Ethics in Acne: Transgender Patients and iPLEDGE

Ben Stoff MD, MA (Bioethics)
Emory Department of Dermatology
Emory Center for Ethics
Acne Treatment Controversies: S043
February 18, 2018
DISCLOSURE OF RELEVANT RELATIONSHIPS WITH INDUSTRY

Ben Stoff MD MAB
Acne Treatment Controversies: S043

Ethics in Acne:
Transgender Patients and iPLEDGE

No financial relationships exist with commercial interests
Objectives

• Epidemiology of transgender people in the US
  – Skin disease

• Health disparities

• Cultural/structural awareness
  – Terminology
  – Care environment

• Ethical problem of iPLEDGE for transgender patients
  – Appropriate contraception discussion
Epidemiology of Transgender People in US

• 1.4 million (0.6%) 2014 - increasing

• Trans men receive exogenous testosterone during transitioning:
  – ~90% develop acne < 6 months
  – Most improve >12 months – respond to topicals and oral abx
  – ~30% develop severe alopecia > 10 years

• Chest binding also exacerbates acne

Zucker KJ. Sexual Health 2017
Yeung H et al. JAAD in press
Health Disparities

• Higher rates of STIs, HIV, violence, uninsurance
• 41% attempted suicide
  – 60% among those unable to establish medical care
• 31% lack regular access to care
  – 20% denied healthcare
• 28% harassed in healthcare setting – avoid doctors
• Minority stress model

• Policy priority for NIH, AAMC, ACP, JAHCO
• AAD ERG in 2016

Yeung H et al. JAAD in press
Ulaby N. NPR 2017
Objectives

• Epidemiology of transgender people in the US
  – Skin disease

• Health disparities

• Cultural sensitivity/structural awareness
  – Terminology
  – Care environment

• Ethical problem of iPLEDGE for transgender patients
  – Appropriate contraception discussion
Terminology

• Sex = assigned at birth, based on anatomy
• Gender identity = sense of being man, woman, other
• Gender expression = way of communicating identity

• Transgender = gender identity/expression varies from sex assigned at birth
  – Trans man = female sex assigned at birth, IDs as man
  – Trans woman = male sex assigned at birth, IDs as woman

Yeung H et al. JAAD in press
Controversy Question

• “He, she, or they? What is the correct terminology to use for transgender patients?”
Welcoming/Affirming Care Environment

- Use patient-preferred language
  - “Which pronouns do you use?”
  - “How would you like me to address you?”
  - Include “other, please specify” for ?’s about gender

- Avoid assumptions (e.g. Just “hello” > “hello sir/ma’am”)

- Gender neutral bathrooms

Yeung H et al. JAAD in press
Objectives

• Epidemiology of transgender people in the US
  – Skin disease

• Health disparities

• Cultural/structural awareness
  – Terminology
  – Care environment

• Ethical problem of iPLEDGE for transgender patients
  – Appropriate contraception discussion
iPLEDGE Problems for Transgender Men

• 3 categories
  – Females of reproductive potential
  – Females who cannot get pregnant
  – Males

???

• Some transgender men can get pregnant

Light AD et al. Obstet Gynecol 2014
What Does iPLEDGE Tell Us To Do?

• “Whatever you [the patients] were born with...”

• If not, deemed ‘non-compliant’
  – Citations
  – Termination from program

Katz K JAMA Dermatol 2016
Ethical ‘Dilemma’

**Autonomy**
- Self determination
- Self identification
- Affirm gender identity and expression
- *Action:*
  - Register transgender males as “Males”

**Beneficence/Compliance**
- Contraceptive counseling
- Monitoring
- Comply with iPLEDGE rules
- *Action:*
  - Register transgender males as “Females of reproductive potential”

Yeung H et al. JAAD 2016
Controversy Question

• “What are the contraceptive requirements for iPLEDGE in transgender patients?”
Discussing Contraception With Transgender Patients

• Step 1: Determine child-bearing potential
  – Transgender women = no
  – Transgender men:
    • Hysterectomy, B/L oophrectomy, menopausal/permanent ovarian failure = no
    • Other transgender men = yes (go to step 2)

• Step 2: If the patient has child-bearing potential, consider asking:
  – Plan for hysterectomy or B/L oophrectomy prior to starting drug?
    – If no → step 3
Step 3: Select Appropriate Contraception

The iPLEDGE Program Effective Birth Control Forms

Effective forms of contraception include both primary and secondary forms of contraception:

<table>
<thead>
<tr>
<th>Primary forms</th>
<th>Secondary forms</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Tying my tubes (tubal sterilization)</td>
<td></td>
</tr>
<tr>
<td>• Partner’s vasectomy</td>
<td></td>
</tr>
<tr>
<td>• Intrauterine device</td>
<td></td>
</tr>
<tr>
<td>• Hormonal (combination birth control pills, skin patches, shots, under-the-skin implants, or vaginal ring)</td>
<td></td>
</tr>
</tbody>
</table>

You cannot use 2 hormonal forms together. Progesterone-only “mini-pills” are not effective for the iPLEDGE program.

Female condoms are not an effective secondary form for the iPLEDGE program.

• Are you on testosterone therapy? If yes →
• Testosterone therapy alone is not sufficient (per iPLEDGE)


Yeung H et al. JAAD in press
Solutions

• FDA: *Stop including gender* in classification

• Only *child-bearing potential* is relevant

• Other FDA REMS program drugs: thalidomide, lenalidomide, pomalidomide, and mycophenolate

Katz K JAMA Dermatol 2016
Gender Identity Inclusion and Accountability in REMS D-100.968

Topic: Drugs
Meeting Type: Annual
Policy Subtopic: NA
Year Last Modified: 2017

Our AMA will work with the United States Food and Drug Administration to develop a gender-neutral patient categorization model in Risk Evaluation and Mitigation Strategies programs, focusing exclusively on childbearing potential rather than gender identity.
Summary

• Transgender population in US
  – Small but growing; tremendous disparity
  – Acne is common in trans men on testosterone, may be severe

• Affirming healthcare environment
  – Use patient-preferred language, including pronouns

• iPLEDGE and transgender patients
  – Conflates gender and childbearing potential
  – Contraception discussion based upon childbearing potential
    • Caution: no hormonal contraception in transgender men on testosterone
  – AMA policy: gender neutral categorization for REMS drugs
U072 - LGBT Health: Providing Culturally Competent Care to Patients who are Sexual and Gender Minorities

Sunday, February 18; 4:30 PM - 5:30 PM