Pharmacists' role in pharmacotherapy management of transgender patients

Ashley Floyd, Pharm.D.
PGY1 Community Pharmacy Residency Program
H-E-B Pharmacy
The University of Texas at Austin

Objectives
• Recognize different barriers to care for transgender patients
• List the first line medications for specific transgender populations
• Discuss potential increased risks of hormone therapy during transitioning
• Understand the pharmacists' role in transgender patient care

Patient Scenario
• GH is 34 year old patient and comes to your pharmacy for counseling on the following new medication:
  • Estradiol cypionate  Inject 5 mg IM q week
• When you check the patient profile, it states the GH is a male patient.
• How many of you have encountered this with a patient?
# INTRODUCTION OF GENDER DYSPHORIA AND TRANSGENDER PATIENTS

## Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>Biologic genotype and phenotype without regard of self</td>
</tr>
<tr>
<td>Gender Identity</td>
<td>Inherent sense of being male or female regardless of sex</td>
</tr>
<tr>
<td>Transgender Individual</td>
<td>Individual whose gender identity is different from their sex assigned at birth</td>
</tr>
<tr>
<td>Transsexual</td>
<td>Individual who makes their bodies congruent with their gender identity</td>
</tr>
<tr>
<td>Female-to-Male Individual (FtM)/Male-to-Female Individual (MtF)</td>
<td>Individual whose sex was assigned female/male at birth who has changed their gender role to a more masculine/feminine image</td>
</tr>
<tr>
<td>Transition</td>
<td>Period during which transgender individuals are learning to live as a member of the other sex category OR is beginning hormonal therapy</td>
</tr>
</tbody>
</table>

## Population and Health Disparities

- 0.3% of the United States population
- 700,000 patients total
- 21% of transgender patients avoided ER treatment
- Less likely to have health insurance
- 4 times more likely to test positive for HIV
- Higher risks of tobacco, alcohol, and other substance abuse
- Increased suicide rate (25-43%)
Importance of Pharmacists’ Role

- Hormone therapy
  - Increased risk of cardiovascular disease, type II DM, VTE, etc.
- Surgery
  - Increased risk of infection and urinary incontinence
- Biological sex
  - CrCl and teratogenic drugs
- A healthcare provider to trust

PHARMACOTHERAPY

Therapy Options

- Psychotherapy
- Gender identity, role and expression
- Hormone therapy
- Puberty suppressing therapy
- Masculinizing therapy
- Feminizing therapy
- Surgery

Psychotherapy

- Changing gender expression and role
  - At least for 1 year preceding any other therapy
  - Living part time/full time as the other gender role
- Therapy
  - Individual, couple, family, or group
  - Establish identity and role
  - Improves mental health and body image

Puberty Suppressing Therapy

- For adolescent patients
- Extensive evaluation of psychological, family, and social issues
- Considered fully reversible
- Used as a time to explore their identities
- Prevents development of sexual characteristics

GnRH analogs

- Include goserelin, histrelin, leuprolide, and triptorelin
- All injections or implants
- A/E: limited, injection site reactions, flu-like symptoms, weight gain
- Expensive

GnRH Analogs cont.

- Yearly monitoring:
  - Renal function
  - Liver function
  - Lipid levels
  - Glucose and A1c
  - Bone density tests
  - Every 3 months: sex steroid levels
Masculinizing Therapy

- Testosterone
  - IM, transdermal gel or patch
  - Oral testosterone is not recommended
- Goal: serum testosterone levels of 320-1000ng/dl
- Adverse effects: increased weight, liver dysfunction, lipid changes, acne, erythrocytosis, and aggressiveness
- Concerns with cardiovascular adverse effects

Cardiovascular Risks

<table>
<thead>
<tr>
<th>n</th>
<th>Follow-up</th>
<th>Treatment regimen</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>122</td>
<td>Median duration HRT of 4.6 years</td>
<td>Testosterone enant 250mg i.m. every 2 weeks or transdermal 150mg daily</td>
<td>No increased cardiovascular mortality or mortality rate</td>
</tr>
<tr>
<td>293</td>
<td>Mean duration HRT of 9.6 years</td>
<td>Testosterone enant 250mg i.m. every 2 weeks or transdermal 150mg daily</td>
<td>No increased cardiovascular mortality or mortality rate</td>
</tr>
<tr>
<td>345</td>
<td>Median duration HRT of 18.9 years*</td>
<td>Testosterone enant 250mg i.m. every 2 weeks or transdermal 150mg daily</td>
<td>No increased cardiovascular mortality rate</td>
</tr>
<tr>
<td>110</td>
<td>Median time since HRT 9.5 years</td>
<td>Testosterone enant 250mg i.m. every 2 weeks or transdermal 150mg daily</td>
<td>Higher mortality due to cardiovascular disease compared to controls</td>
</tr>
<tr>
<td>37</td>
<td>Mean duration HRT of 5 years</td>
<td>Different testosterone preparations</td>
<td>No difference in cardiovascular mortality rate and morbidity</td>
</tr>
<tr>
<td>138</td>
<td>Median duration HRT of 5 years</td>
<td>Different testosterone preparations</td>
<td>No difference in cardiovascular mortality compared with controls and morbidity</td>
</tr>
</tbody>
</table>

*Only 110 participants had complete data for duration of HRT.

Pharmacother. 2015;95(12):1130-1139.
Cardiovascular Risks

Studies on cardiovascular endpoints in transmen compared with the general population or control-population.

<table>
<thead>
<tr>
<th>Study</th>
<th>Follow-up</th>
<th>Interventions</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dhejne et al.</td>
<td>Long-term follow-up of transsexual persons undergoing sex reassignment surgery</td>
<td>Transgender group: Not Specified</td>
<td>Higher mortality due to cardiovascular disease compared with control group</td>
</tr>
</tbody>
</table>

CV Risk: Dhejne, et al.

<table>
<thead>
<tr>
<th>Time</th>
<th>Long-term Follow-up of Transsexual Persons Undergoing Sex Reassignment Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects</td>
<td>N=324 transgender patients (133 FtM patients)</td>
</tr>
<tr>
<td>Interventions</td>
<td>Transgender Group: Not Specified</td>
</tr>
<tr>
<td>Compared to patients with similar birthdates and birth sex on the Hospital Discharge Register</td>
<td></td>
</tr>
<tr>
<td>Mean Follow-up</td>
<td>11.4 years</td>
</tr>
<tr>
<td>Results</td>
<td>95% CI: 2.6 (1.2-5.4)</td>
</tr>
<tr>
<td>Strengths</td>
<td>Good sample size</td>
</tr>
<tr>
<td>Long follow-up</td>
<td></td>
</tr>
<tr>
<td>Weaknesses</td>
<td>Mortality due to CV disease was not the primary endpoint</td>
</tr>
<tr>
<td>Data was combined for FtM and MtF patients</td>
<td></td>
</tr>
<tr>
<td>Compared with the general population</td>
<td></td>
</tr>
</tbody>
</table>

### CV Risk: Asscheman H, et al.

<table>
<thead>
<tr>
<th>Title</th>
<th>A long-term follow-up study of mortality in transsexuals receiving treatment with cross-sex hormones</th>
</tr>
</thead>
</table>
| Subjects | N=365 FtM patients  
Age 26.1 +/- 7.6 yrs  
Control: Central Bureau of Statistics of Netherlands |
| Interventions | FtM Group: Prescribed testosterone esters IM 250 mg/2 weeks or testosterone undecanoate 160 mg/28 days  
Control: Central Bureau of Statistics of Netherlands |
| Mean Follow-up | 18.8 +/- 6.3 years |
| Results | One observed case of death due to CV disease  
95% CI: 1.19 (0.39-2.74) |
| Strengths | Large sample size  
Long follow-up |
| Weaknesses | Mortality due to CV disease was not the primary endpoint  
No patients over 56 years of age  
Compared with the general population |


---

### Feminizing therapy

- Estradiol or conjugated estrogens  
  - Oral, IM, or transdermal patch  
  - Goals: serum estradiol levels < 200 pg/ml and testosterone > 55 ng/dl  
  - Adverse effects: increased risk of DVT, elevations in prolactin, weight gain, increased blood pressure, increased insulin resistance, N/V, and headache  
- Concerns about breast cancer incidence


---

### Breast Cancer Risk: Gooren, et al.

<table>
<thead>
<tr>
<th>Title</th>
<th>Breast Cancer Development in Transsexual Subjects Receiving Cross-Sex Hormone Treatment</th>
</tr>
</thead>
</table>
| Subjects | N=2,307 MtF patients  
Age 29.3 +/- 12.7 years  
Control: Dutch incidence numbers of men for breast cancer |
| Interventions | MtF Group: Weakly defined  
Control: Dutch incidence numbers of men for breast cancer |
| Mean Follow-up | 21.4 +/- 8.7 years |
| Results | One observed case of breast cancer  
4.1 per 100,000 person-years; 95% CI: 0.8-13 |
| Strengths | Separated data  
Large patient population |
| Weaknesses | Compared with the general population  
Group intervention was not defined |

Prostate Cancer Risk: Gooren, et al.

<table>
<thead>
<tr>
<th>Title</th>
<th>Prostate cancer incidence in orchidectomised male-to-female transsexual persons treated with oestrogens</th>
</tr>
</thead>
</table>
| Subjects | N=2,306 MtF patients  
Age 29.3 +/- 12.7 years |
| Interventions | MtF Group: surgery and transdermal beta-estradiol 100 µg/day  
Control: Dutch incidence numbers of men |
| Mean Follow-up | 21.6 +/- 8.7 years |
| Results | One observed case of prostate cancer  
Incident rate of 0.13% for subjects over 40 years old (3.18% 10 year incident rate for 40-60 year olds) |
| Strengths | Separated data  
Large patient population |
| Weaknesses | Compared with the general population, not age specific  
No actual statistical analysis |

Health Screening for MtF patients

- Screening guidelines for breast cancer  
  - Every 2 years after age 50  
  - Every 5-10 years while on hormones  
- Prostate cancer screening should be considered  
  - Especially > 20 years of age before transitioning  
- Consider bone mineral density at baseline, if at risk  
  - Previous fracture, family history, chronic steroid use, or prolonged hypogonadism

OTHER CONSIDERATIONS OF CARE
Cultural Competency

- Never make assumptions
- Use of gender pronouns
- Legal name and legal gender
- Consider adding a note to electronic records
- Treat patient with respect

Resources for Pharmacists

- Local:
  - Central Texas Transgender Society
    - http://www.transcentex.org/
- Adolescent care:
  - Genesis program
    - https://www.childrens.com/specialties/specialty-centers-and-
      programs/endocrinology/programs-and-services/genesis-program
- Adult primary care:
  - Transgender Care Listings
    - http://transcaresite.org/
  - Psychological Referral
    - Psychology Today
      - https://therapists.psychologytoday.com/

Pharmacists’ Role

- Know the increased risks for transgender patients
- Identify barriers to care
- Help patients understand their medications
- Provide care with respect in a welcoming environment
PATIENT CASE

Patient Case cont.

GH is 34 year old patient and comes to your pharmacy for counseling on the following new medication: Estradiol cypionate Inject 5 mg IM q week. When you check the patient profile, it states the GH is a male patient.

Which of the following is NOT true when counseling GH?
1. After confirming with GH, place a note in the EMR to address GH as her preferred name.
2. There is no need to measure testosterone for GH.
3. GH needs regular breast and prostate cancer screenings.
4. Counsel GH on signs and symptoms of DVT/PE.

Acknowledgements

Nathan Pope, PharmD
Scott Shelton, PharmD
Lauren Clark, PharmD
Works Cited


QUESTIONS?