CONTINUING EDUCATION ARTICLES:

10 Assessing and Managing the Social Ecology of Transgender and Gender-Diverse Youth [CE]

Jill Wagner, LICSW, Logan England, and Jason Rafferty, MD, MPH, EdM

With increasing recognition that gender diversity is an inherent part of human nature, those who do not identify with traditional gender stereotypes and roles face unique health and social challenges. These challenges present on multiple levels from individual well-being to the influence of one’s family and community on their health and development. Case managers, including social service professionals who work in a case management role, are uniquely situated to support transgender and gender-diverse youth and their families through screening, advocacy, and referrals.

16 What Every Case Manager Should Know About Effectively Facilitating Care for Chronic Respiratory Disease Patients with Bronchiectasis: Part II [CE]

Nancy Linda and Nancy Skinner

Chronic respiratory conditions can negatively impact most, if not all, activities of daily living. Shortness of breath and the inability to consistently maintain adequate oxygenation can become a constant and continued focus of the patient, their family, and their caregivers. Part 2 of this review article describes how the case management process would be implemented for a 69-year-old female with advanced bronchiectasis complicated by several comorbidities including COPD.

CE Exam [CE]

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National Case Management Week will be celebrated October 13–19, 2019. This year’s theme is “Transitioning Patients and Case Managers to Greatness.” The purpose of national case management week is to educate payers, providers, regulators, and consumers of the tremendous value case managers bring to the successful delivery of health care. It also provides an opportunity to recognize case managers for their role in bringing about positive outcomes for their clients and their contributions to the health care process.

According to the dictionary, some of the words to define greatness include:

- Remarkable
- Outstanding
- Superior in quality
- Powerful
- Influential
- Distinguished
- Very skillful
- First rate

Those are powerful words that describe a case manager. As health care has become more complex, the role of the case manager has become more important. Navigating the health care system is very challenging for the typical consumer. The health care system involves issues of access, quality, and outcomes, and there are multifaceted aspects of care delivery.

Case managers make a difference every day with every client they interact with. It is not just the client but a whole long list of individuals/organizations: providers, health care organizations, payers, families, and friends. The list goes on and on.

This week, National Case Management Week is when you proclaim your greatness. Be proud and forthright in telling others about what you do. Let people know you are not invisible. You make a difference. Shout it from the rafters and everywhere else. This is the week you can call attention to yourself and your fellow case managers. Have a party! Celebrate! Thank the people you work with for their support!

I recognize it is a trying time. Health care is very complex. Knowledge of diseases, treatment, and care is increasing complex. But you make a significant difference in the health care system. Stand up! Be proud! You are a case manager making a difference! Thank you.

Gary S. Wolfe, RN, CCM
Editor-in-Chief
gwolfe@academyccm.org

ACCM: Improving Case Management Practice through Education
When patients are discharged from a traditional hospital, they sometimes need continued acute-level care.

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Mentoring: A Mutually Beneficial Professional Relationship

MaryBeth Kurland, CAE, and Vivian Campagna, MSN, RN-BC, CCM

Most of us who have reached a certain point in our careers can remember people who have mentored us over the years—bosses, colleagues, and others who provided encouragement, guidance, and advice on everything from our career paths to the challenges we faced. Many of us have also mentored others, whether formally or informally. Indeed, mentoring is one of the most mutually beneficial professional relationships, grounded in respect, rapport, and a willingness to engage.

In case management, mentoring is essential for professionals who come from a variety of disciplines to gain the knowledge and skills required for today’s increasingly specialized practice. While board-certified case managers are committed to continuing education to attain the required continuing education units (CEUs) to maintain certification, a great deal of learning happens on the job. Mentoring plays a crucial role in that on-the-job learning.

The numbers bear this out: The recent “Develop Others” survey conducted by the Commission for Case Manager Certification (CCMC) revealed that 77% of certified case managers (CCMs) had been a mentor and 74% had been mentored. Of those involved in mentoring, only 39% were part of formal mentoring programs while 61% had informal mentoring relationships.

Mentoring occurs through personal connection, respect, and shared values. To support this important relationship, CCMC offers a variety of mentoring resources as part of the “Develop Others Toolkit.” These resources include videos, podcasts, toolkits, a glossary, and other educational materials to support mentoring in case management, particularly as part of preparation for the CCM board certification examination.

Mentoring is a key component of workforce development and needs to be encouraged as part of “succession planning” in case management practice. As the current generation of professional case managers approaches retirement age, they need opportunities to pass along their knowledge to help ensure that a qualified workforce exists to handle the demands of case management practice in the future.

As Patricia Benner, RN, PhD, FAAN, professor emerita of the University of California at San Francisco School of Nursing observed in a recent webinar sponsored by the Commission, “Mentoring in case management is essential because case management requires so much informal local knowledge.” This knowledge of what Benner called “local practice” is in addition to the clinical knowledge required by case managers today.

Mentoring others requires a

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When Stress Is the Cause: Handling Absences and Supporting Employees

Ed Quick, MA, MBA, CDMS

When an employee is injured on the job—for example, a slip-and-fall accident that results in a broken wrist—the incident is covered by workers’ compensation and the guidelines of this state-mandated coverage. But when the health issue impacting work is stress, workers’ compensation statutes generally have clear and specific requirements to meet the standards of the regulation, making these claims more complex.

As the American Bar Association noted: “Unlike a broken arm or the loss of a limb or even loss of an organ or bodily function, stress-related claims are psychological in nature, not orthopedic or neurological. As such, stress-related claims have a higher standard of proof for a petitioner due to the very nature of the claim.” Often, an employee has generalized stress caused by what’s happening throughout their lives, not just at work. This goes to the foundation of the statutory requirements for filing a workers’ compensation claim, given the specific and exacting standards of the program.

The alternative for employees seeking time off work due to stress is to investigate short-term disability (STD) programs offered by their employer. The gateway to STD is typically through the employer’s time-away program; most often this involves STD, with the employee’s care covered under the employer’s health plan.

This can be very complex for employers and employees alike, which underscores the importance of accessing the right expertise to help manage claims. Professionals who hold the Certified Disability Management Specialist (CDMS) certification, along with Certified Case Managers (CCMs) who have expertise in disability case management, are key for coordinating these cases. When employees need to be off work temporarily due to elevated levels of stress, CDMSs and CCMs can help them navigate the system and access benefits and programs. Across the employee population, CDMSs, in particular, have the workforce management expertise to help employers design and implement programs that help employees maintain their lives—financially, emotionally, and psychologically.

For most mental health claims requiring time off from work, the employee would be covered by STD. Most well-written plans require a certain level of objective medical information to justify the absence. This is where mental health claims can become very challenging, particularly to understand what is meant by “stress” and how it impacts an employee’s ability to work. Does the person need to be off work for several weeks? Does the individual need reduced hours or a flexible work arrangement? Is it possible for the person to remain at work?

The request for time off due to stress may occur during a conversation between the employee and his/her direct line manager. Depending on how comfortable both parties are with discussing life events, the manager may proactively suggest supportive resources as an alternative to taking

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Many case managers work from a distance and interact with a variety of team members they have never physically met, and they also work on-site in a variety of locations and types of delivery models. Both verbal and written communication skills are critical in these situations, no matter where the case manager works, because forming and maintaining an effective team is a major factor for success.

Forming and being a member of a team is different than being a member of a group. A group is defined as people gathered closely together forming a recognizable unit. A case manager could be part of a group of individual doctors, nurses, therapists, health professionals, patients, and families. But in reality, a case manager wants to be recognized as a team member whether on-site or off-site. A team is defined as people working together to achieve a common goal and working together to give their best. Whether it is a safe discharge home, support systems in their community of choice, appropriate equipment, or ongoing contact to ensure success, the case manager is an invaluable team member.

Forming a team has many challenges! Although the role of a case manager is well defined, a situation where the case manager is a team member can be different. At-distance case managers need to quickly establish a relationship with individuals they have never met. Some key components of establishing the team, whether on-site or off-site, are as follows:

- Establish how to communicate
- Determine time frames for communication

It is estimated that nearly 25% of hospital readmissions are avoidable.
How to Handle Sexual Advances by Patients

By Elizabeth Hogue, Esq.

In Gardner v. CLC of Pascagoula, LLC d/b/a Plaza Community Living Center; Case No. 17-60072 in the U.S. Court of Appeals for the Fifth Circuit, June 29, 2018; the Court decided that providers may be responsible for sexual harassment of employees by patients when providers knew or should have known of the conduct and failed to take immediate correction action. In this case, a Certified Nursing Assistant (CNA) claimed that an assisted living facility (ALF) failed to prevent a resident’s repeated harassment.

A resident of the ALF who was diagnosed with dementia, traumatic brain injury, personality disorder with aggressive behavior, and Parkinson’s disease had a reputation for groping female employees and other patients and becoming physically aggressive when reprimanded. The resident would sexually assault female caregivers by grabbing their “breasts, butts, thighs, and try[ing] to grab their private areas.” He asked for explicit sexual acts and made lewd comments to female staff “all the time.”

The CNA experienced these behaviors every day and regularly documented them in the resident’s chart and made complaints to supervisors. The Administrator of the ALF told the CNA to “put [her] big girl panties on and go back to work.” The CNA ultimately refused to provide further care for the resident after she sustained injuries caused by the resident. She was fired for insubordination. The resident was ultimately transferred to an all-male lockdown facility that the ALF also owned.

The Court first affirmed that sexual harassment must be severe and pervasive in order to conclude that there is harassment. The Court then acknowledged “the difficult line-drawing problem of what separates legally actionable harassment from conduct that one should reasonably expect when assisting people suffering from dementia.” In other words, the Court acknowledged that some individuals cannot conform their conduct to societal norms. The Court then concluded that the ALF failed to take appropriate action under the circumstances.

What should providers do when caregivers are subjected to repeated sexual harassment and assaults by patients? Home care staff members are arguably even more vulnerable with regard to inappropriate sexual conduct than caregivers who work in institutional settings. Home care providers, therefore, must take this issue especially seriously.

First, providers must require caregivers, through their policies and procedures, to document each instance of patients’ inappropriate sexual conduct and insist that they do so. Anecdotally, some caregivers seem to think that they have to put up with whatever patients dish out. They don’t!

Management must take repeated instances of sexual harassment by patients seriously. No more “big girl panties!” Specifically, management must talk with patients and their primary caregivers to let them know that such conduct is unacceptable and document that they have done so.

The next step is for management to ensure that patients who engage in inappropriate sexual conduct are thoroughly evaluated clinically. Is there a clinical basis for patients’ inappropriate conduct? Are patients taking medications that may lower inhibitions? Will medication(s) help to mitigate patients’ conduct? Recommendations based on clinical evaluations must be promptly implemented.

If a patient’s conduct has not changed after these steps have been taken, he or she must be discharged consistent with providers’ policies and procedures on discharge.

Based upon this Court decision, it is clear that providers may have liability for the sexual harassment of their staff members. Providers simply must take patients’ inappropriate sexual conduct seriously.

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As the president of the Case Management Society of America, I have the pleasure of traveling throughout the United States and meeting professional case managers from all settings. It has been an invigorating experience and an important opportunity to have an engaging conversation about creating a vision of where we are going and how our professional case manager role impacts the delivery of care across the continuum.

Our discussions have also highlighted the importance of advocating and celebrating our professional accomplishments.

I still encounter questions about how case management professionals can become more visible within their organization and in the health care delivery system. Many case management professionals feel that their own organizational leaders still lack awareness of the vital role we play in the delivery of exceptional care. The good news is that this knowledge and communication gap is correctable!

In 2016, Mary Beth Newman, past president of CMSA, authored a CMSA Today™ article entitled “Keeping the ‘Professional’ in Professional Case Management.” In her article, she described 3 focus areas important in professional case management advocacy: (1) maximize role clarity on the collaborative care team, (2) recognize the significance of professional standards of practice, and (3) advocate for professional solidarity. Her discussion continues to remain relevant today.

Oftentimes, when I hear concerns about the lack of organizational awareness, I reflect on the importance of having an “elevator speech.” This is a short 30-second presentation that uses short powerful sentences to: (1) introduce yourself, (2) explain what the professional case management role offers, and (3) describe how professional case managers benefit the organization. After telling your elevator speech, be prepared to hand the recipient your business card as a way of formalizing the introduction and developing a business relationship.

Remember to stay away from jargon and acronyms that the listener may not understand. Memorize and practice your elevator speech. Develop alternative elevator speeches for different audiences. For example, have an organizational leadership or community stakeholder version, a patient or caregiver version, and a friends and family version. Being prepared will build your confidence and your elevator speech will become second nature to you.

An example of an elevator speech might be:

“Good afternoon, my name is Joan Smith and I am a certified case manager at ABC hospital. I have been a team member at ABC hospital for over 10 years. I am a member of your care team and will assist you in creating a safe discharge and transition plan when you no longer need care at our hospital. I am here to answer your questions and be a resource to you during your hospital stay. Here is my business card if you need to contact me in the future.”

It is important to keep your elevator speech brief and allow opportunity for follow-up questions. Don’t forget that your audience will also interpret your nonverbal messages and body language as you are speaking. You can get great feedback about unintentional nonverbal messaging by practicing your elevator speech in front of your colleagues, friends, or family.

An elevator speech is a great way to start the conversation about the important role of the professional case manager. It is a unique opportunity to demonstrate professionalism and the value you bring to individuals you care for and your organization. Speak up and assist others in understanding your important role!
Introduction
With increasing recognition that gender diversity is an inherent part of human nature, those who do not identify with traditional gender stereotypes and roles face unique health and social challenges. These challenges present on multiple levels from individual well-being to the influence of one’s family and community on their health and development. Case managers, including social service professionals who work in a case management role, are uniquely situated to support transgender and gender-diverse (TGD) youth and their families through screening, advocacy, and referrals. In fact, it is a case manager’s ethical duty to provide advocacy, to work with integrity and fidelity to clients/patients, to maintain objectivity, and to respect the rights and dignity of all clients/patients (see Code of Ethics sidebar).

A large national survey conducted in 2016 found that 0.6% of US adults identify as transgender, double the estimate from over a decade ago, and translating into almost 1.5 million transgender adults.1 This survey also suggests that adolescents are more likely to identify as transgender than adults,1 although there have been no large-scale prevalence studies among children and adolescents to date.2 In the setting of increasing awareness of gender diversity, particularly in children and adolescents, early identification and affirmation fosters healthy growth and development in a particularly vulnerable population, which leads to positive long-term health outcomes as well as decreased morbidity and mortality.3,4

TGD youth face a variety of psychosocial challenges at higher rates than age-matched peers, including depression, anxiety, suicidality, eating disorders, and autism spectrum disorders.5-8 Case managers in any setting where TGD youth may present have an essential role in ensuring that these youth and their families are being properly cared for and connected with needed supports. Regardless of their own beliefs and biases, case managers must follow the CCMC principles 2 and 3 (board-certified case managers [CCMs] will respect the rights and inherent dignity of all of their clients; CCMs will always maintain objectivity in their relationships with clients) and the CDMS principle 2 (certificants shall respect the integrity and protect the welfare of those persons or groups with whom they are working; certificants shall always maintain objectivity in their relationships with clients). This article aims to review important terminology and the relevant frameworks of gender affirmative care and minority stress. Challenges specific to TGD youth and their families will be reviewed from a multisystemic and social ecology perspective, including factors relevant to individual well-being as well as those related to family, school, and health care settings. Finally, considerations for making effective referrals will be discussed.

Terminology
Early in life, often before a person is born, labels are imposed on people identifying them as male or female on the basis of their anatomy or genetics. This label is a person’s assigned sex. As people develop, they begin to recognize an internal sense of who they are as an individual. Asserted gender or gender identity are labels that people use to reflect their internal sense of self, which may include male, female, somewhere in between, a combination of both, or neither. For some people, gender identity can be fluid, shifting in different contexts. Self-recognition of gender

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identity often develops through childhood and adolescence, much the same way a person's physical body develops. Gender diversity is a term that reflects the complexity and variation of gender identities that exist. Cisgender is when one's assigned sex and asserted gender are congruent, but when they vary from each other, then the label of transgender can be used. It is important to note that these terms are not diagnoses. However, gender dysphoria is a diagnosis that may be applied in some cases where the incongruence between assigned sex and asserted gender leads to clinically significant distress as defined in the Diagnostic and Statistical Manual of Mental Disorders (DSM–5). Also, gender identity is not synonymous with sexual orientation, which are labels used to describe one's sexual and romantic attractions. TGD individuals might separately identify as straight, gay, or bisexual on the basis of their attractions to others.

Theoretic Frameworks
Gender Affirmative Care
The gender affirmative care model, endorsed by the American Academy of Pediatrics, recognizes gender diversity as a normal part of human development, not to be pathologized or labeled as a disorder. It recognizes increased prevalence of mental health disorders among TGD populations, with an understanding that such disorders most often result from stigma and negative experiences rather than being intrinsic to an individual’s gender. Providers following a gender affirmative model of care validate a youth’s asserted gender identity, creating a nonjudgmental environment for further gender exploration and support. They also aim to validate related emotions, uncertainties, and aspirations of the youth and their family. An additional goal for case managers is to help a person as they consider...
Case managers, including social service professionals who work in a case management role, are uniquely situated to support transgender and gender-diverse (TGD) youth and their families through screening, advocacy, and referrals.

Affirming their gender through a number of interventions employed at developmentally appropriate times (Table 1), while fostering resiliency through bolstering family, peer, and community supports.

### Minority Stress Model
The minority stress model asserts that people belonging to a minority group experience stressors through various pathways, causing increased levels of traumatic stress and psychopathology. One pathway is through stressful environmental and external events that occur in a person’s life as a result of their minority status. Another pathway is through anticipating that an external stressful event will occur, which causes hypervigilance. Finally, negative attitudes and prejudices can be internalized by the individual themselves. In TGD individuals, this final process may contribute to gender dysphoria and internalized transphobia, which is prejudice and shame towards one’s own TGD identity. These pathways may initially lead to positive outcomes associated with minority status, such as the development of coping strategies and resiliency in the face of stigma and prejudice. Morbidity develops as chronic or severe minority stress overwhelms these protective systems. This model has been specifically applied to TGD populations. The transgender resilience intervention model suggests that minority stress among TGD youth can be buffered through social support, community inclusion, family acceptance, participating in activism, and having positive role models as well as self-worth and self-acceptance.

### Challenges and Assessment
Case managers working with TGD youth benefit from having an understanding of the social and emotional stressors that could be impacting the lives of these young people. TGD youth face specific challenges at various levels of their social ecology. Case managers should regularly be screening TGD youth for mental health concerns, suicide risk, substance use, and instances of violence, victimization, or exploitation. There are freely available standardized questionnaires and measures that may be helpful (Table 2).

### Individual
TGD youth have been shown to experience high rates of depression, anxiety, substance use, eating disorders, and self-harm. Multiple studies have consistently reported high rates of suicidal ideation and suicide attempts among TGD youth. While exact numbers can be difficult to obtain, the most recent Youth Risk Behavior Survey (YRBS) provides a snapshot into self-reported instances of suicidal ideation as well as substance use among TGD students. In the 2017 YRBS, 43% of TGD students reported considering suicide in the past year while 34.3% reported making an actual attempt. This same data shows that lifetime substance use was significantly higher among TGD students, with 70.0% reporting alcohol use, 27.2% reporting cocaine use, and 26.1% reporting heroin use.

The prevalence of mental health sequelae experienced by TGD youth can be understood through the minority stress model as outlined above. Social rejection and victimization contribute to internalized transphobia,

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### TABLE 1

Various interventions a TGD individual may explore or pursue, when developmentally appropriate. There is no prescribed sequence, timeline, or number of interventions a TGD individual may pursue.

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social Affirmation</td>
<td>Reversible process of affirming one’s gender identity through outward expression, may include:</td>
</tr>
<tr>
<td></td>
<td>• Hair style</td>
</tr>
<tr>
<td></td>
<td>• Clothing</td>
</tr>
<tr>
<td></td>
<td>• Name and pronoun</td>
</tr>
<tr>
<td></td>
<td>• Peer groups, activities</td>
</tr>
<tr>
<td>Legal Affirmation</td>
<td>Changing name and/or gender marker on official documents (eg, birth certificate, driver’s license)</td>
</tr>
<tr>
<td>Medical Affirmation</td>
<td>Medications (hormones, puberty blockers, contraceptives) used to cause partially reversible physical changes that affirm one’s gender identity.</td>
</tr>
<tr>
<td>Surgical Affirmation</td>
<td>Nonreversible surgical interventions to align one’s body with their identified gender</td>
</tr>
</tbody>
</table>

Abbreviation: TGD, transgender and gender-diverse.
which is associated with having a thwarted sense of belongingness and a perceived burdensomeness. This internal and external stress contributes to increased depression, anxiety, and suicidality among TGD individuals,\textsuperscript{19,20} as described in the interpersonal-psychological theory of suicide.\textsuperscript{28} Individual psychotherapy can focus on recognizing internalizing processes, increasing self-acceptance of one’s TGD identity, and developing more-effective coping skills for managing external stressors. Social support and connectedness are protective factors against depression and promote self-esteem.\textsuperscript{20,29} Case managers can increase a TGD youth’s connection to peers by connecting them to established support groups and organizations that serve LGBTQ (lesbian, gay, bisexual, transgender, and queer) youth.

**Family**

An important consideration when working with TGD youth is the role of family. TGD adolescents who have at least one supportive person in their life endorse less distress than those who only experience rejection.\textsuperscript{30} Suicide attempts were over 10 times higher in one sample of TGD youth who believed that their parents were unsupportive compared with youth who believed their parents were supportive.\textsuperscript{31} However, families, and parents in particular, may struggle with accepting their TGD family member for various reasons, including lack of accurate information, fear of judgment or rejection from others, fear for their child’s safety, and their own personal beliefs and prejudices.\textsuperscript{32,33} Parents may experience a wide range of emotions associated with their child’s TGD identity including shock, confusion, denial, anger, and loss.\textsuperscript{32-34} Siblings can also struggle with feelings of resentment, grief, embarrassment, and feeling neglected by parents.\textsuperscript{35,36} Families can benefit from having access to accurate education on transgender identities and how to support a transgender family member.\textsuperscript{37} A family member can be supportive of and provide safe space for their TGD relative, even if they struggle to accept their relative’s gender identity. Family members may benefit from referrals to their own individual therapy and peer support groups, where they can have a safe space to process the complex emotions they may be experiencing.\textsuperscript{35,37}

Among TGD youth, familial and parental support has been associated with lower rates of depression, anxiety, suicidality, and substance abuse and has been linked to increased rates of self-esteem and overall life satisfaction.\textsuperscript{31,38,39} Given what is known about the high risk for mental health concerns among TGD youth, every effort should be made to support familial relationships when possible and encourage familial support and affirmation. At times, referrals to family therapy may be warranted to facilitate improved communication, foster mutual understanding, and bolster family connections.\textsuperscript{32,36}

**School**

Schools represent another important environmental factor in the lives of TGD youth. Every student has a right to learn in a safe and accepting school environment.\textsuperscript{40} However, this is far from the reality for many TGD students, where the struggle for acceptance at school can exacerbate tensions at home. Many schools still struggle with creating and implementing policies to respect the needs of TGD youth regarding bathroom use, locker rooms, clothing, and extracurricular activities.\textsuperscript{41,42} A 2017 national survey of sexual and gender minority students in the United States painted a harsh picture of the experiences of TGD youth in public schools. Only one in ten students reported that their school had policies to protect TGD students, 44% felt unsafe at school because of their gender expression, and nearly an equal number had been prevented from using their asserted name or pronoun. Over half of students experienced verbal harassment due to their gender expression, and nearly a quarter were pushed or shoved with one in ten being punched, kicked, or injured with a weapon for this reason. Half of those acknowledging such abuse did not report it because of fear of retaliation or fear that school administrators would not respond. These

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**TABLE 2**

<table>
<thead>
<tr>
<th>Category</th>
<th>Assessment &amp; Web Address</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trauma</td>
<td>Child and Adolescent Trauma Screen (CATS), Child and Parent Versions</td>
<td>3–17</td>
</tr>
<tr>
<td>Anxiety</td>
<td>Screen for Child Anxiety Related Disorders (SCARED), Child and Parent Versions</td>
<td>8–18</td>
</tr>
<tr>
<td>Anxiety</td>
<td>Penn State Worry Questionnaire for Children (PSWQ-C)</td>
<td>7–17</td>
</tr>
<tr>
<td>Depression</td>
<td>Columbia Depression Scale, Child and Parent Versions</td>
<td>11+</td>
</tr>
<tr>
<td>Depression</td>
<td>Mood and Feelings Questionnaire (MFQ), Child and Parent Versions</td>
<td>6–17</td>
</tr>
<tr>
<td>Depression</td>
<td>Patient Health Questionnaire for Adolescents (PHQ-A)</td>
<td>11–17</td>
</tr>
<tr>
<td>General</td>
<td>Strengths and Difficulties, Child and Parent Versions</td>
<td>2–17</td>
</tr>
</tbody>
</table>

In the setting of increasing awareness of gender diversity, particularly in children and adolescents, early identification and affirmation fosters healthy growth and development in a particularly vulnerable population, which leads to positive long-term health outcomes as well as decreased morbidity and mortality.

same students were 3 times as likely to miss school and had lower grades. Nearly 90% of students heard negative remarks about TGD people, which represents a steady increase compared with a previous version of the study going back to 2013.42

Despite these disturbing findings, this same study also identified factors associated with improved student experiences. Students reported they were less likely to miss school, feel unsafe, and hear negative remarks about TGD people if their school had identified supports or curriculum that included topics on sexual and gender minorities. Students also felt a greater sense of belonging in their school community and performed better academically. In schools that had explicit policies against bullying or discrimination based on gender identity, students experienced less victimization and believed staff were more likely to intervene with a response that was effective and appropriate.42 Additionally, policies that allow the use of students’ affirmed name are essential as studies have shown that chosen name use is linked to decreased suicidality.43

Case managers can support TGD youth by maintaining objectivity (per CCMC and CDMS Codes of Ethics), providing education on these risks, exploring ways to mitigate them, and advocating on the youth’s behalf. They can help school administrators develop affirming policies around TGD youth—inclusive bathrooms and dressing rooms, the use of asserted name and pronouns, and bullying prevention. Encouraging and supporting schools in starting clubs such as a gender and sexualities alliances (GSA) enhance the well-being of all students.44 When schools create policies to accommodate individual TGD youth they may inadvertently disclose a student’s gender identity and target them for harassment and prejudice. Instead, schools should proactively discuss policies and approaches to foster a school environment that celebrates gender diversity, along with all other forms of human diversity.45

Health Care
Another area of concern to TGD youth is access to quality affordable health care. While the Affordable Care Act has expanded some access for the transgender population,46 there are still barriers to accessing care. One in five TGD people reported having been denied care by a doctor due to their gender identity, and one-third of TGD people who sought out health care reported having 1 negative experience, such as being refused treatment or being verbally harassed in the clinic.4 Case managers who know gender-affirming clinicians can provide referrals that help ensure positive experiences, thereby improving access and retention in care from an early age.

In this setting of poor access to care, gender-diverse individuals experience higher rates of cardiac disease and multiple chronic health conditions, and they also have a higher burden of disability.46 In addition, TGD individuals are over 3 times more likely to have a positive HIV test than their cisgender peers.47 These health complications have high complexity that may necessitate support by a case manager to coordinate between multiple specialists and appointments.

Even in cases where TGD individuals find affirming medical providers, there are often challenges with insurance coverage. TGD individuals have higher rates of being uninsured and having care delayed more often due to cost.46 One quarter of TGD individuals reported a problem with insurance coverage, such as being denied coverage for routine preventative care, often due to erroneous anatomic assumptions based on one’s gender marker.48 In a survey of insurance plans available to TGD youth, only 14% included a behavioral health benefit.48 Case managers can advocate for their clients by educating insurers on the need for coverage, in addition to helping with prior authorizations and appeals when necessary.

Other Systems
To better comprehend some of the disproportionate risks that TGD youth encounter, it is important to understand the experiences of systemic victimization they face. TGD youth experience high rates of familial rejection and violence, which can contribute to homelessness and engagement in child protection services.4,49,50 Many transgender youth run away from home to avoid violence or “reparative” therapies that deny them the right to express their gender identity. Forty percent of unaccompanied homeless youth identify as TGD.51 Within child
welfare systems and homeless shelters, TGD youth often experience additional harassment and victimization.\textsuperscript{49,50,52} The experience of homelessness and involvement in child welfare systems has also been linked to increased risk for engagement in sex trafficking, especially among TGD youth.\textsuperscript{53} TGD youth also face higher rates of sexual harassment, assault, and intimate partner violence.\textsuperscript{27,54,55}

TGD youth are often subject to increased instances of discipline in school and in the community compared with their cisgender peers.\textsuperscript{8,12} Increased disciplinary actions have been linked to increased likelihood of involvement in the juvenile justice system, which has a disproportionate number of TGD youth.\textsuperscript{56,57} While incarcerated, they also experience higher rates of physical and sexual assault. Over half of TGD individuals reported they would feel uncomfortable asking the police for help if it was needed, and the same number reported mistreatment by police in the community.\textsuperscript{8}

Whether homeless, incarcerated, or experiencing some other hardship, these individuals, especially youth, will rely on case managers to coordinate services, advocate on their behalf, and maintain access to care. TGD youth can experience difficulty navigating the social and legal aspects of gender affirmation. Inconsistent and changing laws regarding name and gender marker adjustments on legal documents (ie, driver’s license, birth certificate) can leave TGD youth and their families confused. This process may be unfeasible due to costs and excessive requirements, and the process can lead to unnecessary disclosure of their TGD status at many points. Yet many medical institutions and schools require legal identity change before using a TGD youth’s asserted name and gender identity.\textsuperscript{43} Legal identity change can allow TGD youth to feel confident and safe in many settings.\textsuperscript{58} Case managers should be aware of local laws governing identity markers to help families navigate the process efficiently and to advocate on the youth’s behalf. Peer navigators or community health workers can be particularly helpful in supporting TGD youth and their families through each step. TGD youth with legal identity marker change feel more comfortable and confident applying for jobs, financial aid, internships, and engaging in their community.\textsuperscript{58}

**Referrals**

With a greater understanding of health and social disparities that TGD individuals face, case managers can properly build a system of support and affirmation through assessment, coordination, and appropriate referrals. Referrals to crisis intervention and stabilization units, community mental health agencies, domestic violence or homeless shelters, peer and family supports, and child welfare agencies may be needed at various times. Every effort should be made to connect youth with agencies that follow a gender affirmative care model where the youth’s gender identity is supported and affirmed. Being aware of clinical services that are trauma-informed is also important for ensuring that safety, respect, and autonomy are prioritized among youth who have been victimized. Overall, clients do best when they are empowered as active participants in their care.\textsuperscript{11,59} In contrast, every precaution should be

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**TABLE 3** Various agencies and resources relevant to supporting TGD youth and their families.

<table>
<thead>
<tr>
<th>Audience</th>
<th>Agency</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parent and family</td>
<td>PFLAG</td>
<td>pflag.org</td>
</tr>
<tr>
<td>Parent and family</td>
<td>HealthyChildren.org</td>
<td>healthychildren.org/English/ages-stages/gradeschool/Pages/Gender-Diverse-Transgender-Children.aspx</td>
</tr>
<tr>
<td>Parent and family</td>
<td>Family Acceptance Project</td>
<td>familyproject.sfsu.edu</td>
</tr>
<tr>
<td>Parent and family</td>
<td>Human Rights Campaign</td>
<td>hrc.org/explore/topic/parenting</td>
</tr>
<tr>
<td></td>
<td></td>
<td>hrc.org/blog/living-openly-coming-out-guides-and-resources</td>
</tr>
<tr>
<td>Parent, family, and schools</td>
<td>Gender Spectrum</td>
<td>genderspectrum.org</td>
</tr>
<tr>
<td>Schools</td>
<td>American Psychological Association</td>
<td>apa.org/pi/lgbt/programs/safe-supportive/lgbt/</td>
</tr>
<tr>
<td>Schools</td>
<td>GLSEN</td>
<td>glsen.org</td>
</tr>
<tr>
<td>TGD youth</td>
<td>Trevor Project</td>
<td>thetrevorproject.org</td>
</tr>
<tr>
<td>General</td>
<td>National Center for Transgender Equality</td>
<td>transequality.org</td>
</tr>
<tr>
<td>Legal</td>
<td>GLBTQ Legal Advocates &amp; Defenders (GLAD)</td>
<td>glad.org</td>
</tr>
<tr>
<td>Legal</td>
<td>Transgender Law Center</td>
<td>transgenderlaw.org</td>
</tr>
</tbody>
</table>

Abbreviation: TGD, transgender and gender-diverse.
Ms. Davis experiences frequent episodes of increasing shortness of breath. During visits to the pulmonologist, she reports a relentless wet cough with wheezing that “wears her out.” Activities of daily living such as cleaning, cooking, attending church, and getting to appointments become burdensome. She expresses how hard it was to follow a treatment plan with multiple components including use of a positive expiratory pressure airway clearance device, nebulized therapies, and multiple changes to her medications.

Over 2 years, Ms. Davis made 6 trips to the emergency department for increasing dyspnea. She was admitted to the hospital on 3 of those occasions with pneumonia and respiratory distress related to chronic production of large volumes of purulent secretions with mucus plugging resulting in atelectasis. *Pseudomonas aeruginosa* was noted in her sputum, which may be an indicator of increased airflow obstruction that results in greater severity of disease and a poorer quality of life. Chest radiography demonstrated dilated airways that were subsequently confirmed by a chest high-resolution computed tomography scan. A diagnosis of bronchiectasis COPD overlap syndrome (BCOS) was confirmed.

Ms. Davis received therapeutic bronchoscopy whenever impacted mucus triggered a respiratory crisis. She had 4 procedures in a single year for recurrent mucus plugging and increased dyspnea. Bronchoscopy was an unsatisfactory method for managing her chronic mucus hypersecretion and retention problem. In addition to facility and technology expenses, bronchoscopy was inconvenient, was uncomfortable, and was risky for the patient. With bronchoscopy, mucus cannot be removed from small airways. Infection and bacterial colonization may continue to occur in those regions. Reacting to events of respiratory compromise rather than implementing a treatment plan to address airway clearance failed to achieve the primary goals of improved health and decreased health care costs.

The Practice of Case Management

The American Case Management Association (ACMA) describes the practice of case management in hospitals and health care systems as “a collaborative practice model including patients, nurses, social workers, physicians, other practitioners, caregivers and the community. The Case Management process encompasses communication and facilitates care along a continuum through effective resource coordination. The goals of case management include the achievement of optimal health, access to care and appropriate utilization of resources, balanced with the patient’s right to self-determination.”

The Case Management Society of America (CMSA) offers a slightly different definition of case management: “a collaborative process of assessment, planning, facilitation, care coordination, evaluation and advocacy for options and services to meet an individual’s and family’s comprehensive health needs through communication and available resources to promote patient safety, quality of care, and cost-effective outcomes.”

The commonality in definitions includes advancement of desired patient outcomes while balancing fiscal responsibility with patient advocacy. It includes assessing a patient’s health

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**Nancy Skinner,** the principal consultant for Riverside HealthCare Consulting, has over 30 years’ experience in the practice of case management and advancing programs that promote excellence in care coordination and other transitional care strategies.

**Nancy Linda,** the National Education Manager at Hillrom Respiratory Care, has over 20 years’ experience caring for patients with respiratory disease, mechanically ventilated patients, quadriplegics, closed head injury patients, comatose patients, and other neurologically impaired patients.

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status and continuing health care needs as the patient navigates through transitions of care.

Standards from both organizations advance a case management practice that includes timely patient identification, screening, or selection; a comprehensive assessment of the patient’s current health status and projected transitional needs; care coordination and facilitation of an efficient and effective transitional care plan; and maintaining a consistent focus on patient advocacy.²,³

Standards of Practice must be carefully considered as interventions are provided to unique patients. Consider which specific case management functions and interventions might have assisted this hypothetical patient to achieve the optimal health options she sought over the course of several years.

**The Case Management Process to Enhance a Safe Patient-Specific Journey**
Since the health care journey for this patient appears chaotic with multiple respiratory exacerbations compromising her health and quality of life, let’s consider this case once more with a specific focus on case management interventions throughout Ms. Davis’ health care journey.

**The Case Management Process Implemented**
After several years of experiencing progressive respiratory disease, a 69-year-old patient presents to the emergency department with dyspnea, unrelenting cough with copious secretions, fever, and general fatigue. Ms. Davis is well known to the emergency department as she has been treated for dyspnea and recurrent pneumonia many times. She was admitted for a therapeutic bronchoscopy for the removal of impacted mucus that may have triggered the current respiratory crisis. Selected as a patient who is appropriate for coordination of care, a case manager begins a comprehensive assessment. Ms. Davis reported several years of decreasing quality of life due to frequent respiratory exacerbations. Her biggest concern related to her health was, “no matter what the doctors do or tell me to do, I just don’t get better.”

The episodes of retained mucus this patient experienced offered a perfect environment for bacterial growth and infection. When patients experience repeated cycles of infection and associated inflammation, damage to the lungs may occur, causing respiratory compromise and failure (Figure 1).⁴ This cycle of disease contributes to hospital readmissions and increasing cost of care.⁴

Following the bronchoscopy to remove numerous mucus plugs, the case manager, patient, and treatment team collaborated to develop a transitional care plan to address her physical and psychosocial needs.

**Figure 1 LUNG INFLAMMATION CYCLE**  
**LUNG INFLAMMATION TRIGGERED**  
**INFLAMMATORY RESPONSE ACTIVATED:**  
- mucus production  
- cellular defenses  
- chemical defenses  
**PULMONARY DEFENSES INEFFECTIVE:**  
- lung infection  
**INCREASED:**  
- mucus production  
- inflammation  
**MUSCUS PLUGGING/ AIRWAY OBSTRUCTION**  
**MUSCUS RETAINED**

**Transitional Care Plan**
Ms. Davis told the case manager she had become isolated from church activities and spending time with friends. She described life as “one concern about breathing after another.” Her treatment plan was confusing, and her medications changed frequently resulting in a “trail mix” of medications that she took without understanding why. She delayed appointments because of insurance deductibles and copays that strained her limited budget and because of transportation challenges in getting to appointments.

Ms. Davis lacked the necessary respiratory force to fully benefit from her current airway clearance therapy, so High Frequency Chest Wall Oscillation (HFCWO) therapy was recommended. Therapy is administered via an inflatable garment fitted over the thorax.⁴ On inflation, the chest wall compresses to generate a short burst of expiratory airflow. On deflation, the chest wall recoils to its resting position, causing inspiratory airflow.³

Effects of HFCWO include:
1. Increased air volume changes and airflow velocities⁶,⁷  
2. Shear forces that decrease mucus viscosity and loosen mucus from airway walls⁶,⁸  
3. Rapid repetitive “mini-coughs” that induce greater mucus clearance than single coughs⁷

In a study of 865 patients with bronchiectasis and 135 patients with chronic obstructive pulmonary disease (COPD) entitled “Outcomes with high-frequency chest wall oscillation among patients with non-CF bronchiectasis or COPD,”
hospitalizations, physician office visits, emergency department visits, and prescriptions were all lowered during the 3-month period after the start of HFCWO therapy.9

HFCWO proved to be effective in mobilizing Ms. Davis’ secretions. Treatment was administered with minimal effort and therefore met this patient’s needs. In-home instruction on HFCWO therapy was offered by the therapy provider. Her prescribed therapy specified 2–4 20-minute treatments each day.10 Remote Bluetooth therapy session monitoring was available to assess patient adherence and provide a timely indicator of the need for additional education or support. It was determined that in-home HFCWO therapy would be an important component of the transitional care plan.

Because Ms. Davis was unable to leave her home without considerable effort, home health care was suggested as a component of the transitional care plan. A hospital pharmacist met with her before discharge from the hospital to review prescribed medications, gauge her understanding of the value of adhering to the prescribed medications, and to provide a 30-day supply of medications.

Ms. Davis’s church identified members who were available to assist her with errands such as grocery shopping. The parish nurse visited before discharge to offer support and to identify community resources that might assist her to remain in her home with less need for emergent health care services.

Transition of Care
At discharge, the hospital case manager provided a smooth handover of the transitional care plan to the primary care physician and the case manager at the home health agency.

The HFCWO trainer met the patient in her home on the day of discharge to confirm that the patient understood the use and value of HFCWO therapy. A registered nurse and a social worker from the home health agency accessed the patient within 24 hours of discharge. Ms. Davis’ income was above the threshold for Medicaid coverage, so the social worker indicated he would focus on identifying programs that might provide some financial assistance to her. The home health nurse suggested a physical therapy evaluation to explore both physical and pulmonary rehabilitation strategies.

During the following 90 days, Ms. Davis did not experience any respiratory exacerbations. She reported no respiratory-related hospitalizations, emergency department visits, or urgent care visits. At a subsequent physician visit, she denied increased cough or signs of infection. She began attending church and was able to adhere to scheduled physician visits with the assistance of transportation services provided by community partners. For Ms. Davis, a well-defined, patient-centered, and effectively communicated continuing care plan advanced the desired outcome of care that she had sought to achieve.

Hypothetical Situations versus the Real World
Changing the trajectory of patient care and outcomes is easily accomplished when reporting hypothetical situations and not so easy in daily practice. In the first hypothetical patient report, secretion production and retention were affecting Ms. Davis’ quality of life. A diagnosis of BCOS accounts, in part, for the severity of her symptoms. Patients with BCOS have worse outcomes including greater daily sputum production, more frequent and longer exacerbations, more chronic colonization by potentially pathogenic microorganisms, poorer lung function, and higher mortality rates.11 Patients with BCOS experience extended stays in the intensive care unit and extended hospital lengths of stay.12

In this fictional case report, the patient was socially isolated and had very little support in navigating the health care system. Her quality of life was compromised by respiratory disease and negatively impacted by several social determinants of health that challenged her ability to fully participate as a member of her health management team.

Her course changed dramatically when the treatment team partnered with her to consider each aspect of her condition—physical, social, and psychological. When an individualized plan that focused not only on pharmaceutical interventions but also on airway clearance therapy was developed for the patient and she was able to adhere to this plan, her treatment was more successful.

This fictional case report demonstrates the value of case management interventions that reflect established
Standards of Practice that include but are not limited to appropriate patient selection; assessment of the patient’s health status including both symptom burden and the social determinants of health; development of a care management and coordination plan reflective of patient-specific goals; sequencing of required acute care services; facilitation and implementation of a transitional care plan that is consistent with patient preferences; and the timely communication of the plan to each member of the care management team and each patient as well as caregivers, community providers, and partners. These functions advance the quality of care and the outcomes patients endeavor to achieve.

This hypothetical case represents another important aspect of a professional case management practice, which is commitment to “lifelong learning” and “demonstrating current knowledge, skills, and competence to effectively provide holistic, client-centered care.” The case manager in this fictional case report appreciated the importance of finding the most-effective therapy for maintaining clear airways for this patient. Since the scope of some of our practices may include disease states that require additional knowledge and further consideration, it is essential to identify sources for further information that may facilitate a greater ability to assist patients in achieving desired goals.

Summary
The information regarding bronchiectasis and BCOS is offered to further an understanding of these conditions. Bronchiectasis remains underdiagnosed in most primary care settings. Diagnosis may be delayed for months or years, with symptoms misdiagnosed as bronchitis, asthma, or recurrent pneumonia. Bronchiectasis should be considered in a patient with chronic cough, abnormal sputum production, purulent sputum, and frequent respiratory infections that resolve slowly or partially. Undertreated bronchiectasis is costly and associated with significant morbidity and mortality.

Bronchiectasis considerations:
- Prevalence is increasing, requiring a greater awareness in primary and secondary care
- Prevalence in patients with moderate-to-severe COPD is high, and these patients have worse outcomes
- Most patients are unable to mobilize their secretions
- Airway clearance is a cornerstone of effective treatment
- HFCWO overcomes most limitations and obstacles to achieving effective airway clearance while addressing strategies to prevent readmissions
- Daily HFCWO may contribute to reduced rate of pulmonary deterioration, reduction in the frequency and/or severity of exacerbations, and reduced health care utilization
- Case managers who understand this unique condition can help patients improve their quality of life, reduce the frequency of recurrent infections, and manage their disease rather than having their disease manage them.

PATIENT EDUCATION RESOURCES
1. Bronchiectasis
   a. Chest Foundation
      https://foundation.chestnet.org/patient-education-resources/bronchiectasis/#living
   b. American Thoracic Society
      www.thoracic.org/patients/patient-resources/resources/bronchiectasis-pt1.pdf
2. COPD
   a. COPD Educational Library

CONTINUING EDUCATION COURSES
1. Bronchiectasis; A Paradigm Shift in Management and Treatment
2. Secretion Mobilization with High Frequency Chest Wall Oscillation (HFCWO)

Or access both courses directly through the HealthStream® Website: http://www.healthstream.com/hlc/hillromcourses

Continues on page 32
Nourianz™ (istradefylline) tablets, for oral use

INDICATIONS AND USAGE
Nourianz is indicated as adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease (PD) experiencing "off" episodes.

DOSAGE AND ADMINISTRATION

Dosing Information
The recommended dosage of Nourianz is 20 mg administered orally once daily. The dosage may be increased to a maximum of 40 mg once daily, based on individual need and tolerability. Initial dose titration is not required. Nourianz can be taken with or without food.

Dosage Adjustment with Strong CYP 3A4 Inhibitors
The maximum recommended dosage of Nourianz with concomitant use of strong CYP3A4 inhibitors is 20 mg once daily.

Dosing with Strong CYP 3A4 Inducers
Avoid use of Nourianz with strong CYP3A4 inducers.

Dosage Adjustment in Patients with Hepatic Impairment
The maximum recommended dosage of Nourianz in patients with moderate hepatic impairment (Child-Pugh B) is 20 mg once daily. Closely monitor patients with moderate hepatic impairment for adverse reactions when on Nourianz treatment. Avoid use of Nourianz in patients with severe hepatic impairment (Child-Pugh C).

Dosage Adjustment for Tobacco Smokers
The recommended dosage of Nourianz in patients who use tobacco in amounts of 20 or more cigarettes per day (or the equivalent of another tobacco product) is 40 mg once daily (see Use in Specific Populations).

DOSEAGE FORMS AND STRENGTHS
- 20 mg tablets: Peach-colored, pillow-shaped, film-coated tablets with "20" debossed on one side.
- 40 mg tablets: Peach-colored, almond-shaped, film-coated tablets with "40" debossed on one side.

CONTRAINdications
None.

WARNINGS AND PRECAUTIONS

Dyskinesia
Nourianz in combination with levodopa may cause dyskinesia or exacerbate pre-existing dyskinesia. In controlled clinical trials, the incidence of dyskinesia was 15% for Nourianz 20 mg, 17% for Nourianz 40 mg, and 8% for placebo, in combination with levodopa. One percent of patients treated with either Nourianz 20 mg or 40 mg discontinued treatment because of dyskinesia, compared to 0% for placebo.

Hallucinations/Psychotic Behavior
Because of the potential risk of exacerbating psychosis, patients with a major psychotic disorder should not be treated with Nourianz. Consider dosage reduction or discontinuation if a patient develops hallucinations or psychotic behaviors while taking Nourianz. In controlled clinical trials, the incidence of hallucinations was 2% for Nourianz 20 mg, 6% for Nourianz 40 mg, and 3% for placebo. In patients treated with Nourianz 40 mg, 1% discontinued because of hallucinations, compared to 0% for placebo and 0% for patients treated with Nourianz 20 mg. The incidence of "abnormal thinking and behavior" (paranoid ideation, delusions, confusion, mania, disorientation, aggressive behavior, agitation, or delirium) reported as an adverse reaction was 1% for Nourianz 20 mg, 2% for Nourianz 40 mg, and 1% for placebo.

Impulse Control/Compulsive Behaviors
Patients treated with Nourianz and one or more medication(s) for the treatment of Parkinson's disease (including levodopa) may experience intense urges to gamble, increased sexual urges, intense urges to spend money, binge or compulsive eating, and/or other intense urges, and the inability to control these urges. In controlled clinical trials, one patient treated with Nourianz 40 mg was reported to have impulse control disorder, compared to no patient on placebo or Nourianz 20 mg. In some postmarketing cases, these urges were reported to have stopped when the dose was reduced or the medication was discontinued. Because patients may not recognize these behaviors as abnormal, it is important for prescribers to specifically ask patients or their caregivers about the development of new or increased gambling urges, sexual urges, uncontrolled spend-
ing, binge or compulsive eating, or other urges while being treated with Nourianz. Consider dose reduction or discontinuation if a patient develops such urges while taking Nourianz.

ADVERSE REACTIONS

The following clinically significant adverse reactions were reported in clinical trials:

• Dyskinesia
• Hallucinations /Psychotic Behavior
• Impulse Control /Compulsive Behaviors

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no adequate data on the developmental risk associated with the use of Nourianz in pregnant women. The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risks of major birth defects and miscarriage in clinically recognized pregnancies are 2–4% and 15–20%, respectively.

Lactation

There are no data on the presence of istradefylline in human milk, the effects of istradefylline on the breastfed infant, or the effects of istradefylline on milk production. Istradefylline was present in the milk of lactating rats at concentrations up to 10 times that in maternal plasma. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for Nourianz and any potential adverse effects on the breastfed infant from Nourianz or from the underlying maternal condition.

Females and Males of Reproductive Potential Contraception

Use of Nourianz during pregnancy is not recommended. Women of childbearing potential should be advised to use contraception during treatment with Nourianz.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

No adjustment of Nourianz dosage is recommended on the basis of age. Of the total number of PD patients who received Nourianz in clinical trials, 53% were ≥65 years and 13% were ≥75 years of age. No overall differences in effectiveness were observed between these patients and younger patients.

Renal Impairment

No adjustment of Nourianz dosage is needed in patients with mild renal impairment (estimated creatinine clearance [CrCL] by Cockcroft-Gault equation: 60-89 mL/min), moderate renal impairment (CrCL 30-59 mL/min), or severe renal impairment (CrCL 15-29 mL/min). Nourianz has not been evaluated in patients with end-stage renal disease (ESRD) or in patients receiving hemodialysis.

Hepatic Impairment

No adjustment of Nourianz dosage is needed in patients with mild hepatic impairment (Child-Pugh Class A). In patients with moderate hepatic impairment (Child-Pugh B), the steady-state exposures (AUC0-24h) were predicted to be 3.3-fold higher than in healthy subjects, based on the estimated mean terminal half-life. Therefore, the maximum recommended dosage of Nourianz in patients with moderate hepatic impairment (Child-Pugh B) is 20 mg once daily. Closely monitor patients with moderate hepatic impairment for adverse events when on Nourianz treatment. Nourianz has not been studied in patients with severe hepatic impairment (Child-Pugh Class C). Avoid use of Nourianz in patients with severe hepatic impairment.

Tobacco Smokers

Tobacco smoking decreased Nourianz steady-state systemic exposures by 38% to 54%, which may decrease efficacy. Therefore, the recommended Nourianz dosage in patients who smoke 20 or more cigarettes per day (or the equivalent amount of another tobacco product) is 40 mg once daily.

CLINICAL STUDIES

The efficacy of Nourianz for the adjunctive treatment to levodopa/carbidopa in patients with Parkinson’s disease experiencing “off” episodes was shown in four randomized, multicenter, double-blind, 12-week, placebo-controlled studies.

HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

Nourianz (istradefylline) tablets are available as:

• 20 mg Tablets: Peach-colored, pillow-shaped, film-coated tablets with “20” debossed on one side.
• 40 mg Tablets: Peach-colored, almond-shaped, film-coated tablets with “40” debossed on one side.

Storage and Handling

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

Nourianz is manufactured by Kyowa Kirin, Inc., Bedminster, N.J.

Gvoke (glucagon) injection, for subcutaneous use

INDICATIONS AND USAGE

Gvoke is indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes ages 2 years and above.

DOSAGE AND ADMINISTRATION

Important Administration Instructions

Gvoke auto-injector and pre-filled syringe are for subcutaneous injection only. Instruct patients and their caregivers on the signs and symptoms of severe hypoglycemia. Because severe hypoglycemia requires the help of others to recover, instruct the patient to inform those around them about Gvoke and its Instructions for Use. Administer Gvoke as soon as possible.
when severe hypoglycemia is recognized. Instruct the patient or caregiver to read the Instructions for Use at the time they receive a prescription for Gvoke. Emphasize the following instructions to the patient or caregiver:

• Do not open foil pouch until ready to administer Gvoke.
• Administer Gvoke according to the printed instructions on the foil pouch label, carton, or the Instructions for Use.
• Visually inspect Gvoke before administration. The solution should appear clear and colorless to pale yellow and be free of particles. If the solution is discolored or contains particulate matter, do not use.
• Administer the injection in the lower abdomen, outer thigh, or outer upper arm.
• Call for emergency assistance immediately after administering the dose.
• When the patient has responded to treatment, give oral carbohydrates to restore the liver glycogen and prevent recurrence of hypoglycemia.
• Do not attempt to reuse Gvoke. Each Gvoke device contains a single dose of glucagon and cannot be reused.

**Dosage in Adults and Pediatric Patients ≥2 Years**

**Adults and Pediatric Patients ≥12 Years**

- The recommended dose of Gvoke is 1 mg administered by subcutaneous injection into lower abdomen, outer thigh, or outer upper arm.
- If there has been no response after 15 minutes, an additional 1 mg dose of Gvoke from a new device may be administered while waiting for emergency assistance.

**Pediatric Patients Aged 2 to Under 12 Years of Age**

- The recommended dose for pediatric patients who weigh <45 kg is 0.5 mg Gvoke administered by subcutaneous injection into the lower abdomen, outer thigh, or outer upper arm.
- The recommended dose for pediatric patients who weigh ≥45 kg is 1 mg Gvoke administered by subcutaneous injection into the lower abdomen, outer thigh, or outer upper arm.
- If there has been no response after 15 minutes, an additional weight-appropriate dose of Gvoke from a new device may be administered while waiting for emergency assistance.

**DOSAGE FORMS AND STRENGTHS**

Gvoke injection is a clear, colorless to pale yellow solution available as follows:

- 0.5 mg/0.1 mL single-dose pre-filled HypoPen auto-injector
- 1 mg/0.2 mL single-dose pre-filled HypoPen auto-injector
- 0.5 mg/0.1 mL single-dose pre-filled syringe
- 1 mg/0.2 mL single-dose pre-filled syringe

**CONTRAINDICATIONS**

Gvoke is contraindicated in patients with:

- Pheochromocytoma
- Insulinoma because of the risk of hypoglycemia
- Known hypersensitivity to glucagon or to any of the excipients in Gvoke. Allergic reactions have been reported with glucagon and include anaphylactic shock with breathing difficulties and hypotension.

**WARNINGS AND PRECAUTIONS**

**Catecholamine Release in Patients with Pheochromocytoma**

Gvoke is contraindicated in patients with pheochromocytoma because glucagon may stimulate the release of catecholamines from the tumor. If the patient develops a dramatic increase in blood pressure and a previously undiagnosed pheochromocytoma is suspected, 5 to 10 mg of phentolamine mesylate, administered intravenously, has been shown to be effective in lowering blood pressure.

**Hypoglycemia in Patients with Insulinoma**

In patients with insulinoma, administration of glucagon may produce an initial increase in blood glucose; however, glucagon administration may directly or indirectly (through an initial rise in blood glucose) stimulate exaggerated insulin release from an insulinoma and cause hypoglycemia. Gvoke is contraindicated in patients with insulinoma. If a patient develops symptoms of hypoglycemia after a dose of Gvoke, give glucose orally or intravenously.

**Hypersensitivity and Allergic Reactions**

Allergic reactions have been reported with glucagon; these include generalized rash, and in some cases anaphylactic shock with breathing difficulties and hypotension. Gvoke is contraindicated in patients with a prior hypersensitivity reaction.

**Lack of Efficacy in Patients with Decreased Hepatic Glycogen**

Gvoke is effective in treating hypoglycemia only if sufficient hepatic glycogen is present. Patients in states of starvation, with adrenal insufficiency or chronic hypoglycemia may not have adequate levels of hepatic glycogen for Gvoke administration to be effective. Patients with these conditions should be treated with glucose.

**Necrolytic Migratory Erythema**

Necrolytic migratory erythema (NME), a skin rash commonly associated with glucagonomas (glucagon-producing tumors) and characterized by scaly, pruritic erythematous plaques, bullae, and erosions, has been reported postmarketing following continuous glucagon infusion. NME lesions may affect the face, groin, perineum, and legs or be more widespread. In the reported cases NME resolved with discontinuation of the glucagon and treatment with corticosteroids was not effective. Should NME occur, consider whether the benefits of continuous glucagon infusion outweigh the risks.

**Hypoglycemia in Patients with Glucagonoma**

Glucagon administered to patients with glucagonoma may cause secondary hypoglycemia. Test patients suspected of having glucagonoma for blood levels of glucagon before treatment and monitor for changes in blood glucose levels during treatment. If a patient develops symptoms of hypoglycemia after a dose of Glucagon for Injection, give glucose orally or intravenously.
ADVERSE REACTIONS
The following serious adverse reactions were reported in clinical trials:
• Hypersensitivity and Allergic Reactions
• Necrolytic Migratory Erythema

DRUG INTERACTIONS
Beta-Blockers
Patients taking beta-blockers may have a transient increase in pulse and blood pressure when given Gvoke.

Indomethacin
In patients taking indomethacin, Gvoke may lose its ability to raise blood glucose or may even produce hypoglycemia.

Warfarin
Gvoke may increase the anticoagulant effect of warfarin.

USE IN SPECIFIC POPULATIONS

Pregnancy
Risk Summary
Available data from case reports and a small number of observational studies with glucagon use in pregnant women over decades of use have not identified a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. Multiple small studies have demonstrated a lack of transfer of pancreatic glucagon across the human placental barrier during early gestation. The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. 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.

Lactation
Risk Summary
There is no information available on the presence of glucagon in human or animal milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production. However, glucagon is a peptide and would be expected to be broken down to its constituent amino acids in the infant's digestive tract and is therefore, unlikely to cause harm to an exposed infant.

Pediatric Use
The safety and effectiveness of Gvoke for the treatment of severe hypoglycemia in patients with diabetes have been established in pediatric patients ≥2 years. Use of Gvoke for this indication is supported by evidence from a study in 31 pediatric patients ≥2 years with type 1 diabetes mellitus. The safety and effectiveness of Gvoke have not been established in pediatric patients 2 years of age.

Geriatric Use
Clinical studies of Gvoke did not include sufficient numbers of subjects ≥65 years to determine whether they respond differently from younger subjects. Limited clinical trial experience has not identified differences in responses between the elderly and younger patients.

OVERDOSAGE
If overdosage occurs, the patient may experience nausea, vomiting, inhibition of GI tract motility, increase in blood pressure, and pulse rate. In case of suspected overdosing, serum potassium may decrease and should be monitored and corrected if needed. If the patient develops a dramatic increase in blood pressure, phentolamine mesylate has been shown to be effective in lowering blood pressure for the short time that control would be needed.

CLINICAL STUDIES

Adult Patients Type 1 Diabetes Mellitus
Gvoke was evaluated in adult patients aged 18 to 74 years with type 1 diabetes in two multicenter 2-way crossover studies, Study A was double-blinded with 80 patients, and Study B was single-blinded with 81 patients. In a pooled analysis of Study A and Study B, the proportion of patients who achieved treatment “success” was 98.7% in the Gvoke group and 100% in the GEK group and the comparison between groups met the prespecified noninferiority margin. The mean time to treatment “success” was 13.8 minutes in the Gvoke group and 10 minutes in the GEK group.

Pediatric Patients with Type 1 Diabetes Mellitus
Gvoke was evaluated in a study in 31 pediatric patients with type 1 diabetes mellitus. Patients were administered insulin to induce a plasma glucose of 80 mg/dL. Ages 2 to under 6 years and 6 to under 12 years of age then received a 0.5 mg dose of Gvoke. Patients ≥12 received a 0.5 mg or 1 mg dose of Gvoke. All evaluable pediatric patients (30/30) achieved a target glucose increase of at least 25 mg/dL. Following administration, plasma glucose levels over time showed similar glucose responses for patients in each age group.

HOW SUPPLIED/STORAGE AND HANDLING
Gvoke injection is supplied as a clear, colorless to pale yellow solution in the following configurations:

Gvoke Strength Package Size
- HypoPen 0.5 mg per 0.1 mL 1 single-dose auto-injector
- HypoPen 0.5 mg per 0.1 mL 2 single-dose auto-injectors
- HypoPen 1 mg per 0.2 mL 1 single-dose auto-injector
- HypoPen 1 mg per 0.2 mL 2 single-dose auto-injectors
- PFS 0.5 mg per 0.1 mL 1 single-dose pre-filled syringe
- PFS 0.5 mg per 0.1 mL 2 single-dose pre-filled syringes
- PFS 1 mg per 0.2 mL 1 single-dose pre-filled syringe
- PFS 1 mg per 0.2 mL 2 single-dose pre-filled syringes

• Store at Controlled Room Temperature, 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F). Do not refrigerate or freeze.
• Store in original sealed foil pouch until time of use.
• Do not expose to extreme temperatures.
• Do not use Gvoke after the expiration date printed on the carton and foil pouch.

Gvoke is manufactured for Xeris Pharmaceuticals, Inc. by Pyramid Laboratories Inc., Costa Mesa, CA.
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.


**Neurosyphilis treatment outcomes after intravenous penicillin G versus intramuscular procaine penicillin plus oral probenecid.**

Dunaway SB, Maxwell CL, Tantalo LC, Sahi SK, Marra CM.

BACKGROUND: Data comparing neurosyphilis treatment regimens are limited.

METHODS: Participants were enrolled in a study of cerebrospinal fluid (CSF) abnormalities in syphilis conducted at the University of Washington between April 2003 to May 2014. They were diagnosed with syphilis and referred by their providers due to concerns for neurosyphilis. One hundred fifty people with CSF abnormalities treated with intravenous aqueous penicillin G (PenG) or intramuscular aqueous procaine penicillin G plus oral probenecid (APPG-P) were evaluated. Abnormal CSF was defined as white blood cells (WBC) >20/µL, CSF protein >50 mg/dL, or reactive CSF Venereal Disease Research Laboratory test (VDRL). Hazard ratios (HR) for normalization of CSF or serum measures were determined using Cox regression.

RESULTS: In individuals treated with either PenG or APPG-P, CSF WBCs and CSF-VDRL reactivity normalized within 12 months after treatment, while protein normalized more slowly and less completely. There was no relationship between treatment regimen or HIV status and likelihood of normalization of any measure. Among those with HIV, CSF WBCs and CSF-VDRL reactivity were more likely to normalize in those treated with antiretrovirals. Unexpectedly, CSF WBCs were more strongly defined as a reactive CSF-VDRL, the relationship with CD4+ T cell count remained unchanged.

CONCLUSIONS: In the current antiretroviral treatment era, neurosyphilis treatment outcome is not different for PenG and APPG-P, regardless of HIV status. The relationship between normalization of CSF WBCs and CD4+ T cell count may indicate continued imprecision in neurosyphilis diagnostic criteria due to HIV-related CSF pleocytosis.


**A modeling framework to inform preexposure prophylaxis initiation and retention scale-up in the context of 'Getting to Zero' initiatives.**

Khanna AS, Schneider JA, Collier N, et al.

OBJECTIVE(S): ‘Getting to Zero’ (GTZ) initiatives aim to eliminate new HIV infections over a projected time frame. Increased preexposure prophylaxis (PrEP) uptake among populations with the highest HIV incidence, such as young Black MSM, is necessary to accomplish this aim. Agent-based network models (ABNMs) can help guide policymakers on strategies to increase PrEP uptake.

DESIGN: Effective PrEP implementation requires a model that incorporates the dynamics of interventions and dynamic feedbacks across multiple levels including virus, host, behavior, networks, and population. ABNMs are a powerful tool to incorporate these processes.

METHODS: An ABNM, designed for and parameterized using data for young Black MSM in Illinois, was used to compare the impact of PrEP initiation and retention interventions on HIV incidence after 10 years, consistent with GTZ timelines. Initiation interventions selected individuals in serodiscordant partnerships, or in critical sexual network positions, and compared with a controlled setting where PrEP initiators were randomly selected. Retention interventions increased the mean duration of PrEP use. A combination intervention modeled concurrent increases in PrEP initiation and retention.

RESULTS: Selecting HIV-negative individuals for PrEP initiation in serodiscordant partnerships resulted in the largest HIV incidence declines, relative to other interventions. For a given PrEP uptake level, distributing effort between increasing PrEP initiation and retention in combination was approximately as effective as increasing only one exclusively.

CONCLUSION: Simulation results indicate that expanded PrEP interventions alone may not accomplish GTZ goals within a decade, and integrated scale-up of PrEP, antiretroviral therapy, and other interventions might be necessary.
**Circulation.** 2019 Sep 12. doi: 10.1161/CIRCULATIONAHA.119.039920. [Epub ahead of print]

**Prognostic implications of congestion on physical examination among contemporary patients with heart failure and reduced ejection fraction: PARADIGM-HF.**


BACKGROUND: The contemporary prognostic value of the physical examination, beyond traditional risk factors including natriuretic peptides (NPs), risk scores, and symptoms, in heart failure with reduced ejection fraction (HFrEF) is unknown. We sought to determine the association between physical signs of congestion at baseline and during study follow up with quality of life (QoL) and clinical outcomes and to assess the treatment effects of sacubitril/valsartan on congestion.

METHODS: We analyzed participants from PARADIGM-HF (Prospective Comparison of Angiotensin Receptor-Nephrilysin Inhibitor With Angiotensin Converting Enzyme Inhibitor to Determine Impact on Global Mortality and Morbidity in HF) with an available physical examination at baseline. We examined the association of the number of signs of congestion (jugular venous distention, edema, rales, and S3) with the primary outcome (cardiovascular death or HF hospitalization), its individual components, and all-cause mortality using time-updated, multivariable-adjusted Cox regression. We further evaluated whether sacubitril/valsartan reduced congestion during follow-up, and whether improvement in congestion is related to changes in clinical outcomes and QoL, assessed by Kansas City Cardiomyopathy Questionnaire clinical summary scores (KCCQ-OSS).

RESULTS: Among 8380 participants, 0, 1, 2, and 3+ signs of congestion were present in 70%, 21%, 7%, and 2%. Patients with baseline congestion were older, more often female, had higher Meta-Analysis Global Group in Chronic Heart Failure (MAGGIC) risk scores and lower KCCQ-OSS (p<0.05). After adjusting for baseline NPs, time-updated MAGGIC score, and time-updated New York Heart Association class, increasing time-updated congestion was associated with all outcomes (p<0.001). Sacubitril/valsartan reduced the risk of the primary outcome irrespective of clinical signs of congestion at baseline (p=0.16 for interaction), and treatment with the drug improved congestion to a greater extent than enalapril (p=0.011). Each 1-sign reduction was independently associated with a 5.1 (95%CI: 4.7-5.5) point improvement in KCCQ-OSS. Change in congestion strongly predicted outcomes even after adjusting for baseline congestion (p<0.001). Conclusions: In HFrEF, the physical exam continues to provide significant, independent prognostic value even beyond symptoms, NPs, and MAGGIC risk score. Sacubitril/valsartan improved congestion to a greater extent than enalapril. Reducing congestion in the outpatient setting is independently associated with improved QoL and reduced cardiovascular events, including mortality.


**Outcomes of heart transplantation from hepatitis C virus-positive donors.**

Aslam S, Yumul I, Mariski M, et al.

BACKGROUND: National data demonstrate that increasing opportunities exist for organ donation among hepatitis C virus (HCV)-infected individuals.

METHODS: We developed a clinical practice protocol for the acceptance of HCV+ organs for HCV- patients who underwent heart transplantation (HT) and retrospectively reviewed the outcomes at our institution. Inclusion criteria were as follows: all adult patients listed for HT. Exclusion criteria were as follows: pre-existing HIV or active hepatitis B viremia in the recipient/donor.

RESULTS: We transplanted 21 patients from HCV+ donors. Nineteen were viremic donors, and 2 were non-viremic donors. The recipients included 18 patients who underwent HT alone, and 3 patients who underwent combined heart-kidney transplants. There was no HCV transmission from the non-viremic donors (n = 2). All 19 recipients of the viremic donors developed HCV infection (100% transmission). The median age of the viremic donors was 34 years (interquartile range 30-46), and 84.2% were considered US Public Health Service-increased risk. Induction immunosuppression consisted of anti-thymocyte globulin (7/21), basiliximab (7/21), or none (8/21). Maintenance immunosuppression comprised tacrolimus, mycophenolate mofetil, and prednisone. Post-operative Week 2 HCV viral load was not related to induction. Direct anti-viral agent (DAA) therapy for a 12-week course consisted of glecaprevir/pibrentasvir (14/19, 74%), sofosbuvir/velpatasvir (2/19, 11%), elbasvir/grauprevir (2/19, 11%), and ledipasvir/sofosbuvir (1/19, 5%). All the patients on DAA therapy cleared viremia. The sustained virological response rate at 12 weeks in 18 evaluable patients was 100%.

CONCLUSIONS: We report successful single-center experience using HCV+ organs for HT into HCV- recipients. We believe that there is utility in using such organs to expand the current donor pool. Further long-term follow-up is needed.
Defining the hepatitis C cure cascade in an urban health system using the electronic health record.


Hepatitis C virus (HCV) infection is a public health threat. The electronic health record (EHR) can be used to monitor patients along the HCV cure cascade and highlight opportunities for interventions to improve cascade outcomes. We developed an HCV patient registry using data from Grady Health System’s (GHS) EHR and performed a cross sectional analysis of 72,745 GHS patients who received anti-HCV testing from 2004-2016. We created a testing cascade: 1) anti-HCV reactive, 2) HCV RNA tested, and 3) HCV RNA detectable; and a cure cascade: 1) HCV RNA detectable, 2) engaged in care, 3) treatment prescribed, 4) sustained virologic response (SVR) tested, and 5) SVR documented. 9,893 (16%) of 61,852 with detectable RNA were tested, and 4,224 (14%) achieved SVR. Factors associated with HCV treatment included cirrhosis, tobacco use, depression, diabetes, obesity, alcohol use, male gender, black race, and Medicare insurance. Uninsured patients were significantly less likely to be prescribed HCV treatment. In conclusion, Using EHR data, we identified high anti-HCV prevalence and noted gaps in HCV RNA testing, linkage to care, and treatment. The EHR can be used to evaluate the effectiveness of targeted interventions to overcome these gaps.


Examining changes in the hypertension awareness, treatment and control (i.e., the hypertension control cascade) by population subgroup can inform targeted efforts to improve hypertension control and reduce disparities. We analyzed data from the 1999-2016 National Health and Nutrition Examination Survey and examined trends across 6-year periods in hypertension awareness, treatment, and control by age, sex and race/ethnicity. We included 39,589 participants (16,141 with hypertension). Hypertension awareness, treatment, and control increased from 1999 to 2016 among all age groups. However, there were few changes after 2010. Across all time periods, awareness, treatment, and control were higher among younger women (versus younger men), while control was higher among older men (versus older women). Hypertension control was persistently lower for blacks than whites of all ages, and awareness, treatment, and control were lower among younger Hispanics. There have been few changes in hypertension awareness, treatment, and control since 2010. Disparities in hypertension control by sex highlight the need for effective interventions among younger men and older women. Concerted efforts are also needed to reduce persistent racial/ethnic disparities, particularly to improve treatment to control among blacks and further address gaps at all stages among younger Hispanics.


BACKGROUND: Treatment decisions for patients with non-small cell lung cancer (NSCLC) are based upon patient and tumor characteristics, including socioeconomic status (SES) factors. The objective was to assess the contribution of SES factors to treatment and outcomes among patients with stage I NSCLC.

METHODS: The National Cancer Database was queried for operable patients with stage I NSCLC. Patients were divided into 3 treatment groups: primary resection (SUR), nonstandard treatments (chemotherapy with or without radiation) (NST), and no therapy (NoT). The SES of patients who made up the treatment groups was assessed and the 5-year survival of all groups was analyzed.

RESULTS: The cohort included 69,168 patients with stage I NSCLC. Each of these patients had between 0 and 5 SES risk factors. The factors associated with no surgery were: low income, nonwhite race, low high school graduation rate, Medicaid or no insurance, rural residence, and distance <12.5 miles from treatment facility. Patients with multiple SES risk factors have a linearly increasing odds of undergoing NST and a quadratically increasing odds of undergoing NoT (up to OR=4.7; 95% CI 3.44-6.30 for those with 5 factors). SUR was associated with significantly longer 5-year survival (71.8%) compared to NST (22.7%) and NoT (21.8%), (p<0.0001).

CONCLUSIONS: SES factors increase the risk of undergoing guideline discordant therapy for Stage I NSCLC. As the number of
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SES factors increases, the odds of NoT rises quadratically while the odds of NST rises constantly. The SUR group had significantly longer survival than NST and NoT groups.


The association between Medicare accountable care organization enrollment and breast, colorectal, and prostate cancer screening.


BACKGROUND: Despite the rapid diffusion of accountable care organizations (ACOs), the effect of ACO enrollment on cancer diagnosis, treatment, and survival remains unknown. The objective of this study was to determine whether Medicare Shared Savings Program (MSSP) ACO enrollment was associated with changes in screening for breast, colorectal, and prostate cancers.

METHODS: The authors built a cohort of Medicare beneficiaries from 2006 through 2014 comprising 39,218,652 person-years of observation before and 17,252,345 person-years of observation after MSSP enrollment. The Centers for Medicare & Medicaid Services attribution methodology was recapitulated; and screening services were identified for breast, colorectal, and prostate cancer, implementing both sensitive and specific definitions of cancer screening. Adjusted difference-in-differences analyses were performed using linear regression to characterize changes in annual screening rates after ACO enrollment relative to contemporaneous changes in a non-ACO control group of Medicare beneficiaries.

RESULTS: Medicare beneficiaries attributed to ACO-enrolled providers had higher rates of breast, colorectal, and prostate cancer screening before enrollment. A 1.8% relative reduction in breast cancer screening was observed among women attributed to ACO providers (P < .0001), a 2.4% relative increase was observed in colorectal cancer screening (P = .0259), and a 3.4% relative reduction was observed in prostate cancer screening among men attributed to ACO providers (P = .0025) compared with contemporaneous changes in non-ACO controls.

CONCLUSIONS: Small-magnitude reductions were observed in breast and prostate cancer screening rates, and a small increase was observed in colorectal cancer screening associated with ACO enrollment. Although ACO enrollment does not appear to drive wholesale changes in cancer screening, small differences may map to meaningful changes in the epidemiology of screen-detected cancers among Medicare beneficiaries.


Members of racial and ethnic minority groups make up nearly 50% of US patients with end-stage kidney disease and face a disproportionate burden of socioeconomic challenges (ie, low income, job insecurity, low educational attainment, housing instability, and communication challenges) compared with non-Hispanic whites. Patients with end-stage kidney disease who face social challenges often have poor patient-centered and clinical outcomes. These challenges may have a negative impact on quality-of-care performance measures for dialysis facilities caring for primarily minority and low-income patients. One path toward improving outcomes for this group is to develop culturally tailored interventions that provide individualized support, potentially improving patient-centered, clinical, and health system outcomes by addressing social challenges. One such approach is using community-based culturally and linguistically concordant patient navigators, who can serve as a bridge between the patient and the health care system. Evidence points to the effectiveness of patient navigators in the provision of cancer care and, to a lesser extent, caring for people with chronic kidney disease and those who have undergone kidney transplantation. However, little is known about the effectiveness of patient navigators in the care of patients with kidney failure receiving dialysis, who experience a number of remediable social challenges.

Ortiz AP, Engels EA, Nogueras-González GM, et al.

BACKGROUND: Human papillomavirus (HPV) causes 10% of cancers among human immunodeficiency virus (HIV)-infected people in the United States. Because Hispanics are disproportionately affected by the HIV epidemic and by infection-related cancers, this study compared incidence rates for HPV-related cancers and survival between Hispanics and non-Hispanic...
whites (NHWs) and non-Hispanic blacks (NHBs) in the HIV-infected US population.

METHODS: Based on data from the HIV/AIDS Cancer Match Study, standardized incidence ratios (SIRs) were used to estimate cancer risk in HIV-infected Hispanics and the general US Hispanic population. Among HIV-infected people, cancer rates were compared with incidence rate ratios (IRRs), and survival was compared with hazard ratios between Hispanics and NHWs and NHBs.

RESULTS: Five hundred two HPV-related cancers occurred in 864,067 person-years of follow-up among HIV-infected Hispanics. Except for oropharyngeal cancer, the risk of HPV-related cancers was higher among HIV-infected Hispanics than in the general population (SIR range, 3.59 [cervical cancer] to 18.7 [anal cancer in men]). Among HIV-infected females, Hispanics had higher cervical cancer rates than NHWs (IRR, 1.70; 95% confidence interval [CI], 1.19-2.43) but lower vulvar cancer rates than NHWs (IRR, 0.40; 95% CI, 0.24-0.67) and NHBs (IRR, 0.62; 95% CI, 0.41-0.95). Among HIV-infected males, Hispanics had higher penile cancer rates than NHWs (IRR, 2.60; 95% CI, 1.36-4.96) but lower anal cancer rates than NHWs (IRR, 0.54; 95% CI, 0.46-0.63) and NHBs (IRR, 0.65; 95% CI, 0.56-0.77). Among HIV-infected Hispanics, 5-year survival was greater than 50% across HPV-related cancer types, with no major differences by racial/ethnic group.

CONCLUSIONS: HIV-infected Hispanics have an elevated risk for HPV-related cancers. Similarly to the general population, HIV-infected Hispanics have higher rates of cervical and penile cancer than NHWs and NHBs. HPV vaccination should be promoted among HIV-infected individuals to reduce the burden of HPV-related cancers.

Brain. 2019 Sep 1;142(9):2787-2799. doi: 10.1093/brain/awz212.

Chronic white matter lesion activity predicts clinical progression in primary progressive multiple sclerosis.


Chronic active and slowly expanding lesions with smouldering inflammation are neuropathological correlates of progressive multiple sclerosis pathology. T1 hypointense volume and signal intensity on T1-weighted MRI reflect brain tissue damage that may develop within newly formed acute focal inflammatory lesions or in chronic pre-existing lesions without signs of acute inflammation. Using a recently developed method to identify slowly expanding/evolving lesions in vivo from longitudinal conventional T2- and T1-weighted brain MRI scans, we measured the relative amount of chronic lesion activity as measured by change in T1 volume and intensity within slowly expanding/evolving lesions and non-slowly expanding/evolving lesion areas of baseline pre-existing T2 lesions, and assessed the effect of ocrelizumab on this outcome in patients with primary progressive multiple sclerosis participating in the phase III, randomized, placebo-controlled, double-blind ORATORIO study (n = 732, NCT01194570). We also assessed the predictive value of T1-weighted measures of chronic lesion activity for clinical multiple sclerosis progression as reflected by a composite disability measure including the Expanded Disability Status Scale, Timed 25-Foot Walk and 9-Hole Peg Test. We observed in this clinical trial population that most of total brain non-enhancing T1 hypointense lesion volume accumulation was derived from chronic lesion activity within pre-existing T2 lesions rather than new T2 lesion formation. There was a larger decrease in mean normalized T1 signal intensity and greater relative accumulation of T1 hypointense volume in slowly expanding/evolving lesions compared with non-slowly expanding/evolving lesions. Chronic white matter lesion activity measured by longitudinal T1 hypointense lesion volume accumulation in slowly expanding/evolving lesions and in non-slowly expanding/evolving lesion areas of pre-existing lesions predicted subsequent composite disability progression with consistent trends on all components of the composite. In contrast, whole brain volume loss and acute lesion activity measured by longitudinal T1 hypointense lesion volume accumulation in new focal T2 lesions did not predict subsequent composite disability progression in this trial at the population level. Ocrelizumab reduced longitudinal measures of chronic lesion activity such as T1 hypointense lesion volume accumulation and mean normalized T1 signal intensity decrease both within regions of pre-existing T2 lesions identified as slowly expanding/evolving and in non-slowly expanding/evolving lesions. Using conventional brain MRI, T1-weighted intensity-based measures of chronic white matter lesion activity predict clinical progression in primary progressive multiple sclerosis and may qualify as a longitudinal in vivo neuroimaging correlate of smouldering demyelination and axonal loss in chronic active lesions due to CNS-resident inflammation and/or secondary neurodegeneration across the multiple sclerosis disease continuum.
U.S. Preventive Services Task Force Recommends Expanded Treatment to Battle Perinatal Depression

A recommendation by the U.S. Preventive Services Task Force published in JAMA notes that 1 in 7 women suffer from depression either during pregnancy or in the postpartum year. “It is well established that perinatal depression can result in negative short- and long-term effects on both the woman and child,” the recommendation states.

The recommendation updates a 2016 Task Force recommendation about screening for depression among adults, including pregnant women. It says that if depressive symptoms are detected, then adults (including pregnant women) should be treated. The new recommendation focuses primarily on pregnant women, telling doctors to look for symptoms before, during, and after pregnancy.

Doughnut Hole Is Gone, But Medicare’s Uncapped Drug Costs Still Bite Into Budgets

Beneficiaries pay 25% of the price of their brand-name drugs until they reach $5,100 in out-of-pocket costs. After that, their obligation drops to 5%. But it never disappears. It’s that ongoing 5% that hits hard for people who take expensive medications.

Just over 1 million Medicare beneficiaries in Part D plans who did not receive low-income subsidies had drug costs that pushed them into catastrophic coverage in 2015, more than twice as many as the 2007 total, an analysis by the Kaiser Family Foundation found.

Identifying Mental Health Issues Reduces Care Plan Failure Rate

Clients with serious mental illness often have difficulty managing other health conditions or engaging in ongoing treatment, resulting in poor clinical outcomes, relapse, and rehospitalizations. There are a number of variables that can affect their level of engagement, including early diagnosis, proper treatment, accessibility of care, trust in the treatment plan, and strong connection to their care manager. Case managers can improve care plan success by assessing patients for anxiety and depression, extreme mood changes, changes in sleeping habits, weight or appetite changes, inability to deal with daily activities, heightened sensitivity, feeling guilty or worthless, difficulty relating to other people, substance abuse, and multiple physical ailments without an obvious cause.

Behavioral Intervention to Change Physical Activity in Patients with Type 2 Diabetes

The IDES_2 Trial, which studied 300 patients with diabetes over 3 years, found a significant increase in physical activity resulting from a behavioral intervention. The trial results are reported in JAMA.

Workplace Wellness Programs Barely Move the Needle

New research published in JAMA detected some changes in healthy behavior related to weight and stress but little overall impact in workers’ health status or employer health care spending.

The New England Journal of Medicine Provides Free Learning Module on Pain Management and Opioids

As a recipient of an independent educational grant through the REMS (Risk Evaluation and Mitigation Strategy) program, The New England Journal of Medicine (NEJM) announces the launch of the NEJM Knowledge+ Pain Management and Opioids module. This module, available free of charge, features more than 60 case-based questions on pain management, safer prescribing of opioid analgesics, and the recognition and treatment of opioid use disorder. To ensure the development of high-quality, unbiased content in this module, they partnered with experts at Boston University School of Medicine’s Safer/Competent Opioid Prescribing Education (SCOPE of Pain) program.

Merck Manuals Joins Epic App Orchard Marketplace to Power Provider Reference and Patient Education

Merck Manuals has joined Epic App Orchard to directly embed clinical decision support and patient education content within the Epic electronic health record (EHR) workflow. The patient education material can be electronically sent to patients through the EHR system or printed out at the point-of-care. Merck Manuals, a comprehensive digital medical reference, announced it has joined the Epic App Orchard Marketplace, enabling Epic customers with access to provider reference and patient education content within the Epic EHR.
Assessing and Managing the Social Ecology of Transgender and Gender-Diverse Youths

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taken to avoid interventions that aim to prevent TGD youth from expressing and affirming their gender. These approaches, often termed as “conversion” or “reparative,” have been shown to be ineffective and harmful and are not considered to be appropriate interventions for TGD youth.11,13,60,61

Case managers should also be prepared to connect TGD youth with services aimed at supporting their gender affirmation needs. Social affirmation can be supported through partnerships with many community-based organizations to access gender-affirming clothing and equipment, understanding and affirming supports, and spaces where TGD youth can feel safe and supported in their gender, such as peer support groups. Studies have shown that youth who are socially affirmed in their gender have decreased rates of depression and anxiety,62 and youth who have their asserted name used in multiple settings have lower rates of depression.15 TGD youth may also benefit from referrals to medical and, if necessary, surgical care to support their affirmation needs. Research suggests that youth who are able to access medical interventions have improved psychological functioning and life satisfaction and have reduced dysphoria.62-65 There are many national agencies that help direct case managers and TGD youth to local services and resources (Table 3).

Conclusion and Recommendations

TGD youth face numerous health and social disparities on multiple levels of their social ecology. Case managers can play an essential role in assessing, advocating, referring, and developing care plans toward affirmation and resiliency. In this regard, case managers should:

- Be familiar with terminology, theories, and evolving models relevant to affirming TGD youth.
- Recognize challenges TGD youth face at the individual and systemic level.
- Offer a welcoming and affirming office environment, including using asserted name and pronouns.
- Support families that are struggling to understand and accept their TGD child.
- Be knowledgeable of local laws and regulations around legal identity changes, discrimination, and access to services (eg, health care, housing, and employment).
- Advocate with schools, law enforcement, health care organizations, insurance companies, and other organizations toward policies that are gender inclusive and affirming.
- Prioritize referrals to providers that use a gender-affirmative care approach.
- Contribute to ongoing research and publications, particularly around improving the various systems that TGD youth and their families encounter.

By following these suggestions, case managers will not only provide appropriate care for all patients but will also improve the access to care for TGD youth. Understanding these problems of TGD youth and adult patients and applying them in daily practice will ensure that case managers are meeting the Codes of Ethics of CCMC and CDMS, specifically principle 5 of each organization that addresses the need for case managers to maintain their competency.

Mentoring: A Mutually Beneficial Professional Relationship

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commitment of time and energy, yet it also offers opportunities for personal growth and shared learning experiences. Whether it involves short-term mentoring or longer-term relationships, mentorship is a win/win. It is not uncommon for a mentee to come back, many years later, and thank a mentor for imparting knowledge and experiences that shaped their understanding and advanced their careers. For the mentor, there is no better feeling than knowing that someone benefited from what they shared.

This is the ultimate payback for those of us who have been mentored in our career. As we become mentors, we contribute to the development of others and we can watch them grow and become better at what they do. For case managers, the fruits of these labors are found in helping individual case managers who go on to become certified (and stay certified) and in contributing to a highly qualified professional case management workforce that is ready and willing to be deployed along the healthcare continuum.
When Stress Is the Cause: Handling Absences and Supporting Employees

extended time away, such as accessing the Employee Assistance Program (EAP) or a perhaps taking off a day or two. Empowering managers to have conversations with employees around work/life stress can help both parties. The employee needs to feel comfortable requesting what they want and need, whether it’s to leave work early, have more flexibility, or take a few days off. The manager needs to exhibit empathy (while keeping appropriate boundaries), to listen to the employee, and to help identify what can be done to alleviate stress.

Otherwise, the message to the employee may be to “contact your doctor or the third-party administrator to file a claim.” While that may be the policy and practice within a particular work environment, it lacks the engagement of employer and employee to find helpful resources and solutions that could alleviate stress and the need for an extended leave.

When supervisors feel empowered and comfortable in having these conversations, they can inform employees about specific programs. For example, an employee may not be aware of the EAP, which is not just for referrals but also includes access to counseling sessions. Among some employers, EAP programs are expanding from being “triage” for employees in crisis—whether due to mental, family, financial, or other issues—to establishing longer-term care relationships. Some EAPs are extending the number of counseling sessions available from 3 to 5 to 15 or 25, and in some cases unlimited.

Other support may be available to the employee, whether they want to remain on the job or to receive support when they return from a short-term absence. The same return-to-work and stay-at-work programs that are put in place after a physical injury can help an employee who is dealing with stress or other mental health issues. The CDMS can facilitate discussions between the employer and employee to identify changes to the job demands, which may reduce the employee’s level of stress. This may involve taking short breaks throughout the day, working from home or other telecommuting arrangements, or reducing the workload.

As mental health issues, including stress, become more common—and more commonly discussed—employers need to understand their role in helping employees get the support they need to better manage their stress and remain productive. CM

References

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Teams need to recognize filters and biases that team members may have. Personal filters are the way in which we see, interact with, and interpret the world around us. These personal filters decide what we pay attention to and what we ignore when communicating with others.

Being a Good Team Member From a Distance continued from page 7

- Identify key information needed for the team to have both effective and efficient communication and produce the desired result.

- Some characteristics of an effective team are:
  - A clear mission—define what you will do as a team and how you are going to do it
  - Specific roles and expectations
  - Strategies to get team members working together
- Being a team from the beginning
- Confirm expectations
- Collaborate and work toward the desired established result
- Understand that we support each other
- Clarify expectations when necessary
- Give and receive feedback when expectations are not being met

Teams need to recognize filters and biases that team members may have. Personal filters are the way in which we see, interact with, and interpret the world around us. These personal filters decide what we pay attention to and what we ignore when communicating with others. Our filters influence how we listen to and interpret information and can actually prevent us from hearing or valuing something that is being shared.

Some of the filters include the population being worked with, the geography where services are or will be delivered, culture, size/scope of programs, resources available and/or needed, and subtle and ingrained. It is an excellent exercise to occasionally reflect on the process of how you came to a particular opinion or conclusion. It is important to engage others who represent different opinions and attitudes and to be a dynamic listener. It is imperative to focus on the message or information being delivered or shared and not the means of delivery or the messenger.

When a case manager practices tolerance and professionalism, it doesn’t necessarily mean approval or that you have to give up deeply held values or views. However, you do need to:
- Accept and respect another’s right to come to his or her own conclusions
- Appreciate differences
- Maintain awareness and sensitivities of others
- Avoid offensive behaviors

Case management is the glue for many interactions and results in positive outcomes for people being served, but case managers should be reminded of the responsibilities of being a member of a successful team.

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