CareManagement

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Gary S. Wolfe

HIV/AIDS Epidemic

In June 1981, I was living in Los Angeles, California, when I started hearing about seriously ill gay men presenting to hospital emergency departments. Symptoms included diarrhea, vomiting, respiratory distress and pneumonia, severe weight loss, and purple skin lesions. Gay men were very ill, and they were dying because they were not responding to any treatment. About the same time, similar reports were circulating in New York City and San Francisco, California. As I reflect back over the last 30 plus years, significant progress has been made in all aspects of the HIV epidemic: prevention, diagnosis, and treatment. A lot has been done, but the fight and struggle continues.

Some facts:

- Today there are more than 1.1 million people in the United States living with HIV infection and more than 700,000 people have died since the beginning of the epidemic.
- Nearly 1 in 7 of people living with HIV infection is unaware of their status.
- There are approximately 38,500 new HIV infections annually.
- It is estimated that 30% of new HIV infections are transmitted by people who are living with undiagnosed HIV infection, making increasing access to testing and counseling a fundamental priority for HIV prevention.
- There are approximately 6,000 AIDS-related deaths annually.
- Around 70% of annual new HIV infections occur among gay and other men who have sex with men; among this population, African-American/black men are most affected, followed by Latino/Hispanic men. Heterosexual African-American/black women and transgender women of all ethnicities are also disproportionately affected by HIV infection.
- Rates of HIV infection are higher in southern states, which are home to around 45% of all people living with HIV infection and account for around half of the new diagnoses annually in the United States even though these states comprise roughly one-third (37%) of the population. Ten states accounted for about two-thirds (65%) of HIV infections diagnoses among adults and adolescents in 2016.
- Mother-to-child transmission of HIV infection continues to decline in the United States but rates remain higher among African-American/black women and their infants.
- Preexposure prophylaxis, a way for HIV-negative people to receive treatment before exposure to HIV to prevent infection, has been recommended in the United States since 2012 for individuals who have a substantial ongoing risk of HIV infection.
- For every 100 people living with HIV infection in the United States in 2014, only 62 initiated treatment, 48 were retained in care, and 49 achieved viral suppression.
- Antiretroviral therapy has substantially reduced AIDS-related morbidity and mortality and improved long-term outcomes for people with HIV infection. Treatment guidelines recommend initiating treatment as soon as one is diagnosed with HIV infection. According to the U.S. Centers for Disease Control

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THE COMMISSION FOR CASE MANAGER CERTIFICATION

CERTIFICATION OF DISABILITY MANAGEMENT SPECIALISTS COMMISSION

Empathy in Action: Advocating for Individuals in Workers' Compensation Cases

By Chikita Mann, MSN, RN, CCM, Commission for Case Manager Certification (CCMC)

An employee is injured on the job. Immediately, the policies and procedures are followed under each state's workers' compensation laws: medical attention and filing a workers' compensation claim. But more can and should be done. Displaying empathy for the injured worker whose life has been disrupted enhances communication and adds a human component to care delivery.

Often that communication falls to the case manager assigned to the case. In Georgia, where I practiced workers' compensation case management for many years, having a case manager was voluntary, according to the employee's discretion. When injured employees resisted case management services it was often due to the perception that the case manager was an "extension" of the employer. In other words, the individual and his/her family or other support system could not accept at first that the case manager was acting as an advocate.

The resistance is understandable. In workers' compensation, case managers practice within a complex intersection of involved parties: the employer, workers' compensation insurance carrier and often a third-party case management provider, and, at the center, the employee. It takes patience to explain to the injured person that, while the case manager is contracted by the insurance company, the case manager is first and foremost an advocate for the individual. For Certified Case Managers (CCMs), advocacy for the individual is one of the governing principles of practice and a core tenet of our Code of Professional Conduct.

Confusion about the role of the case manager is not limited to workers' compensation. Case managers in any practice setting may encounter questions about their roles. There may be mistaken perceptions about how case managers handle cases—ie, that we fulfill administrative functions. That's why communication with the individual and family/support system must start with who we are, what being a certified case manager stands for, and what it means to be an advocate. We need to let people know that we're "there for them," that we can help them set goals for their recovery, and that we can help them access the care, treatment, and other services they need.

Financial limitations, what insurance will pay for, and regulatory constraints in workers' compensation cases may mean it's not possible to get everything the person wants. For example, a certain hospital, rehabilitation facility, or doctor may not be among the approved providers. Or the employee may be consumed with worries that are not directly related to the work injury: for example, financial concerns, child or elder care, or a family member's mental health issues. But knowledge of other benefits and resources offered in the community or by the employer (for example, an Employee Assistance Program [EAP]), allows the case manager to provide additional options.

With every case and in every case management practice setting, the individual is at the center. Although workers' compensation, by law, focuses on a specific incident, we cannot remove the human component. By exercising communication skills, particularly motivational interviewing, case managers build rapport and increase their understanding of what the person wants and needs. The open-ended questions asked in motivational interviewing encourage the person to express themselves;

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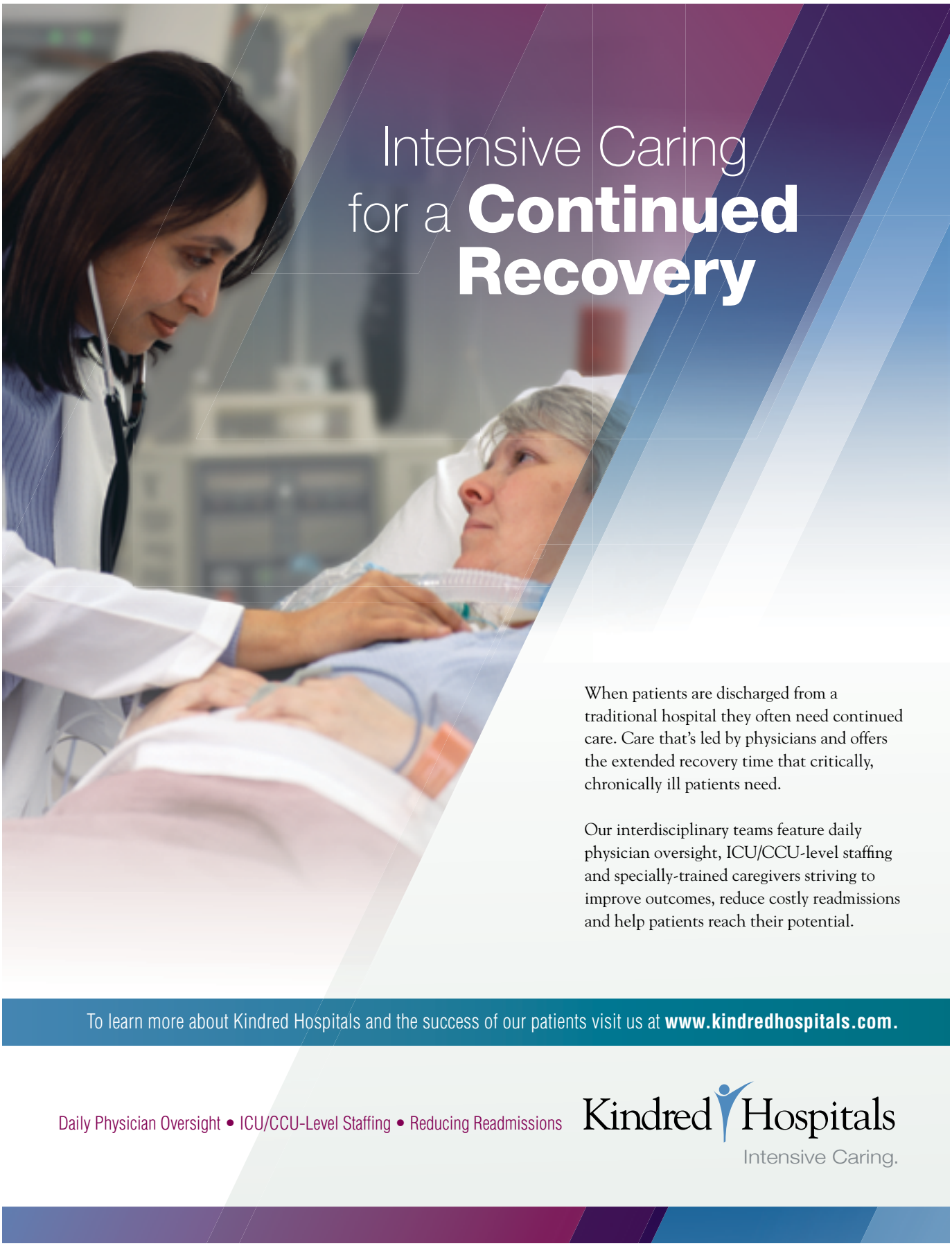
Chikita Mann, MSN, RN, CCM, *is a Commissioner of the Commission for Case Manager Certification (CCMC) and currently serves as Secretary. The CCMC is the first and largest nationally accredited organization that certifies case managers with its Certified Case Manager® (CCM®) certification. It also administers the Certified Disability Management Specialist® (CDMS®) certification. With more than 25 years of experience in case management, Chikita has been a disability case manager supervisor in the state of Georgia. She currently works to improve employee health and wellness for a Fortune 500 company.*



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In workers' compensation, case managers practice within a complex intersection of involved parties: the employer, workers' compensation insurance carrier and often a third-party case management provider, and, at the center, the employee. It takes patience to explain to the injured person that, while the case manager is contracted by the insurance company, the case manager is first and foremost an advocate for the individual.

Empathy in Action: Advocating for Individuals in Workers' Compensation Cases

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this provides case managers with a more complete picture. The case manager can see if the individual is motivated. Noncompliance with the physician's order may be due to barriers and obstacles in the individual's life and circumstances that seem insurmountable without help.[1]

Motivational interviewing can help uncover why, for example, an injured worker has not kept follow-up appointments or gone to physical therapy. It may only take one question: "I notice you missed your last 2 appointments. What help do you need?" By responding with empathy, instead of accusations of not adhering to care treatment and follow-up regimens, the case manager opens the door to greater understanding and exploring solutions.

It may be, for example, that the worker who wants to put off the surgery is concerned about losing his job. Or the single mother who wants to return to work before medically advisable may be 2 months behind on her rent and fears eviction. Today's "sandwich generation" with both dependent children and older parents to care for face dual pressures when recuperating from a work-related injury and surgery.

Admittedly, services delivered under workers' compensation coverage are limited to the workplace injury. But workers' compensation case managers, like their case management colleagues in other practice settings, must see the "whole person." The case manager acknowledges the problem—"I understand that you're concerned about …."—and explains that while workers' compensation will not cover certain services there may be other options.

When the employer offers an EAP program, it should be the number 1 recommendation. EAP services typically cover such issues as job stress, death of a loved one, substance abuse (by the person or a loved one), financial counseling, and child behavior.[2] When suggesting EAP services to the individual, it's important to stress the confidentiality of participating in the program. Often, people are reluctant to reach out to EAP because they fear their information will be disclosed.

A close colleague for every case manager should be the certified disability management specialist (CDMS), who specializes in workplace issues including return-to-work (RTW) and stay-at-work. RTW programs allow the employee to return to the workplace with modified duties and/or assignments with less demanding tasks while they recuperate. This allows the person to earn a full salary while healing "in place" with a process known as work hardening.

A CDMS is also an expert in job protection, such as the federal Family and Medical Leave Act (FMLA) and comparable state programs, as well as the Americans with Disabilities Act Amendments Act (ADAAA).

Other needs can be addressed outside of workers' compensation (or, in nonoccupational cases, separate from health care coverage). For example, the employee may be concerned about child care or elder care. Some services may exist in the community or others may be accessed through private pay. But when an individual is overwhelmed by the sudden change in their health status, addressing these issues alone may feel impossible. As advocates, case managers in every practice setting should inform individuals and their families/support systems about the resources available to them so they can make informed health care decisions.

It's empathy in action: to do for others what you would want done for you or your loved one. CM

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When Burnout Leads to Entrepreneurship

Michelle Greene Rhodes, MHS, RN, CCM, CMCN

Being a case manager for an insurance company can be both rewarding and frustrating. The main reasons most nurses go into case management in the first place is because it puts them into a position to use their expertise as a patient advocate. It is an ideal role to be in if you want to help people navigate the intricacies of the health care system.

There are often challenges of working for an insurance company: although the pay is fairly good on the end of the case manager spectrum, the caseload is high and is constantly increasing. This set of circumstances usually translates to a poor life/work balance and low satisfaction for case managers. It is not usually because they aren't enjoying what they're doing, it's because they are simply being overworked.

In any work environment, nurses are the ones in the trenches, dealing with both the patients and the physicians. They are the conduit through which important information flows and the ones responsible for maintaining this delicate balance. This is the reason many nurses end up becoming case managers; they get to continue to advocate for their patients and use their critical thinking skills without getting drowned in clinical tasks, long hours, and backbreaking work.

However, as case managers start to get overloaded with cases and end up spending more and more time working with no additional compensation, joy and life satisfaction plummet. This was what happened to me. This article serves to showcase my journey from case manager to nurse entrepreneur.

I was trained as a nurse 23 years ago and had worked for a workers' compensation insurance company as a case manager for 5 years. I was comfortable in my position and enjoyed my work, but after some reflection I realized that I was letting my true priorities take a backseat to the company's needs. I longed to have some autonomy over my career, and I was feeling fenced in and constrained due to never-ending caseloads and jam-packed schedules. Additionally, I felt that my income was capped based on what my employer felt I was worth. I often found myself working harder but not getting rewarded. I couldn't really do the things I enjoyed because I was often just trying to make ends meet.

Don't get me wrong, I was happy to be helping more people with my increasing caseload, but it seemed more and more that it was at the expense of my own welfare. I was burning myself out so that I could help more patients, but there was no tangible reward for my trouble.

That's when I started entertaining the idea of going independent. I had heard of independent certified case managers, but I had never truly envisioned myself in that role. I wasn't sure how reliable of an income it could provide or whether it was worth risking the security that my insurance company job provided me. It wasn't much security, but it was something.

Naturally cautious and pragmatic, I knew I wouldn't simply jump into something like this and hope for the best. That's why I made it a priority to do some thorough research before I made any sudden moves. Although some days at the insurance company had me wanting to abandon ship immediately, I knew deep down that if I was going to be successful I was going to need a plan. Autonomy, flexibility, and the ability to create my own salary were the primary reasons why I knew I needed to explore this alternative way to be a case manager.

If those were the goals, then I knew I needed to learn more about what going independent meant. Would I be able to make a reasonable living at it? Did I have the skills I needed to go out on my own? And how much time would it take to replace my current salary?

These were some of my initial questions, and I did online research to try to answer them. Once it seemed like there was definitely a viable market for independent case managers and that, based on my experience, I was aptly qualified to take on this role, new questions rolled in. How do I get my name out there? Should I build a website or should I focus on getting customers before I start branding?

There were also fears that manifested as well. For instance, would I be able to generate a steady stream of clients just on my hard work alone? Would I be able to differentiate myself and stand out from all the other independent case managers in the area? What if I failed?

When doing online research, you

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Michelle Greene Rhodes *is the Owner of Michelle Rhodes, RN, Media LLC located in Tampa, Florida. She disseminates information regarding entrepreneurship in health care, she is a women's empowerment lecturer, and she is a four-time self-published author*

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Transitioning to an independent case manager is not a glamorous career path or a get-rich-quick route; it is for nurses who are excellent patient advocates, good teachers, expert collaborators, and multitasking whizzes. It is for case managers who are losing sight of what they initially loved about the job and long to get back to really helping people and making a difference. It is for people who are ready for a change and not afraid to try something new.

When Burnout Leads to Entrepreneurship *continued from page 8*

will find both sides of the story. There is both the positive, empowering information as well as the horror stories of others' failures. That's when I connected with my mentor. My mentor, who I found through LinkedIn, had her own independent case management company. Fortuitously, my mentor had gone through the same transition that I was contemplating and started her own case management business after being in the insurance industry for years. This relationship was a vital part of my own transition. Here was real, live proof that the idea that until now was just a thought in my head was actually a viable business endeavor that could actually work and bring me all of the things that I was longing for. My mentor was succeeding, and with a plan and some hard work I could also succeed.

Having a mentor who has already blazed the trail that you hope to follow is an essential impetus. Research alone is helpful, but interacting with someone who has already done it provides invaluable information that can't be gleaned anywhere else. It's like getting experience without doing the work. Plus you have an ally and advocate in your corner during a transition that is full of unknowns.

For me, it was important to be realistic about the transition. I knew that, especially at the beginning, I'd be working a lot of hours, which I was used to. But now all that time put in would be bringing me closer to the autonomous, flexible, and profitable lifestyle that I dreamed of. I wouldn't simply be burning myself out just to keep up with the ever-growing caseloads I was used to.

The next task was to create a brand. If I was going to make it as an independent case manager, I understood that I was the product I was selling and that I needed to make myself stand out from the pack. I knew I had specific traits, characteristics, and experiences that made me a great case manager, but I needed to figure out how I could quickly, easily, and effectively communicate that to the people who would hire me. I definitely did not just want to be another name on a list of case managers, so I knew that I really needed to determine what set me apart from other nurses in this field. I checked out other independent case manager websites to see what they were saying and how they presented themselves. And then I also pinpointed exactly what it was about me that stood out, where I had an edge, and how I was best positioned to help. I figured that if I focused on my strengths and the specifics that I excelled at, I'd attract the clients and cases that would be meaningful. It was definitely important to me to attract working relationships that cultivated my passion for the field; I didn't want to be a generic and boring name on a page.

It took some time and thought, but I eventually settled on branding that perfectly reflected who I am. As important as branding is, don't sweat getting it perfect to the point that you get stuck in this stage. Put in the time and energy, but if it's not quite right, don't worry too much. Your branding can always evolve as you grow. If you put too much emphasis on your branding and you are never quite satisfied, you will end up spending too much time and money trying to get it just right. Whatever you do, don't let the branding phase get in the way of your ultimate goal, which is to get out there and start helping people.

Once my branding was solid, my next goal was to directly target the insurance companies that I wanted to work with. I sent letters, networked at local workers' compensation meetings, and attended conferences. I knew that if I was going to succeed I needed to hit the ground running, so I shook as many hands as possible and tried to make as many connections as I could. I also made sure not to treat this transition as if I were just dabbling at going out on my own. I knew that it would be to my own detriment if I spoke about my role as if it were something I was "trying" or "thinking about." Instead, I used language that emanated confidence even if I wasn't necessarily feeling it yet. I was firm and confident about this new path I was embarking on and didn't refer to it lightly. I made it a priority not to give the impression that if it didn't work out I would just go back to my former job. This was what I was doing, and I was sticking to it.

Once the networking was well under way, it was time for more research. This time I needed to know what to charge for my services. Settling on a number that was too low would make

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The Crucial Importance of Nurses' Clinical Judgment

By Elizabeth Hogue, Esq.

An article entitled "Quantifying a Nurse's 'Gut'" by nurse Theresa Brown that appeared in *The New York Times* on August 12, 2018, underscores the importance of nurses' clinical judgment. The article begins with a story about a former patient of Ms. Brown that still haunts her months later. A few days following the patient's admission to the hospital, the author sensed that something was not quite right even though there were no obvious red flags. Sure enough, by the end of Ms. Brown's shift, the patient developed bleeding in her brain and was moved to intensive care and died.

Ms. Brown says:

"Every nurse most likely knows the feeling. The patient's vital signs are just a little off, she seems not quite herself, her breathing is just a little off, she seems not quite herself, her breathing is slightly more labored. But on paper she looks stable..."

In these types of situations, nurses often talk about "gut feelings." Ms. Brown points out that they actually aren't feelings at all. Instead, they are the result of years of observation and experience that result in something called "clinical judgment." Clinical judgment is honed only from many years of caring for patients.

Efforts are underway to convert clinical judgment into tools that monitor patients' clinical conditions and help to predict adverse events, such as the Rothman Index. The Rothman Index is a commercial product that uses data from patients' records, including lab results, vital signs, cardiac rhythms, and key aspects of nursing assessments, to identify hospital patients who might look stable, but who are, in fact, fragile.

In the meanwhile, and perhaps on a continuing basis even after such products are fully developed, nurses' gut feelings or clinical judgment when they "eyeball" patients remains crucial to patients' outcomes.

Ms. Brown goes on to say:

"Part of why I still feel haunted by my patient who suddenly took a turn for the worse and then died is because of that nagging sense I had, early on, that something was wrong. Her disease put her at risk for spontaneous bleeding, but at the start of her third day in the hospital a treatment plan still wasn't in place. My gut feelings told me that we were moving too slowly, and I was able to push here and there. But there was nothing I could articulate as a sign of impending calamity."

Ms. Brown concludes the article by saying:

"...But I can promise myself that in the future, I will take any sense of urgency very seriously, document my concern and speak up. *There's now solid evidence that when a nurse says she's got a bad feeling about a patient, the entire care team needs to listen* [Emphasis added]."

Yes, exactly! There are good reasons why nursing remains the most respected profession. It's in large part because *they know.* Nursing remains at the heart of health care of all types. Providers should pay close attention to what nurses say about their patients. *They know!* CM

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

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~Dorothy

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Acute Care and Workers' Compensation Case Managers: a Necessary Alliance

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

"My mission in life is not merely to survive, but to thrive; and to do so with some passion, some compassion, some humor, and some style." –*Maya Angelou*

As professional case managers, we know that there are essential skills case managers must have in order to have successful transitions of care. Some of those requirements include the case manager's ability to:

- Coordinate medical and behavioral interventions;
- Have a professional, yet empathic demeanor;
- Collaborate and advocate with all stakeholders to develop a care plan;
- Focus on patient-centered autonomy and assist the patient in defining goals;
- Have meaningful communication with all stakeholders.

The Role of Case Managers

Case management is neither linear nor a one-way exercise. Assessment responsibilities of the case manager occur at all points in the process, with facilitation, coordination, and collaboration occurring throughout the client's health care encounter. When the payer is workers' compensation, this coordination of care cannot occur successfully without collaboration.

Kathleen Fraser, RN-BC, MSN, MHA, CCM, CRRN, *is the Executive Director of the Case Management Society of America.*

It is the case manager's role to coordinate cost-effective plans and to provide high-quality continuous care that eliminates duplication of services and wasted benefit dollars. Case management is a collaborative process promoting quality care and cost-effective outcomes in order to enhance the physical and psychosocial health of individuals.

Throw in the vocational health aspect and what do we have? A workers' compensation case manager.

"Alone we can do so little; together we can do so much." –*Helen Keller*

Fractionation of care can be avoided when an important alliance occurs: the acute care case manager works with the workers' compensation case manager. While the patient benefits greatly from this collaboration, there is the added benefit of making life easier for the acute care case manager. Workers' compensation case managers can achieve in-stay approvals as well as handle discharge care needs, including durable medical equipment, home health, transportation, and therapy.

The case management process is carried out within the ethical and legal realm of a case manager's scope of practice, using critical thinking and evidence-based knowledge. We are patient advocates and serve as resources to one another. Our health care system operates in silos and information queues, making reciprocal operation with other related management systems and different departments of organizations difficult. However, by working together we can achieve the best possible outcomes for our patients.

Assessment with a patient or injured worker is an ongoing process. Keep it a fluid process by:

- Keep assessments flexible, varying with presenting problem or opportunity.
- Regularly reassess the patient's/caregiver's needs and progress in meeting objectives.
- Facilitate goal-setting discussion based on their needs during all phases of their care.
- Assess the effectiveness of interventions in achieving patient's goals.
- Communicate changes to the health care team.

Case managers on both sides (in this case, the workers' compensation and acute care settings) have roles in educating the patient. Of course, the primary focus is patient safety and self-management. In addition, we need to:

- Verify with the patient that she/he is knowledgeable about and is adhering to the treatment regimen as prescribed.
- Notify the treating physician and/or specialist of any patient discrepancies, inconsistencies, or misunderstandings.
- Keeping the employer informed helps to allay fears and uncertainty for the patient/injured worker (IW).

"Be the thermostat, not just the thermometer"
–Dr. Martin Luther King

Moving from Engagement to Activation

Motivating our patients and injured workers to wellness requires recognizing the knowledge, skills, confidence, and resources that patients have to manage their disease state in an active and informed manner. A patient-centered approach to case management meets patients at their personal level of readiness to learn and accomplish their health-related goals, focusing on patient-provider shared decision making in all phases of their treatment.

Patients with highest levels of activation display interest and involvement and actively decide his or her best course of involvement. In addition, high activation levels are associated with decreased health care costs.

Barriers to Collaboration

While alliances between organizations and care settings is important, there are barriers to collaboration. One common barrier is case load and work overload, which particularly affects acute care case managers, who can feel bombarded and overwhelmed. In addition, sometimes case managers might be reluctant to change how cases are coordinated. Workers' compensation case managers can assist acute care case managers in many areas, which can lighten the responsibilities involved for cases involving injured workers as well as speed up transitions. Moving beyond the status quo of how cases are typically handled, as well as the trust issues that can arise between professionals, benefits the patient and his or her caregivers.

Integrating the physical and behavioral health aspects through active communication by the acute care and workers' compensation case managers can and will decrease these statistics:

- An estimated 26 percent of physically healthy Americans age 18 and older are living with a mental health disorder in any given year;
- 46 percent will have a mental health disorder over the course of their lifetime;
- An estimated 8 percent of Americans need drug or alcohol abuse treatment.

The U.S. Department of Labor reports on the likelihood that a worker will return to work (RTW) following an injury:

- Off work 6 months: 50% chance of RTW
- Off work 1 year: 25% chance of RTW
- Off work 2 years or more: Virtually no chance of RTW

These stats demonstrate the importance of acute care and workers' compensation case managers working together to ensure that workers can return to work sooner and healthier.

Another reason for case managers to collaborate across care settings involves the opioid epidemic. Opioid analgesics are now responsible for more deaths than the number of deaths from suicide and motor vehicle crashes as well as cocaine and heroin overdoses combined! Together, we can improve outcomes for individuals with complex injuries or diagnoses. These cases tend to be complexity-focused and relationship-based, with few cross-disciplinary case manager handoffs. Medication reconciliation between case management genres can decrease the pitfalls of opioid addiction.

CASE MANAGER SURVIVAL SKILLS

- **Keep a Sense of Humor**
- **Keep Things in Perspective**
- **Embrace Change**
- **Stay Connected to the Industry**
- **Always Have a Plan "B"**

Yes another reason to collaborate to improve transitions of care is the opportunity to communicate with non-English-speaking patients. In these cases, we can:

- Use a professional medical interpreter to be less affected by "false fluency" with medical phrases.
- Use words that are more easily understood by people outside of medical care.
- Inform the interpreter that you want an interpretation that is as

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Integrated Behavioral Health Program Can Improve Health of Patients With Type 2 Diabetes

Sweta Tewary, PhD, MSW, BI, Andrew L. Brickman, PhD, and Nicole Cook, PhD, MPA

Type 2 diabetes (T2D) is the sixth leading cause of death in the United States and impacts approximately 9.4% of the US population.[1] It is estimated that 31% of people with T2D also have a comorbid diagnosis of depression.[2] Comorbid depression among people with T2D is associated with reduced patient engagement, poor medication management, uncontrolled blood glucose level, and an increase in health care expenditures, thereby leading to poorer controlled diabetes.[3] Vulnerable populations, including those who are underemployed, underinsured, and from racially and ethnically diverse backgrounds, have disproportionately higher rates of T2D with depression,[2] yet these populations also face increased barriers to care including access to specialists and lack of transportation and they often have limited family support.[4]

Community Health Centers (CHCs) were established by the Human Resources Services Administration (HRSA) to serve as a primary care safety net for vulnerable populations. Over the past 2 decades, CHCs, with the support of HRSA, have developed health care delivery strategies to treat patients with T2D, depression, and other comorbid chronic disorders through initiatives such as disease and care management programs that are supported by innovative health information technologies.

In 2014, Health Choice Network (HCN), a large health center–controlled network with 27-member CHCs, collaborated with the Bristol-Myers Squibb Foundation to implement an Integrated Behavior Health Program (IBHP). The primary goal of the IBHP, an expanded disease management initiative targeting high-risk patients with comorbid T2D and depression, was to integrate behavioral health services into an existing diabetes disease management program. This paper evaluates the effectiveness of the IBHP program for improving management of diabetes and reducing symptoms of depression.

Methodology

Study Population

The program was implemented at two CHCs in Miami-Dade County, Florida. The structure was population-based in that all participants who met the inclusion criteria were offered enrollment into the IBHP program.

Inclusion and Exclusion Criteria

Participants were identified for the IBHP program through an electronic health record (EHR) data query. Participants were eligible for the IBHP program if they were a current patient (visit within the past 12 months), were 19 years of age or older, had a current diagnosis of T2D, had either a current diagnosis of major depressive disorder or results of a screening test for depression suggesting moderate or major depression, and had a hemoglobin A1C (HbA1c) >8 within the past 12 months. The screening test used for major depression was a score of >9 on the Patient Health Questionnaire-9 (PHQ-9) or a diagnosis of depression. The PHQ-9 is a well-validated measure used by CHCs to assess depressive symptoms.[5] Pregnant women were excluded from the study.

IBHP Program Model

The IBHP program incorporated dedicated community health workers (CHWs) from 2 CHCs to engage participants with T2D and depression. Participants who met the inclusion criteria were proactively contacted by CHWs and invited to participate in the program. As part of the program, CHWs engaged with participants via telephone and face-to-face to navigate

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Comorbid depression among people with type 2 diabetes is associated with reduced patient engagement, poor medication management, uncontrolled blood glucose level, and an increase in health care expenditures, thereby leading to poorer controlled diabetes.

the patient through scheduling 4 primary care visits with their provider and 3 behavioral health appointments with a licensed therapist.

Data Collection and Analysis

Community health workers employed at two CHCs in Miami received a list of eligible participants extracted from the EHRs for engagement and recruitment. These participants were engaged through at-home visits and assisted with removing barriers to medical and behavioral health care. A record of the patient agreeing to participate was created in the EHR, and the patient was tracked for his/her clinical progress and appointments. After participants were successfully engaged by the CHW, they were incorporated into the existing care management infrastructure of the health center's integrated primary and behavioral health care services systems. Secondary data analyses were performed on data collected through EHR (2014-2016) using SPSS 21. Institutional review board approval was received from the Nova Southeastern University Institutional Review Board.

Measures

1. Depression

The PHQ-9 was used to assess depressive symptoms. PHQ-9 is a well-validated measure used by CHCs to assess depressive symptoms.[5] The instrument consists of 9 items with a 4-point scale indicating the degree of severity from 0 (not at all) to 3 (nearly every day). These items were then summed to form a total severity score ranging from 0 to 27. Participants were also eligible if there was a recent diagnosis of major depressive disorder in their medical record.

2. Diabetes

Participants were identified as having T2D if (1) there was a diagnosis of diabetes in their EHR (other than during pregnancy); and if (2) they had an HbA1c >8.

Step-by-Step Implementation Protocol

Implementation protocol

- Health Choice Network provided in-depth training to health center staff to implement an IBHP. Booster training was provided if required.
- Existing participants in the CHC were identified through a query that met inclusion/exclusion criteria. A list of participants who met the criteria was provided to the health centers using a secure file transfer protocol to facilitate patient contact. Participants were telephoned and were told that they had an elevated HbA1c and an elevated measure on a test of psychosocial distress. They were then encouraged to schedule an appointment at their health center. They were enrolled in the IBHP program either on the phone or in person. Program participation was documented in the EHR along with any additional appointment reminders. Multiple phone calls facilitated patient engagement, especially when a patient did not answer the first phone call.
- During the first face-to-face contact with the patient, the CHW provided diabetes education and information about the contribution of mood to diabetes self-care.
- At the first behavioral health visit after enrollment, participants were seen by a behavioral health professional. The PHQ-9 was administered to the patient if it had not been previously administered. Results for PHQ-9 were documented in the EHR. The patient's initial scores for the PHQ-9 established a baseline for subsequent assessments.
- Subsequent follow-up appointments were made for 3 behavioral health and 3 primary care appointments. For each appointment, the health center received financial incentives; there was a cash incentive of $150 for the first behavioral health and $80 for subsequent behavioral health visits. The cash incentive for each primary care visit was $50. When the patient was seen by behavioral and primary care specialists, HbA1c and PHQ-9 scores were documented.

Results

Patient Demographics

The target enrollment for the 3-year project was 250 participants, but the study included 207 participants recruited between 2014 and 2016 as it is hard to reach population. Seventy-two (35%) of the enrolled completed 4 primary care and 3 behavioral health visits. The average age of these participants was 56 years (standard deviation

TABLE 1 **Demographics of 207 patients in an Integrated Behavior Health Program**

Ethnicity	Race					
Hispanic/ Non-Hispanic	White	Black	Asian	Native Hawaiian	More than 1 race	Missing
Hispanic	137	5			4	8
Non-Hispanic	14	30	1	1	2	3
Missing		1				1
Total	151	36	1	1	6	12

Note: Data source was an electronic health record.

[SD] = 11.08; range, 24-75); 66% were Hispanic-White, 6% were Non-Hispanic-White, 2% were Hispanic-Black, and 14% were Non-Hispanic-Black. The sample comprised 63% female participants, and the average body mass index of the participants was 33.05. Our bivariate analysis did not find any a significant correlation between HbA1c and PHQ-9 scores. Furthermore, although there were no correlations between total number of visits and clinical outcomes, age was correlated with both depressive symptoms and HbA1c.

TABLE 2 **Paired sample t-test**

	Mean of paired differences	SD	SE of the mean	95% CI of the difference		t	df	Significance (2-tailed)
				Lower	Upper			
Pre/post HbA1c	0.44042	1.85621	0.14321	0.15768	0.72315	3.075	167	0.002*

Abbreviations: df, degrees of freedom; PHQ-9, Patient Health Questionnaire-9; SD, standard deviation; SE, standard error.
*Significant at the .05 level

TABLE 3 **Statistics for paired samples**

	Mean	N	SD	SE of the mean
Before	10.11	168	1.611	0.124
After	9.67	168	1.7	0.131

Abbreviations: SD, standard deviation; SE, standard error.

Statistical Analysis

We analyzed descriptive statistics of patient demographic characteristics and the rates at which the participants adhered to appointments. Variables of interest were changes in HbA1c and scores measured with the PHQ-9.

TABLE 4 **Paired sample t-test**

	Mean of paired differences	SD	SE of the mean	95% CI of the difference		t	df	Significance (2-tailed)
				Lower	Upper			
Baseline PHQ-9 score – Last PHQ-9 score	1.432	9.209	0.668	0.114	2.749	2.143	189	0.033

Abbreviations: df, degrees of freedom; PHQ-9, Patient Health Questionnaire-9; SD, standard deviation; SE, standard error.
*Significant at the .05 level.

TABLE 5 **Statistics for paired samples**

	Mean	N	SD	SE of the mean
Baseline PHQ-9 score	7.51	190	8.285	0.601
Last PHQ-9 score	6.07	190	7.691	0.558

Abbreviations: PHQ-9, Patient Health Questionnaire-9; SD, standard deviation; SE, standard error.

We also used multivariate analyses to examine the association between total number of visits, PHQ-9, HbA1c, and the demographic characteristic of participants. We compared pre/post intervention data for 207 participants using a paired sample t-test. Each patient was measured twice (before and after the completion of the program), resulting in pairs

of observations. Participants with an HbA1c ≥7.5 were included in the analysis.

Impact of IBHP services on patient's diabetes
Results of IBHP services on HbA1c after the intervention had a significant effect on patient HbA1c levels (Table 2). Participants with an HbA1c >7.5 before the intervention had significantly reduced blood glucose levels after completion of the program. A t-test was significant with P < .002. Mean HbA1c decreased from 10.11 to 9.67 (Table 3). We suspect that participants had psychosocial barriers to adherence that responded readily to brief therapeutic intervention.

Impact of IBHP services on patients' behavioral health
To answer our second research question, we analyzed PHQ-9 scores before and after the intervention. The t-test was significant with P = .03 (Table 4). Several participants were not included in the analysis because pre/post scores were not available (N = 190). The mean PHQ-9 score decreased from 7.51 to 6.07 (Table 5).

Regression Analysis
Since demographic and clinical variables (age and HbA1c) were significantly associated with depression at the bivariate level, we used linear regression analysis to further examine the impact of age and diabetes on depression. Regression analysis revealed

TABLE 6 **Regression analysis.**

Model	R	R square	Adjusted R square	Standard error of the estimate	Change Statistics				
					R square change	F change	df1	df2	Significant F change
1	.284[a]	0.081	0.050	7.878	0.081	2.600	5	148	0.028

Abbreviations: df, degrees of freedom.
[a]Predictors: (Constant), Total Visits, Gender, Base Line HbA1c value, body mass index, age

TABLE 7 **ANOVA**

Model		Sum of squares	df	Mean square	F	Significance
1	Regression	804.969	5	160.994	2.594	.028*
	Residual	9186.745	148	62.073		
	Total	9991.714	153			

Abbreviations: ANOVA, analysis of variance; df, degrees of freedom; PHQ-9, Patient Health Questionnaire-9.
[a]Dependent variable: last PHQ-9 score.
*Significant at the .05 level.

TABLE 8 **Coefficients**

Model		Unstandardized coefficients		Standardized coefficients		Significance
		B	Standard error	beta	t	
1	(Constant)	15.583	5.098		3.057	.003
	Total visits	.003	.067	.003	.042	.967
	Gender	-.654	1.361	-.038	-.480	.632
	Body mass index	.002	.001	.124	1.569	.119
	Age	-.217	.074	-.234	-2.925	.004*
	Last HbA1c value	1.111	1.095	.080	1.015	.312

[a]Dependent variable: last PHQ-9 score.
*Significant at the .05 level.

Over the past 2 decades, community health centers, with the support of the Human Resources Services Administration, have developed health care delivery strategies to treat patients with type 2 diabetes, depression, and other comorbid chronic disorders through initiatives such as disease and care management programs that are supported by innovative health information technologies.

that HbA1c scores along with other independent predictors (age, gender, and number of visits) can significantly predict depressive symptoms (Tables 6 and 7). This is an interesting finding, but after examining independent predictors, only age was significantly associated with increased PHQ-9 scores. The linear changes are relatively small and not that meaningful (Table 8).

Discussion

This study demonstrates the feasibility of an integrated behavior health project in a safety net population. Findings from the study indicate that brief therapeutic intervention can help resolve underlying levels of stress and may be useful in addressing barriers and challenges to treatment adherence. Specifically, the project resulted in a reduction in clinical outcomes (HbA1c and PHQ-9 scores) in a safety net population of two CHCs in Miami, Florida. However, results should be interpreted with caution because, as with any project implementation, our study also encountered multiple challenges.

First, it was difficult to enroll and engage patients to complete 3 primary care and 4 behavioral health visits, particularly in communities with health disparities. Multiple factors (eg, medical illness, transportation, sick child at home) affected participant enrollment and the engagement process. Since the participants did not get the full intervention of 4 behavioral health and 3 primary care visits, it was difficult to assess the impact of total number of visits on clinical outcomes. In addition, our inclusion criteria for behavior health was PHQ-9 score >9 as well as participants with only a diagnosis of depression. Some of the participants with a diagnosis of depression had a PHQ-9 score <9 and were included in the subset of analysis. Our study results are indicative of the success of an IBHP, although the long-term impact on clinical measures scores still needs to be evaluated.

Second, since this was a grant-funded study, we were able to involve a multidisciplinary team for the recruitment processes. We provided start-up trainings to implement the redesigned project. These trainings included information about documenting patient information, referrals, and follow-ups in the EHR. Oftentimes CHCs do not have the staff support for patient engagement and sustaining this methodology can be expensive and time consuming. Third, CHCs are imbedded within the communities they serve and have providers fluent in the languages spoken within their neighborhoods. Our program did not have the ability at this time to track participants as they move through the referral pathway. Fourth, this is a hard-to-reach population and we provided incentives to the health centers for engaging participants for each visit; CHCs dealing with uninsured and Medicaid participants may not have the time and money to motivate participants to keep their appointments. Finally, internal validity may be weakened because participants received treatments from multiple specialists. At one CHC, behavior treatment was provided by a psychologist, whereas at another CHC a trained behavior specialist provided the treatment.

One strength of implementing this intervention within the structure of a CHC is their organizational expertise to deal with barriers that are commonly encountered in populations with health disparities that are usually associated with poverty. For example, federal requirements and resources are routinely applied for uninsured individuals and families. The care coordinator is responsible for appropriately guiding the patient who encounters this barrier to the appropriate department within the CHC. Implementation of the behavioral health integration program has also highlighted differences in chronic illness management because of compliance challenges that may be secondary to social determinants versus compliance challenges that may be due to mental health issues alone.

Conclusion

Participants in a safety net population are often lost to care because of multiple challenges. Community health care centers are uniquely positioned to engage participants with health disparities. Some of the strengths of integrating primary and behavior health services include improved clinical outcomes and reduced hospitalization. Participants are also more likely to see

their primary care physician when their behavioral health conditions are managed. We found similar results through our study with improved processes of care and patient engagement.

We also believe that clinical staff are more sensitive to the many challenges faced by their patient populations because of the program. The role of CHWs in improving health care access and outcomes is well documented.[6] In this study, CHWs played a pivotal part in tracking and referring participants to the respective health care provider. We highly encourage CHCs to model similar programs with modifications that can facilitate the implementation of the care delivery. Services and care coordination provided through the IBHP program can facilitate the necessary clinical and behavioral intervention for the participants and their health outcomes. CE 1

Conflict of Interest

The authors declare that they have no competing interests.

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CE II The Insight from Experience: Lessons from Case Management Experts

Nancy Murray, RN, PhD

Abstract

Purpose: Caring professionals face numerous challenges in their daily practice. A convergence of anecdotal and research-based evidence demonstrates that their use of a tacit-intuitive perspective in complex circumstances is increasing. Improved understanding of insight phenomenology, commonly known as the "aha" moment of solution discovery and new knowledge creation, can support caring professionals in meeting the challenges of their role.

Design: Qualitative phenomenological study using a modified hermeneutic model of data collection and analysis.

Methods: Nonaka's dynamic organizational knowledge creation theory was used as the conceptual framework. Interviews were conducted with eight experienced community case managers in the province of Ontario, Canada.

Results: A nature of insight and new knowledge creation education framework was developed based on the interview data and factors contributing to tacit-intuitive decision processes for complex situations. Caring professionals invest time to actively listen and build trusting relationships. They employ gestalt-systems thinking; mental models, metaphors, and concept maps; strategic thinking; creative problem solving; and reflective processing to experience the insight moment of solution discovery and new knowledge creation. New knowledge is disseminated through informal and formal workplace exchanges.

Keywords: "aha" moment, healthcare professionals, case managers, insight phenomenology, tacit knowledge

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Background

Caring professionals face numerous challenges in their daily practice. Logical deductive reasoning supported by reliable and concrete data is frequently used in structured situations with unequivocal outcomes.[1] However, there is increasing anecdotal and research-based evidence that tacit knowledge and intuitive skill are used in unstructured situations that present conflicting, novel, or alternative outcomes.[2] Enhanced understanding of the tacit-intuitive experience at the "aha" moment of solution discovery and new knowledge creation can support healthcare professionals in meeting the demands of their role.

Explicit knowledge is well documented in the form of organizational policy manuals, written business processes, and decision-making algorithms. In contrast, tacit knowledge, sometimes referred to as practical or intuitive understanding, is learned independently of direct instruction. Research emphasizes that intuitive knowledge is not simply a by-product of tacit knowledge; it is distinct.[3,4] Tacit knowledge can be conceptualized as an idiosyncratic, subjective, highly individualized store of knowledge and practical expertise gathered through years of experience and direct interaction within a domain.[5,6,7,8]

In discussing the transition from novice to expert nurse, Benner highlighted the importance of making implicit tacit knowledge explicit: "A wealth of untapped knowledge is embedded in the practices and the 'know-how' of expert nurse clinicians, but this knowledge will not expand or fully develop unless…[they] systematically record what they learn from their experiences."[9] While much has been written about tacit-intuitive knowledge creation and how to facilitate its development,[5,7,10] literature on the application of tacit knowledge to the intuitive process is lacking. To address this gap and improve understanding, a qualitative phenomenological study was conducted to determine how caring professionals experience the "aha" moment of solution discovery and new knowledge creation. The following subquestions were also explored:

1. What is the essence of the "aha" moment?
2. What is learned in that moment by caring professionals?
3. How does the caring professional create this new knowledge?

Methods

Nonaka's dynamic organizational knowledge creation theory[5,10] was used as the conceptual framework. Interviews were held with 8 experienced community case managers in Ontario, Canada, who were asked to reflect on their lived experiences during moments of insight. To be included in the study, participants were required to have at

Improved understanding of insight phenomenology, commonly known as the "aha" moment of solution discovery and new knowledge creation, can support caring professionals in meeting the challenges of their role.

least 5 years of successful employment as a case manager. Interviews were audiotaped and transcribed verbatim. Informed consent was obtained before the interviews and confidentiality was assured and maintained.

Results

Themes emerged in relation to the subquestions. The case managers described the essence of the "aha" moment as the application of tacit knowledge to intuitive processes during solution discovery and cited various occurrences. These included the comprehensive elements of case management service; body language revealing elder abuse; the element of culture; the real story behind a client's words; collaborative partnership making an impossible situation possible; realizing that what is real is not always what is portrayed; the importance of reciprocally respectful partnerships; and the strengths of social networks.

Participants agreed that case management practice requires a professional service-oriented attitude that includes active listening vs. passive hearing, being open minded, and caring. One case manager noted that interpersonal relationships are built "by listening, by being informed by the client, by having their stories, their personhood, [and] the big picture." There was consensus that building a trusting relationship was essential to the solution discovery process, but it requires time and tenacity. Complex client situations have many elements and are not easily or quickly resolved. A case manager remarked, "What I had to do was spend time just listening to them and . . . hearing their concerns. …They needed to have support that was beyond the ordinary." Another stated, "You never give up. I think people deserve that from us."

In discussing what they had learned in the "aha" moment and what was in their minds at the time, case managers shared experiences of gestalt-systems thinking and the use of mental models. They emphasized that solution discovery requires a broad lens. One case manager observed, "I need to take the big picture of the whole person—the comprehensive model." In connecting the "aha" moment to the gestalt-systems navigator role, another acknowledged: "[I am] the link to all of the services…all of the resources that are in the community, not just the services that [our organization] provides." Case managers variously described the "aha" moment as a "jigsaw puzzle," a "quilt," a series of "little boxes that connect to each other" and "circles that overlap." These mental models provided clarity for the case managers and facilitated their learning.

The case managers created new knowledge by way of the "aha" experience. They shared this new knowledge with their peers through informal exchange, which contributed to knowledge diffusion: "You would just pass on that information . . . for it [to expand]." They indicated that the acquisition of new knowledge enriched their tacit knowledge reservoir and enhanced their practice: "When you pick [more] brains you usually come up with something…that will solve the problem."

All study participants used creative, strategic, and reflective thinking. Creativity was essential to come to solution-focused realities. However, for cases that were complex and provided elaborate yet subtle details, the case managers approached their work with a contemplative, absorbed mindset. One case manager explained, "I think that's where the intuition comes in. It was just you go one-step further. I think that's based on experience. A cookie-cutter approach was not going to work." Another case manager said, "If things worked for one person, you couldn't be sure that you could apply the same [solution to another person]. You may need strategic solutions."

For all the case managers, the influence of tacit knowledge and information exchange occurred. It was accomplished via the application of reflective processes to creative and strategic thinking as new knowledge was created and shared. All case managers provided evidence of experience and learning at the moment of insight, which was facilitated by building trusting relationships, focusing on the client, taking the necessary time, and being tenacious. Eventually, all participants were able to confirm that what they learned in their "aha" moment was accurate.

Discussion

This study was conducted to determine how caring professionals experience the "aha" moment of solution discovery and new knowledge creation. Interview

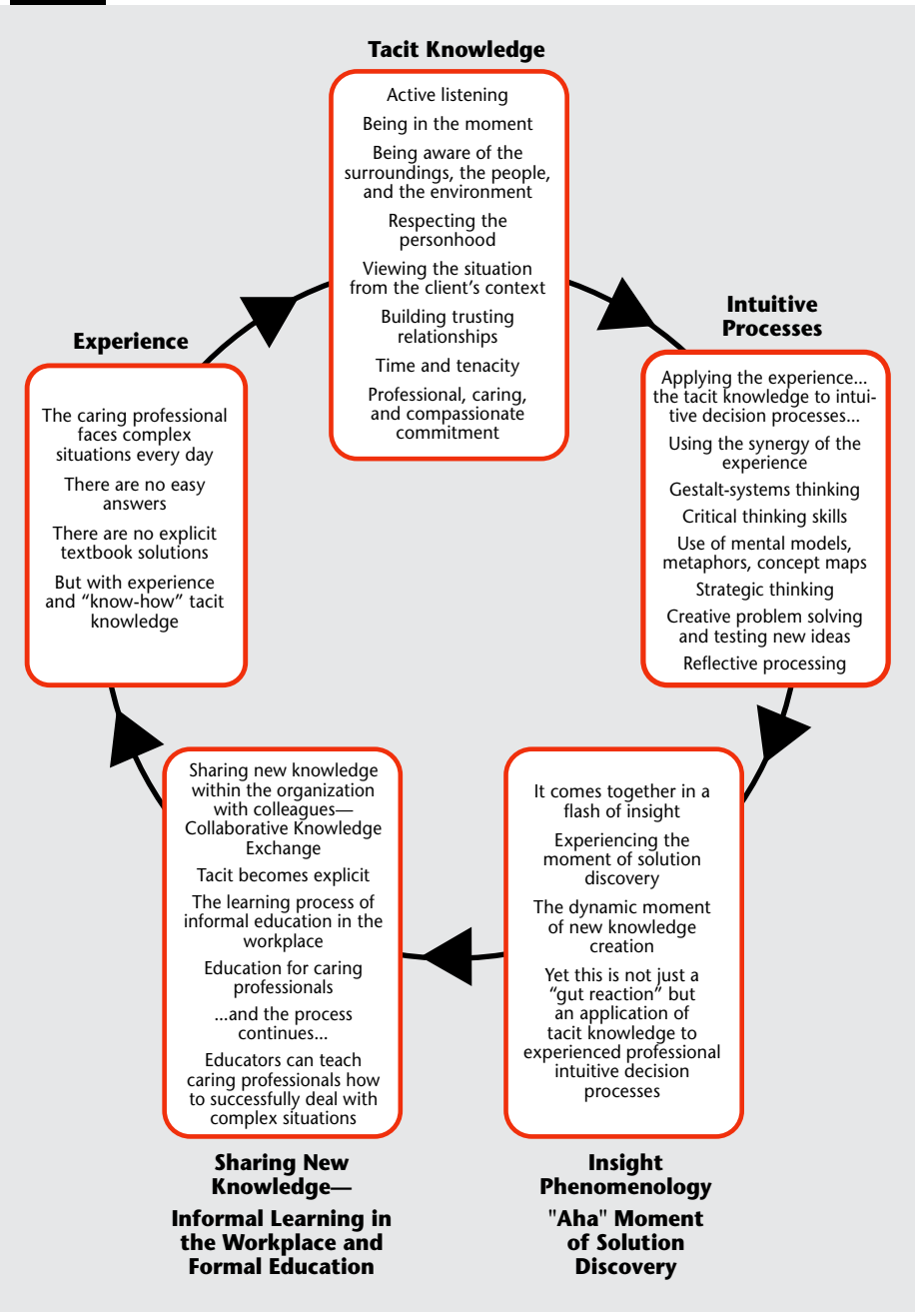
In moving forward, professionals must apply intuitive processes. These include using the synergy of the experience; gestalt-systems thinking; critical thinking; mental models, metaphors, and concept maps; strategic thinking; creative problem solving; and reflective processing.

data were used to construct a nature of insight and new knowledge creation education framework that illustrates the essential components of the insight experience. The arrows indicate trajectory (Figure 1).

The framework begins with the challenge presented to caring professionals working with clients who are experiencing a crisis that is complex, difficult-to-impossible to resolve satisfactorily, and has no easy textbook solutions. In such situations, it is vital that professionals position themselves in the moment and try to see the situation from the client's viewpoint. Furthermore, they need to use active listening skills while being aware of surroundings, people, and the environment. The professional should respect the client's personhood and invest the time needed to engage and build a trusting relationship with the client. They must also maintain a professional, caring, and compassionate commitment. As these situations are not quickly resolved, tenacity in addressing the client's issues and concerns is vital.

In moving forward, professionals must apply intuitive processes. These include using the synergy of the experience; gestalt-systems thinking; critical thinking; mental models, metaphors, and concept maps; strategic thinking; creative problem solving; and reflective processing. It is through a combination of these processes that the professional arrives at the "aha" moment of solution discovery and new knowledge creation. Professionals share this new knowledge with their colleagues via

FIGURE 1 **The nature of insight and new knowledge creation education framework**



Evidence-informed tacit knowledge is essential and thus should be responsibly shared with neophyte professionals and students in the formal classroom setting using real-life experiences as models for instructive learning.

collaborative exchange, which leads to new experiences and supports further tacit knowledge acquisition and dissemination.

When asked if they had any advice for novice case managers, one case manager commented, "You need to spend time just sitting down and listening to them. Get [the client's] story." Another said, "Listen to your gut and get to know the person. This isn't textbook. This is a relationship that you build with the individual that you are working with. …You need to listen." Case managers also offered the following recommendations (listed in terms of frequency):

1. Listen to the client—close your laptop
2. Build a trusting relationship
3. Be a caring, compassionate professional
4. Consider the client's personhood
5. Take the necessary time/be tenacious
6. Use gestalt-systems thinking
7. Use reflective, critical thinking
8. Learn from others—it's a learning-knowledge exchange collaboration!
9. Build your tacit-explicit knowledge reservoir
10. Use the tacit-intuitive perspective

Scope and Limitations

The scope of this study was limited to 8 experienced case managers in 1 Canadian province.[11] Selection of participants was based on 5 or more years of successful employment as a case manager with a service provider center.[12] Findings from the study may not be generalizable to all case managers.

Conclusion

The purpose of this qualitative phenomenological qualitative study was to understand the "aha" moment of insight and discovery with the application of tacit knowledge to intuitive processes. Caring professionals routinely face unstructured and complex situations and use a tacit-intuitive perspective in these perplexing circumstances. However, a review of the literature revealed there is a lack of research in this area. Based on the findings from the current study, client-related clinical performance can be supported and enhanced through an educational curriculum that includes application of the tacit-intuitive phenomenon.

This study has generated critical messages for educators. Foremost is that evidence-informed tacit knowledge is essential. Thus, it should be responsibly shared with neophyte professionals and students in the formal classroom setting using real-life experiences as models for instructive learning. Professionals also learn from each other in informal evidence-informed innovative idea exchanges. These should be encouraged to support the iterative aspect illustrated by the framework used in this study.

The nature of insight and new knowledge creation education framework serves as a foundation for a core curriculum for the tacit-intuitive phenomenon. Educators should provide opportunities for students to learn from the lived evidence-based experiences of seasoned professionals. Enriching educational opportunities for client-caring professionals will further develop their knowledge, skills, and confidence in addressing complex situations. Most importantly, it can improve client-related clinical performance with the successful application of the tacit-intuitive phenomenon.

Recommendations for Future Research

This study revealed opportunities for further research. The current study focused on case managers who work with clients in complex situations. Future research agendas could include an examination of the informal milieu of workplace settings in which new knowledge exchange is encouraged among multidisciplinary professional peers. In this regard, future studies could also explore the nature, type, and context of tacit knowledge that provides the best learning experiences for students. **CE II**

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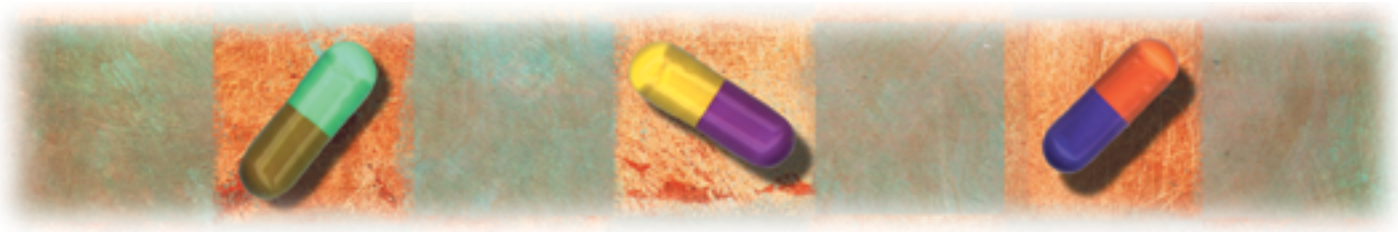
PharmaFacts for Case Managers



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WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions (e.g., rash, urticaria, and dyspnea) have been reported with Emgality in clinical studies. If a serious or severe hypersensitivity reaction occurs, discontinue administration of Emgality and initiate appropriate therapy. Hypersensitivity reactions can occur days after administration, and may be prolonged.

ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Hypersensitivity Reactions

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no adequate data on the developmental risk associated with the use of Emgality in pregnant women. Administration of Emgality to rats and rabbits during the period of organogenesis or to rats throughout pregnancy and lactation at plasma exposures greater than that expected clinically did not result in adverse effects on development.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2%–4% and 15%–20%, respectively. The estimated rate of major birth defects (2.2%–2.9%) and miscarriage (17%) among deliveries to women with migraine is similar to rates reported in women without migraine.

Lactation

Risk Summary

There are no data on the presence of Emgality in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Emgality and any potential adverse effects on the breastfed infant from Emgality or from the underlying maternal condition.

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

Geriatric Use
Clinical studies of Emgality did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients.

CLINICAL STUDIES
The efficacy of Emgality was evaluated as a preventive treatment of episodic or chronic migraine in three multicenter, randomized, double-blind, placebo-controlled studies: two 6-month studies in patients with episodic migraine (Studies 1 and 2) and one 3-month study in patients with chronic migraine (Study 3).

Episodic Migraine
Study 1 (NCT02614183) and Study 2 (NCT02614196) included adults with a history of episodic migraine (4 to 14 migraine days per month). All patients were randomized in a 1:1:2 ratio to receive once-monthly subcutaneous injections of Emgality 120 mg, Emgality 240 mg, or placebo. All patients in the 120 mg Emgality group received an initial 240 mg loading dose. Patients were allowed to use acute headache treatments, including migraine-specific medications (i.e., triptans, ergotamine derivatives), NSAIDs, and acetaminophen during the study.

The studies excluded patients on any other migraine preventive treatment, patients with medication overuse headache, patients with ECG abnormalities compatible with an acute cardiovascular event and patients with a history of stroke, myocardial infarction, unstable angina, percutaneous coronary intervention, coronary artery bypass grafting, deep vein thrombosis, or pulmonary embolism within 6 months of screening.

The primary efficacy endpoint for Studies 1 and 2 was the mean change from baseline in the number of monthly migraine headache days over the 6-month treatment period. Key secondary endpoints included response rates (the mean percentages of patients reaching at least 50%, 75%, and 100% reduction from baseline in the number of monthly migraine headache days over the 6-month treatment period), the mean change from baseline in the number of monthly migraine headache days with use of any acute headache medication during the 6-month treatment period, and the impact of migraine on daily activities, as assessed by the mean change from baseline in the average Migraine-Specific Quality of Life Questionnaire version 2.1 (MSQ v2.1) Role Function-Restrictive domain score during the last 3 months of treatment (Months 4 to 6). Scores are scaled from 0 to 100, with higher scores indicating less impact of migraine on daily activities.

In Study 1, a total of 858 patients (718 females, 140 males) ranging in age from 18 to 65 years, were randomized. A total of 703 patients completed the 6-month double-blind phase. In Study 2, a total of 915 patients (781 female, 134 male) ranging in age from 18 to 65 years, were randomized. A total of 785 patients completed the 6-month double-blind phase. In Study 1 and Study 2, the mean migraine frequency at baseline was approximately 9 migraine days per month, and was similar across treatment groups.

Emgality 120 mg demonstrated statistically significant improvements for efficacy endpoints compared to placebo over the 6-month period. Emgality treatment with the 240 mg once-monthly dose showed no additional benefit over the Emgality 120 mg once-monthly dose.

Chronic Migraine
Study 3 (NCT02614261) included adults with a history of chronic migraine (≥15 headache days per month with ≥8 migraine days per month). All patients were randomized in a 1:1:2 ratio to receive once-monthly subcutaneous injections of Emgality 120 mg, Emgality 240 mg, or placebo over a 3-month treatment period. All patients in the 120 mg Emgality group received an initial 240 mg loading dose.

Patients were allowed to use acute headache treatments including migraine-specific medications (i.e., triptans, ergotamine derivatives), NSAIDs, and acetaminophen. A subset of patients (15%) was allowed to use one concomitant migraine preventive medication. Patients with medication overuse headache were allowed to enroll.

The study excluded patients with ECG abnormalities compatible with an acute cardiovascular event, and patients with a history of stroke, myocardial infarction, unstable angina, percutaneous coronary intervention, coronary artery bypass grafting, deep vein thrombosis, or pulmonary embolism within 6 months of screening.

The primary endpoint was the mean change from baseline in the number of monthly migraine headache days over the 3- month treatment period. The secondary endpoints were response rates (the mean percentages of patients reaching at least 50%, 75% and 100% reduction from baseline in the number of monthly migraine headache days over the 3-month treatment period), the mean change from baseline in the number of monthly migraine headache days with use of any acute headache medication during the 3-month treatment period, and the impact of migraine on daily activities as assessed by the mean change from baseline in the MSQ v2.1 Role Function-Restrictive domain score at Month 3. Scores are scaled from 0 to 100, with higher scores indicating less impact of migraine on daily activities.

In Study 3, a total of 1113 patients (946 female, 167 male) ranging in age from 18 to 65 years, were randomized. A total of 1037 patients completed the 3-month double-blind phase. The mean number of monthly migraine headache days at baseline was approximately 19.

Emgality 120 mg demonstrated statistically significant improvement for the mean change from baseline in the number of monthly

migraine headache days over the 3-month treatment period, and in the mean percentage of patients reaching at least 50% reduction from baseline in the number of monthly migraine headache days over the 3-month treatment period. Emgality treatment with the 240 mg once-monthly dose showed no additional benefit over the Emgality 120 mg once-monthly dose.

Study 3 utilized a sequential testing procedure to control the Type-I error rate for the multiple secondary endpoints. Once a secondary endpoint failed to reach the required level for statistical significance, formal hypothesis testing was terminated for subsequent endpoints, and p-values were considered nominal only. In Study 3, Emgality 120 mg was not significantly better than placebo for the proportion of patients with ≥75% or 100% reduction in migraine headache days. Patients treated with Emgality 120 mg showed a nominally greater reduction in the number of monthly migraine headache days that acute medication was taken (-4.7 for Emgality 120 mg vs. -2.2 for placebo; nominal p-value).

A treatment benefit over placebo for Emgality is seen across a range of changes from baseline in monthly migraine headache days.

HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

Emgality (Emgality) injection is a sterile, preservative-free, clear to opalescent, colorless to slightly yellow to slightly brown solution for subcutaneous administration. Emgality is not made with natural rubber latex.

Emgality is supplied in a 120 mg/ml pre-filled pen or syringe.

Storage and Handling

- Store refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect Emgality from light until use.
- Do not freeze.
- Do not shake.
- Emgality may be stored out of refrigeration in the original carton at temperatures up to 30°C (86°F) for up to 7 days. Once stored out of refrigeration, do not place back in the refrigerator.
- If these conditions are exceeded, Emgality must be discarded.
- Discard the Emgality single-dose prefilled pen or syringe after use in a puncture-resistant container.

Emgality is manufactured and distributed by Eli Lilly and Company.

Talzenna (talazoparib capsule)

INDICATIONS AND USAGE

Talzenna is indicated for the treatment of adult patients with deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutated (gBRCAm) human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer. Select patients for therapy based on an FDA-approved companion diagnostic for Talzenna.

DOSAGE AND ADMINISTRATION

Patient Selection

Select patients for the treatment of advanced breast cancer with Talzenna based on the presence of germline BRCA mutations. Information on the FDA-approved test for the detection of BRCA mutations is available at http://www.fda.gov/companiondiagnostics.

Recommended Dosing

The recommended dose of Talzenna is 1 mg taken orally once daily, with or without food.

The 0.25-mg capsule is available for dose reduction.

Patients should be treated until disease progression or unacceptable toxicity occurs.

The hard capsules should be swallowed whole and must not be opened or dissolved. If the patient vomits or misses a dose, an additional dose should not be taken. The next prescribed dose should be taken at the usual time.

TABLE 1

DOSE REDUCTION LEVELS FOR ADVERSE REACTIONS

Dose Level	Dose
Recommended starting dose	1 mg (one 1 mg capsule) once daily
First dose reduction	0.75 mg (three 0.25 mg capsules) once daily
Second dose reduction	0.5 mg (two 0.25 mg capsules) once daily
Third dose reduction	0.25 mg (one 0.25 mg capsule) once daily

Dose Modifications for Adverse Reactions

To manage adverse reactions, consider interruption of treatment with or without dose reduction based on severity and clinical presentation. Recommended dose reductions are indicated in Table 1 and Table 2. Treatment with Talzenna should be discontinued if more than 3 dose reductions are required.

Dose Modifications for Patients with Renal Impairment

For patients with moderate renal impairment (CLcr 30-59 mL/min), the recommended dose of Talzenna is 0.75 mg once daily.

Dose Modifications for Use with P-glycoprotein (P-gp) Inhibitors

Reduce the Talzenna dose to 0.75 mg once daily when coadministered with certain P-gp inhibitors. When the P-gp inhibitor is discontinued, increase the Talzenna dose (after 3-5 half-lives of the P-gp inhibitor) to the dose used before the initiation of the P-gp inhibitor.

TABLE 2

Dose Modification and Management

Monitor complete blood counts monthly and as clinically indicated.

Adverse Reactions	Withhold Talzenna until levels resolve to	Resume Talzenna
Hemoglobin <8 g/dL	≥9 g/dL	Resume Talzenna at a reduced dose
Platelet count <50,000/μL	≥75,000/μL	
Neutrophil count <1,000/μL	≥1,500/μL	
Nonhematologic Grade 3 or Grade 4	≤Grade 1	Consider resuming Talzenna at a reduced dose or discontinue

DOSAGE FORMS AND STRENGTHS

Capsules:

0.25 mg capsule with an ivory cap (printed with "Pfizer" in black) and a white body (printed with "TLZ 0.25" in black)
1 mg capsule with a light red cap (printed with "Pfizer" in black) and a white body (printed with "TLZ 1" in black)

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Myelodysplastic Syndrome/Acute Myeloid Leukemia

Myelodysplastic syndrome/acute myeloid leukemia (MDS/AML) have been reported in patients who received Talzenna. Overall, MDS/AML has been reported in 2 of 584 (0.3%) solid tumor patients treated with Talzenna in clinical studies. The duration of Talzenna treatment in these 2 patients before developing MDS/AML was 4 months and 24 months, respectively. Both patients had received previous chemotherapy with platinum agents and/or other DNA damaging agents including radiotherapy.

Do not start Talzenna until patients have adequately recovered from hematological toxicity caused by previous chemotherapy. Monitor complete blood counts for cytopenia at baseline and monthly thereafter. For prolonged hematological toxicities, interrupt Talzenna and monitor blood counts weekly until recovery. If the levels have not recovered after 4 weeks, refer the patient to a hematologist for further investigations, including bone marrow analysis and blood sample for cytogenetics. If MDS/AML is confirmed, discontinue Talzenna.

Myelosuppression

Myelosuppression consisting of anemia, leukopenia/neutropenia, and/or thrombocytopenia have been reported in patients treated with Talzenna. Grade ≥3 anemia, neutropenia, and thrombocytopenia were reported, respectively, in 39%, 21%, and 15% of patients receiving Talzenna. Discontinuation due to anemia, neutropenia, and thrombocytopenia occurred, respectively, in 0.7%, 0.3%, and 0.3% of patients.

Monitor complete blood count for cytopenia at baseline and monthly thereafter. Do not start Talzenna until patients have adequately recovered from hematological toxicity caused by previous therapy. If this occurs, dose modifications (dosing interruption with or without dose reduction) are recommended.

Embryo-Fetal Toxicity

Based on findings from genetic toxicity and animal reproduction studies, advise male patients with female partners of reproductive potential or who are pregnant to use effective contraception during treatment and for at least 4 months following the last dose of Talzenna.

ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Myelodysplastic syndrome/acute myeloid leukemia
- Myelosuppression

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Based on findings from animal studies and its mechanism of action, Talzenna can cause embryo-fetal harm when administered to a pregnant woman. There are no available data on Talzenna use in pregnant women to inform a drug-associated risk. Apprise pregnant women and females of reproductive potential of the potential risk to a fetus.

The background risk of major birth defects and miscarriage for the indicated population is unknown. In the general U.S. population, the estimated background risks of major birth defects and miscarriage in clinically recognized pregnancies are 2% to 4% and 15% to 20%, respectively.

continues on page 38

LITSCAN FOR CASE MANAGERS

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

Hepatology. 2018 Nov 6. doi: 10.1002/hep.30297.

Estimating prevalence of hepatitis C virus infection in the United States, 2013-2016.

Hofmeister MG, Rosenthal EM, Barker LK, et al.

Hepatitis C virus (HCV) infection is the most commonly reported bloodborne infection in the United States, causing substantial morbidity and mortality and costing billions of dollars annually. To update the estimated HCV prevalence among all adults aged ≥18 years in the United States, we analyzed 2013-2016 data from the National Health and Nutrition Examination Survey (NHANES) to estimate the prevalence of HCV in the noninstitutionalized civilian population and used a combination of literature reviews and population size estimation approaches to estimate the HCV prevalence and population sizes for four additional populations: incarcerated people, unsheltered homeless people, active-duty military personnel, and nursing home residents. We estimated that during 2013-2016 1.7% (95% confidence interval [CI], 1.4-2.0%) of all adults in the United States, approximately 4.1 (3.4-4.9) million persons, were HCV antibody-positive (indicating past or current infection) and that 1.0% (95% CI, 0.8-1.1%) of all adults, approximately 2.4 (2.0-2.8) million persons, were HCV RNA-positive (indicating current infection). This includes 3.7 million noninstitutionalized civilian adults in the United States with HCV antibodies and 2.1 million with HCV RNA and an estimated 0.38 million HCV antibody-positive persons and 0.25 million HCV RNA-positive persons not part of the 2013-2016 NHANES sampling frame. Conclusion: Over 2 million people in the United States had current HCV infection during 2013-2016; compared to past estimates based on similar methodology, HCV antibody prevalence may have increased, while RNA prevalence may have decreased, likely reflecting the combination of the opioid crisis, curative treatment for HCV infection, and mortality among the HCV-infected population; efforts on multiple fronts are needed to combat the evolving HCV epidemic, including increasing capacity for and access to HCV testing, linkage to care, and cure.

Clin Cardiol. 2018 Jul;41(7):916-923. doi: 10.1002/clc.22974. Epub 2018 Jul 20.

Etiologies, predictors, and economic impact of readmission within 1 month among patients with takotsubo cardiomyopathy.

Shah M, Ram P, Lo KBU, et al.

BACKGROUND: Limited data exist on readmission among patients with takotsubo cardiomyopathy (TC), a commonly reversible cause of heart failure.

HYPOTHESIS: We sought to identify etiologies and predictors for readmission among TC patients.

METHODS: We queried the National Readmissions Database for 2013-2014 to identify patients with primary admission for TC using ICD-9-CM code 429.83. Patients readmitted to hospital within 1 month after discharge were further evaluated to identify etiologies, predictors, and resultant economic burden of readmission. Additionally, we analyzed readmission for TC at 6 months.

RESULTS: We studied 5997 patients admitted with TC, of whom 1.2% experienced in-hospital mortality. Median age was 67 years, with 91.5% being female. Among survivors, 10.3% were readmitted within 1 month; 25% of the initial 1-month readmissions occurred within 4 days, 50% within 10 days, and 75% within 20 days from discharge. The most common etiologies for readmission were cardiac (26%), respiratory (16%), and gastrointestinal (11%) causes. Heart failure was the most common cardiac etiology. Significant predictors of increased 1-month readmission included systemic thromboembolic events, length of stay ≥3 days, and underlying psychoses. Obesity and private insurance predicted lower 1-month readmission. The annual national cost impact for index admission and 1-month readmissions was ≈$112 million. Recurrent TC was seen among 1.9% of patients readmitted within 6 months.

CONCLUSIONS: Though the overall rate of 1-month readmission following TC is low, associated economic burden from readmission is still significant. Patients are readmitted mostly for noncardiac causes. Readmission for another episode of TC within 6 months was uncommon.

Clin Transplant. 2018 Nov 2:e13440. doi: 10.1111/ctr.13440

Outcomes in human immunodeficiency virus infected recipients of heart transplants.

Chao C, Wen X, Yadav A, Belviso N, Kogut S, McCauley J.

BACKGROUND: With the advent of combined antiretroviral therapy (cART), growing evidence has shown Human Immunodeficiency Virus (HIV) may no longer be an absolute contraindication for solid organ transplantation. This study compares outcomes of heart transplantations between HIV positive and HIV negative recipients using SRTR transplant registry data.

METHODS: Patient survival, overall graft survival and death-censored graft survival were compared between HIV positive and HIV negative recipients. Multivariate Cox regression and Cox regression with a disease risk score (DRS) methodology were used to estimate the adjusted hazard ratios among heart transplant recipients (HTRs).

RESULTS: In total 35 HTRs with HIV+ status were identified. No significant differences were found in patient survival (88% vs 77%; p=0.1493), overall graft survival (85% vs 76%; p=0.2758) and death-censored graft survival (91% vs 91%; p=0.9871) between HIV positive and HIV negative HTRs in 5-year follow-up. No significant differences were found after adjusting for confounders.

CONCLUSIONS: This study supports the use of heart transplant procedures in selected HIV positive patients. This study suggests that HIV positive status is not a contraindication for life saving heart transplant as there were no differences in graft, patient survival.

J Acquir Immune Defic Syndr. 2018 Dec 1;79(4):453-457. doi: 10.1097/QAI.0000000000001837.

Brief Report: HIV pre-exposure prophylaxis engagement among adolescent men who have sex with men: the role of parent-adolescent communication about sex.

Thoma BC, Huebner DM.

BACKGROUND: Adolescent men who have sex with men (AMSM) are severely affected by the HIV epidemic in the United States. Pre-exposure prophylaxis (PrEP) has proven extremely effective in preventing new HIV infections among adult men who have sex with men, but no research has examined PrEP awareness among AMSM. Furthermore, initial research investigating PrEP adherence among AMSM has found low adherence to the medication regimen. Effective parent-adolescent communication about sex is associated with safer sexual health behaviors among AMSM, and parent-adolescent communication is one potential avenue to increase PrEP engagement among AMSM.

SETTING: Participants included 636 AMSM in the United States who completed a cross-sectional online survey in 2015.

METHODS: Self-reported data on PrEP awareness, attitudes about PrEP, and perceived behavioral control for PrEP usage as well as frequency and quality of parent-adolescent communication about HIV were collected from AMSM. Regression models predicting PrEP awareness, attitudes, and perceived behavioral control from communication constructs were estimated, adjusting for demographic covariates.

RESULTS: Sixteen percent of AMSM were aware of PrEP. AMSM who reported more frequent communication about HIV with their parents were more likely to report being aware of PrEP. Among AMSM aware of PrEP, higher quality parent-adolescent communication about HIV was associated with higher perceived behavioral control for PrEP usage.

CONCLUSIONS: Despite high HIV incidence among AMSM in the United States, PrEP awareness is low in this population. Effective parent-adolescent communication about HIV and sexual health could increase AMSM engagement with PrEP and enhance PrEP adherence within future trials among AMSM.

AIDS. 2018 Nov 28;32(18):2719-2726. doi: 10.1097/QAD.0000000000002012.

Sex differences in HIV-associated cognitive impairment.

Sundermann EE, Heaton RK, Pasipanodya E, et al.

OBJECTIVE: We determined whether there are sex differences in the prevalence and profile of HIV-associated neurocognitive impairment, and whether sex moderates the effect of HIV-serostatus on neurocognitive impairment among HIV-positive and HIV-negative individuals. Secondarily, we assessed whether differences were explained by greater biopsychosocial risk factors in HIV-positive women.

DESIGN: An observational cohort study.

METHODS: Analyses included 1361 HIV-positive (204 women) and 702 HIV-negative (214 women) (ages=18-79 years) participants from the UCSD HIV Neurobehavioral Research Program. Demographically corrected standardized T-scores from 15 neuropsychological tests were used to calculate domain-specific and global deficit scores (GDS). GDS at least 0.5 defined neurocognitive impairment. Biopsychosocial risk factors included low education, low reading level (education quality), lifetime

substance use disorders, depressed mood (clinically significant depressive symptoms and/or current major depressive disorder) and a cumulative syndemic count (sum of biopsychosocial risk factors, range=0-4). Race-stratified analyses were conducted. Analyses were adjusted for relevant demographic and clinical factors.

RESULTS: HIV-associated neurocognitive impairment was more prevalent in women versus men; however, the difference was eliminated after adjustment for reading level. In sex-stratified logistic regressions, the association between HIV-seropositivity and higher likelihood of neurocognitive impairment was stronger in women versus men; however, the association was attenuated in women, but not men, after adjusting for reading level. These results in the overall sample were specific to blacks. Sex differences in the profile of HIV-associated neurocognitive impairment varied by race.

CONCLUSION: Women, particularly black women, were most at-risk for HIV-associated neurocognitive impairment. Higher rates of HIV-associated neurocognitive impairment in women versus men may reflect differences in educational quality.

Am Heart J. 2018 Sep 30;207:19-26. doi: 10.1016/j.ahj.2018.09.006

Admission diagnoses among patients with heart failure: variation by ACO performance on a measure of risk-standardized acute admission rates.

Benchetrit L, Zimmerman C, Bao H, et al.

BACKGROUND: A key quality metric for Accountable Care Organizations (ACOs) is the rate of hospitalization among patients with heart failure (HF). Among this patient population, non-HF-related hospitalizations account for a substantial proportion of admissions. Understanding the types of admissions and the distribution of admission types across ACOs of varying performance may provide important insights for lowering admission rates.

METHODS: We examined admission diagnoses among 220 Medicare Shared Savings Program ACOs in 2013. ACOs were stratified into quartiles by their performance on a measure of unplanned risk-standardized acute admission rates (RSAARs) among patients with HF. Using a previously validated algorithm, we categorized admissions by principal discharge diagnosis into: HF, cardiovascular/non-HF, and noncardiovascular. We compared the mean admission rates by admission type as well as the proportion of admission types across RSAAR quartiles (Q1-Q4).

RESULTS: Among 220 ACOs caring for 227,356 patients with HF, the median (IQR) RSAARs per 100 person-years ranged from 64.5 (61.7-67.7) in Q1 (best performers) to 94.0 (90.1-99.9) in Q4 (worst performers). The mean admission rates by admission types for ACOs in Q1 compared with Q4 were as follows: HF admissions: 9.8 (2.2) vs 14.6 (2.8) per 100 person years (P < .0001); cardiovascular/non-HF admissions: 11.1 (1.6) vs 15.9 (2.6) per 100 person-years (P < .0001); and noncardiovascular admissions: 42.7 (5.4) vs 69.6 (11.3) per 100 person-years (P < .0001). The proportion of admission due to HF, cardiovascular/non-HF, and noncardiovascular conditions was 15.4%, 17.5%, and 67.1% in Q1 compared with 14.6%, 15.9%, and 69.4% in Q4 (P < .007).

CONCLUSIONS: Although ACOs with the best performance on a measure of all-cause admission rates among people with HF tended to have fewer admissions for HF, cardiovascular/non-HF, and noncardiovascular conditions compared with ACOs with the worst performance (highest admission rates), the largest difference in admission rates were for noncardiovascular admission types. Across all ACOs, two-thirds of admissions of patients with HF were for noncardiovascular causes. These findings suggest that comprehensive approaches are needed to reduce the diverse admission types for which HF patients are at risk.

Am J Cardiol. 2018 Oct 18. pii: S0002-9149(18)31958-1. doi: 10.1016/j.amjcard.2018.10.006

Interrelations between hypertension and electrocardiographic left ventricular hypertrophy and their associations with cardiovascular mortality.

Cao X, Broughton ST, Waits GS, Nguyen T, Li Y, Soliman EZ.

Electrocardiogram (ECG) is the most common method for assessment of left ventricular hypertrophy (LVH) in contemporary clinical trials. However, our understanding of the relation between hypertension and LVH is based on studies used imaging to ascertain LVH. To fill this gap in knowledge, we examined the interrelationships between hypertension, ECG-LVH and cardiovascular disease (CVD) mortality in 6,105 patients free of CVD who were followed for 14.0 years (median). The was an exponential ECG-LVH prevalence rates (2.40%, 4.45%, 5.75%, 8.51%, 14.38%) were exponentially increases as systolic blood pressure increases (<120 mm Hg, 120 to 129 mm Hg, 130 to 139 mm Hg, 140 to 159 mm Hg, >160 mm Hg, respectively); trend p value <0.001. Hypertension was associated with more than double the risk of ECG-LVH (odds ratio (95% confidence interval [CI]) 2.45 [1.83, 3.30]), and each standard-deviation increase in systolic blood pressure (19 mm Hg) was associated with 49% increased odds of ECG-LVH (odds ratio

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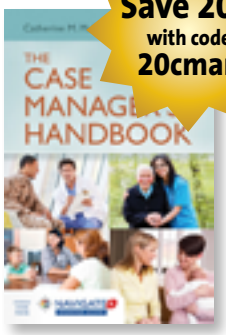

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[95% CI] 1.49 [1.38, 1.61]). During follow-up, 733 CVD-deaths occurred. In separate Cox models, both ECG-LVH and hypertension were associated with CVD mortality (hazard ratio [95% CI] 1.39 [1.07, 1.81] and 1.39 [1.18, 1.62], respectively). However, when ECG-LVH and hypertension were entered together in the same model, the risk of CVD mortality was essentially unchanged for hypertension after adjusting for ECG-LVH, but markedly attenuated for ECG-LVH after adjusting for hypertension. In conclusion, the relation between hypertension and ECG-LVH follows a similar pattern to that reported in literature for imaging-LVH which provides support for the current practice of using ECG for assessment of LVH in contemporary hypertension clinical trials. The inability of ECG-LVH to explain the association between hypertension and CVD mortality suggests that LVH is only one of many factors by which hypertension exerts its impact on CVD.

J Am Soc Hypertens. 2018 Sep 20. pii: S1933-1711(18)30281-X. doi: 10.1016/j.jash.2018.09.006

Predicting the risk of apparent treatment-resistant hypertension: a longitudinal, cohort study in an urban hypertension referral clinic.

Buhnerkempe MG, Botchway A, Nolasco Morales CE, Prakash V, Hedquist L, Flack JM.

Apparent treatment-resistant hypertension (aTRH) is associated with higher prevalence of secondary hypertension, greater risk for adverse pressure-related clinical outcomes, and influences diagnostic and therapeutic decision-making. We previously showed that cross-sectional prevalence estimates of aTRH are lower than its true prevalence as patients with uncontrolled hypertension undergoing intensification/optimization of therapy will, over time, increasingly satisfy diagnostic criteria for aTRH. aTRH was assessed in an urban referral hypertension clinic using a 140/90 mm Hg goal blood pressure target in 745 patients with uncontrolled blood pressure, who were predominately African-American (86%) and female (65%). Analyses were stratified according to existing prescription of diuretic at initial visit. Risk for aTRH was estimated using logistic regression with patient characteristics at index visit as predictors. Among those prescribed diuretics, 84/363 developed aTRH; the risk score discriminated well (area under the receiver operating curve = 0.77, bootstrapped 95% CI [0.71, 0.81]). In patients not prescribed a diuretic, 44/382 developed aTRH, and the risk score showed a significantly better discriminative ability (area under the receiver operating curve = 0.82 [0.76, 0.87]; P < .001). In the diuretic and nondiuretic cohorts, 145/363 and 290/382 of patients had estimated risks for development of aTRH <15%. Of these low-risk patients, 139/145 and 278/290 did not develop aTRH (negative predictive value, diuretics - 0.94 [0.91, 0.98], no diuretics - 0.95 [0.93, 0.97]). We created a novel clinical score that discriminates well between those who will and will not develop aTRH, especially among those without existing diuretic prescriptions. Irrespective of baseline diuretic treatment status, a low-risk score had very high negative predictive value.

Ann Thorac Surg. 2018 Oct 31. pii: S0003-4975(18)31537-6. doi: 10.1016/j.athoracsur.2018.09.022

Patterns of recurrence and overall survival in incidental lung cancer in explanted lungs.

Ahmad U, Hakim AH, Tang A, et al.

BACKGROUND: Recurrence and overall survival for incidental lung cancer in explanted lungs vary between different series. Recurrence patterns are also not well described. The primary objective of this study is to study the recurrence patterns and time to recurrence for various stages of lung cancer in lung transplant recipients.

METHODS: A retrospective review of our institutional database was performed to identify patients who had incidental lung cancer found in transplant pneumonectomy specimens from 1990-2017. Demographic, radiographic and peri-operative clinical variables were collected. Time to recurrence, overall survival and recurrence patterns were recorded. Freedom from recurrence and overall survival were estimated using Kaplan Meier analysis.

RESULTS: Thirty-one patients had unexpected malignancy and 29 (1.6%) had primary lung carcinoma in the explanted lung. Indication for transplantation was COPD in 15 (48%) and interstitial lung disease for 16 (52%) Pre-operative imaging showed indeterminate nodules in 10 (32%) patients. Pathologic review showed stage I in 15 (54%), stage II in 10 (35%) and stage III in 2 (7%) patients. Recurrence was noted in 8 (28%) patients. Majority of patients had nodal (25%) and/or systemic recurrence (75%) All recurrences occurred within 2 years of the transplantation. For stage I and II patients, freedom from recurrence at 1, 3, and 5 years was 91%, 55%, and 55% respectively. Overall survival at 1, 3, and 5 years was 78%, 18%, and 14%.

CONCLUSIONS: Most recurrences occur within two years after transplantation and are the cause of death in these patients. Patients with nodal disease tend to have higher recurrence rates. Multidisciplinary review of abnormal pre-transplant radiographic

continues on page 37

Team-Based Infection Control Helps Reduce Late-Onset Sepsis and Central Line-Associated Bloodstream Infections

In preterm and neonatal infants in the intensive care unit, multifaceted, team-based infection control bundles help sustain reductions in late-onset sepsis (LOS) and central line–associated bloodstream infections (CLABSI). Approaches may include standardized protocols, education to ensure uniform peripheral central catheter placement, monthly monitoring of infections, and identifying best practices. The following findings have resulted from a prospective 15-year surveillance study evaluating the influence of bundled standardized infection control strategies on neonatal LOS:

- Neonatal intensive care unit admissions increased from 776 (2002) to 952 (2016)
- Total central line exposure (2003 onward) was 28,899 days
- Significant decline in LOS rate from 4.3/1000 patient days (2002) to 1.6/1000 patient days (2016, P < .001)
  - Average yearly LOS decline was 0.17/1000 patient days
- Despite increase in central line utilization rate (CLUR; from 0.11 to 0.19 central line days/patient days, R2 = 31.8%), CLABSI rates (per 1000 central line days) declined significantly from 25 (2003) to 5 (2016, P = .001)
- Average yearly CLABSI decline: 1.20 (95% CI, –1.84 to –0.56) per 1000 central line days, CLUR increase: 0.004 (95% CI, 0.000-0.007) central line days/patient days

A limitation of the study was the inability to link specific interventions to reduced infection rates. ■

Upcoming Meetings of Interest to Case Managers

2019 Medicare Star Ratings & Quality Management Forum
Orlando, FL
January 14–15, 2019

2019 Opioid Abuse Management Forum
Scottsdale, AZ
January 28–29, 2019

2019 Population Health Management Summit for Payers & Providers
Miami, FL
February 21–22, 2019

2019 CCMC New World Symposium
National Harbor, MD
February 28–March 2, 2019

2019 Case Managers Cruise
Departing Orlando, FL
March 16–23, 2019

2019 ACMA National Case Management and Transitions of Care Conference
Seattle, WA
April 14–17, 2019

2019 CMSA Navigating the Full Spectrum of Case Management
Las Vegas, NV
June 10–14, 2019

Crohn's Disease:

Fecal Calprotectin Useful for Detecting Small Bowel Inflammation

According to a multicenter cross-sectional observational study of 69 patients with Crohn's disease (39 of whom had small bowel disease only), fecal calprotectin (FC) levels accurately predict Crohn's disease activity in both the large and small bowel when evaluated against balloon-assisted endoscopy (BAE). Fecal calprotectin is less invasive and less expensive than BAE. ■

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Health Law Sign-Ups Down 11% from Last Year

With open enrollment ending December 15, 3.2 million Americans signed up for health insurance coverage with Obamacare plans in the first 5 weeks of the enrollment period. This is a reduction of 11% from the same period last year, when 3.6 million enrolled. ■

Opioid Treatment Program

Opioid treatment programs provide medication-assisted treatment (MAT) for persons diagnosed with opioid-use disorder. The Substance Abuse and Mental Health Services Administration (SAMHSA) explains, "MAT is the use of medications, in combination with counseling and behavioral therapies, to provide a whole-patient approach to the treatment of substance use disorders. Research shows that when treating substance-use disorders, a combination of medication and behavioral therapies is most successful. MAT is clinically driven with a focus on individualized patient care."

The duration of treatment should be based on the needs of the persons served and take into consideration the benefits of MAT. The medications used to achieve treatment goals include methadone and buprenorphine, which are approved by the U.S. Food and Drug Administration (FDA) for use in the treatment of opioid-use disorder.

Services are directed at reducing or eliminating the use of illicit drugs, criminal activity, and/or the spread of infectious disease while improving the quality of life and functioning of the persons served. Opioid treatment programs follow rehabilitation stages of sufficient duration to meet the needs of persons served.

In November 2001, SAMHSA announced that CARF was an approved accreditation provider for opioid treatment programs providing outpatient, residential, and detoxification services in the United States.

SAMHSA's approval of CARF accreditation is part of the federal government's 42 Code of Federal Regulations, Part 8, which shifts regulatory oversight from the FDA to a national accreditation model under SAMHSA/Center for Substance Abuse Treatment (CSAT) oversight.

CARF accredits opioid treatment programs, including:

- Court treatment
- Detoxification
- Day treatment
- Health home
- Integrated behavioral health/primary care
- Intensive outpatient treatment
- Outpatient treatment
- Residential treatment

The following specific population designations may be added to a program:

- Criminal justice
- Older adults

Please refer to the program descriptions for further details. ■

HIV/AIDS Epidemic

continued from page 2

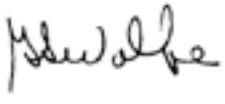
and Prevention, when an individual living with HIV infection is receiving antiretroviral therapy and the level of HIV in their body is undetectable, there is "effectively no risk" of sexual transmission. Still, many people with HIV infection are not in care or treatment and do not have their virus under control.

- HIV-related stigma, socially conservative communities, and low HIV risk perception all serve as barriers to testing.
- There is no cure or immunization for HIV infection.

There are many future challenges ahead. If we want to control and eliminate the epidemic, we must do the following:

- Address the stigma of being infected with HIV.
- Increase testing and counseling so that all people at risk can have access to testing and be tested so their HIV status is known and so that they can be treated.
- Increase HIV education programs.
- Increase harm reduction programs including needle and syringe programs and opioid substitution therapy.
- Ensure that antiviral medications are universally available.
- Increase engagement of people with HIV infection so they receive treatment, stay in treatment, and work towards viral suppression.
- Continue to fund HIV research.

These are significant challenges, and no one person can make it happen. All of us working together can make a significant impact on the HIV epidemic. As a case manager, you should do your part: educate your patients at risk; help employers design patient-centered programs to engage HIV-infected patients so that treatment goals can be achieved; advocate for funding and access to treatment; and talk with neighbors, friends, relatives, and coworkers about HIV disease so that we can reduce the barriers and stigma associated with this disease. Let us not go another 30 years without a cure or an immunization! On every World AIDS Day, December 1, let us remember our family and friends who have died of HIV/AIDS and say "I have done my part."



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ACCM: Improving Case Management Practice through Education

Acute Care and Workers' Compensation Case Managers: a Necessary Alliance *continued from page 15*

literal as possible and ask them to tell you if they cannot provide a literal translation.

- Ensure in advance that the interpreter and the patient understand that the conversation will be confidential.
- Speak directly to the patient and watch the patient while the interpreter speaks and when the patient replies, paying close attention to the body language.

Case Manager Survival Skills

As case managers, we have the opportunity to make a difference not only with our patients but also with our fellow case managers across the care continuum. How do you keep your passion for case management when our patients, their families, bosses, physicians, employers, and adjusters can drain the passion completely out of you? Just remember:

"The pessimist may be right in the long run, but the optimist has a better time during the trip."
–Anonymous

CE I **Integrated Behavioral Health Program Can Improve Health of Patients With Type 2 Diabetes** *continued from page 21*

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CE II **The Insight from Experience: Lessons from Case Management Experts** *continued from page 25*

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LITSCAN FOR CASE MANAGERS

continued from page 34

findings and close follow up may allow for detection of undiagnosed cancers.

Curr Opin Pulm Med. 2018 Nov 1. doi: 10.1097/MCP.0000000000000531.

Obesity and adult asthma: diagnostic and management challenges.

Grace J, Mohan A, Lugogo NL.

PURPOSE OF REVIEW: Despite advances in our understanding of the obese asthma phenotype, heterogeneity and large gaps in knowledge have hindered significant advances in directed interventions.

RECENT FINDINGS: Obesity is associated with poorer asthma-related outcomes and increased risk of progression to severe asthma. Obese asthma is associated with variability in the expression of inflammatory markers, lung function impairments, and response to conventional and biologic therapies. In addition, traditional asthma biomarkers are not as reliable in obese patients. Several mechanistic pathways that uniquely impact asthma in obesity have been identified. Pathways involving innate lymphoid cells (ILC) type 2 (ILC-2) cells, surfactant protein-A, cell division control protein (CDC)42, interleukin (IL)-6, IL-17, and IL-33 are likely causal inflammatory pathways. Obesity also confounds lung function parameters making accurate diagnosis more challenging. As such, personalized asthma therapies directed towards obese asthma endotypes remain elusive.

SUMMARY: Obesity confounds traditional asthma biomarkers and lung function measurements, thus defining obese asthma endotypes remains challenging. Novel pathways are being identified and hold promise for future targeted therapies. However, we are in dire need of updated guidelines regarding asthma diagnosis in obese patients and the development of biomarkers that more accurately identify specific endotypes.

TALZENNA CAPSULES			
Package Configuration	**Capsule Strength (mg)**	**NDC**	**Print**
Bottles of 30 capsules	0.25	NDC: 0069-0296-30	Ivory cap (printed with "Pfizer" in black) and a white body (printed with "TLZ 0.25" in black).
Bottles of 30 capsules	1	NDC: 0069-1195-30	Light red cap (printed with "Pfizer" in black) and a white body (printed with "TLZ 1" in black).

Lactation

Risk Summary

There are no data on the presence of Talzenna in human milk, the effects of the drug on milk production, or the effects of the drug on the breastfed child. Because of the potential for serious adverse reactions in a breastfed child from Talzenna, advise lactating women not to breastfeed during treatment with Talzenna and for at least 1 month after the final dose.

Females and Males of Reproductive Potential

Pregnancy Testing

A pregnancy test is recommended for females of reproductive potential before initiating Talzenna treatment.

Contraception

Females

Talzenna can cause fetal harm when administered to pregnant women. Advise females of reproductive potential to use effective contraception during treatment and for at least 7 months following the last dose of Talzenna.

Males

Based on genotoxicity and animal reproduction studies, advise male patients with female partners of reproductive potential and pregnant partners to use effective contraception during treatment with Talzenna and for at least 4 months following the last dose.

Infertility

Males

Based on animal studies, Talzenna may impair fertility in males of reproductive potential.

Pediatric Use

The safety and effectiveness of Talzenna have not been established in pediatric patients.

Geriatric Use

In clinical trials of Talzenna enrolling 494 patients with advanced solid tumors who received Talzenna 1 mg daily as monotherapy, 85 (17%) patients were ≥65 years of age, and this included 19 (4%) patients who were ≥75 years old. There were 5 patients ≥85 years old. No overall differences in safety or effectiveness of Talzenna were observed between these patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Renal Impairment

Reduce the recommended dose of Talzenna in patients with moderate renal impairment (CLcr 30-59 mL/min). No dose adjustment is required for patients with mild renal impairment (CLcr 60-89 mL/min). Talzenna has not been studied in patients with severe renal impairment (CLcr < 30 mL/min) or patients requiring hemodialysis.

Hepatic Impairment

Talzenna has not been studied in patients with moderate hepatic impairment (total bilirubin >1.5 to 3.0 × upper limit of normal [ULN] and any aspartate aminotransferase [AST]) or severe hepatic impairment (total bilirubin >3.0 × ULN and any AST). No dose adjustment is required for patients with mild hepatic impairment (total bilirubin ≤1 × ULN and AST > ULN, or total bilirubin >1.0 to 1.5 × ULN and any AST).

HOW SUPPLIED/STORAGE AND HANDLING

Talzenna is supplied in strengths and package configurations as described above:

Storage

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

Talzenna is distributed by Pfizer Labs.

When Burnout Leads to Entrepreneurship *continued from page 10*

me look inexperienced and unsure but going too high could result in missed opportunities. If my fees were too high, it could also make me look inexperienced. I did a lot of research to determine what other independent case manager in my area were charging for their services and I compared those fees with the fees that companies paid their in-house case managers so that I could leverage that knowledge to my advantage. If I could convince insurance companies that I was a cheaper alternative to a permanent case manager employee, and I was still able to make a profit, it'd be a win-win all around.

I also wanted to make sure that I understood what to charge based on how many billable hours I would have once I considered how much of my time would be spent working on business- and marketing-related tasks. If I was working 40 hours per week, but 15 of those hours were spent invoicing, marketing, and generating leads, my hourly rate would have to compensate for those nonbillable hours.

Not long after I had my rates in place, I landed my first client as an independent case manager. Not only was it exciting to be back doing what I loved, but this time I was doing it under my own brand. As with any case that I've been assigned to, I always put in 100%, but the entire experience is so much more gratifying when you are working independently. After landing my first client, my confidence went through the roof. Now it was no longer a hypothetical scenario when I spoke to potential clients about what I did. I had proof that going solo was entirely possible because I had literally done it. It no longer seemed daunting to go out and actually get a contract.

The sooner you can get your first client, the better. It will seem more intimidating than it really is until you jump over that first hurdle and work with a client. From there it is only a matter of repeating the actions that landed you that first job. Now that you know it can be done, the hardest part is over. Plus you can start playing the numbers game. Not everyone you talk to will become a client, but if you talk to enough people, it is only a matter of time before you get another "yes." The pattern simply continues from there.

Within just a few months of starting my business, I landed a contract with an insurance company to be their dedicated independent case manager. The cost savings, relationship building, and open communication with the accounts led to this opening up for me. This was an amazing opportunity that I could never have anticipated while I was working at my insurance company job. Landing this account meant a constant stream of leads, and this was empowering. I knew that with a few more contracts similar to this one, I'd be well on my way to ensuring a steady income stream. From here, it was all a simple matter of repeating the steps that got me to the first client and to the first contract.

If I was going to make it as an independent case manager, I understood that I was the product I was selling and that I needed to make myself stand out from the pack.

I was now finally in control of my career. If I wanted to work more, all I had to do was go out and network more—make more calls, talk to more people, and send more letters. If I wanted to ease up on my caseload, I could turn down the opportunities that didn't match my needs. I'd never be forced to take a case because it was in the job description.

I already anticipate having to bring on another nurse to help. There is so much work out there, I wonder how I ever thought that there wouldn't be enough to support me. It's all about knowing with absolute clarity who you are and what you have to offer and then doing everything you can to get your name and brand in front of the people who need your services. If you're good at what you do, and you have a passion for it, you will always be successful.

I could have made excuses about why going solo could never work and I could have stayed at my workers' compensation insurance job and done the job to the best of my ability. But if I had done that, I'd have lost out on so much. I now have the autonomy I so craved. I have complete flexibility, which gives me time to spend with my family and to do the things I love. And I'm in control of my own salary. If I'm unhappy with my tax form at the end of the year, I can take actions that will change it for the next year. If I'm making extra money, but I'm starting to feel a little overworked, I can take that money and hire another case manager. Of course, sometimes I have to work at an odd hour of the night or I have to deal with people who are challenging to work with, but the benefit is that all the trade-offs directly benefit my business and my brand.

Transitioning to an independent case manager is not a glamorous career path or a get-rich-quick route; it is for nurses who are excellent patient advocates, good teachers, expert collaborators, and multitasking whizzes. It is for case managers who are losing sight of what they initially loved about the job and long to get back to really helping people and making a difference. It is for people who are ready for a change and not afraid to try something new. Take it from me, the rewards of this transition to go solo have been invaluable. CM

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