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Gary S. Wolfe

Addiction Treatment

Drug addiction is one of the most common public health problems in the United States. Over 20 million people are current or former drug addicts in the United States. Drug addiction is a significant factor in health and disease issuaes, incarceration rates, vehicle accidents, unemployment, and financial burdens. Drug abuse and addiction have negative consequences for individuals and for society. Estimates of total overall costs of substance abuse in the United States, including productivity and health- and crime- related costs, exceed $600 billion annually. A staggering amount. Drug harm to society is more significant. Family breakdowns, domestic violence, child abuse, vehicle accidents, education problems and loss of employment are all linked to drug addiction. The statistics are staggering as reported by the National Survey on Drug Use and Health for 2010[1]:

- 22.6 million people or 8.9% of the population older than age 12 were current or former drug users
- 20.2 million people older than age 18 are current illicit drug users
- Marijuana is the most commonly used illegal substance: 17.4 million people are reported to be past-month users
- 7 million people are reported to use prescription medications for nonmedical use

The statistics go on and on.

One of the most difficult issues in the United States with regard to drug addiction is access to treatment. Individuals who are struggling with addiction have limited access to services if they do not have health insurance. Publically funded services to deal with drug addiction are chronically underfunded, under-resourced, and overburdened. This can mean that services can only provide short-stay limited focus treatment options for the addict. This approach does not lead to successful long-term positive outcomes. Relapse is common.

Many people do not understand why or how other people become addicted to drugs. It is often mistakenly assumed that drug abusers lack moral principles or willpower and that they could stop using drugs simply by choosing to change their behavior. In reality, drug addiction is a complex disease, and quitting takes more than good intentions or a strong will. Drugs change the brain in ways that foster compulsive drug abuse, and, therefore, quitting is difficult even for those ready to do so. Through scientific advances, we know more than ever about how drugs work in the brain, and we also know that drug addiction can be successfully treated to help people stop abusing drugs and lead productive lives.

In an article in this issue, "Case Managers as Change Agents for Improving the US Addiction Treatment System," Dr. John Fitzgerald suggests that improvement in the US addiction treatment system can happen with case managers. Not an unrealistic idea! Most case managers have seen the negative impact of drug addiction or our patients, family, or friends.

If case managers are going to improve the addiction treatment system, they will start by educating themselves about addiction. Most of us probably received limited education in our basic program about addiction. Tremendous strides have been made in understanding addiction and how to be successful in treatment. As Dr. Fitzgerald suggests, long-term outpatient therapy with different interventions are needed to be successful.

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Did you know? Today's board-certified case manager is…

- **WELL- EDUCATED:** 70% have a bachelor's degree or higher education– compared to 28% in the general U.S. population.
- **DEDICATED TO EXCELLENCE:** Six in 10 attain board certification within five years of becoming a case manager; almost 9 out of 10 attain it within a decade.
- **FOCUSED:** More than half have specialty training in at least one area–such as geriatrics, worker's compensation, mental health, heart disease or oncology.
- **ACCOMPLISHED:** More than one in four is in a management or executive position.
- **REWARDED:** Nine out of 10 say board certification made a moderate to positive impact on their career and recommend it to others to advance their careers.*

**Source: Health2 Resources and CCMC, Professional and Demographic Characteristics of CCMs, August 2012*

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Commission for Case Manager Certification Announces New Officers, Board Members

Emphasis on expanding and enhancing workforce readiness on 2015–2016 agenda

By Patrice V. Sminkey, RN, CEO, Commission for Case Manager Certification

The new slate of officers was announced today by the Commission for Case Manager Certification.® Their pledge to advance the Commission's mission and vision is demonstrated through their commitment as volunteers to the organization that validates the skills and knowledge required for excellence in case management. New health care reimbursement models that pay for value of care rather than volume are on the path to becoming the norm over the next three years. Most require expansion of successful, innovative approaches that include care coordination and team-based care collaboration across health care settings--functions professional case managers are best prepared to fulfill.

The number of board-certified case managers continues to grow, and more than 37,000 case managers have demonstrated their qualifications by earning the CCM® credential. But further workforce development efforts are required to meet this growing need. The Commission, the oldest and largest nationally accredited organization certifying case managers, will hold its first national meeting, the CCMC New World Symposium™, Jan. 21–23, 2016, to raise the profile of the evolving role of case managers in today's health care terrain. The Commission's new board will preside over this event.

Sandra Zawalski, RN, BSN, CRRN, CCM, ABDA, MSCC, is the Commission's newly elected chair. Zawalski is manager of case management at HealthSpan, which is based in Ohio. Zawalski is responsible for daily oversight, coordination, education and supervision of case managers and social workers. In addition to her service on the Commission, Zawalski has served on the executive committee of the Cleveland chapter of the Case Management Society of America (CMSA) and on the board for the Brain Injury Foundation for the Cleveland Chapter. Zawalski has also served on the education committee for the Northeast Ohio Case Management Network and is a former Boy Scout leader. Zawalski holds a bachelor's degree in nursing.

Other 2015/2016 officers are:

- Immediate Past-Chair: **Jo Carter, BSN, RN, CCM,** vice president of network services, Paradigm Management Services LLC;
- Chair-elect: **Jane Harkey, RN, MSW, CCM,** founder and owner of an independent geriatric care management company;
- Treasurer: **Annette Watson, RN-BC, CCM, MBA**, founder and principal, Watson International Consulting; and
- Secretary: **Charlotte Sortedahl, DNP, MPH, MS, RN, CCM,** assistant professor at the University of Wisconsin Eau Claire.

The Commission also elected four new Members at Large, representing a range of allied health fields and delivery settings:

- **Nina Mottern, RN, BSN, CCM,** geriatric nurse care manager for Seniors Choice Care Management, Rochester, N.Y.
- **Michelle Crook, RN, BSN, CCM, CRRN,** business project program manager, Aetna Medicare Provider Collaboration Program.
- **Chikita Mann, RN, MSN, CCM,** disability case manager supervisor, GENEX Services, Inc.

"This all-volunteer board brings energy and solid commitment to leadership," said Patrice Sminkey, the Commission's CEO. "With backgrounds ranging from geriatric nursing to social work, disability case management and academic leadership, our Commissioners champion professional case management excellence through certification, education and advocacy programs and services." For example, the National Commission for Certifying Agencies (NCCA) granted [re]accreditation to the Commission's CCM credential for demonstrating compliance with the NCCA Standards for the Accreditation of Certification Programs in June.

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***Patrice V. Sminkey, RN,** is the CEO of the Commission for Case Manager Certification.*

Patient Rights to Choice of Provider

By Elizabeth Hogue, Esq.

A member of the upper management team at a home health company recently related the following story regarding patients' right to freedom of choice. The manager, who is a Medicare beneficiary, spoke with her surgeon and knew that he recommended home health services following her discharge from the hospital. She reminded him that she worked for a home health company and wanted to receive services from the company for which she worked. Her physician readily agreed to supervise services from the agency.

Following surgery, the discharge planner/case manager came to the manager's hospital room and told her that an agency owned by the hospital would provide home care services to her. The manager responded by saying that she worked for a home health company and wanted services from that agency. The discharge planner/case manager then said that the manager's physician always used the hospital's agency and that she would have to call the physician to get his "approval" in order for the manager to receive services from a different agency.

The manager continued to insist that her choice was the company that she worked for. The discharge planner/case manager then said that the "protocols" had already been sent to the hospital's agency, so the manager asked her to also send them to the agency for which she worked. The manager also informed the case manager/discharge planner that she had broken the law.

What's wrong with this picture? The patient was not given the opportunity to choose an agency as required by law. When she, nonetheless, clearly expressed her choice, various reasons were given to try to convince her that she could not have the agency of her choice. The case manager/discharge planner did indeed break the law! Why is it so difficult for case managers/discharge planners to present the list to patients in a neutral manner and, if patients express choices, to readily honor them?

Why is it so difficult for case managers/discharge planners to present the list to patients in a neutral manner and, if patients express choices, to readily honor them?

Is it because hospital administration puts pressure on case managers/discharge planners to refer to agencies owned by hospitals? If so, national standards published by The Case Management Society of America make it clear that case managers/discharge planners cannot succumb to pressure from their employers when it comes to advocating for patients and protecting their rights. These standards likely govern the practice of hospital discharge planners/case managers, whether or not they are certified case managers.

Is it because it is easier and more convenient to refer patients to agencies owned by hospitals? If so, it is important to be reminded that Conditions of Participation (CoPs) of the Medicare Program that govern discharge planning at hospitals make it clear that patients' choices cannot be limited in any way.

While it is true that the above is the experience of one patient, there are, undoubtedly, many case managers/discharge planners who are meticulous about compliance with all applicable requirements related to patients' right to freedom of choice. For discharge planners/case managers who are not compliant, here is the gist of what must be done: make a neutral presentation of a list of agencies or other providers to patients. Refer patients to their choices without putting up any barriers or resistance. When patients cannot choose, help them to do so.

Is it really so hard? When case managers/discharge planners are noncompliant with requirements related to patients' right to freedom of choice, they ride roughshod over a very important right of patients to control the care provided to them, including who provides it. It's past time to get it right!

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.*

CEU I

Case Managers as Change Agents for Improving the US Addiction Treatment System

John Fitzgerald, PhD, LPC, CAS

Case managers have a unique opportunity to contribute to and strengthen addiction treatment services. This paper outlines key activities and provides guidance on skill development.

A 27-year-old woman, recently referred to me for daily intravenous heroin use, began using opioids in 2004 when she was given an 80-mg OxyContin tablet and liked how it made her feel. In the years following, she could not maintain her expensive prescription drug habit and switched to cheaper and more easily accessible heroin. Now, sitting in my office high, sores covering many parts of her worn body, track marks visible in her arms, she asked for help because her boyfriend no longer allowed her to see her 5-year-old son.

It's a case repeated many times in our present fight against prescription drug abuse. In the last decade, overdose deaths from opioid pain relievers and heroin have exceeded motor vehicle deaths in many states. Add to these losses the consequences of millions struggling with addictive behaviors to alcohol, gambling, sex, food, and the internet, and the evidence is overwhelming that addiction is among the most challenging of all public health problems. What is not so clear is what we should be doing about it.

Our Broken Addiction Treatment System

The long-standing answer has been treatment, but numerous reports have documented how our $30-billion-a-year addiction treatment system operates far from optimal.[1–3] Less than 10% of those in need of care receive it,[4] and of those who complete a program, about half relapse within a few years. While effective medications and behavioral interventions exist, they are significantly underutilized in practice. In 55% of counties in the US, all rural, there exist no practicing psychiatrists, psychologists, or social workers to treat addiction.[5] Yet in 2014, about 40 million more Americans will have health insurance under the Affordable Care Act and be able to seek help for addiction. Add to this additional strain on the treatment system the significant lack of addiction care for active and veteran military,[6] as well as those behind bars,[7] and the need for rethinking how we treat and deliver treatment in this country is greater than ever.

While investors see the gap in services as a prime opportunity to invest in treatment, sadly much of the increased funding has gone to expensive residential care that for most patients is no more effective than intensive outpatient.8 This has led to excess capacity in residential treatment (9% of patients, 24% of facilities in the US), and under capacity in outpatient resources (90% of patients, 82% of facilities in the US).[9] Even more, because addiction is a chronic, relapsing medical condition,[10] care is optimized when delivered over many months, and most often years. As a result, spending thousands of dollars for a month's residential stay may benefit investors, but patient outcomes suffer when the money could be better utilized to fund treatment over a much longer period of time.

Beyond a Band-Aid Solution

Numerous fixes to our broken addiction treatment system have been put forward,[2] including: (1) better integration of addiction treatment with primary care medicine, (2) enhanced screening, brief interventions and referral to treatment in all health care settings, (3) leveraging principles of disease management to improve addiction intervention outcomes, (4) improved coordination of treatment professionals across disciplines (eg, medical, addiction, mental health, dental), and (5) monitoring patient outcomes and adjusting treatment. While there are other interventions that would likely improve our system of care, without a significant transformation in how they get implemented in practice, our addiction treatment system will remain broken, albeit with a few Band-Aids to stop some of the bleeding.

Returning to my patient, after completing an initial evaluation, I learned she had been in multiple treatment

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An important leverage point for significantly improving addiction treatment in this country, including both increased capacity and greater use of evidence-based practices, is recognizing the critical role those skilled in case management can play in transforming our addiction treatment system.

programs during the past decade—both residential and outpatient—and never once been offered the first-line treatment for daily heroin use, methadone. In addition, she had not been seen by a primary care physician in more than 2 years, had a painful tooth abscess in need of attention, and was on the verge of losing her housing. She also suffered from co-occurring trauma and depression, and had neglected her sleep, diet, and personal hygiene. In short, she needed a lot of things beyond addiction counseling.

The Case for Case Managers

An important leverage point for significantly improving addiction treatment in this country, including both increased capacity and greater use of evidence-based practices, is recognizing the critical role those skilled in case management can play in transforming our addiction treatment system. While there are different models of case management, in general they all involve: (1) assessing patient's needs, (2) developing and collaborating with other professionals on care plans, (3) coordinating and implementing care plans, and (4) monitoring outcomes. Embedded in these processes is the culture of case management that understands the importance of collaborative problem solving, communicating effectively with a broad group of stakeholders, and being the glue that holds many intervention parts together, even when the left and right hand are not talking with one another.

One of the most significant challenges of our present addiction treatment system is a workforce that is too few, aging into retirement, underpaid, undertrained, and stressed to the point where turnover rates are higher than in the fast food industry.[5] Yet even in counties that are understaffed or where no addiction professionals practice, there are likely to be one or more of the 37,000 Board-certified case managers working in some capacity in the health care system. Compared to the addiction treatment workforce where 24% of staff have a bachelor's degree, and 40% have less than a bachelor's degree, Board-certified case managers are required to have at minimum a bachelor's degree in a health or human service–related field, in addition to qualified employment experience. While many may never have been formally educated or trained in addiction care, the foundational knowledge and skills of case management can be adapted to fill many of the gaps in our existing addiction treatment system.

In addition, 75% of all health care spending is on patients suffering from chronic conditions like asthma, diabetes, and hypertension.[11] Case managers play a critical role in the delivery of care to these patients, and have evolved a tool box of disease management interventions that enhance patient outcomes.[12,13] In the past decade, the idea that addiction is also a chronic, relapsing condition similar to other chronic medical conditions has become well accepted within the addiction treatment and medical communities.[10] This suggests that case managers may be among the best qualified and trained health care professionals to deliver addiction care in a system where the present workforce simply cannot meet the demands of those in need.

Case managers also are uniquely positioned to help fulfill the much-needed "no wrong door" policy, which suggests that no matter where someone with addiction presents—primary care medicine, mental health, social service, criminal justice, education, employment, dentistry, housing—the problem will be acknowledged and addressed. While case managers have traditionally been nurses working in hospitals, there is an increasing number of other professional disciplines (eg, counselors, pharmacists, social workers) that have entered the case management field and are now practicing in a variety of community-based settings. This is good news for the addiction treatment system (and the no wrong door policy) if this diverse group of professionals can apply their knowledge and skills of case management to the needs of those with addiction. At the same time, it presents a significant opportunity for those with case management certifications to play an enhanced role in addiction care, furthering their value in the overall health care system.

Another reason why case managers are ideally positioned to play a catalyzing role in transforming our addiction treatment system is their ability to implement the day-to-day delivery of care and many of the fixes previously mentioned. These fixes—and numerous others—represent the recommendations from panels of experts who have studied what is needed to improve addiction treatment in this country. While having a list of fixes is a good start, what often gets overlooked is just how challenging it is to get the fixes implemented into routine practice.[14,15]

Linking primary and behavioral health care, increasing screenings for addiction, and helping patients successfully adhere to care plans are all fixes that necessitate change agents willing to work in the trenches and champion change initiatives. Case managers, because of their education and multifaceted skills sets, knowledge of culture and professional norms, and ability to influence multiple stakeholder groups, have incredible leverage to influence the implementation processes required to overcome individual and organizational barriers to change.

Enhancing Case Managers' Addiction Knowledge and Intervention Skills

Let's consider again my 27-year-old patient. Even if a case manager had little experience with daily heroin use (or addiction in general), given his or her education and training, he or she could easily complete four tasks: (1) assess her needs, (2) coordinate care with multiple professionals (eg, physician, dentist, psychiatrist, counselor, housing specialist), (3) develop a care plan to improve sleep and diet, and (4) engage in a therapeutic relationship—even if contacts were brief and intermittent—that monitors progress over time and makes adjustments to care plans as necessary. Given these interventions, it is understandable how a case manager could positively influence long-term outcomes even while knowing little about addiction, whereas substance abuse counselors, who only focus on addiction-specific interventions, might not fare as well. That said, if case managers are to become change agents in improving the addiction treatment system, enhancing their knowledge of addiction and intervention skills in a few critical areas would be necessary.

Knowledge of Addiction

There are no shortages of theories and models of addiction, nor is there a lack of resources to learn about the nature of addiction. Googling the word *addiction* returns an unbelievable 155 million entries. While such information overload is now commonplace in our world, case managers need only understand a number of key themes to be adequately knowledgeable about addiction.

- **Addiction begins early in life**. About 80% of those who go down the path of addiction begin their journey before the age of 15, and 90% before the age of [20.16] This means that addiction is born in adolescence, evolves during teenage years, and emerges fully in adulthood.
- **Genetics play a role.** Meta-analytic reviews tell us that 23% to 79% of addictive behavior can be explained by genetics, the variability due to different drugs and addictive behaviors. For example, genetic influence on opioid use disorders ranges from 23% to 54%, whereas the genetic range for cocaine addiction is 42% to 79%.[17] While biology clearly deals very different cards to people specific to addiction, environmental influences (interacting with genetics) are far more important in understanding treatment needs of those who suffer.
- **Adverse childhood experiences (ACEs) motivate addiction.** Numerous studies, including the Adverse Childhood Experiences study, provide strong evidence that addiction is an adaptive response to painful early life experiences.[18–21] The more trauma in all forms—emotional, sexual, and physical—and the more shame, the more likely addiction becomes a likely coping strategy. And early trauma often fuels shame—the feeling of brokenness—that becomes a driving force for continued addictive behavior.
- **Addictions come in many forms.** While scientific and political battles debate how best to classify addictive behavior, clinicians know well that people become addicted to a wide variety of both substances and behaviors,[22] including alcohol, illicit drugs, licit drugs, gambling, sex, food, and the internet. Within each of these board categories, new variations are constantly emerging, such as e-cigarettes and powdered alcohol.
- **Addiction comes in packages.** Most people have multiple addictions that interact in predictable ways, which means that for treatment to be effective, it must address the entire package of addictive behavior, not just focus on the primary addiction.[23]
- **Addiction alters the brain.** Neuroimaging studies reveal that engaging in additive behavior over time physically alters the brain, which in turn, changes the person.[24] There is evidence of a molecular switch in the brain (Delta Fos B), that when flipped, essentially leads to a hijacking of the brain that helps us to understand why many who succumb to addiction struggle to overcome it.[25]
- **Addiction is a chronic, relapsing condition.** Like asthma, diabetes, and hypertension, addiction has no cures, produces similar relapse rates, and is best treated with a continuing care model.[10,16,26,27]
- **Addiction negatively impacts relationships**. Most who struggle with addiction have developmental deficits and constrictions that impede the ability to initiate, form, and develop healthy relationships with people. This adversely impacts intimate relationships, parenting, child rearing, and success in the workplace. Successfully overcoming addiction requires developmentally based interventions to close the gap between one's developmental and chronological age.[28,29]
- **Addiction negatively impacts spiritual/faith development.** About 85% of the world population follows a faith tradition, namely because faith

With an increased base of knowledge about addiction, case managers can learn how to deliver one or more of the following evidence-based interventions that complement traditional case management interventions.

provides guidance in grappling with the big questions in life. For those who struggle with addiction, faith often remains unexamined, underdeveloped, and a powerful leverage point for initiating change.[30,31]

While other themes could be added to this list, the above provide a solid starting point for case managers to further their understanding of addiction. Take four steps to learn more about addiction:

1. Read the citations for this paper
2. Attend continuing education programs focused on one or more of the themes
3. Study reliable websites such as NIDA, NIAAA, SAHMSA, and my own site: www.addictionmanagement.org
4. Enroll in addiction courses at local community colleges or universities

In addition, case managers who believe addiction work is their calling may benefit from seeking out certifications in addiction offered by academic institutions.

Intervention Skills

With an increased base of knowledge about addiction, case managers can learn how to deliver one or more of the following evidence-based interventions that complement traditional case management interventions, and address many of the above mentioned themes:

- **Motivational Interviewing (MI).** Now widely utilized in a variety of health care settings, MI is among the most useful interventions for motivating change in those who struggle with addiction, particularly for patients actively engaged in addictive behavior.[32]
- **Screening, Brief Intervention, and Referral to Treatment (SIBIRT).** Designed for use in health care settings, SIBIRT offers case managers a range of approaches for addressing unhealthy alcohol use with medical patients. Some evidence suggests the skills may also be applicable for problematic drug use.[33]
- **Trauma-informed Care (TIC).** Both an organizational structure and treatment framework, TIC offers case managers tools that can address untreated ACEs and trauma fueling addictive behavior. Within TIC are multiple intervention options including: Seeking Safety, The Sanctuary Model, and Risking Connection.[34]
- **Focusing.** Developed by psychotherapist Eugene Gendlin, Focusing is a powerful process that can stimulate change and healing of addiction. Case managers can learn more about this intervention approach at www.focusing.org.
- **Addiction medications.** Case managers should develop a foundational knowledge of FDA-approved addiction medications because they are among the most effective and underutilized evidence-based interventions. Such knowledge can be utilized to inform patients of treatment options, and motivate a referral to a prescriber if appropriate.
- **Mindfulness.** Mindfulness-based interventions can significantly help those struggling with addiction. While there is a wide range of methods for incorporating mindfulness into routine practice (eg, Mindfulness-Based Relapse Prevention, Acceptance and Commitment Therapy, Mindfulness-Based Cognitive Therapy), many can be adopted and flexibly delivered by case managers in a variety of settings and circumstances.[35]
- **Positive psychology.** The field of positive psychology offers numerous evidence-based practices that facilitate positive emotions, well-being, creativity, and many other desirable outcomes that can help those who struggle with addiction.[36,37]
- **Community Reinforcement and Family Training Approach (CRAFT).** Often case managers interface with family members of a patient unmotivated to address addiction. In such cases, CRAFT is an evidence-based intervention that can be taught to family members to motivate the addicted individual to seek treatment, often within weeks.[38]

The options for learning more about addiction are also applicable to the above list of interventions. While the list is far from complete, case managers need to understand that no one approach, intervention, program, or therapist can address all that is necessary to overcome addiction. It is for many a chronic problem that requires *different approaches at different times, delivered by different people, most often over a period of years, not months*. Such a long-term perspective is why case managers are the ideal change agents to improve addiction treatment. They can stay connected to patients by phone, email, apps, or face-to-face meetings, and help connect the treatment dots over time. If patients relapse, they can use their relationship to reengage them back into treatment as soon as possible.[26,39] They can deliver evidence-based interventions, such as those previously listed, that can contribute to long-term outcomes. And they can champion

evolving technological solutions that promise a new frontier of interventions via web-based applications.[40,41]

Returning to my heroin-abusing patient one last time, initial targets of treatment would include:

- Inspiration to motivate her toward change
- Detoxification from heroin
- Use of methadone and psychiatric medications
- Medical and dental checkups
- Securing of safe housing
- Development of healthy diet and sleep habits

Many of the aforementioned interventions could play an important role in facilitating these interventions. Once significant abstinence from heroin is established and the other targets of treatment are met, interventions would then focus on resolution of underlying trauma, developmental catch-up, securing employment, and deepening intimate relationships. Here again, case managers' supportive use of focusing, mindfulness practices, and positive psychology interventions throughout her time in treatment—which would occur over years, not months—would contribute greatly to her long-term success.

Summary: An Opportunity for the Taking

Case managers are uniquely positioned within health care and various social systems to play an integral role in transforming our largely acute-based addiction treatment system into a far more effective enterprise that utilizes continuance of care interventions. The needs of those who suffer from addiction currently overwhelm our present system, resulting in incalculable losses when we factor in the many deaths that now occur on a daily basis. While many have put forth fixes to decrease deaths and improve treatment in this country, few have appreciated the significant challenges involved in implementing the fixes into routine practice. Case managers, with their education, skills, experience, and leadership qualities, have an opportunity for the taking.

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CEU II

Managing Heart Failure Through Multidisciplinary Collaboration

By Brenda Spears, Katherine Fetter, Beth Rodgers, Katie Kay

Heart failure (HF) is a clinically complex disease process resulting from an alteration in the structure or function of the ventricles that causes reduced ventricular filling or ejection of blood.1 A diagnosis of HF is often associated with a wide range of functional abnormalities of the heart that cause reduced cardiac output and many physical symptoms that include dyspnea, fatigue, fluid overload, and potential pulmonary edema.[1] Additionally, it is common for patients to suffer from lack of psychological well-being, including depressive symptoms, because of the complex nature of HF management.

Americans have a 20% risk of developing HF after the age of 40, meaning there are approximately 650,000 new cases diagnosed each year. Despite changes made to health care delivery, the rate of HF diagnosis has remained stable over the past few decades. However, what has changed is that the Medicare-eligible patient population has had an increase in HF diagnoses from 91 cases per 1000 individuals to 121 cases per 1000 people in a little over 9 years.[2]

Gaps in Care

The structure of the current health care system will need to evolve so that coordination across disciplines in both inpatient and outpatient settings is possible and high-quality care to this patient population can be provided. The opportunity to bridge the gap between inpatient and outpatient care is great. While inpatient mortality rates are improving for the HF patient population, postdischarge mortality has actually increased from 4.3% to 6.4%.[3]

More than 1 million hospital admissions annually are for patients with the primary diagnosis of HF.[3] These patients remain at a high risk for readmission within 30 days, which can cost health care organizations millions of dollars in uncompensated costs.[4] Additionally, with the Centers for Medicare & Medicaid Services (CMS) financially penalizing hospitals for HF readmissions, costs of care to an organization may end up further driving up costs of care for patients who may already be struggling with expensive co-pays and deductibles.[1] Total costs of care for HF patients hover around $30 billion dollars annually. Thus, there needs to be a greater focus on transitioning patients from hospital to home.[3] This transition will require effective collaboration between the outpatient care manager and all the members involved in the in-hospital patient care. This is not only necessary to improve postdischarge mortality rates, but also essential to reduce the costs of care for this patient population and reduce the fragmented and confusing care that patients are receiving.

Transitioning Care

The inpatient case manager, utilizing disease management programs, has a primary role in transitioning patients from hospital to home medical management. Case management has been defined as the coordination of multidisciplinary treatment for complex patients that recognizes the integral needs of the individual patient, without focusing on only one specific illness or population, as is the case in disease management.[5] On the outside, an outpatient care manager can work closely with the patient to manage the care at home and to assess issues that may contribute to the chronic condition of HF, such as psychosocial triggers, sleeping deficits, addictions to smoking, or even diet-related knowledge deficits.[6] The core elements in case management include assessing patient needs and developing and implementing an individualized treatment plan. A care manager can further assist with this continuity of care upon discharge. Additional variables specific to the care manager are as follows[7]:

- Coordinating care with timing delivery by providers
- Intensively monitoring the care process by reviewing patient compliance/adherence
- Evaluating the treatment plan

Although there are other professionals who interact with both case managers and care managers, each system employs and utilizes different professional resources, further contributing to the potential for fragmented care when a patient is unsure about how to proceed.

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Transitioning from hospital to home is a particularly critical time for patients because of the complexity of the disease process, medical regimen, additional patient conditions including psychosocial concerns, and the coordination of clinicians who need to be involved in the patient care.

HF Disease Management

Disease management began in the 1990s and is a coordinated, comprehensive approach to care along the continuum of the disease process.[8] This management style also addresses issues across health care delivery systems including quality and cost-effectiveness of the care for select patients with a specific chronic illnesses.8 Common components of a HF disease management program include the following.[9]

- Multidisciplinary approach by health care services
- Increased access to health care
- Facilitation of access during episodes of decompensation
- Optimization of medical management with assistance of case management
- Access to advanced treatment options
- Adequate patient education with emphasis on adherence and self-care management
- Patient involvement in symptom monitoring with flexible diuretic use

Disease management programs for patients with HF include components of a case management approach, patient-specific education, and additional elements of counseling.[10] The current evidence has demonstrated that case management can optimize chronic disease outcomes, like those of patients with HF, by enhancing the focus from disease-oriented to patient-centered care. Intensifying outreach to the patient and his/her social environment includes the use of care managers within the home setting, and integrating the care for a patient not only within the medical specialty of HF but also between different medical specialties across health care settings.[10] The care manager can orchestrate the delivery of care to be patient-centered, eliminating the loose ends that lead to frequent, fragmented care for patients.

Patient-centered Transition and Home Management Care Considerations

Transitioning from hospital to home is a particularly critical time for patients because of the complexity of the disease process, medical regimen, additional patient conditions including psychosocial concerns, and the coordination of clinicians who need to be involved in the patient care. Patients who receive focused education regarding activity, diet, medications, follow-up care, symptom management, weight management, and when to call the provider generally have improved outcomes. However, significant gains can be made in quality care during early postdischarge follow-up. Consistency in providers has been demonstrated to minimize gaps in understanding of the care plan and reduce readmission rates. Follow-up phone calls should be made within 3 days of discharge with provider-based appointments completed within 1 week. Of concern is that providers and health care professionals often fail to recognize the individual factors that contribute to poor health outcomes in HF patients. These additional concerns can include HF patients living within skilled nursing facilities, who have significantly higher mortality rates, as well as patients living within the community who may have lower socioeconomic status that leads to the inability to afford and take medications as prescribed.[1] Unfortunately, having to choose which medications to pay for or which appointments are affordable can lead to fragmented care, further complicating patient outcomes.

Attending to Psychosocial Issues

Psychosocial issues that patient may face can be important variables in the proper management of HF. Many times these issues are easily and unintentionally overlooked. Patients may have anxiety, poor coping skills, family issues, lack of support, and an inability to purchase medications. All of these issues can and typically do lead to depression. Approximately 50% of the population diagnosed with HF has had to deal with the symptoms of depression.[11]

Discussion with patients on how they should manage stressors in life is important. No single patient processes information the same way; an initial interview that seeks to understand how a patient deals with stressful life events can provide a framework for the care manager to better understand how the patient may respond to HF treatment. Case managers can start the process during the inpatient stay by working with the nursing staff collaboratively to show patients that they can have control over this disease. Inpatient education about adherence to medications and the importance of support systems is effective in increasing patient motivation and adherence to the medical regimen. Enhanced motivation and the patient's ownership of the disease process during hospitalization may transition to decreased likelihood of depression

when he or she is discharged to home.

For some patients, friends may be closer than family. This fact should not be discounted; obtaining consent from the patient is all that is necessary to discuss patient information with friends or family, and this could be a very comforting component to the patient's care. Care managers can include the social support system the patient deems important to them when they meet with the patient, which can give the patient a tangible, emotional sense of support.

There are a multitude of local support groups for patients with HF and broader groups that include all heart disease issues. There are also reputable groups online if the patient prefers to be at home, or is too ill initially to go out to a meeting. These support groups, combined with family and friends, lend positive support and can reduce the readmission rates for this population of patients.

Considering Financial Concerns

Patient access to insurance, the type of coverage they have, and their ability to pay for insurance, copays, or co-insurance costs tend to be constant issues in health care today. The constant sense of insecurity pertaining to costs of medications, hospital stays, and doctors' office visits can feel insurmountable to patients. Sometimes, patients may need different insurance carriers if they are having financial concerns. Collaboration with hospital financial counselors can be beneficial to patients who have financial difficulties. Encouragement thorough education regarding the available resources can help to reduce the possibility of fragmented care, thus reducing the percentage of patients who are nonadherent with medications and follow-up care.

Prevention is the key to better outcomes in health care. However, further exploration is necessary to determine potential processes that will support the HF patient in optimizing psychosocial aspects of the transition from the inpatient to outpatient setting.

Dealing with the stress of HF can be overwhelming enough for the patient, but more often than not, that stress is compounded by issues that arise with fragmented health care. One of the reasons fragmented health care occurs is because a patient receives care in multiple offices or facilities, or fills prescriptions at numerous pharmacies. According to Hoffman,[12] competition and regulation of health care providers and organizations drives the patients, or paying customers, to seek "the best deal," because the decision is made to choose between the lesser of two evils—financial or physical well-being. Other reasons for fragmented health care include inconvenience, availability of specialty health care providers, and lack of knowledge.

Many patients seek the convenience of health care providers that are closest to home, which does not always mean within the same health care system as the primary care physician who is trying to manage their care. This becomes a more significant problem when patients become more advanced in age or develop more chronic diseases, such as HF, chronic obstructive pulmonary disease, coronary artery disease, or a multitude of other diseases that require frequent modifications of medications and treatments. Adjustments of medications at one facility may not be relayed to the next facility by the patient, or the patient may present to the emergency room rather than first visiting the primary care physician, so updates may be missed. This can be a life-threatening mistake. In our health care system, communication back to the primary provider is lacking, increasing the errors and the costs of the duplicated treatments, thus increasing mortality rates.[13]

The care that is closest to home may not always be the best care that is required. Patients may need to see a specialist who is inconveniently located far from home but is the best medical choice for the prescribed care. Patients who are forced to travel to specialists may continue to receive all other care close to home, increasing the probability of error when communication issues arise between the specialist and the primary care physician. This is further complicated for older adults or those with chronic diseases who are more likely to have frequent hospitalizations. Although health care providers receive reimbursement incentives or penalties based on the quality or lack thereof of certain types of care (eg, reducing the readmission of HF patients),[14] there are gaps in the requirements surrounding provider-provider and provider-patient communication. This leads to knowledge deficits for both providers and patients and can cause devastating gaps in care.

Inpatient case managers and outpatient care managers are tasked with providing the glue that holds together the pieces of medical, nursing, and psychosocial care. It is impossible to have a care manager with the patient 24 hours each day, of course. But by providing knowledge and education to patients, allowing patients and families to be the "frontline caregivers," the likelihood of patients understanding the importance of receiving all care within the same system, or at the very least, keeping the chain of communication thoroughly oiled will be dramatically improved. Expecting patients to assume the responsibilities of this role without explaining why it is so important is unrealistic, but when the importance of the role is explained, patients are much more likely to take responsibility for their part.

Summary

Heart failure is the primary cause of hospitalization among the elderly, with approximately 10% of total Medicare

inpatient spending and 5% of total Medicare spending. Managing this complex, chronic illness has many challenges. Case and care managers, working with disease management programs, provide a structured and formalized assessment and address all health risks, clinical, psychosocial, and environmental factors to efficiently and effectively manage the disease course of HF patients from the inpatient to outpatient setting.10 Individual concerns must be considered when dealing with the complexities of managing HF. The earlier these concerns are addressed, the greater the benefit for the patient. The patient may be dealing with psychosocial stressors, lack of support, financial instability, fragmented health care issues while also trying to manage their HF symptoms to maintain their highest level or quality of life. The case and care manager roles must continue to maintain a patient-centered educational approach as a pivotal component for enhancing positive long-term outcomes for the HF patient, especially during the transition from the inpatient setting to ongoing medical home management. CEU II

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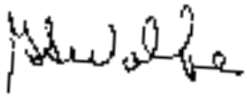
Addiction Treatment

continued from page 2

Addiction treatment is a challenge for all. Everyone at sometime is affected by a person who is addicted. Do your part! Become knowledgeable about addiction treatment.



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Reference

Substance Abuse and Mental Health Services Administration. National Survey on Drug Use and Health (NSDUH). 2010. http://www.samhsa.gov/data/population-data-nsduh. Accessed July 31, 2015.

Certified Case Manager News

continued from page 28

The authors also found that PCV13 could provide net cost savings of $6.14 billion and $4.24 billion, respectively, to those payers by preventing pneumococcal disease and its associated costs, with another $1.66 billion in savings to be realized for uninsured patients. ■

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exam I

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Case Managers As Change Agents for Improving the US Addiction Treatment System

1. The annual cost of the US addiction treatment system is:
a. $20 billion b. $25 billion c. $30 billion d. $35 billion

2. What percentage of people relapse within a few years of completing an addiction program?
a. 25% b. 50% c. 75% d. 100%

3. What percentage of rural counties have no practicing psychiatrists, psychologists, or social workers to treat addiction?
a. 25% b. 35% c. 45% d. 55%

4. There is excess capacity in residential treatment programs and undercapacity in outpatient resources.
a. True b. False

5. Numerous fixes to the broken addiction treatment system have been put forward, including:
a. Better interaction with primary care
b. Enhanced screening level interaction and referral to treatment in all health care settings
c. Improved coordination of treatment professionals across disciplines
d. All of the above

6. One of the most significant challenges of our present addiction treatment system is a workforce that is too few, aging into retirement, underpaid, and undertrained, and has high turnover rates.
a. True b. False

7. In the past decade, the idea that addiction is also a chronic, relapsing condition similar to other chronic medical conditions has become accepted within the addiction treatment and medical communities.
a. True b. False

8. Some of the key themes care managers need to understand about addiction include:
a. Addiction begins early in life
b. Genetics play a role
c. Addiction alters the brain
d. All of the above

9. Evidence-based intervention for treatment of addiction includes:
a. Positive psychology
b. Addiction medication
c. Motivational interviewing
d. All of the above

10. Successful addiction treatment requires different approaches at different times delivered by different people, mostly for a period of years.
a. True b. False

exam II

Take this exam online >

Managing Heart Failure through Multidisciplinary Collaboration

1. Heart failure is a clinically complex disease process resulting from an alternation in the structure or function of the ventricles that causes reduced ventricular filling or ejection of blood.
a. True b. False

2. What percentage of Americans are at risk of developing heart failure after the age of 40?
a. 10% b. 15% c. 20% d. 25%

3. Postdischarge mortality for heart failure has increased to:
a. 6% b. 6.4% c. 7% d. 7.4%

4. The total cost of care for heart failure hovers around:
a. $15 billion
b. $20 billion
c. $25 billion
d. $30 billion

5. Heart failure disease management programs include the following:
a. Multidisciplinary approach by health care services
b. Increased access to health care
c. Access to advanced treatment options
d. All of the above

6. Approximately what percentage of the population diagnosed with heart failure have had to deal with symptoms of depression?
a. 25% b. 50% c. 75% d. 100%

7. Discussion with patients on how they should manage stressors in life in important.
a. True b. False

8. The case manager can include the social support system that the patient deems is important.
a. True b. False

9. Considering financial concerns is important so the issues don't seem insurmountable to patients or have a negative impact on care.
a. True b. False

10. Heart failure is the primary cause of hospitalizations among the elderly.
a. True b. False

exam I Case Managers As Change Agents for Improving the US Addiction Treatment System

Objectives:

1. Describe the short falls of the US addiction treatment system. _____
2. State four factors that influence addiction. _____
3. List four interventions used for treating addiction. _____

Please indicate your answer to the exam questions on page 15 by filling in the letter:

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

exam II Managing Heart Failure through Multidisciplinary Collaboration

Objectives:

1. Define heart failure. _____
2. State gaps in heart failure care. _____
3. List three components of a successful heart failure treatment program. _____

Please indicate your answer to the exam questions on page 15 by filling in the letter:

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

Continuing Education Program Evaluation

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

	exam I	exam II
1. The objectives were met.	1 2 3 4 5	1 2 3 4 5
2. The article was clear and well organized.	1 2 3 4 5	1 2 3 4 5
3. The topic was both relevant and interesting to me.	1 2 3 4 5	1 2 3 4 5
4. The amount and depth of the material was adequate.	1 2 3 4 5	1 2 3 4 5
5. The quality and amount of the graphics were effective.	1 2 3 4 5	1 2 3 4 5
6. I would recommend this article.	1 2 3 4 5	1 2 3 4 5
7. This has been an effective way to present continuing education.	1 2 3 4 5	1 2 3 4 5

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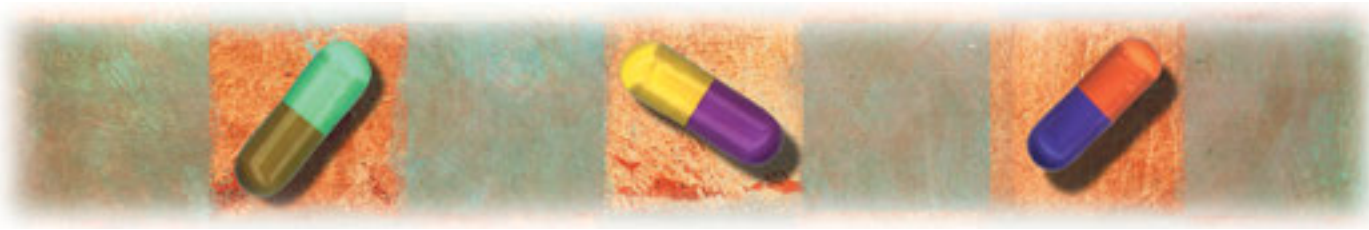

New Approvals

PraluentTM (alirocumab) injection, for subcutaneous use

Indications and Usage

Primary Hyperlipidemia

Praluent is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of LDL-C.

Limitations of Use

The effect of Praluent on cardiovascular morbidity and mortality has not been determined.

Dosing Information

The recommended starting dose of Praluent is 75 mg administered subcutaneously once every 2 weeks, since the majority of patients achieve sufficient LDL-C reduction with this dosage. If the LDL-C response is inadequate, the dosage may be increased to the maximum dosage of 150 mg administered every 2 weeks.

Measure LDL-C levels within 4 to 8 weeks of initiating or titrating Praluent to assess response and adjust the dose, if needed.

If a dose is missed, instruct the patient to administer the injection within 7 days from the missed dose and then resume the patient's original schedule. If the missed dose is not administered within 7 days, instruct the patient to wait until the next dose on the original schedule.

Important Administration Instructions

- Provide proper training to patients and/or caregivers on the preparation and administration of Praluent prior to use according to the Instructions for Use. Instruct patients and/or caregivers to read and follow the Instructions for Use.
- Allow Praluent to warm to room temperature for 30 to 40 minutes prior to use. Use Praluent as soon as possible after it has warmed up. Do NOT use Praluent if it has been at room temperature [77°F (25°C)] for 24 hours or longer.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. If the solution is discolored or contains visible particulate matter, the solution should not be used.
- Follow aseptic injection technique.
- Administer Praluent by subcutaneous injection into the thigh, abdomen, or upper arm using a single-dose pre-filled pen or single-dose pre-filled syringe.
- Rotate the injection site with each injection.
- Do NOT inject Praluent into areas of active skin disease or injury such as sunburns, skin rashes, inflammation, or skin infections.
- Do NOT co-administer Praluent with other injectable drugs at the same injection site.

Dosage Forms and Strengths

Praluent is a clear, colorless to pale yellow solution available as follows: Injection: Single-dose pre-filled pen or pre-filled syringe.

Contraindications

Praluent is contraindicated in patients with a history of a serious hypersensitivity reaction to Praluent. Reactions have included hypersensitivity vasculitis and hypersensitivity reactions requiring hospitalization.

Warnings and Precautions

Allergic Reactions

Hypersensitivity reactions (eg, pruritus, rash, urticaria), including some serious Study 2 s events (eg, hypersensitivity vasculitis and hypersensitivity reactions requiring hospitalization), have been reported with Praluent treatment. If signs or symptoms of serious allergic reactions occur, discontinue treatment with Praluent, treat according to the standard of care, and monitor until signs and symptoms resolve

Clinical Trials Experience

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

The safety of Praluent was evaluated in 9 placebo-controlled trials that included 2476 patients treated with Praluent, including 2135 exposed for 6 months and 1999 exposed for more than 1 year (median treatment duration of 65 weeks). The mean age of the population was 59 years, 40% of the population were women, 90% were Caucasians, 4% were Black or African American, and 3% were

Asians. At baseline, 37% of patients had a diagnosis of heterozygous familial hypercholesterolemia and 66% had clinical atherosclerotic cardiovascular disease.

Adverse reactions reported in at least 2% of Praluent-treated patients, and more frequently than in placebo-treated patients, were nasopharyngitis, injection-site reactions, influenza, urinary tract infection, diarrhea, bronchitis, myalgia, muscle spasms, sinusitis, cough, contusion, and musculoskeletal pain.

Adverse reactions led to discontinuation of treatment in 5.3% of patients treated with Praluent and 5.1% of patients treated with placebo. The most common adverse reactions leading to treatment discontinuation in patients treated with Praluent were allergic reactions (0.6% versus 0.2% for Praluent and placebo, respectively) and elevated liver enzymes (0.3% versus <0.1%).

Local Injection-Site Reactions

Local injection site reactions including erythema/redness, itching, swelling, and pain/tenderness were reported more frequently in patients treated with Praluent (7.2% versus 5.1% for Praluent and placebo, respectively). Few patients discontinued treatment because of these reactions (0.2% versus 0.4% for Praluent and placebo, respectively), but patients receiving Praluent had a greater number of injection site reactions, had more reports of associated symptoms, and had reactions of longer average duration.

Allergic Reactions

Allergic reactions were reported more frequently in patients treated with Praluent than in those treated with placebo (8.6% versus 7.8%). The proportion of patients who discontinued treatment due to allergic reactions was higher among those treated with Praluent (0.6% versus 0.2%). Serious allergic reactions, such as hypersensitivity, nummular eczema, and hypersensitivity vasculitis were reported in patients using Praluent in controlled clinical trials.

Neurocognitive Events

Neurocognitive events were reported in 0.8% of patients treated with Praluent and 0.7% of patients treated with placebo. Confusion or memory impairment were reported more frequently by those treated with Praluent (0.2% for each) than in those treated with placebo (<0.1% for each).

Liver Enzyme Abnormalities

Liver-related disorders (primarily related to abnormalities in liver enzymes) were reported in 2.5% of patients treated with Praluent and 1.8% of patients treated with placebo, leading to treatment discontinuation in 0.4% and 0.2% of patients, respectively. Increases in serum transaminases to greater than 3 times the upper limit of normal occurred in 1.7% of patients treated with Praluent and 1.4% of patients treated with placebo.

Low LDL-C Values

In a pool of both placebo- and active-controlled clinical trials, 796 Praluent -treated patients had two consecutive calculated LDL-C values <25 mg/dl, and 288 had two consecutive calculated LDL-C values <15 mg/dl. Changes to background lipid-altering therapy (eg, maximally tolerated statins) were not made in response to low LDL-C values, and Praluent dosing was not modified or interrupted on this basis. Although adverse consequences of very low LDL-C were not identified in these trials, the long-term effects of very low levels of LDL-C induced by Praluent are unknown.

Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity with Praluent. In a pool of 10 placebo- and active-controlled trials, 4.8% of patients treated with Praluent had anti-drug antibodies (ADA) newly detected after initiating treatment as compared with 0.6% of patients treated with control.

Patients who developed ADA had a higher incidence of injection site reactions compared with patients who did not develop ADA (10.2% vs 5.9%).

A total of 1.2% of patients treated with Praluent developed neutralizing antibodies (nab) on at least one occasion as compared with no patients treated with control, and 0.3% of patients both tested positive for nab and exhibited transient or prolonged loss of efficacy. The long-term consequences of continuing Praluent treatment in the presence of persistent nab are unknown.

Immunogenicity data are highly dependent on the sensitivity and specificity of the assay as well as other factors. Additionally, the observed incidence of antibody positivity in an assay may be influenced by several factors, including sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to Praluent with the incidence of antibodies to other products may be misleading.

Use in Specific Populations

Pregnancy

Risk Summary

There are no available data on use of Praluent in pregnant women to inform a drug- associated risk. In animal reproduction studies, there were no effects on embryo-fetal development when rats were subcutaneously administered alirocumab during organogenesis at dose exposures up to 12-fold the exposure at the maximum recommended human dose of 150 mg every 2 weeks. In monkeys, suppression of the humoral immune response was observed in infant monkeys when alirocumab was dosed during organogenesis to parturition at dose exposures 13-fold the exposure at the maximum recommended human dose of 150 mg every 2 weeks. No additional effects on pregnancy or neonatal/infant development were observed at dose exposures up to 81-fold the maximum recommended human dose of 150 mg every 2 weeks.

Measurable alirocumab serum concentrations were observed in the infant monkeys at birth at comparable levels to maternal serum,

indicating that alirocumab, like other igg antibodies, crosses the placental barrier. FDA's experience with monoclonal antibodies in humans indicates that they are unlikely to cross the placenta in the first trimester; however, they are likely to cross the placenta in increasing amounts in the second and third trimester. Consider the benefits and risks of Praluent and possible risks to the fetus before prescribing Praluent to pregnant women.

In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2%-4% and 15%-20%, respectively.

Lactation

Risk Summary

There is no information regarding the presence of alirocumab in human milk, the effects on the breastfed infant, or the effects on milk production. The development and health benefits of breastfeeding should be considered along with the mother's clinical need for Praluent and any potential adverse effects on the breastfed infant from Praluent or from the underlying maternal condition. Human igg is present in human milk, but published data suggest that breastmilk igg antibodies do not enter the neonatal and infant circulation in substantial amounts.

Pediatric Use

Safety and efficacy in pediatric patients have not been established.

Geriatric Use

In controlled studies, 1158 patients treated with Praluent were ≥65 years of age and 241 patients treated with Praluent were ≥75 years of age. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, 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.

Renal Impairment

No dose adjustment is needed for patients with mild or moderately impaired renal function. No data are available in patients with severe renal impairment.

Hepatic Impairment

No dose adjustment is needed for patients with mild or moderate hepatic impairment. No data are available in patients with severe hepatic impairment.

Clinical Studies

The efficacy of Praluent was investigated in 5 double-blind placebo-controlled trials that enrolled 3499 patients; 36% were patients with heterozygous familial hypercholesterolemia (HEFH) and 54% were non-FH patients who had clinical atherosclerotic cardiovascular disease. Three of the five trials were conducted exclusively in patients with HEFH. All patients were receiving a maximally tolerated dose of a statin, with or without other lipid-modifying therapies. In the trials that enrolled patients with HEFH, the diagnosis of HEFH was made either by genotyping or clinical criteria ("definite FH" using either the Simon Broome or WHO/Dutch Lipid Network criteria). All trials were at least 52 weeks in duration with the primary efficacy endpoint measured at week 24 (mean percent change in LDL-C from baseline).

Three studies used an initial dose of 75 mg every 2 weeks (Q2W) followed by criteria-based up- titration to 150 mg Q2W at week 12 for patients who did not achieve their pre-defined target LDL-C at week 8. The majority of patients (57% to 83%) who were treated for at least 12 weeks did not require up-titration. Two studies used only a 150 mg Q2W dose.

Study 1 was a multicenter, double-blind, placebo-controlled trial that randomLy assigned 1553 patients to Praluent 150 mg Q2W and 788 patients to placebo. All patients were taking maximally tolerated doses of statins with or without other lipid-modifying therapy, and required additional LDL-C reduction. The mean age was 61 years (range 18-89), 38% were women, 93% were Caucasian, 3% were Black, and 5% were Hispanic/Latino. Overall, 69% were non-FH patients with clinical atherosclerotic cardiovascular disease and 18% had HEFH. The average LDL-C at baseline was 122 mg/dl.

The proportion of patients who prematurely discontinued study drug prior to the 24-week endpoint was 8% among those treated with Praluent and 8% among those treated with placebo.

At week 24, the treatment difference between Praluent and placebo in mean LDL-C percent change was -58% (95% CI: -61%, -56%; P <0.0001).

Cost

Estimated Average Wholesale price: $14,600 annually

Manufactured by: sanofi-aventis U.S. LLC

Entresto™ (sacubitril and valsartan) tablets, for oral use

Indications and Usage

Heart Failure

Entresto is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction.

Entresto is usually administered in conjunction with other heart failure therapies, in place of an ACE inhibitor or other ARB.

Dosage and Administration

Entresto is contraindicated with concomitant use of an angiotensin-converting enzyme (ACE) inhibitor. If switching from an ACE inhibitor to Entresto allow a washout period of 36 hours between administration of the two drugs.

The recommended starting dose is 49/51 mg (sacubitril 49 mg/valsartan 51 mg) twice-daily.

Double the dose of Entresto after 2 to 4 weeks to the target

maintenance dose of 97/103 mg twice daily, as tolerated by the patient.

Adjustment for Patients Not Taking an ACE inhibitor or ARB or Previously Taking Low Doses of These Agents
A starting dose of 24/26 mg twice-daily is recommended for patients not currently taking an ACE inhibitor or an angiotensin II receptor blocker (ARB) and for patients previously taking low doses of these agents. Double the dose of Entresto every 2 to 4 weeks to the target maintenance dose of 97/103 mg twice daily, as tolerated by the patient.

Dose Adjustment for Severe Renal Impairment
A starting dose of 24/26 mg twice-daily is recommended for patients with severe renal impairment (eGFR <30 mL/min/1.73 m2). Double the dose of Entresto every 2 to 4 weeks to the target maintenance dose of 97/103 mg twice daily, as tolerated by the patient.

No starting dose adjustment is needed for mild or moderate renal impairment.

Dose Adjustment for Hepatic Impairment
A starting dose of 24/26 mg twice-daily is recommended for patients with moderate hepatic impairment (Child-Pugh B classification). Double the dose of Entresto every 2 to 4 weeks to the target maintenance dose of 97/103 mg twice daily, as tolerated by the patient.

No starting dose adjustment is needed for mild hepatic impairment. Use in patients with severe hepatic impairment is not recommended.

Entresto is supplied as unscored, ovaloid, film-coated tablets in the following strengths:

- Entresto 24/26 mg, (sacubitril 24 mg and valsartan 26 mg) are violet white and debossed with "NVR" on one side and "LZ" on the other side
- Entresto 49/51 mg, (sacubitril 49 mg and valsartan 51 mg) are pale yellow and debossed with "NVR" on one side and "L1" on the other side.
- Entresto 24/26 mg, (sacubitril 24 mg and valsartan 26 mg) are violet white and debossed with "NVR" on one side and "LZ" on the other side 97/103 mg, (sacubitril 97 mg and valsartan 103 mg) are light pink and debossed with "NVR" on one side and "L11" on the other side.

Contraindications

Entresto is contraindicated:

- In patients with hypersensitivity to any component
- In patients with a history of angioedema related to previous ACE inhibitor or ARB therapy
- With concomitant use of ACE inhibitors. Do not administer within 36 hours of switching from or to an ACE inhibiton
- With concomitant use of aliskiren in patients with diabete

Warnings and Precautions

Fetal Toxicity
Entresto can cause fetal harm when administered to a pregnant woman. Use of drugs that act on the renin-angiotensin system during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity and death. When pregnancy is detected, consider alternative drug treatment and discontinue Entresto. However, if there is no appropriate alternative to therapy with drugs affecting the renin-angiotensin system, and if the drug is considered lifesaving for the mother, advise a pregnant woman of the potential risk to the fetus

Angioedema
Entresto may cause angioedema. In the double-blind period of PARADIGM-HF, 0.5% of patients treated with Entresto and 0.2% of patients treated with enalapril had angioedema. If angioedema occurs, discontinue Entresto immediately, provide appropriate therapy, and monitor for airway compromise.

Entresto must not be re-administered. In cases of confirmed angioedema where swelling has been confined to the face and lips, the condition has generally resolved without treatment, although antihistamines have been useful in relieving symptoms.

Angioedema associated with laryngeal edema may be fatal. Where there is involvement of the tongue, glottis or larynx, likely to cause airway obstruction, administer appropriate therapy, eg, subcutaneous epinephrine/adrenaline solution 1:1000 (0.3 mL to 0.5 mL) and take measures necessary to ensure maintenance of a patent airway.

Entresto has been associated with a higher rate of angioedema in Black than in non-Black patients.

Patients with a prior history of angioedema may be at increased risk of angioedema with Entresto. Entresto should not be used in patients with a known history of angioedema related to previous ACE inhibitor or ARB therapy

Hypotension
Entresto lowers blood pressure and may cause symptomatic hypotension. Patients with an activated renin-angiotensin system, such as volume- and/or salt-depleted patients (eg, those being treated with high doses of diuretics), are at greater risk. In the double-blind period of PARADIGM-HF, 18% of patients treated with Entresto and 12% of patients treated with enalapril reported hypotension as an adverse event, with hypotension reported as a serious adverse event in approximately 1.5% of patients in both treatment arms. Correct volume or salt depletion prior to administration of Entresto or start at a lower dose. If hypotension occurs, consider dose adjustment of diuretics, concomitant antihypertensive drugs, and treatment of other causes of hypotension (e.g., hypovolemia). If hypotension persists despite such measures, reduce the dosage or temporarily discontinue Entresto. Permanent discontinuation of therapy is usually not required.

Impaired Renal Function
As a consequence of inhibiting the renin-angiotensin-aldosterone

system (RAAS), decreases in renal function may be anticipated in susceptible individuals treated with Entresto. In the double-blind period of PARADIGM-HF, 5% of patients in both the Entresto and enalapril groups reported renal failure as an adverse event . In patients whose renal function depends upon the activity of the renin-angiotensin-aldosterone system (eg, patients with severe congestive heart failure), treatment with ACE inhibitors and angiotensin receptor antagonists has been associated with oliguria, progressive azotemia and, rarely, acute renal failure and death. Closely monitor serum creatinine, and down-titrate or interrupt Entresto in patients who develop a clinically significant decrease in renal function.

As with all drugs that affect the RAAS, Entresto may increase blood urea and serum creatinine levels in patients with bilateral or unilateral renal artery stenosis. In patients with renal artery stenosis, monitor renal function.

Hyperkalemia

Through its actions on the RAAS, hyperkalemia may occur with Entresto. In the double-blind period of PARADIGM-HF, 12% of patients treated with Entresto and 14% of patients treated with enalapril reported hyperkalemia as an adverse event. Monitor serum potassium periodically and treat appropriately, especially in patients with risk factors for hyperkalemia such as severe renal impairment, diabetes, hypoaldosteronism, or a high potassium diet. Dosage reduction or interruption of Entresto may be required.

Adverse Reactions

Clinically significant adverse reactions that appear in other sections of the labeling includeangioedema, hypotension, impaired renal function, and hyperkalemia.

Clinical Trials Experience

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

In the PARADIGM-HF trial, subjects were required to complete sequential enalapril and Entresto run-in periods of (median) 15 and 29 days, respectively, prior to entering the randomized double-blind period comparing Entresto and enalapril. During the enalapril run-in period, 1,102 patients (10.5%) were permanently discontinued from the study, 5.6% because of an adverse event, most commonly renal dysfunction (1.7%), hyperkalemia (1.7%) and hypotension (1.4%).

During the Entresto run-in period, an additional 10.4% of patients permanently discontinued treatment, 5.9% because of an adverse event, most commonly renal dysfunction (1.8%), hypotension (1.7%) and hyperkalemia (1.3%). Because of this run-in design, the adverse reaction rates described below are lower than expected in practice.

In the double-blind period, safety was evaluated in 4,203 patients treated with Entresto and 4,229 treated with enalapril. In PARADIGM-HF, patients randomized to Entresto received treatment for up to 4.3 years, with a median duration of exposure of 24 months; 3,271 patients were treated for more than one year. Discontinuation of therapy because of an adverse event during the double-blind period occurred in 450 (10.7%) of Entresto treated patients and 516 (12.2%) of patients receiving enalapril.

Adverse reactions occurring at an incidence of ≥5% in patients who were treated with Entresto in the double-blind period included hypotension, hyperkalemia, cough, dizziness, and renal failure/ acute renal failure.

In the PARADIGM-HF trial, the incidence of angioedema was 0.1% in both the enalapril and Entresto run-in periods. In the double-blind period, the incidence of angioedema was higher in patients treated with Entresto than enalapril (0.5% and 0.2%, respectively). The incidence of angioedema in Black patients was 2.4% with ENTRESTO and 0.5% with enalapri .

Orthostasis was reported in 2.1% of patients treated with Entresto compared to 1.1% of patients treated with enalapril during the double-blind period of PARADIGM-HF. Falls were reported in 1.9% of patients treated with Entresto compared to 1.3% of patients treated with enalapril.

Laboratory Abnormalities

Hemoglobin and Hematocrit

Decreases in hemoglobin/hematocrit of >20% were observed in approximately 5% of both Entresto- and enalapril- treated patients in the double-blind period in PARADIGM-HF.

Serum Creatinine

Increases in serum creatinine of >50% were observed in 1.4% of patients in the enalapril run-in period and 2.2% of patients in the Entresto run-in period. During the double-blind period, approximately 16% of both Entresto- and enalapril-treated patients had increases in serum creatinine of >50%.

Serum Potassium

Potassium concentrations >5.5 meq/L were observed in approximately 4% of patients in both the enalapril and Entresto run-in periods. During the double-blind period, approximately 16% of both Entresto- and enalapril- treated patients had potassium concentrations >5.5 meq/L.

Drug Interactions

Dual Blockade of the Renin-Angiotensin-Aldosterone System

Concomitant use of Entresto with an ACE inhibitor is contraindicated because of the increased risk of angioedema

Avoid use of Entresto with an ARB, because Entresto contains the angiotensin II receptor blocker valsartan.

The concomitant use of Entresto with aliskiren is contraindicated in patients with diabetes. Avoid use with aliskiren in patients with renal impairment (eGFR <60 mL/min/1.73 m²).

Potassium-Sparing Diuretics

As with other drugs that block angiotensin II or its effects, concomitant use of potassium-sparing diuretics (eg, spironolactone, triamterene, amiloride), potassium supplements, or salt substitutes containing potassium may lead to increases in serum potassium.

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) Including Selective Cyclooxygenase-2 Inhibitors (COX-2 Inhibitors)
In patients who are elderly, volume-depleted (including those on diuretic therapy), or with compromised renal function, concomitant use of NSAIDs, including COX-2 inhibitors, with Entresto may result in worsening of renal function, including possible acute renal failure. These effects are usually reversible. Monitor renal function periodically.

Lithium
Increases in serum lithium concentrations and lithium toxicity have been reported during concomitant administration of lithium with angiotensin II receptor antagonists. Monitor serum lithium levels during concomitant use with Entresto.

Use in Specific Populations

Pregnancy
Entresto can cause fetal harm when administered to a pregnant woman.

Clinical Considerations

Fetal/Neonatal Adverse Reactions
Oligohydramnios in pregnant women who use drugs affecting the renin-angiotensin system in the second and third trimesters of pregnancy can result in the following: reduced fetal renal function leading to anuria and renal failure, fetal lung hypoplasia, skeletal deformations, including skull hypoplasia, hypotension, and death.

Perform serial ultrasound examinations to assess the intra-amniotic environment. Fetal testing may be appropriate, based on the week of gestation. Patients and physicians should be aware, however, that oligohydramnios may not appear until after the fetus has sustained irreversible injury. If oligohydramnios is observed, consider alternative drug treatment.

Closely observe neonates with histories of in utero exposure to Entresto for hypotension, oliguria, and hyperkalemia. In neonates with a history of in utero exposure to Entresto, if oliguria or hypotension occurs, support blood pressure and renal perfusion. Exchange transfusions or dialysis may be required as a means of reversing hypotension and replacing renal function.

Lactation

Risk Summary
There is no information regarding the presence of sacubitril/valsartan in human milk, the effects on the breastfed infant, or the effects on milk production. Sacubitril/valsartan is present in rat milk. Because of the potential for serious adverse reactions in breastfed infants from exposure to sacubitril/valsartan, advise a nursing woman that breastfeeding is not recommended during treatment with Entresto.

Pediatric Use
Safety and effectiveness in pediatric patients have not been established.

Geriatric Use
No relevant pharmacokinetic differences have been observed in elderly (≥65 years) or very elderly (≥75 years) patients compared to the overall population

Hepatic Impairment
No dose adjustment is required when administering 2to patients with mild hepatic impairment (Child-Pugh A classification). The recommended starting dose in patients with moderate hepatic impairment (Child-Pugh B classification) is 24/26 mg twice daily. The use of 2in patients with severe hepatic impairment (Child-Pugh C classification) is not recommended, as no studies have been conducted in these patients.

Renal Impairment
No dose adjustment is required in patients with mild (egfr 60 to 90 mL/min/1.73 m2) to moderate (egfr 30 to 60 mL/min/1.73 m2) renal impairment. The recommended starting dose in patients with severe renal impairment (egfr <30 mL/min/1.73 m2) is 24/26 mg twice daily.

Overdosage
Limited data are available with regard to overdosage in human subjects with Entresto. In healthy volunteers, a single dose of Entresto 583 mg sacubitril/617 mg valsartan, and multiple doses of 437 mg sacubitril/463 mg valsartan (14 days) have been studied and were well tolerated.

Hypotension is the most likely result of overdosage due to the blood pressure lowering effects of Entresto. Symptomatic treatment should be provided.

Entresto is unlikely to be removed by hemodialysis because of high protein binding.

Clinical Studies
Dosing in clinical trials was based on the total amount of both components of Entresto, ie, 24/26 mg, 49/51 mg and 97/103 mg were referred to as 50 mg, 100 mg, and 200 mg, respectively.

PARADIGM-HF
PARADIGM-HF was a multinational, randomized, double-blind trial comparing Entresto and enalapril in 8,442 adult patients with symptomatic chronic heart failure (NYHA class II–IV) and systolic dysfunction (left ventricular ejection fraction ≤ 40%). Patients had to have been on an ACE inhibitor or ARB for at least four weeks and on maximally tolerated doses of beta-blockers. Patients with a systolic blood pressure of < 100 mm Hg at screening were excluded.

The primary objective of PARADIGM-HF was to determine whether Entresto, a combination of sacubitril and a RAS inhibitor

(valsartan), was superior to a RAS inhibitor (enalapril) alone in reducing the risk of the combined endpoint of cardiovascular (CV) death or hospitalization for heart failure (HF).

After discontinuing their existing ACE inhibitor or ARB therapy, patients entered sequential single-blind run-in periods during which they received enalapril 10 mg twice-daily, followed by Entresto 100 mg twice-daily, increasing to 200 mg twice daily. Patients who successfully completed the sequential run-in periods were randomized to receive either Entresto 200 mg (N=4,209) twice-daily or enalapril 10 mg (N=4,233) twice-daily. The primary endpoint was the first event in the composite of CV death or hospitalization for HF. The median follow-up duration was 27 months and patients were treated for up to 4.3 years.

The population was 66% Caucasian, 18% Asian, and 5% Black; the mean age was 64 years and 78% were male. At randomization, 70% of patients were NYHA Class II, 24% were NYHA Class III, and 0.7% were NYHA Class IV. The mean left ventricular ejection fraction was 29%. The underlying cause of heart failure was coronary artery disease in 60% of patients; 71% had a history of hypertension, 43% had a history of myocardial infarction, 37% had an eGFR < 60 mL/min/1.73 m2, and 35% had diabetes mellitus. Most patients were taking beta-blockers (94%), mineralocorticoid antagonists (58%), and diuretics (82%). Few patients had an implantable cardioverter-defibrillator (ICD) or cardiac resynchronization therapy-defibrillator (CRT-D) (15%).

PARADIGM-HF demonstrated that Entresto, a combination of sacubitril and a RAS inhibitor (valsartan), was superior to a RAS inhibitor (enalapril), in reducing the risk of the combined endpoint of cardiovascular death or hospitalization for heart failure, based on a time-to-event analysis (hazard ratio [HR]: 0.80, 95% confidence interval [CI], 0.73, 0.87, P <0.0001). The treatment effect reflected a reduction in both cardiovascular death and heart failure hospitalization. Sudden death accounted for 45% of cardiovascular deaths, followed by pump failure, which accounted for 26%.

Entresto also improved overall survival (HR 0.84; 95% CI [0.76, 0.93], P = 0.0009). This finding was driven entirely by a lower incidence of cardiovascular mortality on Entresto.

Distributed by: Novartis Pharmaceuticals Corporation

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Antivir Ther. 2015 Jul 21. doi: 10.3851/IMP2979. [Epub ahead of print]

Low bone mineral density and risk of incident fracture in HIV-infected adults.

Battalora L, Buchacz K, Armon Cet al; HIV Outpatient Study (HOPS) and SUN Study Investigators.

BACKGROUND: Prevalence rates of low bone mineral density (BMD) and bone fractures are higher among HIV-infected adults compared with the general United States (U.S.) population, but the relationship between BMD and incident fractures in HIV-infected persons has not been well described. METHODS: Dual energy X-ray absorptiometry (DXA) results of the femoral neck of the hip and clinical data were obtained prospectively during 2004-2012 from participants in two HIV cohort studies. Low BMD was defined by a T-score in the interval >-2.5 to <-1.0 (osteopenia), or ≤-2.5 (osteoporosis). We analyzed the association of low BMD with risk of subsequent incident fractures, adjusted for sociodemographics, other risk factors and covariables, using multivariable proportional hazards regression. RESULTS: Among 1,006 participants analyzed (median age 43 years [interquartile-range (IQR) 36-49], 83% male, 67% non-Hispanic white, median CD4+ cell count 461 cells/mm3 [IQR 311-658]), 36% (n = 358) had osteopenia and 4% (n = 37) osteoporosis; 67 had a prior fracture documented. During 4,068 person-years of observation after DXA scanning, 85 incident fractures occurred, predominantly rib/sternum (n=18), hand (n=14), foot (n=13), and wrist (n=11). In multivariable analyses, osteoporosis (adjusted hazard ratio [aHR] 4.02, 95% confidence interval [CI] 2.02-8.01) and current/prior tobacco use (aHR 1.59, 95% CI 1.02-2.50) were associated with incident fracture. CONCLUSIONS: In this large sample of HIV-infected adults in the U.S., low baseline BMD was significantly associated with elevated risk of incident fracture. There is potential value of DXA screening in this population.

Colorado School of Mines, Golden, CO, USA.

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No perinatal transmission of HIV-1 from women with effective antiretroviral therapy starting before conception.

Mandelbrot L, Tubiana R, LeChenadec J, et al; ANRS-EPF Study Group.

BACKGROUND: The efficacy of prevention of perinatal transmission (PT) of HIV-1 depends on both viral load (VL) and treatment duration. The objective of this study was to determine whether initiating highly active antiretroviral therapy (HAART) before conception has the potential to eliminate perinatal transmission. METHODS: 8075 HIV-infected mother/infant pairs included from 2000 to 2011 in the national prospective multicenter French Perinatal Cohort (ANRS-EPF) received ART, delivered liveborn children with determined HIV infection status and did not breastfeed. PT was analyzed according to maternal VL at delivery and timing of ART initiation with child HIV outcome determined. RESULTS: The overall rate of PT was 56/8075 (0.7%). No transmission occurred among 2651 infants born to women who were on ART before conception, continued throughout the pregnancy and delivered with a plasma VL <50 copies / mL (upper 95% confidence interval: 0.1%). VL and timing of HAART initiation were independently associated with PT in logistic regression. Regardless of viral load, the transmission rate increased from 0.2% (6/3505) for women initiating ART prior to conception to 0.4% (3/709) during the 1st trimester, 0.9% (24/2810) during the 2nd trimester and 2.2% (23/1051) during the 3rd trimester, p<0.001. Regardless of timing of HAART initiation, the rate was higher for women with VL between 50 and 400 copies/mL near delivery than for those with <50 copies/mL: adjusted odds ratio =4.0 (95%CI: 1.9 - 8.2). CONCLUSIONS: Perinatal HIV-1 transmission is virtually zero in mothers who start antiretroviral therapy before conception and maintain suppression of plasma viral load.

J Viral Hepat. 2015 Jul 20. doi: 10.1111/jvh.12437. [Epub ahead of print]

Dialysis-requiring acute kidney injury among hospitalized adults with documented hepatitis C virus infection: a nationwide inpatient sample analysis.

Nadkarni GN, Patel A, Simoes PK, et al.

Abstract
Chronic hepatitis C virus (HCV) infection may cause kidney injury, particularly in the setting of cryoglobulinemia or cirrhosis; however, few studies have evaluated the epidemiology of acute kidney injury in patients with HCV. We aimed to describe national temporal trends of incidence and impact of severe acute kidney injury (AKI) requiring renal replacement 'dialysis-requiring AKI' in hospitalized adults with HCV. We extracted our study cohort from the Nationwide Inpatient Sample of the Healthcare Cost and Utilization Project using data from 2004 to 2012. We defined HCV and dialysis-requiring acute kidney injury based on previously validated ICD-9-CM codes. We analysed temporal changes in the proportion of hospitalizations complicated by dialysis-requiring AKI and utilized survey multivariable logistic regression models to estimate its impact on in-hospital mortality. We identified a total of 4 603 718 adult hospitalizations with an associated diagnosis of HCV from 2004 to 2012, of which 51 434 (1.12%) were complicated by dialysis-requiring acute kidney injury. The proportion of hospitalizations complicated by dialysis-requiring acute kidney injury increased significantly from 0.86% in 2004 to 1.28% in 2012. In-hospital mortality was significantly higher in hospitalizations complicated by dialysis-requiring acute kidney injury vs those without (27.38% vs 2.95%; adjusted odds ratio: 2.09; 95% confidence interval: 1.74-2.51). The proportion of HCV hospitalizations complicated by dialysis-requiring acute kidney injury increased significantly between 2004 and 2012. Similar to observations in the general population, dialysis-requiring acute kidney injury was associated with a twofold increase in odds of in-hospital mortality in adults with HCV. These results highlight the burden of acute kidney injury in hospitalized adults with HCV infection.

Division of Nephrology, Department of Medicine; Department of Public Health; Department of Internal Medicine; Division of Gastroenterology and Hepatology; Icahn School of Medicine at Mount Sinai, New York, NY; Department of Internal Medicine, St. Luke's Roosevelt Hospital Center at Mount Sinai, New York, NY; Division of Rheumatology, Department of Medicine, Vanderbilt University Medical Center, Nashville, TN; Division of Critical Care, Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute, Mumbai, India.

Dig Dis Sci. 2015 Jul 21. [Epub ahead of print]

Hepatitis C virus infection increases the risk of developing chronic kidney disease: a systematic review and meta-analysis.

Fabrizi F, Verdesca S, Messa P, Martin P.

BACKGROUND AND RATIONALE: Chronic kidney disease and hepatitis C virus are prevalent in the general population worldwide, and controversy exists about the impact of HCV infection on the development and progression of kidney disease. DESIGN: A systematic review of the published medical literature was made to assess whether positive anti-HCV serologic status plays an independent impact on the development of chronic kidney disease in the adult general population. We used a random-effects model to generate a summary estimate of the relative risk of chronic kidney disease (defined by reduced glomerular filtration rate or detectable proteinuria) with HCV across the published studies. Meta-regression and stratified analysis were also conducted. RESULTS: Twenty-three studies (n = 2,842,421 patients) were eligible, and separate meta-analyses were performed according to the outcome. Pooling results of longitudinal studies (n = 9; 1,947,034 unique patients) demonstrated a relationship between positive HCV serologic status and increased incidence of chronic kidney disease, the summary estimate for adjusted hazard ratio was 1.43 (95 % confidence interval 1.23; 1.63, P = 0.0001), and between-studies heterogeneity was noted (P value by Q test <0.0001). The risk of the incidence of chronic kidney disease associated with HCV, in the subset of Asian surveys, was 1.31 (95 % confidence interval 1.16; 1.45) without heterogeneity (P value by Q test = 0.6). HCV positive serology was an independent risk factor for proteinuria; adjusted odds ratio, 1.508 (95 % confidence intervals 1.19; 1.89, P = 0.0001) (n = 6 studies; 107,356 unique patients). CONCLUSIONS: HCV infection is associated with an increased risk of developing chronic kidney disease in the adult general population.

Division of Nephrology, Maggiore Hospital, IRCCS Foundation, Milan, Italy.

Eur J Heart Fail. 2015 Jul 21. doi: 10.1002/ejhf.317. [Epub ahead of print]

Insulin resistance in heart failure: differences between patients with reduced and preserved left ventricular ejection fraction.

Scherbakov N, Bauer M, Sandek A, et al.

AIMS: Insulin resistance (IR) is a characteristic feature of heart failure (HF) pathophysiology that affects symptoms and mortality. Differences in the pathophysiological profile of IR in HF with preserved ejection fraction (HFpEF) and HF with reduced ejection fraction (HFrEF) are not characterized in detail. The aim of this study was to evaluate features of IR in HFpEF vs. HFrEF. METHODS AND RESULTS: Wee included 18 patients with HFrEF (EF 30 ± 11%, body mass index (BMI) 26.5 ± 3.3 kg/m2), 22 HFpEF patients (EF 63 ± 7%, BMI 28.6 ± 4.8 kg/m2), and 20 healthy controls of similar age, all without diabetes mellitus. Patients were in stable ambulatory condition and on stable medical regimens for HF. IR was assessed at fasting steady state by the homeostasis model assessment (HOMA) index and within the physiological range of insulin-glucose interactions by the short insulin sensitivity test (SIST). Fasting-state IR was observed in HFpEF and in HFrEF in comparison with controls (HOMA 1.9, interquartile range (IQR) 1.5-3.6 vs. HOMA 3.1, IQR 1.4-3.7 vs. controls 1.2, IQR 1.8-0.9, respectively; analysis of variance $P < 0.001$), but no statistical difference was observed between HFpEF and HFrEF. The dynamic test over the physiological range of insulin-glucose interactions revealed a more severe IR in HFrEF as compared with HFpEF. Thus, glucose levels remained the highest in HFrEF (76 (64-89) mg/dL) at the end of the SIST compared with HFpEF and controls (68 (58-79) and 56 (44-66) mg/dL, respectively, $P < 0.001$). CONCLUSION: IR is present in non-diabetic patients with HFpEF and HFrEF. However, distinct differences in the insulin sensitivity characteristics in HFpEF and HFrEF become apparent by more advanced testing. Patients with HFrEF showed more severe IR.

Center for Stroke Research Berlin, Charite Universitätsmedizin Berlin, Germany; German Centre for Cardiovascular Research (DZHK), partner site Berlin, Germany; Department of Cardiology, Campus Virchow, Charite Universitätsmedizin Berlin, Germany; Working Group on Cardiovascular Magnetic Resonance, Experimental and Clinical Research Center, a joint cooperation between the Charité Medical Faculty and the Max-Delbrueck Center for Molecular Medicine Berlin, Germany; HELIOS Klinikum Berlin Buch, Department of Cardiology and Nephrology, Berlin, Germany; Cardiology Department, Centre for Heart Diseases, Military Hospital, Wroclaw, Poland; Department of Heart Diseases, Wroclaw Medical University, Wroclaw, Poland; Innovative Clinical Trials, Dept of Cardiology and Pneumology, University Medicine Göttingen (UMG), Göttingen, Germany; Division of Cardiology, General Hospital Celje, Slovenia; Institute of Clinical Pharmacology, Hannover Medical School, Germany.

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Heart rate is associated with progression of atrial fibrillation, independent of rhythm.

Holmqvist F, Kim S, Steinberg BA, et al; ORBIT-AF Investigators.

OBJECTIVE: Atrial fibrillation (AF) often progresses from paroxysmal or persistent to more sustained forms, but the rate and predictors of AF progression in clinical practice are not well described. METHODS: Using the Outcomes Registry for Better Informed Treatment of AF, we analysed the incidence and predictors of progression and tested the discrimination and calibration of the HATCH (hypertension, age, TIA/stroke, chronic obstructive pulmonary disease, heart failure) and CHA_2DS_2VASc scores for identifying AF progression. RESULTS: Among 6235 patients with paroxysmal or persistent AF at baseline, 1479 progressed, during follow-up (median 18 (IQR 12-24) months). These patients were older and had more comorbidities than patients who did not progress ($CHADS_2$ 2.3±1.3 vs 2.1±1.3, p<0.0001). At baseline, patients with AF progression were more often on a rate control as opposed to a rhythm control strategy (66 vs 56%, p<0.0001) and had higher heart rate (72(64-80) vs 68(60-76) bpm, p<0.0001). The strongest predictors of AF progression were AF on the baseline ECG (OR 2.30, 95% CI 1.95 to 2.73, p<0.0001) and increasing age (OR 1.16, 95% CI1.09 to 1.24, p<0.0001, per 10 increase), while patients with lower heart rate (OR 0.84, 95% CI 0.79 to 0.89, p<0.0001, per 10 decrease ≤80) were less likely to progress. There was no significant interaction between rhythm on baseline ECG and heart rate (p=0.71). The HATCH and CHA_2DS_2VASc scores had modest discriminatory power for AF progression (C-indices 0.55 (95% CI 0.53 to 0.58) and 0.55 (95%

CI 0.52 to 0.57)). CONCLUSIONS: Within 1.5 years, almost a quarter of the patients with paroxysmal or persistent AF progress to a more sustained form. Progression is strongly associated with heart rate, and age.

Duke Clinical Research Institute, Durham, NC; Columbia University, New York, NY; Department of Medicine, Stanford University, Stanford, CA; Mayo Clinic College of Medicine, Rochester, MN; Ahmanson-UCLA Cardiomyopathy Center, Los Angeles, CA; Penn State Milton S. Hershey Medical Center, Hershey, PA; Janssen Pharmaceuticals, Inc., Raritan, NJ; Department of Internal Medicine, Cardiovascular Medicine, Yale University School of Medicine, New Haven, CT; Lankenau Hospital and Medical Research Center, Philadelphia, PA, USA.

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Effect of sitagliptin on cardiovascular outcomes in type 2 diabetes.

Green JB, Bethel MA, Armstrong PW, et al; TECOS Study Group.

BACKGROUND: Data are lacking on the long-term effect on cardiovascular events of adding sitagliptin, a dipeptidyl peptidase 4 inhibitor, to usual care in patients with type 2 diabetes and cardiovascular disease. METHODS: In this randomized, double-blind study, we assigned 14,671 patients to add either sitagliptin or placebo to their existing therapy. Open-label use of antihyperglycemic therapy was encouraged as required, aimed at reaching individually appropriate glycemic targets in all patients. To determine whether sitagliptin was noninferior to placebo, we used a relative risk of 1.3 as the marginal upper boundary. The primary cardiovascular outcome was a composite of cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, or hospitalization for unstable angina. RESULTS: During a median follow-up of 3.0 years, there was a small difference in glycated hemoglobin levels (least-squares mean difference for sitagliptin vs. placebo, -0.29 percentage points; 95% confidence interval [CI], -0.32 to -0.27). Overall, the primary outcome occurred in 839 patients in the sitagliptin group (11.4%; 4.06 per 100 person-years) and 851 patients in the placebo group (11.6%; 4.17 per 100 person-years). Sitagliptin was noninferior to placebo for the primary composite cardiovascular outcome (hazard ratio, 0.98; 95% CI, 0.88 to 1.09; P<0.001). Rates of hospitalization for heart failure did not differ between the two groups (hazard ratio, 1.00; 95% CI, 0.83 to 1.20; P=0.98). There were no significant between-group differences in rates of acute pancreatitis (P=0.07) or pancreatic cancer (P=0.32).

Am J Med Sci. 2015 Jul 18. [Epub ahead of print]

Choice of antihypertensive combination therapy based on daily salt intake.

Toyoda S, Inami S, Kato T, Tsukada K, et al.

BACKGROUND: It is unclear whether thiazide diuretics (TZs) or calcium channel blockers (CCBs) are more effective as add-on therapy to angiotensin receptor blockers (ARBs) in controlling hypertension. Because TZs are a rational choice in salt-sensitive hypertension, patients with high salt intake might preferentially benefit from ARB/TZ over ARB/CCB combination therapy. METHODS: Hypertensive patients who failed to reach blood pressure goals despite treatment with ARBs alone were randomly assigned to receive either ARB/TZ or ARB/CCB combination therapy. Estimated daily sodium intake was calculated from spot urine values of sodium and creatinine. RESULTS: Blood pressure was measured at baseline, and at 4, 8 and 12 weeks after starting combination therapy. For all study patients (n = 87), diastolic blood pressure reduction was greater in patients receiving ARB/CCB treatment. However, in the 37 patients with a baseline estimated daily salt intake greater than 10 g and baseline systolic blood pressure (SBP) ranging from 150 to 200 mm Hg, SBP was lower (P < 0.05) and SBP reduction was greater (P < 0.05) 4 weeks after starting combination therapy in those receiving ARB/TZ treatment. In the 31 patients whose estimated daily salt intake increased at 12 weeks compared with baseline, SBP at 12 weeks was lower in those receiving ARB/TZ treatment (P < 0.05). CONCLUSIONS: Estimated daily salt intake is a useful tool for guiding antihypertensive therapy and should be measured repeatedly during the therapeutic course.

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ARTHROSCOPIC KNEE SURGERY OVERUSED

According to a systematic review and meta-analysis of arthroscopic knee surgery, there is no benefit to the surgery. The harms of arthroscopic knee surgery are rare but serious, including death. In contrast, nonsurgical exercise therapy does have benefits and no serious harms.

The review covered 9 trials with 1270 middle-aged or older patients with knee pain and degenerative disease, with or without radiographic signs of osteoarthritis, who were randomized to surgery involving partial meniscectomy, debridement, or both; or to control groups with placebo surgery or exercise.

Interventions including arthroscopy showed a benefit at 3 and 6 months of 3-5 mm on a 0-100 mm visual analogue scale, but that benefit disappeared after 6 months.

A separate analysis of larger, non-randomized trials calculated the harms. Mortality was 1 per 1,000 procedures (confidence interval 0.04-24). Deep vein thrombosis was 4 per 1,000 procedures (confidence interval 1.8-9.6). Every year, more than 700,000 knee arthroscopies are done in the US and 150,000 in the United Kingdom.

The research report and editorial argue that knee arthroscopy is often performed based on MRI of abnormalities, such as meniscal tears, osteophytes, cartilage damage, and bone marrow lesions, which are common in painful knees but also common in the general asymptomatic population. Patients with early stage knee osteoarthritis should be treated according to the guidelines, with information, exercise, and weight loss, they write.

"In light of this evidence, why is arthroscopy still so common?" asks Andy Carr in an editorial, which discusses biases and flaws in scientific studies. "Surgeon confirmation bias in combination with financial aspects and administrative policies may be factors more powerful than evidence in driving practice patterns," conclude the investigators. See more at Carr A. Editorials: Arthroscopic surgery for degenerative knee. Overused, ineffective, and potentially harmful. 16 June 2015;350:h2983 doi: 10.1136/bmj.h2983. and Thorlund JB, Juhl CB, Roos EM, Lohmander LS. Research: Arthroscopic surgery for degenerative knee: systematic review and meta-analysis of benefits and harms.16 June 2015;350:h2747 doi: http://dx.doi.org/10.1136/bmj.h2747 ■

New Herpes Zoster Vaccine Is Effective in Older Adults

A recombinant subunit vaccine significantly lowered the risk for herpes zoster in adults aged 50 years or older without immunosuppressive conditions, according to a randomized, placebo-controlled, phase 3 trial. The study, published online April 28 in the *New England Journal of Medicine,* showed similar vaccine efficacy in adults who were 70 years of age or older as that seen in adults in their 50s and in their 60s.

In phase 1 and 2 trials, the experimental vaccine, which contains VZV glycoprotein E and the AS01B adjuvant system (called HZ/su, GlaxoSmithKline Biologicals), elicited a strong immune response that lasted for at least 3 years in adults and had an acceptable safety profile, even in adults with immunosuppression, note Himal Lal, MD, from GSK Vaccines.

The current phase 3 trial, called the Zoster Efficacy Study in Adults 50 Years of Age or Older, aimed to determine whether two doses of HZ/su would safely lower the risk for herpes zoster among adults at least 50 years of age. Participants, who were stratified according to age group (50 - 59 years, 60 - 69 years, and ≥70 years), received two intramuscular doses of the vaccine or placebo 2 months apart.

Of 15,411 participants who could be evaluated, 7698 received HZ/su vaccine and 7713 received placebo. During a mean follow-up time of 3.2 years, six participants in the vaccine group developed herpes zoster, as did 210 participants in the placebo group (incidence rate, 0.3 vs 9.1 per 1000 person-years). Vaccine efficacy did not decline with age. Read the whole article at: http://www.medscape.com/viewarticle/843998?src=wnl_edit_tpal&uac=25701MV. ■

Improved Pneumococcal Vaccine Costs More, But 10-Year Savings Projected

According to Health Affairs, In 2010 the US Advisory Committee on Immunization Practices (ACIP) recommended that the pneumococcal seven-valent conjugate vaccine (PCV7) given routinely to children up to two years old be replaced by the pneumococcal thirteen-valent version (PCV13) because of the additional health benefits. Since the new vaccine is more expensive, payers have voiced concerns that these costs could increase health insurance premiums and strain fixed public health agency budgets. A new study, being released as a Web First by Health Affairs, estimated the additional cost of PCV13 use by public and private US insurance payers to be $3.5 billion and $2.6 billion, respectively, over PCV7, between 2010 and 2019.

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Case Managers as Change Agents for Improving the US Addiction Treatment System *continued from page 10*

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Commission for Case Manager Certification Announces New Officers, Board Members *continued from page 4*

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