

Healthcare Challenges and Unmet Medical Needs of Transgender Teens - FDA-Requested Listening Session (Session #2)

June 29, 2021

Objectives of Session

- To gain a better understanding of the barriers to obtaining health care, areas of unmet medical need, and the most important goals of individuals who are contemplating or undergoing transition to their affirmed gender.

Discussions in FDA Listening Sessions are informal and not meant to replace, but rather complement, existing patient engagement opportunities in the Agency. All opinions, recommendations, and proposals are unofficial and nonbinding on FDA and all other participants. This report summarizes the input provided by persons from the transgender community at the meeting. To the extent possible, the terms used in this summary describe the health needs, perspectives, preferences and impacts reflect those of the individual participants. This report is not meant to be representative of the views and experiences of the entire transgender population or any specific group of individuals or entities. There may be experiences that are not mentioned in this report.

Summary of Discussion by Question

Round 1 – Perspectives related to gender transition

1. In thinking about where you are in your transition right now, what outcomes are most important to you in your transition? What are your ultimate goal/s with regard to your transition?

- All five participants stated that the most important outcome for them at this point in their transition is that their body matches who they are inside.
- One participant noted that safety is a primary outcome in their transition. They expressed that they would like to present as a male to avoid being the potential target of a hate crime.
- One participant shared that their ultimate goal is to have a painless transition.
 - This participant acknowledged that there will be physical pain as part of the surgery process, but they are hoping to achieve an emotionally painless transition process.
- Another participant stated that their ultimate goal is to reach a point where they can present as either masculine or feminine depending on where they are in their transition without fear of judgment by society.

2. Follow up question from CDER's Division of Urology, Obstetrics & Gynecology – I noticed that all but one person has started the process of transitioning. At what point did you first seek out medical assistance for transitioning?

- Four participants responded to this question.
- Two participants mentioned that they have known they were trans since they were able to recognize they were individuals.
- One participant mentioned they have been ready to begin their transition for a long time but were forced to wait due to lack of accessible healthcare for the transgender community.
- One participant mentioned that they have been prescribed testosterone but have not taken it yet. They shared that they had to do a lot of research on their own to determine what they wanted before speaking with their parents and seeing an endocrinologist.

3. FDA recognizes that surgeries, medical procedures, and treatments (such as hormone therapy) can involve potential risks. We are interested in understanding how you view these risks. What risks of treatment or surgeries are you willing to accept to achieve your goals related to your transition? For example, how do you view the potential for serious side effects of hormone treatment, such as strokes and heart attacks? How do you find (or learn about) information on the risks associated with these treatments or surgeries?

- All participants stated that they are willing to accept any risk/s related to surgeries, medical procedures, and treatments in order to achieve their goals related to their transition.
- Two participants shared that they believe the bigger risk is not continuing their transition as it can lead to body and gender dysmorphia which in turn can lead to depression and self-harm.
 - One participant noted that they have already been hospitalized due to an attempted suicide caused by gender dysphoria.
- Three participants mentioned getting information about potential risks from their therapists.
- Three participants stated that their physicians (endocrinologists, surgeons, etc.) have also been helpful with finding information regarding risks.
- The internet was mentioned by three participants as a helpful resource.
- One participant shared that they use forums focusing on the trans community to find information about potential risks.
 - They noted that there are few forums focused on the trans community, and those that do exist are typically catered to adults.
- Another participant stated that they learn about potential risks from their school peers. They shared that they attend a school that has a large trans community, so they are able to gather information from others' experiences.

4. What would you consider to be a significant or meaningful improvement to your quality of life (such as looking or feeling a certain way) that currently is not being addressed?

- Two participants mentioned that better(?) access to information and medications would be a meaningful improvement in their lives.
 - A participant shared that they often go long periods of time between prescription refills due to a variety of unspecified reasons.
- Two participants expressed a desire to be taken seriously by the medical community.
- One participant shared that having top surgery would be a significant improvement to their quality of life.
- Another participant stated that voice therapy would be an important improvement in their quality of life
 - This participant shared a friend's experience with self-attempted vocal therapy that resulted in torn vocal cords.
- A participant said that better understanding by people that there are unobtainable examples of body types for trans people would be meaningful. They used the example of Chris Hemsworth as someone trans men will never look like, but there are ways to work towards that body type.

Round 2 – Healthcare challenges, barriers & unmet medical needs

5. What barriers unrelated to costs or insurance coverage have you experienced accessing the healthcare that you need?

- Two participants expressed that one barrier they have experienced is a lack of medical access for transgender people in certain areas.
 - One participant mentioned that even if you are able to find a gender-affirming healthcare practice within traveling distance there is often a several months-long wait time before seeing a doctor.
 - Another participant stated that oftentimes a referral to a healthcare professional specialized in working with transgender individuals is required and finding a physician to provide a reliable referral is difficult.
- One participant shared that their biggest barrier to accessing the healthcare they need is that they had to undergo procedures related to fertility preservation prior to beginning hormone therapy. The participant described undergoing two rounds of the early stages of the IVF process (e.g. egg retrieval) for the purpose of fertility preservation before going on testosterone.
- One participant noted that societal pressure acts as a barrier.
- State laws related to gender identity and the transgender community were also mentioned as a barrier. One participant stated that they have to get both parents' approval before starting any treatment, which can be harmful if one parent does not accept their child's identity.
- One participant shared that they have been fortunate to have not experienced any barriers to accessing healthcare.

6. What healthcare-related products are your most important need? Are there certain unmet areas of need?

- Four of the five participants stated that better, more accessible binders are an important healthcare product.
 - One participant shared that they have had to order binders through an adult-oriented website. Accessibility such as being sold in department stores would be an important development.
 - Another participant noted that they purchased a binder from an online costume store and broke two ribs.
- Two participants expressed desire for realistic, quality packers.
 - One participant lamented that binders and packers are often viewed as accessories when in reality they are important to trans people's bodies matching their identity.
- Two participants mentioned a need for better testosterone injections.
 - One participant shared that they are allergic to the oil currently used in testosterone injections so they have a reaction at the injection site.
- One participant stated they would like more access to and more information on taking testosterone and the associated risks.
- One participant mentioned they would like to see more studies regarding safety concerns for transgender populations.

Round 3 - Miscellaneous

7. How and where do you find support services, including those related to medical and mental healthcare, that you may need?

- Three participants stated that they often speak with their therapists to find support services.
- Three participants shared that they often reach out to friends for support when needed.
- One participant mentioned that they go to the Trevor Project for support.
 - The Trevor Project provides online resources, a mental health lifeline, and a chat service where they connect you with a therapist.
- One participant mentioned they have connected with a few charities in their area when searching for support services.
- Another participant listed social media as place they turn to when looking for support services.

8. Follow up question – If you were looking for transgender healthcare information how would you like to find info?

- Four participants responded to this follow up question.
- Two participants expressed their wish for information about transgender healthcare to be readily available in school settings like libraries and health classes.
 - Schools offer people with limited resources such as at-home internet, an opportunity to find information.
- One participant stated that they would like to see greater transgender representation in popular culture.
- One participant shared that they would like to see more outreach from the government in regard to information on healthcare needs for the trans community.

9. Follow up question from CDER's Division of Urology, Obstetrics & Gynecology – How old were each of you when you first actively tried to seek out assistance with either approaching transition or wanting to start hormonal treatments? When did you feel you were mature enough to understand your gender identity? What age did you have first conversation with first healthcare provider?

- Four participants responded to this question.
- Two of the participants mentioned that they first realized they wanted to transition around 9 years old.
- Two participants stated that they were around 11 years old when they first decided to seek assistance regarding transitioning medically.
- All the participants who responded noted that they did not discuss treatment options and goals with medical providers until at least a year or two after they had their own realization that they were transgender. Ages at first conversation with healthcare providers were: 15, 12, 14, and 11.

Round 4 - (optional)

10. Is there anything else you would like to share with FDA about your healthcare concerns and needs?

- One participant shared that they would like to see increased accessibility and development in bottom surgery for trans men.

- One participant stated that they have developed asthma due to binding using poorly designed binders.
- Another participant expressed a desire for more government-driven improvements for the trans community to demonstrate that the government values and recognizes the transgender community.
- A participant stated that their family relocates frequently and if they start testosterone/hormone therapy in their current location before moving to another state with stricter requirements they will be forced off testosterone. They are concerned that disparate state requirements and regulations could set their transition back.
- One participant shared that they believe conversations about transgender health needs should happen more openly.

FDA Offices and Divisions Represented

- Office of the Commissioner
 - Office of Patient Affairs (*organizer*)
 - Attendees: Office of Clinical Policy; Office of Clinical Policy & Programs; Office of Combination Products; Office of Minority Health and Health Equity; Office of Pediatric Affairs; Office of Orphan Products Development; Office of Regulatory Science and Innovation; Oncology Center of Excellence
- Center for Biologics Evaluation & Research
 - Attendees: Office of the Center Director
- Center for Devices and Radiological Health
 - Attendees: Division of All Hazards Response, Science and Strategic Partnerships; Division of Health Technology III B; Division of Health Technology III C; Patient Science & Engagement
- Center for Drug Evaluation and Research
 - Division of Urology, Obstetrics, & Gynecology (*requestor*)
 - Other attendees: Compounding Branch 3; Division of Biometrics III; Division of Biometrics IV; Division of Clinical Outcome Assessment; Division of General Diabetes, Lipid Disorders & Obesity; Division of General Endocrinology; Division of Oncology I; Division of Oncology III; Division of Psychiatry; Division of Regulatory Operations for Rare Diseases, Pediatrics, Urology & Reproductive Medicine; Professional Affairs and Stakeholders Engagement Staff; Office of Clinical Pharmacology

Non-FDA Attendees

- Reagan-Udall Foundation for the FDA
- European Medicines Agency

Participants Represented

- Seven participants participated in this session.
- Participants' ages ranged from 13-16.

- Participation in this session were assigned female at birth.
- Participants' gender descriptions include trans-male and non-binary/agender/non-conforming.

Prior to the Listening Session, Participants Shared

- A majority of participants are currently undergoing gender transition.
- A majority of participants shared that their biggest concern regarding their overall health and mental health is denial to healthcare or states' laws restricting their options.

Financial Interest

Participants did not identify financial interests relevant to this meeting and are not receiving compensation for participation in this listening session.