

Prescribing isotretinoin for transgender youth: A pledge for more inclusive care

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Abstract

As the transgender community has become increasingly visible in public life, a greater awareness of this group's unique health needs and obstacles to optimal medical care has developed. Unfortunately, transgender youth face multiple barriers within the health care system, including access to equitable and gender-affirming care. As dermatologists who care for children and adolescents, we must be aware of the challenges facing transgender youth and work to correct the disparities that exist for this vulnerable group. An initial step in supporting our transgender patients is to advocate for changes to the iPLEDGE system for prescribing isotretinoin (and other Risk Evaluation and Mitigation Strategy systems), specifically requesting a change to its gender-binary categorization model that compromises an individual's right to self-identify. By promoting a gender-neutral patient categorization that is based instead upon reproductive potential, a simple change to the iPLEDGE program allows us to safely treat all of our patients requiring isotretinoin, while preserving our transgender patients' rights to self-determination and self-identification.

KEYWORDS

acne, isotretinoin, quality improvement, transgender

Gender identity refers to an individual's personal sense of gender; transgender individuals are those whose gender identity differs from the sex assigned to them by others at birth based on the presence of male or female sex organs ("natal gender").¹ As the transgender community has become increasingly visible in public life, a greater awareness of this group's unique health needs and barriers to optimal medical care has developed.² Transgender youth are at increased risk of sexually transmitted infections, mental health problems, substance use and abuse, body image disorders, and bullying.^{2,3} Furthermore, transgender youth face the additional challenge of finding compassionate medical care tailored to their specific needs that is available, accessible, acceptable, and equitable.^{4,5} Although gender clinics have been established at multiple academic institutions across the United States to help provide comprehensive care to transgender children, accessibility is frequently an obstacle to delivery of this care. Moreover, a considerable lack of confidence in providing appropriate care to transgender youth has been reported by

adolescent medicine physicians and pediatric endocrinologists, the providers who most often care for this population.⁶

As care for transgender youth can be challenging, it is important for all pediatric health care providers, regardless of specialty, to be aware how transgender children differentially access and experience their medical care, and to take proactive steps to better serve this vulnerable population. How can the dermatologist caring for children and adolescents begin to address some of the health disparities that exist for transgender youth? Although a role for the dermatologist in the care of transgender adults has been established,⁷ our guidance is no less vital during adolescence, especially amongst transgender teens undergoing hormone therapy. Specifically, although acne is estimated to have a prevalence of approximately 85% amongst all adolescents and young adults, severe acne is an important reported consequence of masculinizing hormone therapy that may disproportionately affect female-to-male transgender individuals (transgender males).^{8,9} Severe inflammatory or nodulocystic acne predisposes

these individuals to further comorbidities including scarring and mental health problems.¹⁰ It is in the care of this common dermatologic condition that any dermatologist can help support transgender youth.

One of the most effective treatments for severe inflammatory or scarring acne is isotretinoin; this efficacy has also been documented in young transgender males.^{11,12} However, given its teratogenic risk, isotretinoin therapy is closely regulated by the Food and Drug Administration (FDA) via the iPLEDGE program.¹³ Patients registering with iPLEDGE are required to identify as male, female who can get pregnant, or female who cannot get pregnant.¹³ While well-intended, this requirement can be problematic for transgender patients who do not clearly fit into any of these categories. Specifically, it is important to recognize that transgender men who possess a uterus and ovaries can still become pregnant while on masculinizing hormone therapy during or after transitioning.¹⁴ This possibility therefore complicates categorizing young transgender males in the current iPLEDGE program, as transgender males of reproductive potential require two forms of birth control to be compliant with iPLEDGE regulations (notably, testosterone therapy does not qualify or act as contraception) and are thus currently required to be misidentified as female.^{13,14} Advocacy efforts are under way throughout organized medicine to modify this gender-binary patient categorization model in iPLEDGE to a gender-neutral one in which the focus is exclusively based upon child-bearing potential, while preserving the iPLEDGE program's capacity to prevent pregnancies amongst those of reproductive potential.¹⁵ This approach would allow for greater access to isotretinoin and other medications (including mycophenolate mofetil and thalidomide) regulated under the FDA's REMS (Risk Evaluation and Mitigation Strategy) programs, while preserving patient dignity, reducing stigma, and affirming identity.¹⁵

Lack of provider competency in gender expansive and gender-affirming health is recognized by transgender youth and their caregivers as a barrier to care for this population.¹⁶ Although recommendations for creating a supportive and inclusive health care environment for transgender youth are available,^{3,5} even the most welcoming dermatology practice will have problems providing gender-affirming care to patients requiring isotretinoin or other REMS-regulated medications as a result of needlessly restrictive patient identification options. This has implications for the health of transgender adolescents, as the perception that a provider is not engaging them in a gender-affirming way may reinforce feelings of stigmatization and disapproval. This sense of rejection may in turn lead to further feelings of depression, anxiety, suicidality, or substance abuse that are already prevalent amongst this marginalized population.³ Conversely, it is known that family acceptance has a positive impact on the mental and physical health of transgender youth; a thoughtful provider who is able to positively affirm their young transgender patient's sense of self in all aspects of their care will likely benefit this patient's overall health, as well.³

What can we do? Given the current restrictions inherent in the iPLEDGE program, ethically it is recommended that transgender

patients be registered according to their natal gender (ie, transgender males are advised to register as female) in order to be compliant with iPLEDGE requirements and avoid intentionally misidentifying patients within the system.^{15,17} However, for some patients this option may be unacceptable and isotretinoin therapy rejected if a patient is unwilling to register in a manner inconsistent with how they self-identify; alternatively, providers who are uncomfortable discussing gender identity may avoid prescribing isotretinoin even when clinically indicated, leading to adverse patient outcomes. In our clinical experience, adult as well as adolescent transgender males have refused to register as female in iPLEDGE despite ideal candidacy for isotretinoin as they felt that such an action would unacceptably compromise their identity. As such, they were not able to receive appropriate treatment, and one individual in particular temporarily abandoned his medical affirmation therapy in an effort to mitigate the worsening cystic acne. Importantly, these obstacles not only affect our self-identified transgender patients, but may also prevent individuals questioning their gender identity or in the early stages of transitioning from seeking appropriate care and establishing durable therapeutic alliances. Ideally, registering patients in the current iPLEDGE program would initially be made less stigmatizing by having a welcoming, inclusive office environment in which all patients' gender identity is confirmed and supported. The registration process should then be accompanied by a thoughtful conversation with the patient that describes the limitations in patient categorization inherent within the iPLEDGE program and actively affirms their ability to self-identify despite this obstacle. Nevertheless, it is clear that current options are untenable for many transgender patients, resulting in deferral of otherwise indicated treatment by patients and providers alike. Continued advocacy for a system that is based on gender-neutral reproductive potential is therefore warranted, as enacting this change would allow for safe and reliable therapy while retaining our young patients' rights to self-identification and determination.¹⁷ Changes to iPLEDGE have been suggested previously for a number of reasons, and we add our voices to the growing chorus of concerned physicians who believe that small changes to the program will allow us to provide more practical, affirming and compassionate care to all of our patients.^{15,18} A gender-neutral patient categorization model of iPLEDGE is also supported by the American Medical Association¹⁹ and the American Academy of Dermatology,²⁰ and we applaud the Society for Pediatric Dermatology's recent decision to formally request both the FDA and iPLEDGE to endorse this model in the name of patient equity and self-determination. Please join us in calling on the Food and Drug Administration to make the necessary changes to iPLEDGE that allow for equitable and just care for our transgender patients (see supplementary advocacy template online).

ACKNOWLEDGMENTS

We would like to thank Dr. Liz Damstetter and Dr. Kara Sternhell-Blackwell for their assistance in composing the accompanying letter advocating for changes to the iPLEDGE system.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

How to cite this article: Boos MD, Ginsberg BA, Peebles JK. Prescribing isotretinoin for transgender youth: A pledge for more inclusive care. *Pediatr Dermatol*. 2018;00:1-3. <https://doi.org/10.1111/pde.13694>