Trauma-informed care Part 2: Transgender and gender nonconforming individuals

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A trauma-informed care (TIC) approach acknowledges that many have experienced or witnessed traumatic events and that this can continue to affect aspects of their lives and how they access and experience healthcare. Transgender and gender nonconforming (TGNC) individuals are highly represented among those who have experienced trauma, often have gender dysphoria, and face substantial healthcare disparities and barriers to care. A high prevalence of suicide attempts, HIV infection, substance use disorders, and other health inequities affect the TGNC communities. Data suggest that 24% of transgender people experience unequal treatment in healthcare environments, 19% are refused care, and 33% do not seek preventive services. The key to being trauma informed in providing healthcare for TGNC individuals encompasses training of providers and staff, and developing policies and procedures in organizational systems that support TIC.

KEY WORDS: trauma-informed care, transgender, gender nonconforming, gender dysphoria, patient-centered care, people who have experienced trauma

Healthcare providers (HCPs) in any setting will see individuals with a history of trauma. (See *Box 1* for the definition of trauma.) It is imperative to have a working knowledge of ways to support these individuals. The connection between trauma, mental health, and co-occurring disorders such as substance abuse, eating disorders, HIV/AIDS, and violence have been well documented.[1–3] Further, data have shown that repeated exposure to traumatic events can decrease treatment adherence.[1–3] Failure to consider a history of trauma can lead to misdiagnosis, poor treatment outcomes, and ineffective therapeutic relationships.

The information gleaned in this article builds on information in the articles published in the June 2021 and August 2020 issues of *Women's Healthcare*.[4,5] In the August 2020 article "Trauma-informed care for the primary care provider," the author provided an overview of trauma, universal screening, and trauma-informed care (TIC) and discussed the four R's and six key principles HCPs can use to implement TIC.[4] In the June 2021 article "Part 1: The road to operationalizing trauma-informed care," the authors discussed strategies HCPs can use to implement a trauma-informed

approach at the clinical level and organizational level.[5] In this article, the author discusses a blueprint for planning and implementing TIC for transgender and gender nonconforming (TGNC) individuals to meet the medical and mental health needs of this underserved and vulnerable population.

Trauma and transgender and gender nonconforming individuals

Individuals who experience or express a gender that differs from their sex assigned at birth may identify as TGNC individuals. These identities may include trans feminine (male to female), trans masculine (female to male), and nonbinary identities. Gender-related terminology with definitions is provided in *Box 2*. In the United States, approximately 150,000 youth and 1.4 million adults identify as transgender.[6] This estimate may actually be low considering that TGNC individuals may not disclose their identities due to fear and harassment.[6] Negative healthcare experiences are frequently reported by TGNC individuals, and they often avoid seeking healthcare due to fear of discrimination. Among respondents to the 2015 US Transgender Survey, "one-third reported having a negative experience with a healthcare clinician in the past year, including being asked unnecessary or invasive questions, having to teach their clinician in order to get appropriate care, or being refused transition-related care."[6] In the same survey, 19% of respondents reported being refused care altogether and 33% reported not seeking preventive services.[6]

TGNC individuals are more likely to experience potentially traumatic events such as physical assault and victimization by acts of prejudice and transphobia, such as misgendering and employment discrimination.[6–8] These experiences have negative mental health impacts, contributing to heightened rates of mental health disorders when comparing TGNC and cisgender individuals. TGNC individuals may have gender dysphoria. Gender dysphoria is a sense of anxiety that a person may have because of a discordance between their biologic sex and their gender identity.[1] Gender dysphoria manifests early in childhood and can persist for years before patients undergo counseling and treatment. In one study of adult patients seeking gender-affirming surgery, approximately 3 out of 4 participants reported they first experienced gender dysphoria by age 7 years.[9] In this same study, transgender women were an average 27.1 years and transgender men 22.9 years before they began social transition and/or hormonal therapy.[9] In other words, their life experiences, beginning with their earliest memories, included the distress and negative health effects brought on by a lack of early counseling and support services that would have eased their gender transition period. Untreated gender dysphoria can result in poor quality of life, beginning in childhood and lasting throughout adolescence and adulthood.[10] High rates of depression, anxiety, self-harm, and feelings of hopelessness are reported.[10]

Gender dysphoria can be successfully treated with gender-affirming hormone and/or surgical treatment along with supportive counseling. Gender-affirming care includes an evaluation of the magnitude, duration, and stability of any gender dysphoria.[11] Existing or preexisting

Box 1. What is trauma?

- A universal definition of trauma does not clearly exist
- Refers to any experience that causes an intense psychological or physical stress reaction
- May occur as a result of violence, abuse, neglect, loss, disaster, war, and other emotionally harmful experiences
- May occur as the result of a single event, a series of events, or a set of circumstances
- The extent to which an event is traumatic depends on how an individual interprets, applies meaning to, and is disrupted by that event

Box 2. Gender terminology and definitions

- Sex: Sex assigned at birth based on appearance of genitals
- Gender: A social construct assigning roles and attributes to a person based on their sex assigned at birth
- Gender identity: A person's internal sense of self from gender perspective
- Gender expression: An outward manner in which a person expresses their gender. Can include hairstyle, clothing choices, mannerisms
- Sexual orientation: Who a person is attracted to physically, spiritually, and/or emotionally
- Cisgender: A person whose gender identity is the same as their sex assigned at birth
- Binary gender: A concept of gender that recognizes only two dichotomous gender identities: male and female
- Transgender: Umbrella term used to describe all people whose gender identity is in some way different from their natal sex
- Gender nonconforming: A person who identifies as somewhere between male and female, both male and female, or having no gender

conditions (eg, depression, body dysmorphic disorder, substance use disorder) may confound the clinical picture and thus must be considered in an evaluation to optimize treatment.[11]

Implementing trauma-informed care for transgender and gender nonconforming individuals into the practice setting

A TIC approach acknowledges that many people have experienced or witnessed traumatic events and that this can continue to affect many aspects of their lives and how they access and experience healthcare. Individuals who have experienced trauma find themselves in healthcare settings that too often re-traumatize them. Learning to interact with those who have experienced trauma in ways that encourage their resiliency and growth is imperative. A TIC approach aims to be sensitive to individuals' experiences of trauma and how their trauma may affect their healthcare.[7,8] Guidelines for TIC emphasize the need for a holistic approach in which all components of an individual's history and identity are considered in treatment planning and service delivery. To provide competent TIC for patients who are TGNC, it is necessary first for practices to guide themselves through a self-assessment process. Comprehensive training and planning based on three principles is key to promoting understanding and to providing optimal care. The three principles address understanding the impact of trauma on TGNC individuals, providing physical and emotional safety, and adapting practice policies and procedures to maximize inclusion of TGNC individuals and minimize re-traumatization. Detailed guidelines on incorporating these principles are available for trauma-informed practice as well as care specific to TGNC individuals.[12]

Principle 1. Understand the impact of trauma on a patient's cognition, emotion, behavior, and perception

The way that we respond and feel about the world is shaped by exposure to trauma. Stigma, rejection by family or peers, and feelings of shame are common trauma experiences for individuals who are TGNC. The ability to form trusting, intimate relationships, manage stress, maintain self-esteem, and achieve self-sufficiency are impacted.[11,13,14] These individuals can be at high risk for depression, violence, substance use, sexual risk behaviors, and truancy.[11,13,14]

When an understanding of trauma is missing in care, patients may be pathologized in a stigmatizing way and this can also lead to misdiagnosis, improper treatment, and poor outcomes.

HCPs who are willing to explore multiple perspectives, recognize and work to eliminate their own biases, and learn more about TIC and the healthcare needs of TGNC individuals can provide compassionate, comprehensive, and high-quality care. They can also support other staff to do the same.[11,13,14]

Principle 2. Provide physical and emotional safety to ensure transgender and gender-diverse individuals' healthcare needs and concerns are met

People who have experienced trauma are frequently hypervigilant. They are often acutely aware of their environment. If there is any indication that the environment is unsafe, it can be a distraction and may re-traumatize the patient. TGNC individuals who have faced stigma in their families and communities can feel powerless and exploited.[15–19] Strategies that establish a safe and welcoming environment are critical in effectively engaging and building a trusting relationship.[19] The physical space where care takes place is important and there are several ways providers can help members of the transgender and broader LGBTQ community feel welcome in the clinical setting. Advertising a practice as accepting of members of the LGBTQ community is imperative. Materials specifically designed and displayed for TGNC populations should be visible and can include posters, brochures, rainbow flags, and flyers about LGBTQ-themed community events. Bathrooms need to have locks and be gender appropriate/neutral.[20–24] Intake forms can be updated to include gender-neutral language and asking two questions to identify chosen gender identity and sex assigned at birth to help identify transgender patients, with each patient having the ability to withhold this information if they so choose. Staff and HCPs should be comfortable in discussing sexual orientation, gender identity, and sexual practices. Emotional safety is promoted when care is nonjudgmental, patient centered, and strengths based. This includes open-ended questions, active listening, and affirmations by the HCP. Gender-affirming language that includes the use of preferred pronouns is essential in creating a welcoming environment in which marginalized people feel seen in a holistic and respectful manner.[15,16]

It is essential to discuss the support and safety of the patient's social environment as it pertains to gender affirmation. Many TGNC individuals have suffered years of abuse, neglect, or exploitation, and they may have lacked role models

for healthy relationships.[11,17,19,25] HCPs can provide a valuable opportunity for patients to examine their relationship history, discuss healthy, safe intimate relationships, and offer referrals where needed. When issues around gender identity are avoided, more individuals are unprepared to navigate these complexities, which can compound shame. HCPs should be equipped to handle the basic mental health needs of TGNC individuals and refer to specialists when needed. TGNC patients typically have high rates of mental health diagnoses. However, it is important not to assume that a patient's mental health concerns are secondary to being transgender. HCPs should consider routine screening for depression, anxiety, posttraumatic stress disorder, eating disorders, substance use, intimate partner violence, self-injury, bullying, truancy, homelessness, high-risk sexual behaviors, and suicidality. Gender dysphoria and past negative experiences can cause significant distress for TGNC patients during the physical examination. Examinations should be based on the patient's specific needs for the visit. Prior to a genital exam, the HCP should ascertain if there has been any gender-affirming surgery such as a neovagina created in a transgender-affirming or a hysterectomy in a transgender man. Screening and diagnostic tests should be appropriate to the patient's anatomy that is present, regardless of gender presentation. Patient education regarding screening tests is important. Transgender men who have a cervix may either not understand the need for cervical cancer screening or may avoid screening because of previous trauma or anxiety related to the pelvic exam.[26]

The HCP should explain to the patient what will take place during the exam including any tests that will be performed beforehand with encouragement to ask questions and/or express any concerns. The patient should be informed that there is the option to decline or defer any part of the exam and that the exam will stop at any time if they request.

The HCP can use general terminology for body parts or ask the patient if they have a term or terms they prefer to use. Strategies that may enhance patient comfort include having a support person in the room, using mindfulness techniques, listening to music on headphones or phone, or using other strategies as a distraction during the exam. Patients who desire to be more involved can be offered the use of a mirror to directly observe the exam. Allowing for self-collection of any needed vaginal specimens (eg, wet prep, STI tests) may negate the need for a speculum exam in certain scenarios.[26]

> Research in the area of healthcare for TGNC individuals has increased substantially across multiple disciplines over the last few decades, yet gaps in knowledge remain. More studies are needed to understand the unique trauma experienced by TGNC individuals and to develop best practices to improve care.

Principle 3. Adapt practice policies and procedures to maximize inclusion of transgender and gender-diverse individuals while minimizing re-traumatization

To determine and evaluate whether or not services are inclusive and respectful, HCPs and staff must engage in constant self-assessment while also requesting feedback from their patients. Intentional efforts to hire and maintain staff, particularly members of the LGBTQ community, that represent diversity in multiple aspects such as gender identity and sexual orientation demonstrate a commitment to inclusivity. Training for new and existing staff is important to develop competency in trauma-informed services for TGNC individuals. It is essential for staff to demonstrate proficiency in these areas. Practice policies that incorporate cultural competency in job descriptions and performance evaluations emphasize its importance. Providing patient brochures on sexually transmitted infection prevention, substance abuse, safe sex practices, mental health, and gender-affirming hormone therapy as well as providing waiting room

(continued on page 29)

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CONTRAINDICATIONS

ANNOVERA (segesterone acetate and ethinyl estradiol vaginal system) is contraindicated and should not be used in women with a high risk of arterial or venous thrombotic diseases; current or history of breast cancer or other estrogen- or progestin-sensitive cancer; liver tumors, acute hepatitis, or severe (decompensated) cirrhosis; undiagnosed abnormal uterine bleeding; hypersensitivity to any of the components of ANNOVERA; and use of Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir.

WARNINGS AND PRECAUTIONS

- Stop ANNOVERA if a thrombotic or thromboembolic event occurs, and at least 4 weeks before and through 2 weeks after major surgery. Start ANNOVERA no earlier than 4 weeks after delivery, in females who are not breastfeeding. Consider cardiovascular risk factors before initiating in all females, particularly those over 35 years.
- Discontinue if jaundice occurs.
- Stop ANNOVERA prior to starting therapy with the combination drug regimen ombitasvir/paritaprevir/ritonavir. ANNOVERA can be restarted 2 weeks following completion of this regimen.
- Do not prescribe ANNOVERA for females with uncontrolled hypertension or hypertension with vascular disease. Monitor blood pressure and stop use if blood pressure rises significantly in females with well-controlled hypertension.
- Monitor glucose in pre-diabetic or diabetic females taking ANNOVERA. Consider an alternate contraceptive method for females with uncontrolled dyslipidemias.
- Patients using ANNOVERA who have a significant change in headaches or irregular bleeding or amenorrhea should be evaluated. ANNOVERA should be discontinued if indicated.
- Other warnings include: gallbladder disease; depression; cervical cancer; increased serum concentrations of binding globulins; hereditary angioedema; chloasma (females who tend to develop

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chloasma should avoid exposure to the sun or UV radiation while using ANNOVERA); toxic shock syndrome (TSS) (if a patient exhibits symptoms of TSS, remove ANNOVERA, and initiate appropriate medical treatment); vaginal use (ANNOVERA may not be suitable for females with conditions that make the vagina more susceptible to vaginal irritation or ulceration).

ADVERSE REACTIONS

The most common adverse reactions reported in at least 5% of women who received ANNOVERA were: headache/migraine, nausea/vomiting, vulvovaginal mycotic infection/candidiasis, lower/upper abdominal pain, dysmenorrhea, vaginal discharge, urinary tract infection, breast pain/tenderness/discomfort, bleeding irregularities including metrorrhagia, diarrhea, and genital pruritus.

DRUG INTERACTIONS

Drugs or herbal products that induce certain enzymes, including CYP3A4, may decrease the effectiveness of ANNOVERA or increase breakthrough bleeding. Counsel patients to use a back-up or alternative method of contraception when enzyme inducers are used with ANNOVERA.

INDICATION

ANNOVERA is a progestin/estrogen combination hormonal contraceptive indicated for use by females of reproductive potential to prevent pregnancy.

Limitations of Use: ANNOVERA has not been adequately studied in females with a body mass index >29 kg/m^2.

Please note this information is not comprehensive. Please see Brief Summary of the Full Prescribing Information on the next page, including BOXED WARNING, or visit Annovera.com/pi.pdf.

References: 1. Annovera® [Full Prescribing Information]. Boca Raton, FL: TherapeuticsMD, Inc; 2020. **2.** Merkatz RB, Plagianos M, Hoskin E, et al. Acceptability of the Nestorone®/ethinyl estradiol contraceptive vaginal ring: development of a model; implications for introduction. *Contraception*. 2014;90(5):514–521. doi:10.1016/j.contraception.2014.05.015. **3.** Kumar N, Koide SS, Tsong YY, Sundaram K. Nestorone: a progestin with a unique pharmacological profile. *Steroids*. 2000; 54:629-636.

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BRIEF SUMMARY OF PRESCRIBING INFORMATION

This Brief Summary does not include all the information needed to use ANNOVERA safely and effectively. Please visit **ANNOVERA.com/pi.pdf** for Full Prescribing Information (PI).

WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS

Cigarette smoking increases the risk of serious cardiovascular events from combination hormonal contraceptive (CHC) use. This risk increases with age, particularly in females over 35 years of age, and with the number of cigarettes smoked. For this reason, CHCs should not be used by females who are over 35 years of age and smoke.

INDICATIONS AND USAGE

ANNOVERA is indicated for use by females of reproductive potential to prevent pregnancy.

Limitations of Use: ANNOVERA has not been adequately studied in females with a BMI >29 kg/m^2.

DOSAGE AND ADMINISTRATION

One ANNOVERA is inserted in the vagina. The vaginal system must remain in place continuously for 3 weeks (21 days) followed by a 1-week (7-day) vaginal system-free interval. One vaginal system provides contraception for thirteen 28-day cycles (1 year). Follow instructions for starting ANNOVERA, including switching from other contraceptive methods, and use after abortion, miscarriage, or childbirth *[see How to Start ANNOVERA (2.2) in PI]*.

Contraceptive efficacy of ANNOVERA may be reduced if a woman deviates from the recommended use. If ANNOVERA is out of the vagina for more than 2 continuous hours or more than 2 cumulative hours during the 21 days of continuous use, then back-up contraception, such as male condoms or spermicide, should be used until the vaginal system has been in the vagina for 7 consecutive days.

CONTRAINDICATIONS

ANNOVERA is contraindicated in females who are known to have the following conditions: • A high risk of arterial or venous thrombotic diseases. Examples include females who are known to: smoke, if over age 35; have current or history of deep vein thrombosis or pulmonary embolism; have cerebrovascular disease; have coronary artery disease; have thrombogenic valvular or thrombogenic rhythm diseases of the heart (for example, subacute bacterial endocarditis with valvular disease, or atrial fibrillation); have inherited or acquired hypercoagulopathies; have uncontrolled hypertension or hypertension with vascular disease; have diabetes mellitus and are over age 35, diabetes mellitus with hypertension or vascular disease, or other end-organ damage, or diabetes mellitus of >20 years duration; have headaches with focal neurological symptoms, migraine headaches with aura, or are over age 35 with any migraine headaches. • Current or history of breast cancer or other estrogen- or progestin-sensitive cancer. • Liver tumors, acute hepatitis, or severe (decompensated) cirrhosis. • Undiagnosed abnormal uterine bleeding. • Hypersensitivity to any of the components of ANNOVERA. Hypersensitivity reactions reported include: throat constriction, facial edema, urticaria, hives, and wheezing. • Use of Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, due to the potential for alanine transaminase (ALT) elevations.

WARNINGS AND PRECAUTIONS

Thromboembolic Disorders and Other Vascular Conditions

Females are at increased risk for a venous thrombotic event (VTE) when using ANNOVERA.

Stop ANNOVERA if a thrombotic or thromboembolic event occurs, or unexplained loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions and evaluate for retinal vein thrombosis immediately. Stop ANNOVERA at least 4 weeks before and through 2 weeks after major surgery. Start ANNOVERA no earlier than 4 weeks after delivery in females who are not breastfeeding. Before starting ANNOVERA, consider history and risk factors of thrombotic or thromboembolic disorders. ANNOVERA is contraindicated in females with a high risk of arterial or venous thrombotic/thromboembolic diseases.

Arterial Events

Consider cardiovascular risk factors before initiating in all females, particularly those over 35 years. CHCs increase the risk of cardiovascular events and cerebrovascular events, such as stroke and myocardial infarction. The risk is greater among older females (>35 years of age), smokers, and females with hypertension, dyslipidemia, diabetes, or obesity.

Venous Events

The use of CHCs increases the risk of VTE, such as deep vein thrombosis and pulmonary embolism. Risk factors for VTEs include smoking, obesity, and family history of VTE, in addition to other factors that contraindicate use of CHCs. The rates of VTE are even greater during pregnancy, and especially during the postpartum period. The risk of VTE is highest during the first year of CHC use and when restarting hormonal contraception following a break of 4 weeks or longer. The risk of VTE due to CHCs gradually disappears after use is discontinued.

Liver Disease

Impaired Liver Function

ANNOVERA is contraindicated in females with acute hepatitis or severe (decompensated) cirrhosis of the liver. Discontinue ANNOVERA if jaundice develops. Acute liver test abnormalities may necessitate the discontinuation of ANNOVERA use until the liver tests return to normal and ANNOVERA causation has been excluded.

Liver Tumors

ANNOVERA is contraindicated in females with benign or malignant liver tumors. Hepatic adenomas are associated with CHC use (estimated 3.3 cases/100,000 CHC users). Rupture of hepatic adenomas may cause death through intra-abdominal hemorrhage.

Risk of Liver Enzyme Elevations with Concomitant Hepatitis C Treatment

Stop ANNOVERA prior to starting therapy with the combination drug regimen ombitasvir/paritaprevir/ritonavir with or without dasabuvir. ANNOVERA can be restarted 2 weeks following completion of treatment with the Hepatitis C combination drug regimen.

Hypertension

ANNOVERA is contraindicated in females with uncontrolled hypertension or hypertension with vascular disease. For all females, including those with well-controlled hypertension, monitor blood pressure at routine visits and stop ANNOVERA if blood pressure rises significantly.

Age-Related Considerations

The risk for cardiovascular disease and prevalence of risk factors for cardiovascular disease increase with age. Certain conditions, such as smoking and migraine headache without aura, that do not contraindicate CHC use in younger females, are contraindications to use in women over 35 years of age. Consider the presence of underlying risk factors that may increase the risk of cardiovascular disease or VTE, particularly before initiating ANNOVERA for women over 35 years, such as hypertension, diabetes, dyslipidemia, and obesity.

Gallbladder Disease

Studies suggest a small increased relative risk of developing gallbladder disease among CHC users. Use of CHCs may also worsen existing gallbladder disease. A past history of CHC-related cholestasis predicts an increased risk with subsequent CHC use. Females with a history of pregnancy-related cholestasis may be at an increased risk for CHC-related cholestasis.

Adverse Carbohydrate and Lipid Metabolic Effects

Hyperglycemia

ANNOVERA is contraindicated in diabetic females over age 35, or females who have diabetes with hypertension, nephropathy, retinopathy, neuropathy, other vascular disease, or females with diabetes of >20 years duration. ANNOVERA may decrease glucose tolerance. Carefully monitor prediabetic and diabetic females who are taking ANNOVERA.

Dyslipidemia

Consider alternative contraception for females with uncontrolled dyslipidemia. ANNOVERA may cause adverse lipid changes. Females with hypertriglyceridemia, or a family history thereof, may be at an increased risk of pancreatitis when using ANNOVERA.

Headache

ANNOVERA is contraindicated in females with certain headaches. Evaluate new or significant changes in headaches, including migraines, and discontinue ANNOVERA if indicated.

Bleeding Irregularities and Amenorrhea

Females using ANNOVERA may experience unscheduled (breakthrough) bleeding and spotting, especially during the first month of use. If unscheduled bleeding occurs or persists, check for causes such as pregnancy or malignancy.

Based on subject diaries from the two clinical efficacy trials of ANNOVERA, 5–10% of females experienced unscheduled bleeding per 28-day cycle. A total of 41 subjects (1.7%) discontinued use due to menstrual disorders including metrorrhagia, menorrhagia, and abnormal withdrawal bleeding. Females who are not pregnant and use ANNOVERA may experience amenorrhea. Based on subject diary data from two clinical trials for up to 13 cycles, amenorrhea occurred in 3–5% of females per cycle using ANNOVERA and in 0.9% of females in all 13 cycles. If scheduled bleeding does not occur, consider the possibility of pregnancy.

Depression

Carefully observe females with a history of depression and discontinue ANNOVERA if depression recurs to a serious degree.

Cervical Cancer

Some studies suggest that CHCs are associated with an increase in the risk of cervical cancer or intraepithelial neoplasia.

Effect on Binding Globulins

The estrogen component of ANNOVERA may raise the serum concentrations of thyroxine-binding globulin, sex hormone-binding globulin, and cortisol-binding globulin. The dose of replacement thyroid hormone or cortisol therapy may need to be increased.

Hereditary Angioedema

In females with hereditary angioedema, exogenous estrogens may induce or exacerbate symptoms of angioedema.

Chloasma

Chloasma may occur with ANNOVERA use, especially in females with a history of chloasma gravidarum. Advise females who tend to develop chloasma to avoid exposure to the sun or ultraviolet radiation while using ANNOVERA.

Toxic Shock Syndrome (TSS)

If a patient exhibits signs/symptoms of TSS, consider the possibility of this diagnosis, remove ANNOVERA, and initiate appropriate medical evaluation and treatment.

Vaginal Use

Some females are aware of the vaginal system on occasion during the 21 days of use or during coitus, and partners may feel the vaginal system during coitus. ANNOVERA may not be suitable for females with conditions that make the vagina more susceptible to vaginal irritation or ulceration. Vaginal and cervical erosion and/or ulceration has been reported in females using other contraceptive vaginal devices. In some cases, the ring adhered to vaginal tissue, which necessitated removal by a healthcare provider.

ADVERSE REACTIONS

Clinical Trial Experience

Most Common Adverse Reactions

In clinical trials, adverse reactions reported in by ≥5% of ANNOVERA-treated subjects include: headache, including migraine (38.6%); nausea/vomiting (25.0%); vulvovaginal mycotic infection/vaginal candidiasis (14.5%); abdominal pain/lower/upper (13.3%); dysmenorrhea (12.5%); vaginal discharge (11.8%); UTI/cystitis/pyelonephritis/genitourinary tract infection (10.0%); breast pain/tenderness/discomfort (9.5%); metrorrhagia/menstrual disorder (7.5%); diarrhea (7.2%); and genital pruritus (5.5%).

Adverse Reactions Leading to Discontinuation

Among subjects using ANNOVERA for contraception, 12% discontinued from the clinical trials due to an adverse reaction. Adverse reactions leading to discontinuation by ≥1% of ANNOVERA-treated subjects, include: metrorrhagia/menorrhagia (1.7%); headache, including migraine (1.3%), vaginal discharge/vulvovaginal mycotic infections (1.3%); nausea/vomiting (1.2%). In addition, 1.4% of subjects discontinued ANNOVERA use due to vaginal system expulsions.

Serious Adverse Reactions

Serious adverse reactions occurring in ≥2 subjects were: VTEs (deep venous thrombosis, cerebral vein thrombosis, pulmonary embolism); psychiatric events; drug hypersensitivity reactions; and spontaneous abortions.

DRUG INTERACTIONS

Drugs or herbal products that induce certain enzymes, including CYP3A4, may decrease the effectiveness of ANNOVERA or increase breakthrough bleeding. Counsel patients to use a backup or alternative method of contraception when enzyme inducers are used with ANNOVERA. Do not co-administer ANNOVERA with HCV drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, due to potential for ALT elevations.

USE IN SPECIFIC POPULATIONS

Pregnancy

Discontinue ANNOVERA if pregnancy occurs.

Lactation

Not recommended for nursing mothers; can decrease milk production.

Pediatric Use

Safety and efficacy of ANNOVERA have been established in women of reproductive age. Efficacy is expected to be the same for postpubertal adolescents under the age of 18 as for users 18 years and older. Use of ANNOVERA before menarche is not indicated.

Geriatric Use

ANNOVERA has not been studied in females who have reached menopause and is not indicated in this population.

Hepatic Impairment

No studies have been conducted to evaluate the effect of hepatic impairment on the disposition of ANNOVERA. Acute or chronic disturbances of liver function may necessitate the discontinuation of CHC use until markers of liver function return to normal and CHC causation has been excluded.

Renal Impairment

No studies were conducted in subjects with renal impairment; ANNOVERA is not recommended in patients with renal impairment.

Body Mass Index (BMI)/Body Weight

The safety and efficacy of ANNOVERA in females with a BMI >29 kg/m^2 have not been adequately evaluated because this subpopulation was excluded from the clinical trials after 2 VTEs occurred in females with a BMI > 29 kg/m^2. Higher body weight is associated with lower systemic exposure of SA and EE.

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magazines about the LGBTQ community is equally important.[20–24]

It should be expected that staff may encounter challenges and part of building a TIC space is to normalize their reactions. Ideally, an open environment for staff is created in which they can discuss their challenges in working with specific populations, explore their own biases, and receive appropriate supervision and training to overcome obstacles.[20–24] It is unrealistic to expect that HCPs and staff and patients will completely abandon racist, homophobic, or transphobic thinking. However, it is compulsory to set the expectation for respectful behavior regardless of personal attitudes or experiences.[15–19] Working with traumatized and marginalized communities can create vicarious trauma for providers and staff. People who have their own traumatic histories may be triggered by the experiences of patients. Organizational policies can be created and implemented that support staff to recognize their own risks and develop healthy coping strategies.

Conclusion

Effectively implementing a TIC approach to care within a practice takes planning, training, and ongoing evaluation. Exposure to trauma related to gender identity impacts if and how an individual may enter the system of care and respond to it. Thoughtful planning can maximize treatment outcomes and provide a safe, supportive and affirming environment for TGNC individuals seeking care. Ensuring that HCPs and staff have comprehensive training is crucial for creating a healthy care environment. Agency policies and procedures may need to be adapted to promote competent care for TGNC patients and others who have experienced trauma. Including patients who have experienced trauma on advisory committees and agency boards can provide valuable input to ensure culturally competent and accessible care. Effective implementation of a trauma-informed approach to care supports treating all patients in a holistic manner. Trauma-informed practices do their best to ensure that patients do not experience re-traumatization while seeking services.

Research in the area of healthcare for TGNC individuals has increased substantially across multiple disciplines over the last few decades, yet gaps in knowledge remain. More studies are needed to understand the unique trauma experienced by TGNC individuals and to develop best practices to improve care. Curriculum in HCP educational programs and continuing education activities must address TGNC health and healthcare needs. As society becomes more accepting of TGNC individuals, there will be growing opportunities for HCPs, particularly women's and gender-related health nurse practitioners, to expand care to include gender-affirming therapies in clinical practice. Through research, education, and practice, an underserved and vulnerable population can move out of the shadows and receive care with respect and compassion. ■

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