44% of all new HIV infections in 2014 and 43% of the total number of people living with HIV infection in the United States despite making up only 12% of the population.
- Most new HIV infections occur among men who have sex with men, with Hispanics/Latinos and African Americans/black men who have sex with men most affected. African American/black heterosexual women are also disproportionately affected.
- Young people (aged 13-24) accounted for 22%, or more than one in five new HIV infections in 2014.
- HIV rates are higher in southern states, which account for around 44% of all people living with HIV infection, despite making up roughly one-third (37%) of the population.
- A complex set of economic and socioeconomic factors drive HIV

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OFFICIAL JOURNAL OF THE ACADEMY OF CERTIFIED CASE MANAGERS AND COMMISSION FOR CASE MANAGER CERTIFICATION

Vol. 23, No. 6, December 2017/January 2018. *CareManagement* (ISSN #1531-037X) is published electronically six times a year, February, April, June, August, October, and December, and its contents are copyrighted by Academy of Certified Case Managers, 2740 SW Martin Downs Blvd. #330, Palm City, FL 34990; Tel: 203-454-1333; Fax: 203-547-7273.

Subscription rates: $120 per year for ACCM members; $150 for institutions.

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

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CCMC Expands Continuing Education Options With New Online Learning Modules

By Vivian Campagna, MSN, RN-BC, CCM

For case managers, both those who are certified and those who want to pursue certification, continuing education is a professional priority. Through ongoing education, case managers stay abreast of changes in the field and best practices for delivering patient-centered case management.

The Commission for Case Manager Certification (CCMC), the first and largest nationally accredited organization that certifies case managers, is committed to promoting the professional development of case managers. The Commission strives to help serve the educational needs of those who are preparing for the Certified Case Manager (CCM) certification examination and to offer continuing education for those who are renewing certification. To ensure that CCMs maintain their knowledge, skills, and abilities, CCMC requires 80 hours of continuing education in focus areas related to the certification examination, including ethics.

At the same time, the Commission is listening to feedback from case managers about their need for a variety of ways to pursue continuing education. In response, CCMC is expanding its learning options with online, in-person, and virtual training.

For case managers, both those who are certified and those who want to pursue certification, continuing education is a professional priority. CCMC is expanding its learning options with online, in-person, and virtual training in order to reach as many case managers as possible.

We believe this mix of offerings will reach as many case managers as possible.

CCMC is expanding its e-learning with its Certification 24/7 online offerings, which are part of its Workforce Development Toolkit (https://ccmcertification.org/workforce-development/workforce-development-toolkit). These e-learning modules are based on our highly popular live workshops on key topics related to case management. Importantly, these modules are prerecorded for release specifically as e-learning modules so as to meet the requirements of online learning for CEs as set by some organizations. To date, two Certification 24/7 modules have been produced, and two more are expected to be recorded by year-end.

Other continuing education offerings from the Commission include:

- **Certification 360 –** 2-day, full immersion learning experiences in the field of case management. The workshops can help case managers fill their knowledge gaps as part of preparation for the CCM certification examination and provide insights for experienced case managers/supervisors who lead their organization's training efforts. (https://ccmcertification.org/get-certified/workshops)
- **Live webinars –** featuring noted experts in the field of case management and from across health and human services. (ccmcertification.org/stay-certified/ce-opportunities/ce-webinars)
- **New World Symposium –** annual 3-day symposium, bringing together leading minds in the field, with educational and networking opportunities for attendees. (symposium.ccmcertification.org/)
- **Case Management Body of Knowledge® (CMBOK®) –** continuing education and information resources in an online format. CMBOK is geared for all case managers and other health care professionals across all practice settings. (www.cmbodyofknowledge.com/)

CCMC recognizes that continuing

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Vivian Campagna, MSN, RN-BC, CCM, is the Chief Industry Relations Officer for the Commission for Case Manager Certification (CCMC), the first and largest nationally accredited organization that certifies case managers, and a former CCMC Commissioner. She has been active in case management for more than 25 years in independent practice as well as in acute care.

Earn Required Ethics CEUs by Reading *CareManagement* Journal!

The Commission for Case Manager Certification (CCMC) now requires CCMs to earn 8 Ethics CEUs by 2018 to renew the prestigious CCM® credential.

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How many Ethics CEUs will CCMC require?

- *Certifications expiring in 2017: four (4) Ethics CEUs will be required for renewal.*
- *Certifications expiring 2018 and after: eight (8) Ethics CEUs will be required for renewal.*

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Case Management Society of America Issues Revised Standards of Practice: Cultural Competency

By Elizabeth Hogue, Esq.

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 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 in order to emphasize the professional nature of the practice and role of case managers as an integral and necessary component of health care delivery systems. These standards likely apply to all case managers, regardless of practice setting or whether they are certified case managers.

CMSA's revised standards also require professional case managers to be aware of and responsive to cultural and linguistic diversity of the demographics of case managers' work settings and to specific clients and their caregivers.

Professional case managers should demonstrate compliance with this standard in the following ways:

- Communications that are effective, respectful, sensitive, and consistent with clients' cultural and linguistic context
- Development of case management plans of care based on assessments and goal setting to accommodate each client's cultural and linguistic needs and preferences
- Identification of appropriate resources to enhance clients' access to care and improve health care outcomes that may include use of interpreters and health educational materials that demonstrate understanding of clients' cultural and linguistic patterns of communication, such as speech volume, context, tone, kinetics, space, and other similar verbal and nonverbal patterns of communication
- Pursuit of professional education to maintain and advance the level of cultural competence and effectiveness when working with diverse client populations

Many professional case managers work with clients who come from a number of cultural and ethnic backgrounds. Patients and their caregivers may be from different ethnic and cultural backgrounds. And there is always the question of how to "square" cultural and ethical diversity with the legal, ethical, and moral standards of our society and culture. The "bottom line" is that establishing and maintaining cultural competency is a continuous process that requires time and resources to achieve. CM

CMSA's revised standards require professional case managers to be aware of and responsive to cultural and linguistic diversity of the demographics of case managers' work settings and to specific clients and their caregivers

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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Setting the Return-to-Work Goal

By Karen N. Provine, MS, CCM, CDMS, CRC, LPCC

When a person is ill or injured and cannot work, the initial focus is understandably on treatment. With the right care and rehabilitation, the person can achieve maximum medical improvement and, ideally, return to work.

While these two steps—recovery and returning to work—appear to be separate, they are integrated. A successful return to work can be facilitated by setting that goal as soon as possible to guide a person-centered treatment and rehabilitation plan. A Certified Disability Management Specialist (CDMS), for example, has the expertise to use the person's job requirements to inform the physical therapy and occupational therapy regimes.

The expectation of returning to work can be introduced gradually, for example, as the individual's treatment and rehabilitation plan are discussed. Although it might seem counterintuitive, having the goal of returning to work is supportive of recuperation. The expectation of returning to work can be especially motivating when a person has significant limitations because of the lingering effects of a serious illness or injury or when the individual has a permanent disability. Getting the person's buy-in and encouraging involvement are crucial to a successful return to work.

Even before the person is released by the physician to return to work, arrangements can be made for temporary or permanent accommodations or other job modifications, as required by law including the Americans with Disabilities Act (ADA). Perhaps the person can only work part time or must perform alternative duties. To support early return to work, while the individual is still recovering, some large employers offer alternative work composed of meaningful tasks until the individual is physically ready to handle the demands of his/her regular job.

Although it might seem counterintuitive, having the goal of returning to work is supportive of recuperation.

If an employee cannot return to his/her former job, retraining may be needed to acquire new skills. Knowing when to introduce going back to work requires sensitivity and must be determined on a case-by-case basis. When the time is right, the disability manager or vocational counselor can introduce options and alternatives to pursue, particularly to learn new skills and expand competencies.

These discussions keep the priority on the workplace before the person decides that working again is impossible or a lack of support at home adds further barriers to progress. In some cases, having the ill/injured person at home helps with childcare or eldercare, which can undermine returning to work. In addition, the prospect of losing the "disability check" may lead some family members to discourage the individual from pursuing a job and becoming more independent.

Advocacy for the individual and his/her goals, however, requires the disability manager or vocational counselor to explore as many options as possible to facilitate return to work. For example, "Jon" became a quadriplegic after a serious accident but was eager to get back to work. Like many people who sustain a life-altering injury or suffer a debilitating illness, he valued the social connection of the workplace and derived self-esteem from being productive. Working with his disability manager/vocational counselor and the employer, Jon was able to return to his job and perform meaningful duties again.

Jon's example is a powerful reminder that people are defined by their abilities, not by disabilities. With the goal of returning to work established early in the recovery process, the focus is on what the person can do and finding ways back into the workplace. CM

Karen N. Provine, MS, CCM, CDMS, CRC, LPCC, *is a vocational rehabilitation counselor and training consultant in private practice. She has been recognized at the state and national level as a leader and subject matter expert in the field of vocational rehabilitation. She is a former Commissioner of the Commission for Case Manager Certification (CCMC), which manages and governs CDMS certification. She has also chaired numerous committees for the Commission and has been a volunteer committee member and test developer for more than 15 years.*

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What's New at CMSA?

By Kathleen Fraser, MSN, MHA, RN-BC, CCM, CRRN, CMSA Executive Director

At CMSA, we are busy serving you and advocating on your behalf for case management!

In the essential area of continuing education, we continue to offer hundreds of educational opportunities to case managers in any stage of the career path, whether you are a new case manager or seasoned professional. We are busy with continuing education activities; in the past year, the newly envisioned Integrated Case Management program for adult and pediatric application was released, and we are working on the upcoming release of our completely redeveloped Career and Knowledge Pathways program. Our Educational Resource Library (known as the ERL) offers approximately 160 online sessions with continuing education credits; access to all courses is a 24/7 benefit included with CMSA membership.

The dedicated members of our organization are the reason CMSA exists, and we continually work on ways to share our gratitude and increase the value of membership. We're proud of the improvements to membership made in 2017, which include a new partnership with The Commission for Case Management Certification (CCMC) to work collaboratively to promote case manager professional development.

With this partnership, CMSA members now receive a 20% discount when applying for the CCM certification as well as a discount upon renewal. Those who hold the CCM certification receive a 20% discount on CMSA membership. We know that working together is the best way to advance the practice of case management, and that's what we're here to do, both for you and the industry as a whole.

A second membership change may come as a surprise to many: free membership! We recognize that many conference attendees who make the commitment to attend year after year sometimes don't take the leap from conference attendee to CMSA member. So, we bridged the gap: for 2018, all full conference registrants receive a complimentary 1-year CMSA membership. Continuing education, camaraderie, and community are important in our field year-round, not only during conference week.

With that said, our annual conference and expo is perhaps our most visible and comprehensive representation of our strength in continuing education. At our June 2018 conference in Chicago, we will offer eight blocks of concurrent sessions, an expo with 250+ exhibitors and sponsors, stellar keynote presenters such as *The Doctors* host Dr. Travis Stork, countless networking opportunities, and a ton of fun. I'll never forget my first conference experience as a case management newbie, and you most certainly shouldn't miss this one!

Finally, one of our most important projects in recent months is the development of the new Case Management Model Act, which recognizes the critical role professional case managers assume in managing chronically ill and complex populations and helping patients in transitions of care, among many other services. The Model Act helps identify and standardize best practices, which in turn can optimize clinical and financial outcomes. Reflecting the scope of services in *CMSA's Standards of Practice for Case Management*, revised 2016, the Model Act seeks to truly demonstrate and recognize the value of professional, licensed case managers.

One of our most important projects in recent months is the development of the new Case Management Model Act, which recognizes the critical role professional case managers assume in managing chronically ill and complex populations and helping patients in transitions of care, among many other services. The Model Act helps identify and standardize best practices, which in turn can optimize clinical and financial outcomes. The Model Act seeks to truly demonstrate and recognize the value of professional, licensed case managers

We released the Model Act at our Hill Day event in mid-September 2017, where 75 strong and energetic case managers from 22 states came to

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Health Information Technology Is Transforming Osteoporosis Care Management

Sharon Chow, RN, DNP, MSN, ANP-BC, PNP-BC, GNP, PHN, CCD

The high prevalence of osteoporotic fractures in the aging population is associated with high morbidity, mortality, and costs. In the United States, only 5% of patients with osteoporosis are properly diagnosed and treated.[1] Approximately 20% of patients who sustain an initial fracture will experience a repeat fracture within 5 years.[2] Annually, 25% of the patients who suffer a hip fracture are placed in nursing homes. Of these, 50% never resume prior functional ability, and 25% die within the first 12 months after a fracture.[3] The health care costs of treating osteoporotic fractures and subsequent complications are projected to be $25 billion by 2025.[2] Meaningful use of electronic health records (EHRs) can improve health outcomes, reduce health care costs, improve program performance, and expand access to affordable care. This article presents an overview of relevant literature and best practice using health information technology (HIT) to close care gaps and transform osteoporosis care.

Review of HIT Literature in Osteoporosis Care

Search Methods

A search for peer-reviewed journal articles about informatics in osteoporosis care was performed using CINAHL, PubMed, Cochrane Library, and Google Scholar. Twenty-one articles were analyzed for key themes as shown in Table 1.

Screening and Treatment

The U.S. Preventive Services Task Force recommends routine osteoporosis screening for women aged 65 years or older and men aged 70 years or older.[4] Osteoporosis, which is a major public health concern impacting approximately 10 million Americans, remains underdiagnosed.[4,5] Dual-energy x-ray absorptiometry (DXA) scans have been routinely used to evaluate bone mineral density for people at high risk for osteoporosis and fracture.[6] The World Health Organization's FRAX (Fracture Risk Assessment Tool) is a calculation tool for the 10-year fracture risk for hip fracture or a major osteoporotic fracture based on certain risk factors, with or without the results of bone density measurement of the hip.[7] The implementation of point-of-care clinical decision support systems increased osteoporosis screening rates.[8] With the use of clinical databases, computerized clinical decision support tools to improve fracture prevention were developed.[9] A population-based informatics system, the PRECARES (PREventive CAre REminder System), which is used to track the last date of osteoporosis screening, significantly improved osteoporosis screening rates and appropriate treatment in primary care practice.[10] A customized scripting editor was used to automatically transfer accurate DXA-generated data into a dictation system.[6]

TABLE 1 OSTEOPOROSIS CARE TRANSFORMATION VIA HEALTH INFORMATION TECHNOLOGY

Theme of Osteoporosis Care Transformation	Key Message
Screening and treatment	Routine osteoporosis screening is for women aged 65 years or older and men 70 years or older, but osteoporosis still remains underdiagnosed.
Medication adherence and efficacy	The lack of consensus with osteoporosis guidelines hinders osteoporosis medication adherence.
Resource utilization	Facing a global aging population, evidence-based guidelines provide effective fracture prevention and resource allocation to reduce the health care burden.
Care management outcome	Worldwide collaborative Fracture Liaison Services as a best practice osteoporosis care model substantially reduce the incidence of secondary fractures.
Osteoporosis disease registers database	The disease registers of patients with osteoporosis are created for reporting and quality improvement.
Portable health device	The tablet computer is highly accepted by older patients and has proved to be an effective assessment, communication, and education tool in community-based clinics.

The high prevalence of osteoporotic fractures in the aging population is associated with high morbidity, mortality, and costs. In the United States, only 5% of patients with osteoporosis are properly diagnosed and treated.

Medication Adherence and Efficacy

Reviewing clinical notes, medication lists, and radiology records in electronic medical records (EMRs), the adherence rates of osteoporosis guidelines for patients at risk of fragility fractures varied by patient, physician, and practice site. Many patients at risk of fragility fractures did not pursue DXA scans or osteoporosis treatment.[11] The lack of consensus in osteoporosis guidelines hindered medication adherence for osteoporosis. A computer simulation model using fracture rates, bisphosphonate treatment effects, health costs, and a hypothetical behavioral intervention in medication adherence improvement enhanced the mediation adherence and cost effectiveness.[11] The eValuation of IBandronate Efficacy (VIBE) database fracture study found that patients treated with oral monthly ibandronate or weekly alendronate and risedronate had low risks of hip fracture, nonvertebral fracture, and any clinical fracture. In addition, patients who received ibandronate had a significantly lower relative risk of vertebral fracture than patients who received weekly alendronate and risedronate.[12] The EHR reminder intervention using standardized phraseology resulted in 51.5% of patients receiving DXA scans or osteoporosis medication.[13]

Resource Utilization

Less than 28% of patients were compliant with osteoporosis treatment.[14] The direct medical resource utilization for fracture treatments, consultations, and hospitalizations in the year after fracture in postmenopausal women was evaluated to determine whether age impacted resource utilization. The valid computerized administrative databases helped track direct medical resource utilization. An algorithm was developed to use the fee-for-service claim database. Age was identified as an important determinant of health resource utilization because of an association with increased office visits, hospitalization, length of stay, long term care admissions, and death.[15] The Premier Perspective Database was used to quantify levels of health care costs, resource utilization, and osteoporosis-related fracture outcomes through hospital discharge records, including patient demographics; admission and discharge dates; admission type; diagnoses and procedures; medications; laboratory, diagnostic, and therapeutic services; diagnosis-related group (DRG); major diagnostic category; DRG-based severity measures; discharge disposition; treatment costs; length of stay; intensive care unit use; and 60-day fracture-related readmission. Facing a global aging population, an evidence-based reference for policymakers in planning cost-effective fracture prevention and resource allocation could reduce the health care burden.[16]

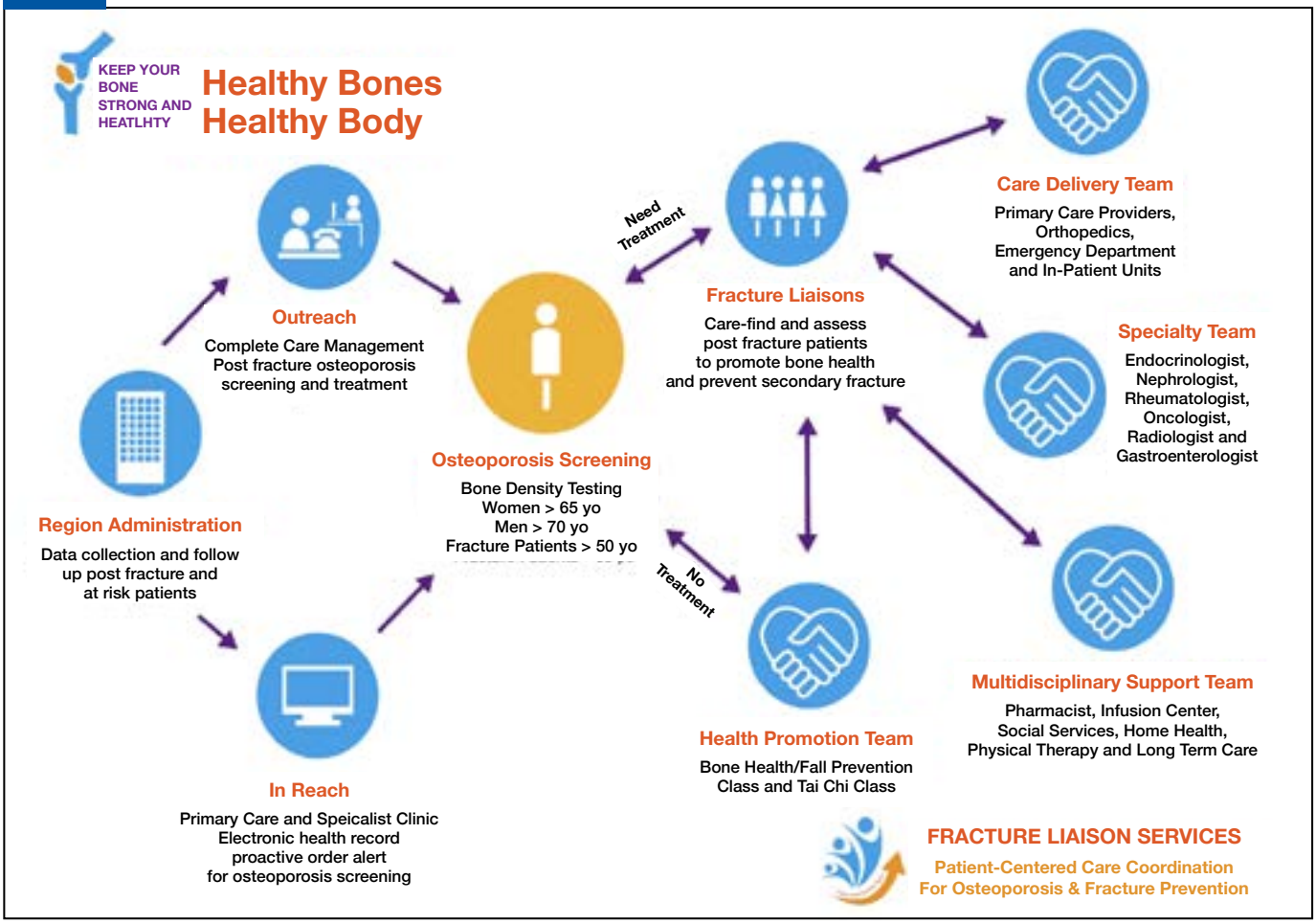
Care Management Outcome

The International Osteoporosis Foundation worldwide advocated collaborative Fracture Liaison Service (FLS) as best practice osteoporosis care model (Figure 1) for substantially reducing the incidence of secondary fractures.[17] Older patients with fractures could greatly benefit from osteoporosis care coordination using EHR and outreach programs.[13] A validated Markov state-transition patient-level computer simulation model was constructed to assess the cost effectiveness of FLS. The results showed a treatment rate of 44% to 66%. The cost savings might be as much as $16.7 million for 2.5 million osteoporotic fractures per year in the United States. The FLS reduced fractures, reduced costs, increased quality-adjusted life-years, and improved osteoporosis disease outcomes.[2] The West Glasgow FLS audit data validated the cost effectiveness of FLS for prevention of secondary fractures (Figure 1).[18]

Southern California Kaiser Permanente Healthy Bones program integrated HIT to collect demographic, DXA scans, and fracture data from a population of over 625,000 patients. The results showed that annual DXA scan utilization rate had a 263% increase from 2002 to 2007. There was a 153% increase in the number of patients receiving antiosteoporotic medication. The overall hip fracture reduction rate in 2007 was 38.1% for all sites. The osteoporosis care management helped achieve at least a 25% reduction in the hip fracture rate.[19] Researchers developed a typical metric set that was suitable for electronic reporting to improve health information exchange. Most of the metric set consisted of process measures, including intermediate and long-term clinical outcomes. Future innovation of metric set could completely shift quality measurement into the domain of electronic clinical data.[20]

Sharon Chow, RN, DNP, ANP-BC, PNP-BC, GNP, PHN, CCD, *is the Healthy Bones Nurse Practitioner Care Manager, Complete Care Services, Kaiser Permanente Fontana Medical Center in Fontana, California.*

FIGURE 1 FRACTURE LIAISON SERVICES MODEL OF CARE



Osteoporosis Registers Database

Applying anonymized audit data from EMR, the disease registers of patients with osteoporosis were created for reporting and quality improvement. Morbidity Query Information and Export Syntax (MIQUEST) software was used to retrieve structured data about secondary causes of osteoporosis, fractures, and falls. To improve osteoporosis care management, providers should search the EMR for patients with diagnoses likely leading to osteoporosis. A systematic approach would be required to integrate the EMR to valid and reliable disease registers for clinical practice.[21]

Portable Health Device

The use of a tablet computer interface for osteoporosis screening recruitment was found to promote patient satisfaction in the primary care setting. The innovative tablet computer was highly accepted by older patients and proved to be an efficient and effective assessment, communication, and education tool in community-based clinics.[22]

Integrating HIT to Transform Osteoporosis Care

Referring to the Data-Information-Knowledge-Wisdom (DIKW) Framework, osteoporosis clinical and research data are analyzed into information of increased refracture rates and morbidity and mortality. The information leads to knowledge of proactive osteoporosis care management. Then, the knowledge contributes general wisdom of collaborative, evidence-based FLSs. The practice wisdom is a complex phenomenon that allows health care professionals to work effectively and efficiently in the clinical setting.[23] The advancement of population-based informatics systems facilitates postfracture patient tracking and information sharing and enhances interprofessional communication with providers, multidisciplinary team members, and patients and families to promote osteoporosis screening and treatment as well as fracture prevention.[10]

In today's digital health environment, HIT supports documentation, ordering of diagnostic tests, evaluation of laboratory results and procedures, and coding for billing.

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The health care costs of treating osteoporotic fractures and subsequent complications are projected to be $25 billion by 2025.

The secure EHR database contains all information regarding patient medical records and provides medication and treatment safety alerts, preventive care reminders, clinical practice guidelines, specialty care referrals, and billing history.[15] The EHR and personal health record (PHR) are designed to electronically connect patients to their health care team and their personal health information. Through the PHR portal, patients will be able to maintain and manage their health information in a private, secure, and confidential environment. The most popular PHR function is online laboratory test results and self-care management strategies.[24] The PHR is specifically designed to help patients with chronic diseases (eg, osteoporosis) to manage their health information and to become more engaged in health promotion as well as to reduce osteoporosis medication errors and improve compliance.

Safe Quality Care

After completing the clinic visit, patients with osteoporosis will be provided with a detailed after-visit summary with the addressed concerns, prescribed medications, applicable self-care instructions, and follow-up appointments. Patients will be able to make the best health decisions for their health. The EHR provides visual cues of patient alerts and provides immediate notifications about any possible drug interactions with a patient's current medications; in addition, health care providers can eprescribe to avoid problems with illegible handwriting.

Computerized Clinical Decision-Making System

The electronic evidence-based research and latest clinical guidelines provide point-of-care recommendations. The country-specific FRAX® is internationally recognized as the "gold standard" of fracture risk measurement based on DXA report. The computer-driven tool assists in identifying those at greatest risk of fractures in 11 languages and guides osteoporosis treatment decisions. The iPhone application is accessible in all clinical settings without internet access.

Medication Compliance and Drug Holiday Decision

According to the current osteoporosis treatment guidelines, if the fracture risk is low after a patient has received 3–5 years of bisphosphonate treatment and no fractures have occurred, stopping bisphosphonate therapy may be applicable.[25] If the fracture risk is high after 3–5 years, the treatment should be continued for up to 10 years or therapy should be changed to a nonbisphosphonate. If the high-risk patient has been taking bisphosphonates for more than 10 years, consider a drug holiday of 1–3 years or until there is significant loss of bone mass density or the patient has a fracture, whichever comes first. The EHR technology assists clinicians in tracking refills of bisphosphonates for medication compliance and helps determine the appropriateness of deciding to take a drug holiday from bisphosphonates.[26]

Clinical Practice Improvement

The excellence of osteoporosis care is correlated with using an advanced EHR system to allow for the identification, risk stratification, and tracking of patients in osteoporosis care coordination. The electronic DXA results are immediately available to provide the best and most efficient care. In a study by Kaiser Permanente, the compelling health care benefits were 153 fewer fractures, 37.43 more quality-adjusted life-years, and a savings of $66,879 compared with traditional postfracture care per every 10,000 postfracture patients.[27] The implementation of EHR offers providers access to a patient's entire medical history, test results, and medications, thus eliminating the expense of duplicate services and facilitating more prompt diagnoses for early detection of disease and proactive treatment.

Follow-Up and Preventive Care

The EHR allows care managers to proactively identify patients who need follow-up visits, laboratory tests, or additional services by generating monthly reports to identify patients who need osteoporosis screening, postfracture interventions, and medication adherence follow-ups to improve osteoporosis care management.[28] Patients can also be reminded about important preventive tests (eg, Pap smears, mammograms, and colonoscopies) to improve health outcomes.

Innovative PHRs Transform Osteoporosis Care

Today health care consumers are demanding convenient ways to manage their health. An influx of effective and convenient PHRs engages patients and caregivers in making healthier decisions and improving clinical performance, thus empowering patients, caregivers, and health care providers

to manage health and improve osteoporosis care. The innovative features of PHRs are:

- 24/7 online access
- Enhanced medication reconciliation, refills, and safety
- Enhanced patient-provider communication
- Improved patient satisfaction, engagement, and empowerment
- Enhanced chronic disease self-care management
- Enhanced preventive care

Implication for Future Nursing/Case Management Practice

Nursing professionals are committed to transform the health care delivery system, to protect health information data, to advocate for safe and quality care, and to support PHR design in today's ever-changing health care environment. Implementing advanced HIT and interprofessional collaboration allows nursing professionals to take a leadership role in advocating for collaborative, evidence-based osteoporosis care management for promoting healthy bones and preventing osteoporosis.[29] The application of DIKW Framework and PHR Enhancement Model promotes patient-driven communication and personalized osteoporosis self-care management. **CE I**

Personal Acknowledgements: *The author thanks Rodney Hicks, PhD, APRN, FAANP, FAAN, Professor at Western University of Health Sciences, for unpaid editorial assistance as the Academic Chair for manuscript publication. The author also thanks Yuki Chong, graphic designer, for designing the Fracture Liaison Services Model of Care.*

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CE II

Comprehensive Case Management and Outcomes for HIV-Infected Clients

By Mark Brennan-Ing, PhD, Liz Seidel, MSW, Leslie Rodgers, Jerome Ernst, Doug Wirth, Daniel Tietz, RN, JD, Antonio Morretti, MS, PhD candidate, and Stephen E. Karpiak, PhD

Introduction

Among the 1.2 million people in the United States who are infected with HIV, only 40% are engaged in HIV medical care and 37% are prescribed antiretroviral (ARV) therapy, with 30% achieving the targeted clinical outcome of viral suppression.[1] Consequently, approximately 840,000 people in the United States are not receiving effective HIV care as evidenced by a lack of viral suppression. This finding is critical since patients who are virally suppressed have better health outcomes and a lower risk of HIV transmission.[2] Research shows that the HIV epidemic could collapse through the reduction of individuals with high HIV viral loads who are the most likely to infect others.[3-5] The failure to achieve better rates of viral suppression can be attributed to a synergy of complex factors including behavioral health problems, unstable housing, incarceration, poor health literacy, and the economic, food, and housing insecurities endemic to poor communities of color, which have the highest rates of HIV infection.[3-7]

Case Management

Case management comprises a subset of care coordination models. Successful care coordination models demonstrate accountability for the organization of patient care, build respectful relationships and agreements among care partners, support patients regardless of where they access health care, and establish good communication among care partners.[8,9] During the early years of the HIV epidemic, New York State implemented case management services for people with HIV who had complex care needs.[10] Case management uses a client-centered multistep process that "ensures coordination and expedient access" to an array of medical and social supports[11] and acts as a megaservice that bridges HIV and non-HIV resources in complex and fragmented service environments.[12] Case management clients are more likely to have lower incomes and education, to be uninsured or publicly insured, to have a history of drug use, and to be racial/ethnic minorities, women, or heterosexuals.[11] The goals of case management are to achieve care engagement and treatment adherence by helping the client to function independently through access to housing and other supportive services.[12-14]

Targeted Case Management in New York State

The Comprehensive Medicaid Case Management Program (also known as COBRA Case Management or Targeted Case Management [TCM]) began in 1990 in New York State. Targeted Case Management targeted Medicaid-eligible populations, including HIV-infected persons, with multiple comorbid conditions including behavioral health issues. Targeted Case Management uses a team of case managers and paraprofessionals to provide comprehensive intensive management services. Targeted Case Management was designed for people with HIV who require frequent contact with care providers and have difficulty accessing and sustaining medical and supportive services. The goals of TCM are to: 1) provide access to services that foster independence and self-sufficiency; 2) ensure adherence to care and treatment; 3) prevent or delay institutionalization; 4) increase universal access to HIV-related services; and 5) promote early intervention-disease prevention.[15] The TCM program has served approximately 14,000 people with HIV infection.[16] To date, case management programs, including TCM, have demonstrated positive outcomes in terms of increased attention to client needs and an uptake in related medical and social services, better care engagement, improved ARV prescription rates and adherence, and a significant increase in CD4 counts between first and second assessments (median = 6.2 months, range = 2.3–26.8 months).[13,17]

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Among the 1.2 million people in the United States who are infected with HIV, only 40% are engaged in HIV medical care and 37% are prescribed antiretroviral therapy, with 30% achieving the targeted clinical outcome of viral suppression. Consequently, approximately 840,000 people in the United States are not receiving effective HIV care as evidenced by a lack of viral suppression

Purpose and Rationale

We sought to examine the effectiveness of TCM services for people with HIV infection in New York State with regard to increased care engagement and improved treatment adherence by analyzing changes in clinical, cost, and utilization data among TCM clients over the course of their case management enrollment.

Results

TCM Utilization Patterns

Four independent patterns of TCM utilization emerged from the cluster analysis. The four orthogonal groupings were labeled as long-term moderate-intensity, moderate-term moderate-intensity, short-term low-intensity, and short-term high-intensity. Long-term moderate-intensity TCM clients (ie, Long-Moderate) evidenced higher means for duration of TCM service utilization during the study period and average median times between consecutive TCM visits (ie, intensity). The moderate-term moderate-intensity group (ie, Moderate-Moderate) exhibited an average number of TCM visits, duration of time in care, and average median times between consecutive visits. Clients within short-term low-intensity (ie, Low Intensity) did not use TCM services for a long period and had a low number of service visits. The short-term high-intensity group (ie, High Intensity) displayed a high number of TCM visits during a short duration of time.

Change in Outcomes over Time

Impact Pro Actuarial Risk Scores

Among TCM clients, there were significant differences in participants' estimated health care utilization costs as indicated by Impact Pro actuarial risk scores by type of TCM utilization, and there was a significant increase in estimated costs from first to final average risk scores. This increase over time was observed in all four groups; Long-Moderate (7.1 vs. 8.6), Moderate-Moderate: (7.5 vs. 8.6), Low Intensity (8.3 vs. 9.5), and High intensity (7.3 vs. 8.5). Collapsing across all TCM utilization groups, the average actuarial score rose from 7.4 to 8.7 at the end of the study period. This short-term change in estimated health care utilization costs is consistent with greater service use and care engagement during the period of TCM enrollment, which is in line with the goal of the TCM program.

Medication and Total Costs

Medication costs among TCM participants differed significantly by utilization pattern and increased significantly from initial to final costs ($10,857 and $28,590, respectively). Total costs were significantly increased over time in all TCM utilization groups, on average from $20,537 rising to $38,404. The increase in average total costs was observed in each of the four groups: Long-Moderate ($20,171 vs. $37,775), Moderate-Moderate ($20,582 vs. $38,028), Low Intensity ($22,633 vs. $42,076), and High Intensity ($20,162 vs. $37,796). The increased total costs over the study period can be attributed to increased health care utilization and medication use.

Health Care Visit Frequency

Among TCM clients there were significant differences in the number of medical visits based on TCM utilization type. The Low Intensity group had the highest average number of trips to the emergency department (2.5) compared with all other groups: Long-Moderate (1.5), Moderate-Moderate (1.5), and High Intensity (1.7). The Low Intensity group also had the most inpatient visits compared with the other groups (1.1). Long-Moderate and Moderate-Moderate users had the highest number of mental health visits (7.2 and 7.0, respectively) compared with Low Intensity (6.2) and High Intensity groups (5.7). With regard to outpatient hospital visits, averages were similar for Long-Moderate (2.0), Moderate-Moderate (1.9), and High Intensity (2.0) and were lowest for Low Intensity clients (0.8). The Low Intensity group had the most primary care visits (14.2) followed by the Moderate-Moderate (12.9), High Intensity (12.7), and Long-Moderate (12.0) groups. There were no significant differences in ratios of visits by visit type among TCM utilization groups, suggesting that emergency department, inpatient, mental health, outpatient, and primary care visits were used with equal intensity by all TCM clients.

Additionally, there were no significant differences in median time between medical visits for any type of services.

Prescription of ARV and Psychotropic Medications

The number of psychotropic prescriptions filled during the first 3 months and the last 3 months did not change significantly (0.5 and 0.5, respectively), and the average number did not differ significantly by intensity group. There was no significant difference between changes in prescriptions for ARV medications from the first 3 months to the last 3 months (4.6 and 4.9, respectively), but there were differences by TCM utilization group: Low Intensity clients reported the greatest number of ARV prescriptions on average during both periods. Thus, we did not observe any significant change in ARV or psychotropic medication use over the course of TCM enrollment, but the number of ARV prescriptions was related to the type of TCM utilization. Because the number of ARV and psychotropic prescriptions did not change during TCM enrollment, the change in medication costs reported earlier are likely due to an increase in non-ARV/psychotropic medications prescribed for other comorbid conditions.

Relationship Between CD4 T-Cell Counts and Time of TCM Enrollment

There was a significant increase in CD4 count from enrollment in TCM to TCM case closure and to the end of the study period (288.7, 295.8, and 503.0, respectively). On average, the first CD4 measurement occurred in 244 days after the start of the study period. The last CD4 measurement while in TCM was at 523 days on average, or a difference on average of 279 days between the first and last CD4 count measurement while enrolled in TCM. The average difference between the last TCM CD4 measurement and the end of the study period was 115 days. This increase in CD4 count from the beginning to end of the study period was observed in TCM utilization groups: Long-Moderate (295 vs. 500), Moderate-Moderate (278 vs. 545), Low Intensity (299 vs. 462), and High Intensity (289 vs. 503). Changes in CD4 count over time did not vary significantly by TCM utilization patterns.

Comparison of CD4 Counts: TCM and Non-TCM Clients

When comparing changes in average CD4 counts, we included age and gender as covariates in preliminary analysis because these factors differed significantly between those enrolled in TCM versus those not enrolled in TCM. Compared with non-TCM members, TCM members were significantly older on average (48 and 47 years, respectively [$t(3027) = 3.37$, $P < .001$]) and had a lower proportion of men (67% and 77%, respectively [$X2(1) = 29.67$, $P < .001$]). However, neither age nor gender had significant effects in the multivariate model ($P = .19$ and $P = .79$, respectively), so we removed these factors from the analysis and report the unadjusted means below. Non-TCM clients had significantly higher CD4 levels compared with TCM clients at first and intermediate assessments (514.4 vs 288.7 and 515.2 vs 295.8, respectively). However, by the end of the study period the TCM group on average had achieved near parity with the non-TCM group with CD4 counts of 502.95 and 525.14, respectively (Table 1).

Discussion

Our examination of case management utilization patterns revealed four distinct typologies that differed based on the frequency, volume, and duration of TCM engagement. These patterns suggest, in part, that TCM services had been responsive to variable client needs, and it is likely that this typology is related to client characteristics, including comorbid health conditions, behavioral health issues, and housing instability. For example, Low Intensity clients had the highest average actuarial risk scores and total costs both before and after TCM engagement. This group also had the highest levels of emergency department, inpatient hospital, and primary care utilization but were among the lowest users of mental health services. Taken together these findings suggest that the Low Intensity TCM clients may represent the most complex cases among this cohort of TCM users, which may be related to their relative lack of engagement in case management services and behavioral health care compared with the other three groups.

With regard to changes over time as a whole, findings support the hypothesis that TCM improves clients'

TABLE 1 CD4 T-CELL COUNTS FOR TCM CLIENTS COMPARED WITH NON-TCM CLIENTS

		First CD4		Intermediate CD4		Final Study CD4	
	N	***Mean***	***SD***	***Mean***	***SD***	***Mean***	***SD***
TCM Clients	838	288.74	160.88	295.83	160.90	502.95	316.15
Non-TCM Clients	937	514.40	287.59	515.20	286.77	525.14	287.15

Targeted Case Management, which uses a team of case managers and paraprofessionals to provide comprehensive intensive management services, was designed for people with HIV who require frequent contact with care providers and have difficulty accessing and sustaining medical and supportive services

engagement with care and treatment adherence as evidenced by significant increases in actuarial risk scores (ie, a proxy for increased service utilization), medication costs, and total costs. Given that we did not observe a significant change in the number of psychotropic or ARV medications, increased medication costs can be attributed to treatment for other comorbid conditions. This is a positive finding because it implies better screening and diagnosis of comorbidities through engagement with health care providers. The most telling evidence, however, was the significant increase in average CD4 T-cell counts over the study period, with the TCM group reaching parity with non-TCM members. Since we did not observe that TCM clients filled more ARV prescriptions following enrollment, the most likely explanation is that they were more adherent and/or may have received more efficacious ARVs through regular engagement with health care providers as indicated by the restoration of immune function. **CE II**

Adapted from The Impact of Comprehensive Case Management on HIV Client Outcomes. PloS One. February 5, 2016.

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PharmaFacts for Case Managers

ABILIFY MYCITE® (aripiprazole tablets with sensor), for oral use

INDICATIONS AND USAGE

Abilify Mycite, a drug-device combination product comprised of aripiprazole tablets embedded with an Ingestible Event Marker (IEM) sensor intended to track drug ingestion, is indicated for the:

- Treatment of adults with schizophrenia
- Treatment of bipolar I disorder
  - Acute treatment of adults with manic and mixed episodes as monotherapy and as adjunct to lithium or valproate
  - Maintenance treatment of adults as monotherapy and as adjunct to lithium or valproate
- Adjunctive treatment of adults with major depressive disorder

Limitations of Use:

- The ability of the Abilify Mycite to improve patient compliance or modify aripiprazole dosage has not been established
- The use of Abilify Mycite to track drug ingestion in "real-time" or during an emergency is not recommended because detection may be delayed or not occur

DOSAGE AND ADMINISTRATION

Overview of the Abilify Mycite System

The Abilify Mycite System is composed of the following components:

- Aripiprazole tablet embedded with an IEM sensor (Abilify Mycite);
- Mycite® Patch (wearable sensor) that detects the signal from the IEM sensor after ingestion and transmits data to a smartphone;
- Mycite app–a smartphone application (app) which is used with a compatible smartphone to display information for the patient;
- Web-based portal for healthcare professionals and caregivers

Prior to initial patient use of the Abilify Mycite System, facilitate use of the combination product and its components (patch, app, portal) and ensure the patient is capable and willing to use smartphones and apps. Before using any component of the Abilify Mycite System, instruct patients to:

- Download the Mycite app and follow all the Instructions for Use.
- Ensure that the app is compatible with their specific smartphone

Although most ingestions will be detected within 30 minutes, it may take up to two hours for the smartphone app and web portal to detect the ingestion of Abilify Mycite; in some cases, the ingestion of the tablet may not be detected. If the tablet is not detected after ingestion, do not repeat the dose.

The status of the Mycite Patch is indicated by a status icon in the app to inform the user that the patch is properly adhered and fully functioning. Instruct patients to ensure that the app is paired with the patch prior to use. Refer to the information provided in the product packaging and electronic Instructions for Use within the Mycite app.

Administration Instructions

Abilify Mycite

Administer Abilify Mycite orally with or without food. Swallow tablets whole; do not divide, crush, or chew.

Mycite Patch

Apply the Mycite Patch only when instructed by the app to the left side of the body just above the lower edge of the rib cage. Do not place the Mycite Patch in areas where the skin is scraped, cracked, inflamed, or irritated, or in a location that overlaps the area of the most recently removed patch. Instruct patients to keep the patch on when showering, swimming, or exercising. The Mycite Patch should be changed weekly or sooner as needed. The app will prompt patient to change the patch and will direct patient to apply and remove the patch correctly. Patients undergoing an MRI need to remove their patch and replace with a new one as soon as possible. If there is skin irritation, instruct patients to remove the patch.

Dosage in Schizophrenia

The recommended starting and target dosage for Abilify Mycite in adults with schizophrenia is 10 or 15 mg daily. Dosage increases should generally not be made before 2 weeks. The maximum recommended dosage is 30 mg daily; however, doses above 15 mg daily have shown no additional clinically meaningful benefit.

Dosage in Bipolar I Disorder

The recommended starting dosage in adults with acute and mixed episodes associated with bipolar I disorder is 15 mg given once daily as monotherapy and 10 mg to 15 mg given once daily as adjunctive treatment with lithium or valproate. The recommended

target dose of Abilify Mycite is 15 mg daily as monotherapy or as adjunctive treatment with lithium or valproate. The dosage may be increased to 30 mg daily based on clinical response. The maximum recommended daily dosage is 30 mg.

Dosage in Adjunctive Treatment of Major Depressive Disorder

The recommended starting dose for Abilify Mycite as adjunctive treatment of adults with major depressive disorder taking an antidepressant is 2 to 5 mg daily. The recommended dosage range is 2 to 15 mg daily. Dosage adjustments of up to 5 mg daily should occur gradually, at intervals of no less than 1 week. The maximum recommended daily dosage is 15 mg. Periodically reassess to determine the continued need for maintenance treatment.

Dosage Adjustments for Cytochrome P450 Considerations

Dosage adjustments are recommended in patients who are known CYP2D6 poor metabolizers and in patients taking concomitant CYP3A4 inhibitors or CYP2D6 inhibitors or strong CYP3A4 inducers. When the coadministered drug is withdrawn from the combination therapy, Abilify Mycite dosage should then be adjusted to its original level. When the coadministered CYP3A4 inducer is withdrawn, Abilify Mycite dosage should be reduced to the original level over 1 to 2 weeks. For patients who may be receiving a combination of strong, moderate, and weak inhibitors of CYP3A4 and CYP2D6 (e.g., a strong CYP3A4 inhibitor and a moderate CYP2D6 inhibitor or a moderate CYP3A4 inhibitor with a moderate CYP2D6 inhibitor), the dosing may be reduced to one quarter (25%) of the usual dose initially and then adjusted based on clinical response.

DOSAGE FORMS AND STRENGTHS

Abilify Mycite (aripiprazole tablets with sensor) is available as described in Table 1.

TABLE 1

ABILIFY MYCITE PRESENTATIONS

Tablet Strength	Tablet Color/Shape	Tablet Markings
2 mg	pale green modified rectangle	"DA-029" and "2"
5 mg	pale blue modified rectangle	"DA-030" and "5"
10 mg	off-white to pale pink modified rectangle	"DA-031" and "10"
15 mg	pale yellow round	"DA-032" and "15"
20 mg	white to pale yellowish white round	"DA-033" and "20"
30 mg	off-white to pale pink round	"DA-034" and "30"

Warnings and Precautions

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS AND SUICIDAL THOUGHTS AND BEHAVIORS

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Abilify Mycite is not approved for the treatment of patients with dementia-related psychosis.

Suicidal Thoughts and Behaviors

Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors. The safety and efficacy of Abilify Mycite have not been established in pediatric patients.

Adverse Reactions

TABLE 2

Adverse Reactions in Short-Term, Placebo-Controlled Trials in Adult Patients Treated with Oral Aripiprazole

	Percentage of Patients Reporting Reaction[a]	
System Organ Class Preferred Term	**Aripiprazole tablets (n=1843)**	**Placebo (n=1166)**
Eye Disorders		
Blurred Vision	3	1
Gastrointestinal Disorders		
Nausea	15	11
Constipation	11	7
Vomiting	11	6
Dyspepsia	9	7
Dry Mouth	5	4
Toothache	4	3
Abdominal Discomfort	3	2
Stomach Discomfort	3	2
General Disorders and Administration Site Conditions		
Fatigue	6	4
Pain	3	2
Musculoskeletal and Connective Tissue Disorders		
Musculoskeletal Stiffness	4	3
Pain in Extremity	4	2
Myalgia	2	1

continues

TABLE 2 *(continued)*

Adverse Reactions in Short-Term, Placebo-Controlled Trials in Adult Patients Treated with Oral Aripiprazole		
Muscle Spasms	2	1
Nervous System Disorders		
Headache	27	23
Dizziness	10	7
Akathisia	10	4
Sedation	7	4
Extrapyramidal Disorder	5	3
Tremor	5	3
Somnolence	5	3
Psychiatric Disorders		
Agitation	19	17
Insomnia	18	13
Anxiety	17	13
Restlessness	5	3
Respiratory, Thoracic, and Mediastinal Disorders		
Pharyngolaryngeal Pain	3	2
Cough	3	2

[a]Adverse reactions reported by at least 2% of patients treated with oral aripiprazole, except adverse reactions which had an incidence equal to or less than placebo.

HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

The Abilify Mycite kit contains aripiprazole tablets embedded with an Ingestible Event Marker (IEM) sensor copackaged with 7 Mycite Patches (wearable sensors) in in the presentations listed below.

TABLE 3

ABILIFY MYCITE KIT PRESENTATIONS

Tablet Strength	Tablet Color/Shape	Tablet Markings	Pack Size	NDC Code
2 mg	pale green modified rectangle	"DA-029" and "2"	Bottle of 30 tablets + 7 Mycite Patches	59148-029-85
5 mg	pale blue modified rectangle	"DA-030" and "5"	Bottle of 30 tablets + 7 Mycite Patches	59148-030-85
10 mg	off-white to pale pink modified rectangle	"DA-031" and "10"	Bottle of 30 tablets + 7 Mycite Patches	59148-031-85
15 mg	pale yellow round	"DA-032" and "15"	Bottle of 30 tablets + 7 Mycite Patches	59148-032-85
20 mg	white to pale yellowish white round	"DA-033" and "20"	Bottle of 30 tablets + 7 Mycite Patches	59148-033-85
30 mg	off-white to pale pink round	"DA-034" and "30"	Bottle of 30 tablets + 7 Mycite Patches	59148-034-85

Storage

Tablet bottle:

Store 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F).

Do not store in conditions where tablets are exposed to humid conditions.

Mycite Patch (Wearable Sensor):

Store between 15°C and 30°C (59°F to 86°F), 15% to 93% relative humidity.

Tablets manufactured by Otsuka Pharmaceutical Co., Ltd., Tokyo,

IEM sensors and Mycite Patches Manufactured by Proteus Digital Health®, Inc.

Fasenra (benralizumab) injection, for subcutaneous use

INDICATIONS AND USAGE

Fasenra is indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older with an eosinophilic phenotype.

Limitations of use:

Fasenra is not indicated for treatment of other eosinophilic conditions.

Fasenra is not indicated for the relief of acute bronchospasm or status asthmaticus.

DOSAGE AND ADMINISTRATION

Recommended Dose

Fasenra is for subcutaneous use only.

The recommended dose of Fasenra is 30 mg administered once every 4 weeks for the first 3 doses, and then once every 8 weeks thereafter by subcutaneous injection into the upper arm, thigh, or abdomen.

Preparation and Administration

Fasenra should be administered by a healthcare professional. In line with clinical practice, monitoring of patients after administration of biologic agents is recommended. Before administration, warm Fasenra by leaving carton at room temperature for about 30 minutes. Administer Fasenra within 24 hours or discard into sharps container.

DOSAGE FORMS AND STRENGTHS

Injection: 30 mg/mL solution of Fasenra in a single-dose prefilled syringe. Fasenra is a clear to opalescent, colorless to slightly

yellow solution and may contain a few translucent or white to off-white particles.

CONTRAINDICATIONS

Fasenra is contraindicated in patients who have known hypersensitivity to benralizumab or any of its excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions (e.g., anaphylaxis, angioedema, urticaria, rash) have occurred following administration of Fasenra. These reactions generally occur within hours of administration, but in some instances have a delayed onset (i.e., days). In the event of a hypersensitivity reaction, Fasenra should be discontinued.

Acute Asthma Symptoms or Deteriorating Disease

Fasenra should not be used to treat acute asthma symptoms or acute exacerbations. Do not use Fasenra to treat acute bronchospasm or status asthmaticus. Patients should seek medical advice if their asthma remains uncontrolled or worsens after initiation of treatment with Fasenra.

Reduction of Corticosteroid Dosage

Do not discontinue systemic or inhaled corticosteroids abruptly upon initiation of therapy with Fasenra. Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a physician. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

Parasitic (Helminth) Infection

Eosinophils may be involved in the immunological response to some helminth infections. Patients with known helminth infections were excluded from participation in clinical trials. It is unknown if Fasenra will influence a patient's response against helminth infections. Treat patients with pre-existing helminth infections before initiating therapy with Fasenra. If patients become infected while receiving treatment with Fasenra and do not respond to anti-helminth treatment, discontinue treatment with Fasenra until infection resolves.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

The data on pregnancy exposure from the clinical trials are insufficient to inform on drug-associated risk. Monoclonal antibodies such as benralizumab are transported across the placenta during the third trimester of pregnancy; therefore, potential effects on a fetus are likely to be greater during the third trimester of pregnancy. In a prenatal and postnatal development study conducted in cynomolgus monkeys, there was no evidence of fetal harm with IV administration of benralizumab throughout pregnancy at doses that produced exposures up to approximately 310 times the exposure at the maximum recommended human dose (MRHD) of 30 mg SC. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Disease-associated maternal and/or embryo/fetal risk:

In women with poorly or moderately controlled asthma, evidence demonstrates that there is an increased risk of preeclampsia in the mother and prematurity, low birth weight, and small for gestational age in the neonate. The level of asthma control should be closely monitored in pregnant women and treatment adjusted as necessary to maintain optimal control.

Data

Animal Data

In a prenatal and postnatal development study, pregnant cynomolgus monkeys received benralizumab from beginning on GD20 to GD22 (dependent on pregnancy determination), on GD35, once every 14 days thereafter throughout the gestation period and 1-month postpartum (maximum 14 doses) at doses that produced exposures up to approximately 310 times that achieved with the MRHD (on an AUC basis with maternal IV doses up to 30 mg/kg once every 2 weeks). Benralizumab did not elicit adverse effects on fetal or neonatal growth (including immune function) up to 6.5 months after birth. There was no evidence of treatment-related external, visceral, or skeletal malformations. Benralizumab was not teratogenic in cynomolgus monkeys. Benralizumab crossed the placenta in cynomolgus monkeys. Benralizumab concentrations were approximately equal in mothers and infants on postpartum day 7 but were lower in infants at later time points. Eosinophil counts were suppressed in infant monkeys with gradual recovery by 6 months postpartum; however, recovery of eosinophil counts was not observed for one infant monkey during this period.

Lactation

Risk Summary

There is no information regarding the presence of benralizumab in human or animal milk, and the effects of benralizumab on the breast fed infant and on milk production are not known. However, benralizumab is a humanized monoclonal antibody (IgG1/κ-class), and immunoglobulin G (IgG) is present in human milk in small amounts. If benralizumab is transferred into human milk, the effects of local exposure in the gastrointestinal tract and potential limited systemic exposure in the infant to benralizumab are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for benralizumab and any potential adverse effects on the breastfed child from benralizumab or from the underlying maternal condition.

continues on page 34

LITSCAN FOR CASE MANAGERS

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

Clin Infect Dis. 2017 Nov 15. doi: 10.1093/cid/cix998. [Epub ahead of print]

Multimorbidity among persons living with HIV in the U.S.

Wong C, Gange SJ, Moore RD, et al.

BACKGROUND: Age-associated conditions are increasingly common among persons living with HIV. A longitudinal investigation of their accrual is needed given their implications on clinical care complexity. We examined trends in the co-occurrence of age-associated conditions among persons living with HIV receiving clinical care, and differences in their prevalence by demographic subgroup.

METHODS: This cohort study was nested within the North American AIDS Cohort Collaboration on Research and Design. Participants from HIV outpatient clinics were antiretroviral therapy-exposed persons living with HIV and receiving clinical care (i.e., having ≥1 CD4 T-cell lymphocyte lab) in the U.S. during 2000-2009. Multimorbidity was irreversible, defined as having ≥2 of: hypertension, diabetes mellitus, chronic kidney disease, hypercholesterolemia, end-stage liver disease, or non-AIDS-related cancer. Adjusted prevalence ratios and 95% confidence intervals comparing demographic subgroups were obtained by Poisson regression with robust error variance, using generalized estimating equations for repeated measures.

RESULTS: Among 22,969 adults, 79% were male, 36% black, and median baseline age was 40 years (IQR: 34-46). Between 2000-2009, multimorbidity prevalence increased from 8.2% to 22.4% (p-trend<0.001). Adjusting for age, this trend was still significant (p<0.001). There was no difference by sex, however, blacks were less likely to have multimorbidity compared to whites (aPR=0.87 [0.77,0.99]). Multimorbidity was the highest among heterosexuals, relative to men who have sex with men (aPR=1.16 [1.01,1.34]). Hypertension and hypercholesterolemia most commonly co-occurred.

CONCLUSIONS: Multimorbidity prevalence has increased among persons living with HIV. Comorbidity prevention and multi-subspecialty management of increasingly complex healthcare needs will be vital to ensuring they receive needed care.

J Acquire Immune Defic Syndr. 2017 Nov 6. doi: 10.1097/QAI.0000000000001578. [Epub ahead of print]

Cost-effectiveness of peer- versus venue-based approaches for detecting undiagnosed HIV among heterosexuals in high-risk New York City neighborhoods.

Stevens ER, Nucifora K, Zhou Q, et al.

INTRODUCTION: We used a computer simulation of HIV progression and transmission to evaluate the cost effectiveness of a scale-up of three strategies to seek out and test individuals with undiagnosed HIV in New York City (NYC).

SETTING: Hypothetical NYC population.

METHODS: We incorporated the observed effects and costs of the three "seek and test" strategies in a computer simulation of HIV in NYC, comparing a scenario in which the strategies were scaled up with a one-year implementation or a long-term implementation with a counterfactual scenario with no scale-up. The simulation combined a deterministic compartmental model of HIV transmission with a stochastic microsimulation of HIV progression, calibrated to NYC epidemiological data from 2003 to 2015. The three approaches were respondent driven sampling (RDS) with anonymous HIV testing ("RDS-A"), RDS with a two-session confidential HIV testing approach ("RDS-C"), and venue-based sampling ("VBS").

RESULTS: RDS-A was the most cost-effective strategy tested. When implemented for only one year and then stopped thereafter, using a societal perspective, the cost per quality-adjusted life-year (QALY) gained versus no intervention was $812/QALY, $18,110/QALY, and $20,362/QALY for RDS-A, RDS-C, and VBS, respectively. When interventions were implemented long-term, the cost per QALY gained versus no intervention was cost-saving, $31,773/QALY, and $35,148/QALY for RDS-A, RDS-C, and VBS, respectively. When compared to RDS-A the incremental cost effectiveness ratios (ICERs) for both VBS and RDS-C were dominated.

CONCLUSION: The expansion of the RDS-A strategy would substantially reduce HIV-related deaths and new HIV infections in NYC, and would be either cost-saving or have favorable cost-effectiveness.

J Am Coll Cardiol. 2017 Oct 31. pii: S0735-1097(17)39761-9. doi: 10.1016/j.jacc.2017.08.074. [Epub ahead of print]

Heart failure with preserved, borderline, and reduced ejection fraction: 5-year outcomes.

Shah KS, Xu H, Matsouaka RA, et al.

BACKGROUND: Patients with heart failure (HF) have a poor prognosis and are categorized by ejection fraction (EF).

OBJECTIVES: This study sought to characterize differences in outcomes in patients hospitalized with heart failure with preserved ejection fraction (HFpEF) (EF ≥50%), heart failure with borderline ejection fraction (HFbEF) (EF 41% to 49%), and heart failure with reduced ejection fraction (HFrEF) (EF ≤40%).

METHODS: Data from GWTG-HF (Get With The Guidelines-Heart Failure) were linked to Medicare data for longitudinal follow-up. Multivariable models were constructed to examine 5-year outcomes and to compare survival to median survival of the U.S. population.

RESULTS: A total of 39,982 patients from 254 hospitals who were admitted for HF between 2005 and 2009 were included: 18,299 (46%) had HFpEF, 3,285 (8.2%) had HFbEF, and 18,398 (46%) had HFrEF. Overall, median survival was 2.1 years. In risk-adjusted survival analysis, all 3 groups had similar 5-year mortality (HFrEF 75.3% vs. HFpEF 75.7%; hazard ratio: 0.99 [95% confidence interval: 0.958 to 1.022]; HFbEF 75.7% vs. HFpEF 75.7%; hazard ratio: 0.99 [95% confidence interval: 0.947 to 1.046]). In risk-adjusted analyses, the composite of mortality and rehospitalization was similar for all subgroups. Cardiovascular and HF readmission rates were higher in those with HFrEF and HFbEF compared with those with HFpEF. When compared with the U.S. population, HF patients across all age and EF groups had markedly lower median survival.

CONCLUSIONS: Among patients hospitalized with HF, patients across the EF spectrum have a similarly poor 5-year survival with an elevated risk for cardiovascular and HF admission. These findings underscore the need to improve treatment of patients with HF.

Transplant Proc. 2017 Nov;49(9):2169-2175. doi: 10.1016/j.transproceed.2017.09.020.

Perioperative prophylaxis for total artificial heart transplantation.

Chambers HE, Pelish P, Qiu F, Florescu DF.

BACKGROUND: Practice variation regarding perioperative antimicrobial prophylaxis in total artificial heart transplantations (TAH-t) across institutions is unknown. The aim of our survey was to assess the current practices for prevention of infection in TAH-t recipients among different programs.

METHODS: An electronic survey was sent to programs that implant Syncardia TAH (Syncardia Systems, Tuscon, Ariz, USA). Proportions were analyzed for categorical variables; means and SDs were analyzed for continuous variables.

RESULTS: The majority of centers (80.8%) had a formal surgical infection prophylaxis protocol. For non-penicillin-allergic patients, five (20.1%) institutions reported using a 4-drug regimen, seven (29.2%) used a 3-drug regimen, five (20.1%) used a 2-drug regimen, and seven (29.2%) used a cephalosporin alone. Similar data was seen in the penicillin-allergic patients. Infections were reported to occur postoperatively in 52.2% centers. During the first month after TAH-t, bacteremia represented 27.3%, driveline infections 27.2%, pulmonary infections 9%, and mediastinal infections 18.2%. The most common organisms seen within the first month were Candida spp., Escherichia coli, and Pseudomonas aeruginosa (21.4%). In 65% of centers, the mean rate of death post-TAH-t due to infection was 14.5% (SD, 22.3%). The mean rate of patients surviving until orthotopic heart transplantation was 58.6% (SD, 27.7%).

CONCLUSIONS: Preventing infections post-TAH-t is key to decreasing morbidity and mortality. All institutions administered perioperative prophylaxis for TAH-t with significant variation among the centers. The majority of the centers have a formal perioperative prophylactic protocol.

Circ Cardiovasc Genet. 2016 Jun;9(3):240-9. doi: 10.1161/CIRCGENETICS.116.001381. Epub 2016 Mar 24.

Treatment gaps in adults with heterozygous familial hypercholesterolemia in the United States: data from the CASCADE-FH Registry.

deGoma EM, Ahmad ZS, O'Brien EC, et al.

BACKGROUND: Cardiovascular disease burden and treatment patterns among patients with familial hypercholesterolemia (FH) in the United States remain poorly described. In 2013, the FH Foundation launched the Cascade Screening for Awareness and Detection (CASCADE) of FH Registry to address this knowledge gap.

METHODS AND RESULTS: We conducted a cross-sectional analysis of 1295 adults with heterozygous FH enrolled in the

CASCADE-FH Registry from 11 US lipid clinics. Median age at initiation of lipid-lowering therapy was 39 years, and median age at FH diagnosis was 47 years. Prevalent coronary heart disease was reported in 36% of patients, and 61% exhibited 1 or more modifiable risk factors. Median untreated low-density lipoprotein cholesterol (LDL-C) was 239 mg/dL. At enrollment, median LDL-C was 141 mg/dL; 42% of patients were taking high-intensity statin therapy and 45% received >1 LDL-lowering medication. Among FH patients receiving LDL-lowering medication(s), 25% achieved an LDL-C <100 mg/dL and 41% achieved a ≥50% LDL-C reduction. Factors associated with prevalent coronary heart disease included diabetes mellitus (adjusted odds ratio 1.74; 95% confidence interval 1.08-2.82) and hypertension (2.48; 1.92-3.21). Factors associated with a ≥50% LDL-C reduction from untreated levels included high-intensity statin use (7.33; 1.86-28.86) and use of >1 LDL-lowering medication (1.80; 1.34-2.41).

CONCLUSIONS: FH patients in the CASCADE-FH Registry are diagnosed late in life and often do not achieve adequate LDL-C lowering, despite a high prevalence of coronary heart disease and risk factors. These findings highlight the need for earlier diagnosis of FH and initiation of lipid-lowering therapy, more consistent use of guideline-recommended LDL-lowering therapy, and comprehensive management of traditional coronary heart disease risk factors.

Thromb Res. 2017 Oct 21;160:109-113. doi: 10.1016/j.thromres.2017.10.012. [Epub ahead of print]

Exploring the impact of route of administration on medication acceptance in hospitalized patients: implications for venous thromboembolism prevention.

Popoola VO, Tavakoli F, Lau BD, et al.

BACKGROUND: Non-administration of venous thromboembolism (VTE) prophylaxis contributes to preventable patient harm. We hypothesized that non-administration would be more common for parenteral VTE prophylaxis than oral infectious disease or cardiac prophylaxis or for treatment medications. The primary study goal was to determine if non-administration of parenteral VTE prophylaxis is more frequent than other prophylactic or treatment medications.

METHODS: In this retrospective cohort study of consecutive admissions we used descriptive statistics and risk ratios (RR) to compare the number of non-administered doses of VTE prophylaxis, oral infectious disease and cardiovascular prophylaxis and treatment medications. To quantify the influence of demographic and clinical characteristics on non-administration, we estimated incidence rate ratios from Poisson regression models.

RESULTS: 645 patients were admitted from July 1, 2014 through March 31, 2015. Median age was 52 years (Interquartile range 43-57) and 365 (56.6%) were male. Subcutaneous VTE prophylaxis doses were not administered nearly 4-fold more frequently than oral infectious disease and cardiovascular prophylaxis (RR=3.93; 95% CI 3.36-4.59) and 3-fold more frequently than treatment medications (RR=3.06; 95% CI 2.91-3.22). Ninety percent of non-administered doses of VTE prophylaxis were refused. Risk factors for non-administration included younger age (age 18–35 years), male sex, uninsured status, HIV-positivity and high VTE risk status.

CONCLUSIONS: Subcutaneous VTE prophylaxis is not administered more frequently than oral infectious diseases or cardiac prophylaxis and treatment medications. These data suggest that availability of an oral medication could improve the effectiveness of VTE prophylaxis in real world settings.

Ann Allergy Asthma Immunol. 2017 Nov;119(5):415-421. e1. doi: 10.1016/j.anai.2017.08.002.

Effect of a mobile health, sensor-driven asthma management platform on asthma control.

Barrett MA, Humblet O, Marcus JE, et al.

BACKGROUND: Asthma inflicts a significant health and economic burden in the United States. Self-management approaches to monitoring and treatment can be burdensome for patients.

OBJECTIVE: To assess the effect of a digital health management program on asthma outcomes.

METHODS: Residents of Louisville, Kentucky, with asthma were enrolled in a single-arm pilot study. Participants received electronic inhaler sensors that tracked the time, frequency, and location of short-acting β-agonist (SABA) use. After a 30-day baseline period during which reference medication use was recorded by the sensors, participants received access to a digital health intervention designed to enhance self-management. Changes in outcomes, including mean daily SABA use, symptom-free days, and asthma control status, were compared among the initial 30-day baseline period and all subsequent months of the intervention using mixed-model logistic regressions and $\chi 2$ tests.

RESULTS: The mean number of SABA events per participant per day was 0.44 during the control period and 0.27 after the

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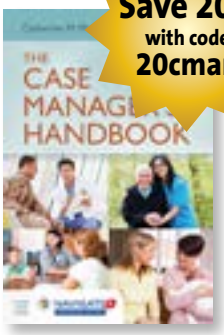

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first month of the intervention, a 39% reduction. The percentage of symptom-free days was 77% during the baseline period and 86% after the first month, a 12% improvement. Improvement was observed throughout the study; each intervention month demonstrated significantly lower SABA use and higher symptom-free days than the baseline month (P < .001). Sixty-nine percent had well-controlled asthma during the baseline period, 67% during the first month of the intervention. Each intervention month demonstrated significantly higher percentages than the baseline month (P < .001), except for month 1 (P = .80).

CONCLUSION: A digital health asthma management intervention demonstrated significant reductions in SABA use, increased number of symptom-free days, and improvements in asthma control.

J Allergy Clin Immunol. 2017 Nov 13. pii: S0091-6749(17)31752-9. doi: 10.1016/j.jaci.2017.09.047. [Epub ahead of print]

Obstruction phenotype as a predictor of asthma severity and instability in children.

Sorkness RL, Zoratti EM, Kattan M, et al.

BACKGROUND: Small airways instability, resulting in premature airway closure, has been recognized as a risk for asthma severity and poor control. Although spirometry has limited sensitivity for detecting small airway dysfunction, a focus on the air-trapping component of obstruction may identify a risk factor for asthma instability.

OBJECTIVE: To use spirometric measurements to identify patterns of airway obstruction in children, and define obstruction phenotypes that relate to asthma instability.

METHODS: Pre- and post-bronchodilation spirometry data were obtained from 560 children in the Asthma Phenotypes in the Inner City study. An air-trapping obstruction phenotype (A Trpg) was defined as forced vital capacity (FVC) Z-score < -1.64, or an increase of FVC ≥ 10% predicted with bronchodilation. The airflow limitation phenotype (A Limit) had forced expiratory volume in 1 s (FEV1)/FVC Z-score < -1.64, but not A Trpg. The None phenotype had neither A Trpg nor A Limit. The 3 obstruction phenotypes were assessed as predictors of number of exacerbations, asthma severity, and airway lability.

RESULTS: The A Trpg phenotype (14% of the cohort) had more exacerbations during the 12-month study, compared with the A Limit (P<0.03) and the None (P<0.001) phenotypes. The A Trpg phenotype also had the highest Composite Asthma Severity Index, the highest asthma treatment step, the greatest variability in FEV1 over time, and the greatest sensitivity to methacholine challenge.

CONCLUSIONS: A Trpg and A Limit patterns of obstruction, defined with routine spirometric measurements, can identify obstruction phenotypes that are indicators of risk for asthma severity and instability.

Gastroenterology. 2017 Nov 1. pii: S0016-5085(17)36296-0. doi: 10.1053/j.gastro.2017.10.036. [Epub ahead of print]

Cost effectiveness of screening individuals with cystic fibrosis for colorectal cancer.

Gini A, Zauber AG, Cenin DR, et al.

BACKGROUND & AIMS: Individuals with cystic fibrosis are at increased risk of colorectal cancer (CRC) compared to the general population, and risk is higher among those who received an organ transplant. We performed a cost-effectiveness analysis to determine optimal CRC screening strategies for patients with cystic fibrosis.

METHODS: We adjusted the existing MISCAN-Colon microsimulation model to reflect increased CRC risk and lower life-expectancy in patients with cystic fibrosis. Modeling was performed separately for individuals who never received an organ transplant and patients who had received an organ transplant. We modeled 76 colonoscopy screening strategies that varied the age range and screening interval. The optimal screening strategy was determined based on a willingness to pay threshold of $100,000 per life-year gained. Sensitivity and supplementary analyses were performed, including fecal immunochemical test (FIT) as an alternative test, earlier ages of transplantation, and increased rates of colonoscopy complications, to assess if optimal screening strategies would change.

RESULTS: Colonoscopy every 5 years, starting at an age of 40 years, was the optimal colonoscopy strategy for patients with cystic fibrosis who never received an organ transplant; this strategy prevented 79% of deaths from CRC. Among patients with cystic fibrosis who had received an organ transplant, optimal colonoscopy screening should start at an age of 30 or 35 years, depending on the patient's age at time of transplantation. Annual FIT screening was predicted to be cost-effective for patients with cystic fibrosis. However, the level of accuracy of the FIT in population is not clear.

CONCLUSIONS: Using a MISCAN-Colon microsimulation model, we found screening of patients with cystic fibrosis for

CRC to be cost effective. Due to the higher risk in these patients for CRC, screening should start at an earlier age with a shorter screening interval. The findings of this study (especially those on FIT screening) may be limited by restricted evidence available for patients with cystic fibrosis.

Cancer. 2017 Nov 3. doi: 10.1002/cncr.31065. [Epub ahead of print]

Long-term sequelae in survivors of childhood leukemia with Down syndrome: a childhood cancer survivor study report.

Goldsby RE, Stratton KL, Raber S, et al.

BACKGROUND: Children with Down syndrome (DS) are at increased risk of developing acute leukemia and are more prone to acute toxicities. We studied the incidence and severity of chronic health conditions among survivors of childhood leukemia with DS compared with those without DS.

METHODS: Chronic health conditions reported by questionnaire were compared between 154 pediatric leukemia survivors with DS and 581 without DS, matched by leukemia, age at diagnosis, race/ethnicity, sex, radiation location and chemotherapy exposure using Cox models to estimate hazard ratios (HRs) and 95% confidence intervals (CIs). Subjects were selected from 7139 5-year survivors of leukemia in the Childhood Cancer Survivor Study.

RESULTS: Risk of at least 1 late onset chronic health condition (grade 1-5) was similar in the DS population compared with the non-DS group (HR, 1.1; 95% CI, 0.7-1.5). Serious chronic health conditions (grade 3-5) were more common in DS survivors (HR, 1.7; 95% CI, 1.1-2.6), as were ≥3 chronic health conditions (grades 1-5) (HR, 1.7; 95% CI, 1.2-2.4). The 25-year cumulative incidence of any condition (grades 1-5) was 83% for DS survivors and 69% for non-DS survivors.

CONCLUSION: Leukemia survivors with DS have therapy-related chronic health conditions comparable to those of similarly treated survivors without DS, with a few notable exceptions: 1) an increased risk of cataracts, hearing loss, and thyroid dysfunction compared with survivors without DS (though these are known risks in the DS population), 2) decreased risk of second cancers, and 3) increased risk of severe or multiple conditions. Practitioners should be aware of these risks during and after therapy. Cancer 2017. © 2017 American Cancer Society.

Gynecol Oncol. 2017 Nov 9. pii: S0090-8258(17)31446-4. doi: 10.1016/j.ygyno.2017.10.024. [Epub ahead of print]

Clinical significance of enlarged cardiophrenic lymph nodes in advanced ovarian cancer: implications for survival.

Mert I, Kumar A, Sheedy SP, et al.

OBJECTIVE: Advanced ovarian cancer (OC) commonly spreads to cardiophrenic lymph nodes (CPLNs), and is often visible on preoperative imaging. We investigated the prognostic significance of abnormal CPLNs in OC detected by preoperative CT scans using three different definitions.

METHODS: Patients undergoing primary debulking surgery for stage IIIC/IV with residual disease (RD) ≤1.0cm and a preoperative abdominopelvic CT scan available were included. Scans were reviewed by two blinded radiologists. We characterized abnormal CPLNs using three different definitions: i) qualitative assessment score (QAS); ii) nodes >7mm on the short axis; or, iii) nodes ≥10mm on the short axis. We compared overall survival (OS) using the log-rank test.

RESULTS: Of the 253 patients (mean age 64.0 years), 136 had no gross residual disease (NGR) and 117 had RD. By the QAS definition, CPLNs were abnormal in 28 (11.1%) patients and removed in one case. Among patients with NGR, presence of abnormal CPLNs was associated with worse OS (median OS, 38.4 vs. 69.6months, p=0.08). We observed no association between abnormal CPLNs and OS among patients with RD (median OS, 37.5 vs. 28.5 months, p=0.49). OS was significantly better in NGR group without abnormal CPLNs (median OS for NGR vs. RD, 69.6 vs. 28.5 months, p<0.001); however, there was no difference in OS between patients with NGR versus RD when abnormal CPLNs were present (median OS, 38.4 vs. 37.5 months, p=0.99). Lack of benefit from NGR when abnormal CPLNs were present was observed for all three definitions tested.

CONCLUSION: Abnormal CPLNs are an important predictor of survival in advanced stage OC. Management of abnormal CPLNs should be considered in treatment planning when the goal is NGR.

Shared Decision-Making Deemed Essential to Diabetes Care

Shared decision-making offers a pathway for determining what is best for the person living with diabetes. Three approaches are described: (1) The informational approach focuses on information that patients and clinicians need. (2) The choice approach emphasizes an individual's values and preferences. (3) The conversation approach establishes an empathic conversation in which patients and clinicians brainstorm how to address the problems of living with diabetes and its comorbidities. Decision aids and evidence-based tools (eg, web-based, pamphlets, videos, or cards) facilitate all 3 shared decision-making approaches. Randomized trials support the use of decision aids in patients with diabetes in urban, rural, academic, and nonacademic clinical settings. However, uncertainty remains about how best to account for patients' capacity and interest in the decision-making process, the necessary skills to communicate and engage with patients, and the sustainability, best practices, and cost effectiveness of large-scale implementation of shared decision-making. ■

New Guidelines for Reducing Hospital Laboratory Testing Takeaway

Among the harms to patients who receive overzealous testing in the hospital is an almost 20% rate of hospital-acquired anemia. Without a pretest rationale to justify the testing, the odds of an accidental finding that snowballs into more interventions are increased. This guideline offers methods for reducing testing on 3 fronts—education, audits, and electronic medical record (EMR) options—for reducing unneeded routine laboratory tests for hospitalized patients. Clinicians who have a better understanding of the need for a pretest rationale may be less likely to order routine tests without a reasonable cause. Auditing and feedback provide information to clinicians in real time about how their ordering patterns compare to an established benchmark. EMR-based approaches can include restrictions on daily testing and alerts showing previous results. ■

New Guidelines Address Language Use in Diabetes Encounters

Use of empowering language can help educate and motivate people with diabetes, whereas words perceived as shaming or judging may undermine those efforts. Language affects motivation, behavior, and outcomes in people with diabetes. Recommendations are to use neutral, nonjudgmental language based on facts, actions, or physiology/biology. For example, state, "patient is taking metformin but blood glucose levels are still high," rather than "poorly controlled" or patient "failed metformin." Use language free of stigma. "She takes her medication about half the time" rather than "patient is nonadherent." Use language that imparts hope and is respectful. "Have you tried…, What about…, What is your plan for…?" Foster collaboration with patients: "May we make a plan for…" rather than "I want you to…." Say "person with diabetes," not "diabetic." ■

Microvascular Dysfunction in Prediabetes

In a study of 609 people with type 2 diabetes (T2D), 335 with prediabetes, and 1,269 with normoglycemia, flicker light–induced retinal arteriolar dilation, heat-induced skin hyperemia (laser-Doppler flowmetry), and glucose metabolism were assessed. After multivariable regression analyses were adjusted for age, sex, body mass index, smoking, physical activity, systolic blood pressure, lipid profile, retinopathy, estimated glomerular filtration rate, (micro)albuminuria, use of lipid and blood pressure medications, and prior cardiovascular disease, researchers found that retinal arteriolar dilation was reduced by .20 in patients with prediabetes and .61 in patients with T2D compared with those who had normal glucose metabolism. Skin hyperemic response was reduced by 46% in patients with prediabetes and 184% in patients with T2D. ■

Telemedicine Is Maturing

More than half of the health system executives in a new survey said their telemedicine programs are growing or expanding (since the 2014 survey). The change has come on the heels of studies showing proven patient outcomes and an increased demand by providers. About half of the health systems surveyed said they track return on investment from telemedicine. Nearly one third are seeing savings of 20% or more, and another 25% are saving 10%-20%. These savings result from avoided emergency department and urgent care visits. Most survey respondents say that third-party reimbursement holds telemedicine growth back. ■

HIV Infection in the United States in 2017 *continued from page 2*

infection risk to affected populations, including discrimination, stigma, poverty, and a lack of access to care. Sexual networks are also a major determining factor, with populations at high risk of HIV infection tending to have sex with people in their own communities.

- Between 2010 and 2014 the overall annual number of new HIV infection diagnoses among people who inject drugs decreased by 26% in the United States.
- The cost of lifetime treatment for an HIV-infected individual is $380,000.
- Since 1981, 675,000 people in the United States have died of AIDS.

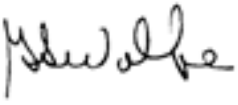
Treatment can be prevention. Pre-exposure prophylaxis is a way for HIV-negative individuals to get treatment before exposure to HIV to prevent infection, and it has been recommended in the United States since 2012 for individuals who are at ongoing substantial risk of HIV infection. This includes HIV-negative individuals in a sexual relationship with an HIV-infected person, people who inject drugs, and men who have sex with men who do not consistently use condoms. Although 1.2 million people were eligible for pre-exposure prophylaxis in the United States in 2015, it was only prescribed to an estimated 30,000 individuals. It is estimated that increasing pre-exposure prophylaxis coverage in the United States could prevent around 48,000 new HIV infections within 5 years and up to 185,000 new HIV infections in the same period if increased coverage were combined with expanded testing and treatment.

Although HIV infection/AIDS started out as a grim, devastating disease, many HIV-infected individuals now have a more-positive outlook. There are, however, still many challenges to overcome: stigma, social isolation, access, cost of treatment, and adherence to name but a few.

What can a case manager do to help in this struggle?

- Encourage testing. If an individual falls into a high-risk group, encourage him or her to know their HIV status. Get tested!
- Educate people so we can decrease the stigma and social isolation of HIV infection. When treated, HIV infection can be a manageable chronic disease, and HIV-infected individuals can live a long life.
- Encourage the use of pre-exposure prophylaxis when appropriate.
- Advocate for a targeted case management program. These programs work based on best practice evidence from programs all over the United States.
- Stay educated. Treatment options change. New research brings to light new treatment approaches.

Remember that the number of new cases of HIV infection has stayed somewhat constant for the last few years. More needs to be done. Do your part!



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ACCM: Improving Case Management Practice through Education

What's New at CMSA? *continued from page 10*

Washington D.C. to advocate on behalf of all case managers. The 2-day event was packed with education, new connections, and productive meetings with many members of Congress. We continued the momentum and celebration of case management in October 2017 during National Case Management Week, with our theme, Together, We Stand Strong.

Strength, togetherness, and advancement through education and action is why our organization exists; you have the power to make a difference with us, not only in the lives of your patients, but also for your colleagues, your practice, and yourself.

Head over to our new website at www.cmsa.org when you have some time and notice what areas peak your interest. Re-energize your passion for case management with a new goal. We're truly here for you, and we will support you and your practice in any way we can!

As Helen Keller said, "Alone we can do so little, together we can do so much!" CM

CCMC Expands Continuing Education Options With New Online Learning Modules *continued from page 4*

education is not "one size fits all." Schedules, professional obligations, and travel budgets impact how and where case managers can access case management. The best way to serve the needs of the professional case managers is with a variety of options—both online and in person. With greater flexibly in delivering continuing education, CCMC strives to reach more case managers to help them achieve their professional development goals. CM

CE 1 **Health Information Technology Is Transforming Osteoporosis Care Management** *continued from page 17*

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PharmaFacts for Case Managers

continued from page 25

Pediatric Use

The pharmacokinetics of benralizumab in adolescents 12 to 17 years of age were consistent with adults based on population pharmacokinetic analysis and the reduction in blood eosinophil counts was similar to that observed in adults following the same Fasenra treatment. The adverse event profile in adolescents was generally similar to the overall population in the Phase 3 studies. The safety and efficacy in patients younger than 12 years of age has not been established.

Geriatric Use

Of the total number of patients in clinical trials of benralizumab, 13% (n= 320) were 65 and over, while 0.4% (n=9) were 75 and over. No overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

CLINICAL STUDIES

The asthma development program for Fasenra included one 52-week dose ranging exacerbation trial, three confirmatory trials, and one 12-week lung function trial.

Dose-Ranging Trial

Results from this trial and exposure-response modeling of exacerbation rate reduction supported the evaluation of benralizumab 30 mg in the subsequent trials. Fasenra is not approved at 2 mg, 20 mg, or 100 mg doses and should only be administered at the recommended dose of 30 mg.

Confirmatory Trials

Fasenra administered once every 4 weeks for the first 3 doses, and then every 4 or 8 weeks thereafter as add-on to background treatment was evaluated compared to placebo.
While 2 dosing regimens were studied in Trials 1, 2, and 3, the recommended dosing regimen is 30 mg Fasenra administered every 4 weeks for the first 3 doses, then every 8 weeks thereafter

Exacerbations

The primary endpoint for Trials 1 and 2 was the rate of asthma exacerbations in patients with baseline blood eosinophil counts of ≥300 cells/μL who were taking high-dose ICS and LABA. Asthma exacerbation was defined as a worsening of asthma requiring use of oral/systemic corticosteroids for at least 3 days and/or emergency department visits requiring use of oral/systemic corticosteroids and/or hospitalization. For patients on maintenance oral corticosteroids, an asthma exacerbation requiring oral corticosteroids was defined as a temporary increase in stable oral/systemic corticosteroids for at least 3 days or a single depo-injectable dose of corticosteroids. In Trial 1, 35% of patients receiving Fasenra experienced an asthma exacerbation compared to 51% on placebo. In Trial 2, 40% of patients receiving Fasenra experienced an asthma exacerbation compared to 51% on placebo.

Subgroup analyses from Trials 1 and 2 identified patients with a higher prior exacerbation history and baseline blood eosinophil count as potential predictors of improved treatment response. Reductions in exacerbation rates were observed irrespective of baseline peripheral eosinophil counts; however, patients with a baseline blood eosinophil count ≥ 300 cells/μL showed a numerically greater response than those with counts < 300 cells/μL. In both trials, patients with a history of 3 or more exacerbations within the 12 months prior to Fasenra randomization showed a numerically greater exacerbation response than those with fewer prior exacerbations.

Oral Corticosteroid Reduction

Trial 3 evaluated the effect of Fasenra on reducing the use of maintenance oral corticosteroids. The primary endpoint was percent reduction from baseline of the final OCS dose during Weeks 24 to 28 while maintaining asthma control. Compared to placebo, patients receiving Fasenra achieved greater reductions in daily maintenance oral corticosteroid dose while maintaining asthma control. The median percent reduction in daily OCS dose from baseline was 75% in patients receiving Fasenra (95% CI: 60, 88) compared to 25% in patients receiving placebo (95% CI: 0, 33). Reductions of 50% or higher in the OCS dose were observed in 48 (66%) patients receiving Fasenra compared to those receiving placebo 28 (37%). The proportion of patients with a mean final dose ≤5 mg at Weeks 24 to 28 was 59% for Fasenra and 33% for placebo (odds ratio, 2.74, 95% CI: 1.41, 5.31). Only patients with an optimized baseline OCS dose of 12.5 mg or less were eligible to achieve a 100% reduction in OCS dose during the study. Of those patients, 52% (22 of 42) receiving Fasenra and 19% (8 of 42) on placebo achieved a 100% reduction in OCS dose. Exacerbations resulting in a hospitalization and/or ER visit were also assessed as a secondary endpoint. In this 28-week trial, patients receiving Fasenra had 1 event while those on placebo had 14 events (annualized rate 0.02 and 0.32 respectively; rate ratio of 0.07, 95% CI: 0.01, 0.63).

Lung Function

Change from baseline in mean FEV1 was assessed in Trials 1, 2, and 3 as a secondary endpoint. Compared with placebo, Fasenra provided consistent improvements over time in the mean change from baseline in FEV1. Subgroup analyses also showed greater improvements in FEV1 in patients with higher baseline blood eosinophil counts and more frequent prior exacerbation history. The clinical development program for Fasenra also included a 12-week, randomized, double-blind, placebo-controlled lung function trial conducted in 211 patients with mild to moderate asthma. Patients were treated with placebo or benralizumab 30 mg SC every 4 weeks for 3 doses. Lung function, as measured by the change from baseline in FEV1 at Week 12 was improved in the benralizumab treatment group compared to placebo.

Patient Reported Outcomes

The Asthma Control Questionnaire-6 (ACQ-6) and Standardized Asthma Quality of Life Questionnaire for 12 Years and Older (AQLQ(S)+12) were assessed in Trials 1, 2, and 3. The responder rate for both measures was defined as improvement in score of 0.5 or more as threshold at the end of Trials 1, 2, and 3 (48, 56, and 28 weeks, respectively). In Trial 1, the ACQ-6 responder rate for Fasenra was 60% vs 50% placebo (odds ratio, 1.55; 95% CI: 1.10, 2.19). In Trial 2, the ACQ-6 responder rate for the Fasenra was 63% vs 59% placebo (odds ratio, 1.16; 95% CI: 0.80, 1.68). In Trial 1, the responder rate for AQLQ(S)+12 for Fasenra was 57% vs 49% placebo (odds ratio, 1.42; 95% CI: 0.99, 2.02), and in Trial 2, 60% Fasenra vs 59% placebo (odds ratio of 1.03; 95% CI: 0.70,1.51). Similar results were seen in Trial 3.

HOW SUPPLIED/STORAGE AND HANDLING

Fasenra (benralizumab) injection is a sterile, preservative-free, clear to opalescent, colorless to slightly yellow solution for subcutaneous injection supplied as a single-dose prefilled syringe. Carton contains one 30 mg/mL single-dose prefilled syringe: NDC 0310-1730-30.

Store the prefilled syringe refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Do not freeze. Do not shake.

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Vol. 23, No. 6, December 2017/ January 2018. *CareManagement* (ISSN #1531-037X) is published electronically six times a year, February, April, June, August, October, and December, and its contents are copyrighted by Academy of Certified Case Managers, Inc., 2740 SW Martin Downs Blvd. #330, Palm City, FL 34990; Tel: 203-454-1333; Fax: 203-547-7273.

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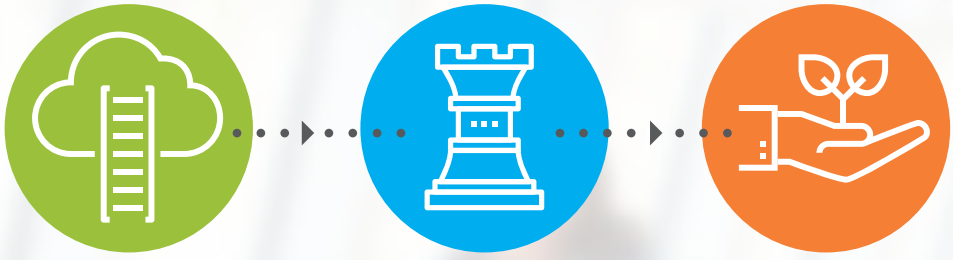

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