

**Indian Standards of Care for
Persons with Gender Incongruence
and People with Differences in
Sexual Development/Orientation**

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Indian Standards of Care for Persons with Gender Incongruence and People with Differences in Sexual Development/Orientation

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**ATHI in Collaboation with
Jamia Hamdard**



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Preface

Why Indian Standards of Care?

Gender for “humans” is more a matter of the “Being” rather than the “Body”. It is perception of “Who am I?” arising as a result of neural connections made in the biochemical milieu during early development, shaped by environmental influences. It is the pedestal on which the construct of “I” stands. It is an outcome of who one identifies as, the “my kind”, prompted by the “cues” others around them provide, the “who, the person is expected to be”, based on their own perception of “who, the person in question is”. A mismatch of the perception of others with that of the individual is what is termed as Gender Incongruence. The degree of incongruence is propagated by the perception and behavior of the majority in the environment, magnified by their degree of acceptance of diversity which is deeply rooted in the culture and societal norms of the place that the individual belongs to. It has been unequivocally endorsed by the strength of scientific evidence that favorable outcome is directly proportional to the resilience shown by the immediate family and willingness of the care-providers to help the individual navigate the societal hurdles. The task is compounded by the binary viewpoint and poor understanding of the “Transgender Experience” by the agencies, entrusted with the task of giving succor. To make matters worse the majority of the transgender persons have poor health-seeking behaviour as a result of the judgmental attitude of the care providers. The misinformed impressionable “client” is drawn to “Procedures” being offered in an unethical covert manner to a privileged few who can afford the high costs. The nonexistence of Indian Standards of Care and nonadherence to existing protocols in the above situation caused more harm than good, hence necessitating the development of Standards of Care which are both current and Indian in content and context for addressing the needs of the persons with Gender Incongruence and people with differences in sexual development/orientation.

The seed for “ISOC-1: Indian Standards of Care for Persons with Gender Incongruence and People with Differences in Sexual Development/Orientation” was planted by the “Association for Transgender Health in India (ATHI)” in its first International Conference on Transgender Healthcare, IPATHCON 2019, organized in collaboration with Jamia Hamdard deemed to be university, at New Delhi, on the 1st and 2nd November 2019, wherein more than 200 professionals from various specialties and subspecialties, both from the medical and social sciences, working in the field of Transgender Healthcare came together on a single platform to share their academic and clinical experiences and interacted with members of the community in order to understand and address their felt needs. Enriched by the collective experience and encouraged by the success of IPATHCON 2019, a core group of professionals, allies and community members, cutting across various specialties, took on the onerous task of revisiting the rich heritage of the Indian culture which has celebrated and worshipped diversity, reviewing the existing guidelines and current medical evidence, brainstorming with policy makers to curate the best. It is indeed a result of their hard work that we announce with a resounding “Yes” on the 1st of November 2020, the release of benchmark document ISOC-1 to the medical fraternity during the IPATHCON 2020 aptly themed “Indian Standards of Care, are we there?”

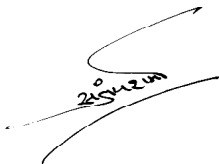
The ISOC-1 endorses the progressive view of WHO which has de-pathologized Gender Incongruence and seeks to fill the lacunae in Transgender Healthcare by formulating best practices which are in sync with the globally accepted Standards of Care published by WPATH, SOC 7 and based on the emerging evidence that conflict arising as a result of incongruity between assigned sex and desired gender magnifies dysphoria and non-resolution may further distort psychosocial development compounded by the insensitive callous attitude of the cisgender majority, perpetuating an environment of mistrust and intolerance forcing the gender incongruent person to further harm at the hands of unscrupulous professionals who peddle pseudo-scientific ‘quick fix’ procedures.

ISOC-1 is a proponent of Affirmative Care, favoring early recognition of gender incongruity, provisioning of a gender-sensitive environment for psychosocial development and early access to Healthcare services stressing the need for adopting a multipronged proactive approach for the management of gender incongruence. The ISOC-1 aspires to be the base document for addressing the stakeholders’ felt-need to acquire and share knowledge, facilitate the delivery of multispecialty Healthcare, empower through advocacy and implement legislation. It presses for a

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holistic public health approach to be adopted by all agencies, both Governmental and Non Governmental, working to ensure equity in the delivery of Healthcare and mandates that existing policies be reworked to address the cause rather than manage the outcomes.

ISOC-1 seeks to be a dynamic document, constantly evolving and stimulating the professionals working in the field of Transgender Health, educationists, academicians, social workers, and community members to step out of their silos, interact with each other, undertake research and share their experiences to improve the successive editions of the Indian Standards of Care, making it a benchmark document for providing holistic and affordable Healthcare to all human forms irrespective of their self-affirmed gender identity or sexual orientation, harnessing the time tested strengths and expertise of the various national and international agencies working with or assisting the government to provide Social Justice and Health for All, laying the foundation of an all-inclusive society, wherein, all forms of gender identity and expression are nurtured and celebrated, where, new abilities emerging as a result of scientific progress permit all form of the human to live in harmony with dignity, embracing diversity and enjoying equal rights and privileges, as bestowed by the constitution.

A handwritten signature in black ink, appearing to read 'Sanjay Sharma', is written over a horizontal line.

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Section 1

Gender Affirmative Care: Mental Health

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Introduction

The problem is social.

The mental health of any individual is impacted by the structures and shape of the world in which they are born and raised. The first step, therefore, in any guideline that aims to help the LGBTQIA+ community would be to identify the nature of the problem and locate it to where it belongs.

We are far from being a world that is affirming of differences and diversity in relation to gender related matters. Historically, many systemic and psychosocial factors have intertwined and led to poor mental health outcomes among LGBTQIA+ individuals (Hafeez et al, 2017). These factors span various social systems such as family, education institutions, employers, government, health care organizations.

Most individuals within these social structures and systems remain unaware of these contributing factors and therefore mental health care of LGBTQIA+ individual is often left to the individual or else to a therapist they are able to access (Wilson et al, 2020). This in itself creates a much higher level of stress and possibly adds to adverse outcomes for an individual. Therefore, the immediate necessity to acknowledge and attempt to address them is essential.

This guideline emphasizes that purely biomedical treatment aimed at the individual is not a complete solution.

“The solutions also need to be created within the social structures, by the social structures.”

The guideline is written in sections. The various sections aim to include the possible role of anyone who is a member of this society, or else part of a social structure or the leader of an organization. Each of these sections attempts to outline and therefore empower the social structure or individual within them, by providing specific ways to help, support and nurture LGBTQIA people.

It fosters the belief that it is as much our responsibility, as members of society, to ensure that each and every individual has the right to an equitable, respectful, safe and healthy life, as it is that of the larger systems, we reside in (Ross et al, 2006).

Understanding the context of a child being brought up in our culture.**The developing sense of self from birth**

Every child needs a secure base, to develop and grow to their full potential. A secure base is formed when the child's basic needs for physical and emotional safety are met, through a secure attachment with a caregiver who is usually, although not necessarily, the mother in the first instance. As the child grows, this widens to include other close members of the family, teachers and friends. It is this secure 'felt experience', during this important stage of early brain development, that will help the child make sense of the world and create a secure sense of self.

The sense of self can only be developed in the context of the 'other' (Brown et al, 2009). It is the sound and tone of a caregiver's voice, their expression and their behaviour in response to a child's needs that allows for the development of a healthy sense of self; of feeling valued, loved, nurtured and also feeling deserving of this. If, for any reason, this is not achieved, the child is likely to develop problems with self-worth, self-esteem and self-confidence, which create an innate vulnerability for the development of mental health difficulties in later years.

The sense of self is also shaped by the complex interplay between Nature (innate inborn traits) vs Nurture (the environment the child grows within; Rutter, 2002). This environment is shaped by the quality and nature of caregiving. Gender forms one part of an integral core of the self. However, even before the child develops an internal awareness of their gender and much later their sexual preference, the world, including parents/caregivers/doctors/nurses, begin to impose their perceived gender upon the child. This, in our culture is usually within a binary male/female construct.

The parents impart this 'supposed fact' to the child, through the use of a male/female name, pronoun, dressing, play and in the direct language and instructions of what their gender role is assumed to be.

Ordinarily, acceptance by the child of their assigned gender is influenced by many factors, including their own internal construct of gender together with the modelling/teaching given by caregivers. Where there is congruence between 'felt sense' of gender and assigned gender, we would not expect dissonance, but one can only imagine the confusion and distress for a child where this is not the case. By now, we are aware that this does occur and is part of natural diversity (Egan et al, 2001).

The perception of not quite ‘fitting in’ within the expected gender construct unsurprisingly leads to emotional distress, and because this is frequently associated with social rejection and ‘non acceptance’, the child’s interactions with the world are perceived through a lens of feeling ‘flawed/different.’ We know that such hurtful and invalidating experiences occurring in a repeated and sustained manner over time, are known to result in emotional trauma, which in turn have a profound impact on the developing brain and future learning.

Thus, it is important to understand the hidden inner world of a child who is growing up in a family and society where the prevailing construct of “binary gender” is seen as a “universal truth”. If such an environment does not entertain even the possibility of existence of a different way of being, this child will need to keep their experience of self, invisible or hidden and perceive it as flawed and therefore, as a corollary themselves as inadequate or flawed. This sense of self has many ramifications on their mental health and wellbeing, many of which are adverse.

The parents and family

It is important to remind ourselves that the behaviour of caregivers may well stem from a well- meaning and non-malevolent stance - with no intent to harm the child, but the dissonance caused by expectations from parents, that the child conform to their assigned gender, nonetheless leads to many of the difficulties described above (Pullen et al, 2020).

Not recognizing that the child might not wish to conform or is unable to naturally conform is just the beginning of the problem between child and the caregiver, or the social structure like school or peer group. Over time this may tragically progress to non-acceptance, ridicule, prejudice, humiliation, frank coercion and even outright abuse and rejection.

The above contextualizes how the child and then adult, grows and gets nurtured in a plethora of social discourses that propagate their “differences” as inadequacy leading to stigma and chronic stress.

The resultant distress may be perceived by society and professionals, as a result of a “disorder” located within the individual. Therefore, the responsibility as well as the need of intervention or care is also mostly targeted at the individual.

However, the contributing determinants resulting in objective distress are also clearly social, therefore, it is essential that the possible management and “care of” is also targeted at the family and social structures.

The following sections indicate possible areas of awareness and solution making.

Section 1: What can you do?

The role of systems

The lived experiences of LGBTQIA+ people are often affected by the larger systems they reside in (Wagaman, 2016). Each person has distinct and dynamic experiences within these social contexts. As a result, there needs to be a greater understanding of individuals and their needs while considering inclusive mental health care and wellbeing in the context of these different social factors. The community discourses and interfaces with the individual often heighten the conflict and create a bigger problem that needs to be navigated essentially by the individual. It is imperative that institutions in varied systems (educational, medico-legal, socio-cultural) are educated about sexual and mental health and human rights of LGBTQIA+ individuals through awareness campaigns and provision of access to basic resources for improved wellbeing. We propose specific guidelines for each of these varied systems and the role they may play in ensuring the well-being of the LGBTQIA+ individual. We provide the following guidelines for individual systems which we hope will be the torchbearers of this change.

What am I?

1. I am a school
2. I am a higher educational institution
3. I am an employer/workplace
4. I am Family
5. I am a Mental Health organization

I am a school

What can you as a system do?

1. Most schools in India advocate binary stereotypes. For example: schools are often described as an “all girls’ school, or an “all-boys school - or the term “Co-education” as a description speaks to a school where “boys and girls” learn together. However, there is absolutely no space to even consider any other framework. Making spaces gender neutral at the very least, and if possible, promoting affirmative practices for acknowledging respect and equality of diversity is essential for social reform practice.

2. The ability to be mindful of developing a non-binary and inclusive system would include educating teachers, management as well as administrative staff
3. Teaching in the school curriculum: Like teaching on sex education and sexual orientation, there should be modules incorporated in the school teaching programmes for gender identity & gender variation. A mindful representation in literature of diversity based on gender and sexual preferences is advised.
4. Normalization of gender variation: Right from preschool/school stage to continue into higher education and the workplace.
5. The established presence and visibility of advocates for the child, role models and supportive adults and peers. For example: calling guest speakers, enacting plays and theatre with representation of diversity would be advised.
6. Supportive and affirming clubs or teams that value and celebrate diversity in gender and sexual preferences in middle school and higher grades.
7. Extra curriculars: Certain sports, dance forms, and even subjects are often populated in a skewed way due to gender-based narratives. For example: Common narratives include “Indian dance forms are overwhelmingly populated by girls in schools”, whereas “sports like football are often populated by boys”. A mindful attempt in schools to help children explore all activities, and encourage gender neutral narratives related to activities, skills and qualities is essential.

I am a higher educational institution

Over the years creating awareness and protecting discrimination against the LGBTQIA+ community has become a matter of concern for everyone including higher educational institutions in India. University Grants Commission, the governing body of Higher education has given a mandate of including an anti-harassment cell, gender sensitization policy which also takes care of ZERO Tolerance for such things in Universities and Colleges. However, currently there are no guidelines for LGBTQIA+ youth.

Here, we propose recommendations at the University/ College level for Teachers and Management to create Emotional Space for LGBTQIA+ youth. These recommendations have been framed after exploring the challenges which the LGBTQIA+ community is facing, what are the related causes, and can be the possible solutions.

What can you as a system do?

1. Abide by the mandatory guidelines given by Higher education regulatory bodies such as UGC and NAAC regarding Gender Sensitization. Along with it, include norms related to the LGBTQ community.
2. Create Awareness among Faculties, Staff, Students, and Administrative people regarding existing policies related to Gender Cell through media campaigns and awareness workshops.
3. Empower Employees, Staff, and students at the time of Orientation about Gender sensitization and norms that everyone needs to abide by at the College/ University Premises.
4. Include Gender Sensitization as part of the course curriculum taught to students in the first semester. Along with its topics related to challenges, causes, and needs of the LGBTQIA+ community should also be included. Inclusion of LGBTQIA+ Topics in Value-added courses will be of great help in promoting awareness and sensitizing students. Inclusion of topics such as Nature Vs nurture, Social Nuances, Diversity in sexual orientation, Gender identities can be included on a wider spectrum.
5. Provide Training, Workshops, Faculty Development Programs, Seminars, Discussion forums for knowledge sharing, and understanding challenges of people belonging to the LGBTQIA+ community and how to overcome them will be very helpful in promoting diverse gender-sensitive environments.
6. Along with teaching exposure in forms of reading material, films, Guest lectures especially by prominent people for LGBTQIA+ community may be organized to understand lived experiences and challenges people are facing and marking the relevance of transformation needed.

I am an employer/workplace

Diversity and Inclusion in the workplace is not just a social but also a business imperative. Diverse workforces create sustainable organizations. Furthermore, companies that embrace LGBTQIA+ policies ensuring mental health of the employees, outperform their competitors. Diversity helps draw top talent and foster innovation, and people perform significantly better when they can be themselves at work (Steiger et al, 2020).

What can you as a system do?

1. Universal Diversity and Inclusion Policy
 - o Include an equality statement in your company's mission. A well-written mission statement should reflect not just the goals, but also the values of your company.
 - o Train staff on diversity and inclusion through awareness campaigns and sensitization workshops. In order to be most effective, diversity and inclusion training should be made available to employees at all levels, not just management. Have consistent focus on building greater awareness around LGBTQIA+ inclusion through workshops and sensitization campaigns
 - o Forming buddy groups or support groups between those who are part of a community and those who are not is a good way to sensitize each segment to the other segment's thought process.
 - o Adopt a clear non-discrimination policy. To ensure that all employees feel safe and comfortable, it's important for organizations to develop clear anti-discrimination policies and then enforce them consistently and fairly. When an employee voices a complaint, be sure to promptly investigate the issue.
2. LGBTQIA specific Diversity and Inclusion Policy
 - o Support and fund employee assistance programme for mental health resources
 - o Offer regular counseling sessions where experts are brought in to offer advice to all employees.
 - o Offer a support network and organize awareness and sensitization workshops.
3. Create, support and fund employee resource groups to encourage open discussions on policy changes that are needed and the support that can help LGBTQIA+ employees perform better in the workplace.
 - Internal Diversity & Inclusion team to raise awareness about LGBTQIA+ individuals in the workplace.
 - Regular and focused sensitization programs to enable individuals to overcome their inherent biases and homophobic ideas.

4. Change workplace culture:
 - Employees should be allowed to select gender when they join the company.
 - Terminology such as 'spouse' could be changed to 'partner'.
 - LGBTQIA+ individuals may be given a paid break for primary caregiving if they choose to adopt.
 - Health insurance coverage and hospitalization benefits should include same sex partners.
 - medical health coverage for any transition-related procedures.
 - Sponsorship of LGBTQIA+ events and job fairs
 - Involvement of senior leadership in all events
 - Mental health leave for LGBTQIA+ individuals

I am Family

In different times in life

1. At birth: Acknowledgement of gender variability at birth: At birth, only the biological gender can be noted and there needs to be acceptance that this may not align with the child's internal representation of self.
2. In early childhood
3. Early puberty
4. If and when a young person comes out: Coming out to family is a defining moment for a queer person. In many ways it informs and shapes how they navigate not only their identity from this point onwards but also their journey as a queer person.

When a loved one comes out to you, they're looking to release a secret they've held for a very, very long time. You are being trusted with a piece of information a lot of queer people feel they can never share with the outside world. For this reason, they can be in a particularly vulnerable state of mind.

As a parent, sibling, friend, or even just as someone important in their lives, your response means the most to them (Politt et al, 2020). There are certain things to remember when this happens:

What can you as a system do?

1. This is about them. Coming out is an emotional moment, as a loved one, despite your own feelings and concerns about the

subject, the first and foremost thing to do is to show them support in their identity as well as their decision to share it with you.

2. Do not imply that you were waiting for them to tell you, unless they ask you. This can set many young queer people into a shame or guilt spiral about not coming to terms with their identity faster. At this present moment, you just need to receive this information.
3. Don't gloss over the more difficult conversations. It's understandable to have questions. Establish an open line of communication with them about their identity. This is going to be a journey they'd like to take you on as they navigate it for themselves. Ask them if they have other queer people in their lives, how they feel about their own identity, what their interaction with the community has been.
4. It's valid to take time for yourself during this time. This is a shift, and for many loved ones, it forces them to shift their own understanding, ideas and expectations of the life you thought your loved one was going to take. Please communicate this to them, let them know that you need time to process this information while reinforcing your love for them.
5. You have the largest resource pool in your own house, it's on your phone. It's likely that your loved one has gone through many readings, videos and resources in their own attempt to understand themselves. Use these resources to understand queer experiences and lives in India. Indian media is known to report horror stories, particularly about queer people. While it's important to keep updated on these, as well as where your loved one's identity stands in our current legislature, it's also equally important to expose yourself to the positive parts of a community that has always managed to fight and thrive
6. As time goes on, talk about telling others. This can be the hardest part for many people. Speak to your loved one, gauge if they'd like to tell other people or keep it a secret for the time being. Indian societal structures are tricky, particularly familial elders. In addition, maybe you're not comfortable with certain people in your life knowing. This is all part of the conversation you need to have with them, and at times help them come out if they'd like you to, to certain people. Do what you feel will cause minimum dissension in both yours and their lives.
7. Queer people navigate their identities in many, different ways after coming out. Some choose to dress in ways that can be

perceived as queer, some choose to go further into their shells, some don't do any of these. There is no linear way to explore your identity, but it is something they look towards doing after they've unloaded their largest secret off of themselves. This is a time you need to let them know they're protected by you.

8. Speak about safety. India being a politically and culturally volatile country, there are many times queer people have to police their own behaviour or expression in order to stay safe. Help them identify these circumstances for their own protection. Furthermore, if you're comfortable discussing if they're sexually active, this is a great time to bring up safe sex and consent

I am a Mental Health Organization

Mental health providers working with LGBTQIA+ youth should be prepared to address disclosure and integration of sexual orientation or gender identity, sexual behavior and risk reduction, use of alcohol and drugs to manage low self-esteem, the effects of discrimination, and the availability of support systems, including families, in and outside the LGBTQIA+ community (Kuzma et al, 2019).

You also need to be aware of your role as an enabler of access and availability for assessment and treatment for those who wish to transition – medical and surgical, together with psychological help for the child/young adult, as well as their caregivers, if this is deemed to be appropriate, on a case-by-case basis (Rutherford et al, 2012).

What can you as a system do?

1. Create an inclusive and nondiscriminatory mental health care environment. Right from the provision in
 - a. The physical spaces, for e.g., Waiting areas with diversity affirmative visuals and messages indicating an LGBTQIA+ - friendly environment (rainbow flags, pink triangles, etc.)
 - b. Including LGBTQIA+-affirming books, magazines, and videos in libraries for waiting areas
 - c. Administrative procedures: Using respectful and inclusive terminology that does not make assumptions about another individual's sexual orientation or gender identity

E.g., Incorporate culturally and linguistically appropriate language and procedures into the intake, data collection, and information sharing process. (provide for preferred name, preferred gender, preferred pronoun)

- i. Review the intake and data collection process and refine the process to accommodate the needs of LGBTQIA+.
 - ii. Create procedures to support and respect youths' ability to self-identify and use language that supports their identity.
 - iii. Include information with youth about how confidentiality is maintained and how information will be shared among staff.
 - d. The service needs to be mindful of usage of affirmative language,
2. Making sure all staff and team are aware of their own concept of gender and sexuality. As this is often binary, it therefore likely to invisibilize the spectrum of difficulties that a LGBTQIA+ individual might bring. The first step usually is for the team and service to acknowledge their own stance and position.
3. Promote reflective practices within the professionals in your organization, and all other staff that help to make diversity visible. Most of the discriminatory stereotypes that exist in a heteronormative structure are invisible to even mental health professionals growing up within that structure.

Ensuring fora and spaces that promote active reflective practice and questioning of dominant discourse about gender and sexual orientation is essential in the workspace.
4. Mental Health Professionals should undergo and subsequently develop staff training programmes for queer affirmative practices. These should address at least the following topics:
 - a. A review of vocabulary and definitions relevant to LGBTQIA+ youth including culture specific labels and not just western labels.
 - b. An exploration of myths and stereotypes regarding LGBTQIA+ youth and adults
 - c. Developmental issues and adaptive strategies for LGBTQIA+ children and youth
 - d. Promoting positive development of LGBTQIA+ children and adolescents
 - e. A review of the coming-out process and how families and adults can support a young person who is coming out
 - f. The issues and challenges unique to transgender youth
 - g. Approaches to working with the families of LGBTQIA+ youth

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- h. Guidance on how to serve LGBTQIA+ youth respectfully and equitably
 - i. Organizational and community resources available to serve LGBTQIA+ youth and their families
 5. Maintaining confidential information appropriately.
 6. Adopt written non-discrimination policies
 - a. Prohibit all forms of harassment and discrimination, including jokes, slurs, and name calling.
 - b. Apply to all personnel from managers to caseworkers, and all direct care staff, and facility staff.
 - c. Include a formal grievance procedure that allows for confidential complaints and neutral third-party investigations.
 7. Prohibit practices that pathologize, punish or criminalize LGBTQIA+ youth.
 - a. Should not condemn, criticize, or pathologize youth who explore their attractions for same-sex youth in an age appropriate, consensual manner.
 - b. Should not practice intervention or therapy that seeks to change sexual orientation or gender dissonance or fluidity.
 8. Promote practices that affirm and celebrate gender and sexual diversity.
 - a. Educate families attending the service about LGBTQIA+ identity and encourage families to allow youth to participate in family activities.
 - b. Openly reaching out to the LGBTQIA+ community to recruit personnel, facility staff, mentors
 9. Promote a progressive and culturally competent environment.
 - a. Include LGBTQIA+ youth and adults in the development of policies, procedures, and practices by creating positions on advisory boards and governing bodies.
 - b. Display signs and symbols that positively represent the LGBTQIA+ community where services are delivered.

The role of Individuals

Stereotypes of all kinds can have an impact on the way LGBTQIA+ people living with mental health issues are treated, both within the LGBTQIA+ community and within the mental health system. People who identify as LGBTQIA+ who also happen to have mental health

issues often experience a double stigma or dual alienation in which they feel they are not accepted within the mental health community because of their LGBTQIA+ identities and are also not accepted within the LGBTQ community because of their mental health issues. It is very important that we as individuals and peers in this community can provide support to ensure the wellbeing of LGBTQIA+ individuals with or without mental illness. As an individual, nonjudgmental and empathetic support towards LGBTQIA+ members of society is intrinsic to improving the well-being and quality of life of these individuals (Garcia et al, 2020).

Who am I?

1. I am a family member/caregiver
2. I am a teacher
3. I am an ally
4. I am a therapist/Mental Health Professional

I am a family member/caregiver

What can you as an individual do?

Role of the family members is probably the most difficult and the most demanding one.

- 1) When a child comes out to you, you need to put your own fears and apprehensions aside and understand what the child is going through. The child is more scared than you are and is putting all their trust in you. Don't break that trust.
- 2) First, accept, and then try to understand. Accept the child's identity, the preferred name and pronoun. Help them with the process. Talk to them on one-to-one basis, discuss options, be an ally rather than an adversary. Read, discuss, know. The documentation and legal procedures may appear daunting to the individual already having identity issues, help them sort it out.
- 3) Be honest in your approach to the child, family, friends and society. Talk to your friends and family. Associate with other families and parents. Meet other parents, children and members of LGBTQIA+, learn from their experience, and share yours with them. Help others go through the process, it will in turn help you understand.

- 4) Don't forget to take care of yourself and other members of the family. There are times when the other sibling feels left out or ignored because too much focus is being given to one child, make sure, they also feel as involved.
- 5) Guide them towards safe spaces, safe attire and safe environments. Help them choose appropriate clothes and accessories.

I am a teacher

What can you as an individual do?

1. Assist and Support Student' needs and concerns individually and separately. It is important to understand gender expression is not a very easy thing in our existing society and culture. And thus, without knowing Gender status, it is not right to impose certain norms which maybe are not suitable for that person.
2. Ensure the right usage of Language: The teacher is an important communication point for any student in the workplace. They help in building the trust of a student in the environment. Thus, it becomes important for them to be sensitive while talking to any student, need to know what words should be avoided, especially the use of homophobic or transphobic language to be avoided as it can offend someone.
3. Confidentiality: A Teacher should be very careful in providing an inclusive environment for all community students. No comments inside or outside should be made on any student related to their gender expression.
4. Promote Positivism: Promoting the culture of positive ethos and providing an environment of open discussion is very important. A teacher needs to talk about the expected environment which will be appreciated in the class. And if discussion on sexual orientation is done that will give students confidence and will provide them validation of their existence.
5. Produce relevant material: While teaching it is very important to cover a broad range of examples related to all categories of gender. Scientific temper and evidence-based examples will help in critical thinking and creating awareness among students about the real facts.

I am an ally

A sense of belonging in a community where we can be ourselves, feel accepted and express ourselves is critical to our mental health. In fact,

being set apart and ostracized has long been seen as a way of punishing what is unacceptable. This happens often with LGBTQIA+ people in mainstream spaces. Finding places and people that are accepting, welcoming, celebrate your identity and make space for fuller expression can be a huge source of relief when you have constantly experienced rejection and suppression. For someone with mental health issues, the community can be a great source of support and acceptance. Any ally is someone who advocates for and supports members of a community other than their own, reaching across differences to achieve mutual goals

Begin initiating conversations around mental health and support a friend who may be experiencing emotional distress. Here are a few ways in which you can help them:

What can you as an individual do?

1. If you think that your loved one is distressed, initiate a conversation with them. At the same time be prepared for the possibility that they are experiencing self-doubt or lower self-esteem and may question their own judgment. This is a period when they require acknowledgement and validation of their emotions from their loved ones.
2. Learn to recognize/identify signs of emotional distress
 - a. Do they begin isolating themselves from others (including people they like), and from their daily activities?
 - b. Do they show a sudden drop in functioning and skip school/work?
 - c. Do they lose interest in things that they used to love doing?
 - d. Do they look consistently sad, teary-eyed?
 - e. Do they have an acute fear of various things and places?
 - f. Are they extremely anxious and irritable?
 - g. Do they have frequent bouts of frustration or uncontrollable anger, or severe mood swings?
 - h. Do they behave in a way that's out of the ordinary (in comparison to how they usually are) They show drastic changes in their sleep patterns, appetite, self-care habits?
3. Listen: Focus your attention on the person you are speaking to and maintain eye contact — this will give them the reassurance that you are being fully present to them. Ask them how they're

coping with their challenges, and how they're feeling. Acknowledge how they feel. Ask specific, open questions: "How are you dealing with that?", or "How can I help?"

4. Offer empathy, not sympathy: Sympathy is when a person feels pity for another person because of what they're going through. We may often feel sympathy for other people when they share their problems with us. Empathy on the other hand is trying to truly understand where the person is coming from. It means hearing someone out, engaging with them, and offering support while keeping aside our own urge to fix their distress. This can happen when we reach out to the other person and connect with what they're experiencing.
 - a. Stay open to their experience, don't assume you understand what they're going through.
 - b. Be aware of the urge to offer suggestions, give advice or share your own story. Remember to keep the focus on the other person.
 - c. Wait until they are finished before you share your own experience or suggestions.
 - d. Ask them how they're feeling instead of making assumptions. For instance, saying, "How do you feel about it?" instead of "Oh! That sounds terrible!" It's okay to not fully understand their circumstances or the situation.
 - e. Listening is about being able to connect with how they are feeling in the moment. Ask before offering suggestions or advice.
 - f. Ask clear, open questions that will help you support them. Such as "How can I help you with that?" or "Is there something you'd like me to do?"
 - g. Gauge your situation and let them know that if they would like to talk, you're there for them

I am a Therapist/Mental Health Professional

What can you as an individual do?

1. Introspection and acknowledgement of own bias: It is entirely likely that you have grown up in a heteronormative, gender binary, promoting culture. This is sure to have constructed an internalized homophobia at worst, or a "normative led social construct for gender and/or sexual orientation "The first step is to acknowledge

the possibility and become aware of your own stance. As a psychologist or Mental Health Professional you must remain aware of how your own attitudes about, and knowledge of, gender identity and gender and sexual preference and expression may affect the quality of care you provide to LGBTQIA+ individuals and their families.

2. Self-reflective practice: Ensure that you have created enough opportunities and forums for self-reflection and continued questioning of your own internal bias.
3. Most Mental Health Practitioners (MHP) in India have not had any training in working with children or youth or adults with gender incongruence, or the spectrum of sexual orientation. However, this is no longer a reason to not support or to not acknowledge the mental health issues that such a client brings in. Create opportunities to read up and stay well informed about current research and ongoing advances about affirmative practice.
4. Learning from the experts: as part of your continuing professional development, learning from clients, advocates, and people with lived experience is essential.
5. Aim to provide nonjudgmental counseling and support and affirm the individual's intrinsic worth regardless of his or her sexual orientation or gender preference.
6. Keep abreast of the language used and the changing terms in the classification systems, as well as the use of appropriate and respectful, non-pathologizing language.
7. Make yourself conversant with the known Mental health difficulties and comorbidities commonly associated with the consequences of navigating the inner world of this diversity and the outer social constructs.
8. Respect confidentiality: There is a reason why most youth keep their "coming out" secret and choose certain spaces and people to come out to. It is a journey and a choice. Confidentiality is not a choice for you as an MHP. It is a necessity.
9. Within the therapeutic space: When someone "comes out" within a session, your first step is to listen. Be accepting and affirming. Strive to understand the specific challenges that the individual is facing. Do not assume that you understand the "generalized challenges" that all diverse individuals would have.

“If you have met one transgender individual, then you have met one transgender individual”. Do not assume that they are representative of the entire LGBTQIA plus community.

10. It is equally important to highlight and amplify the resilience they can develop. Therapeutic space is just as much about identifying and nurturing strengths as about identifying vulnerabilities.
11. There is no particular singular technique of “therapy” that can be learnt. This is not a specialized therapeutic approach. Many therapists in our country refuse or refer out clients for therapy who are seeking help for their journey. This guideline advocates that MHP’s need to change this approach and train and equip themselves to say “yes” to all clients with gender and sexual diversity. The learning is about being inclusive and affirmative.
12. Align practice towards understanding how social change and creating a shift outside the individual therapeutic space is also the work of an affirmative practice.
13. Recognize and remain aware that transgender individuals are more likely to experience positive life outcomes in India when they receive social support, are integrated into their social fabric and/ or receive trans-affirmative care.
14. Documentation: Maintain records and documents about sessions and therapeutic work. Clients should have access to these documents in case they wish to. This may become an important part of witnessing their journey of transition.
15. Taking responsibility and making an effort to enhance Interdisciplinary collaboration - Due to the wide-ranging impact on health, physical and mental health, sexual and reproductive health, surgical and endocrine procedures, family and systemic therapy, legal and social systems, most individuals of the LGBTQIA plus communities have to exert extra effort to navigate the processes required to find appropriate solutions for themselves. Many practitioners in India operate in silos. This leaves the burden of interdisciplinary navigation on the client as an individual. This in itself may result in increased stress and impact the mental health of the individual.
16. Encourage other MHPs’ - strive to increase awareness and a feeling of competence in peers as well as other colleagues and professionals about gender affirmative and diversity celebrating care practices.

17. Writing in popular media: Creating dialogue and increasing conversations that help to generate awareness in popular media, amongst other families, other professionals and medical specialties.

Section 2: Mental Health Care

Expanded guidelines for care of the mental health of LGBTQIA+ identifying Individual as well as their family.

This section will seek to expand on the common findings specifically related to the mental health of **the individual** located within our culture. However, it also strives to understand that more often than not, in India, the mental health care of the **entire family** is often impacted. The acknowledgement that the family needs intervention and “care” is missing.

Common social narratives which directly impact the mental health of this population are represented below (Hall et al, 2018). These act as possible determinants towards adverse outcomes and therefore identifying them clearly and addressing them adequately are an essential part of the mental health care of the identifying individual.

Psychosocial care

1. **Identified psycho-social determinant:** *Lack of present and “normative” role models.* For e.g. Gender Incongruence does not exist in children’s literature, our storytelling, teen movies, or even in adult serious movies or literature except rarely. It is hard to find it even in our local vocabulary. The concept of it being a natural diversity is unavailable therefore the risk of children growing up understanding this as diversity is highly unlikely.

Most narratives that include gender incongruence are mired within mental ill- health, pathology, transition or sensationalism. It forms the basis of “marginalization” and exclusion rather than of being part of a known and natural difference.

Possible solutions: Making sure that LGBTQIA heroes and protagonists are prevalent, the vocabulary, role models and media as well as education systems provide opportunities for these differences to be seen as ordinary human differences is imperative. Popular media, movies, news, print literature to carry stories of real-life role models.

2. **Identified psychosocial determinant:** Inequality and Social-determinants - transgender and gender non-conforming individuals

are at higher risk of experiencing poor health outcomes and restricted access to health care due to increased risk for violence, isolation, and other types of discrimination both inside and outside the health care setting.

Possible solutions: Adding sensitization to medical school curricula, making hospital policies progressive and increasing mandatory diversity-based practices for all health care institutions.

3. **Identified psychosocial determinant:** Increased risk and prevalence of Trauma and its related impact and consequences on both the individual and the family.

This does not just arise from the prevalence of known and established research outlining factually heightened levels of abuse once an individual or family has “come out” to their next level of connectedness.

It is also carried from history and has the burden and force of decades of historical marginalization, invisibility, aggression and violence against individuals who dared to express their individuality or raise their voice. This history that has included the many generations of individuals and their families who had to choose to become invisible and be excluded from living fully integrated social lives, carries the potential to intimidate and create a high degree of perceived trauma in a family and/or child who is growing up with the belief that the collective around them is disapproving and therefore would “punish” or exclude their expression of reality and authenticity.

This reduced and constricted sense of possibility leads often to hopelessness that is pervasive and insidious in its presence within the family and individual’s existence. It often leads to distress and an adverse impact on mental health and social integration of the family and individual.

It also often leads to a feeling and desire of “escape” from the country and culture to allow the idea of possibility that seems to exist in other countries in today’s time.

Possible solutions: Institutions that are held in importance in social narrative may need to come forth to not just acknowledge but apologize for these decades of exclusion and a publicly respectful and compassionate stance towards families and individuals of the LGBTQIA community needs to prevail to help to correct this imbalance and inequity. The author group of these guidelines believe that unless diversity is celebrated, the inequity would continue to prevail.

4. **Identified psychosocial determinant:** Myths and untruths prevalent in social discourse. For example: *Individuals of the community are often misconstrued as hypersexualized/street-walker*. Due to the prevalent social narratives around nonconformity or else diversity in the gender or the sexual preference dimension - there is a “notion” that all individuals identifying as the LGBTQIA community are somehow driven by their sexual desire in all their acts. The reason this statement is used as an example of a “myth” here is because of The absolute untruth in this statement, as well as the prevalence of it despite it being untrue.

Possible solutions: Stories of relatability carried by media, in children’s literature, in news, on TV, in professional fora and a deliberate attempt to include and highlight multidimensional personalities who belong to the community. Rather than sensationalizing the narrative, the attempt to make it relatable and affirming is advised.

5. **Psychosocial determinant:** Absence of accurate or/and respectful language and vocabulary in the vernacular and the resultant adverse impact on mental health.

For example:

- a. A meta-analysis of the National Transgender Discrimination Survey examined respondents who used the “gender not listed here” option on the survey and their experiences with accessing health care. Over a third of the people who chose that option said that they had avoided accessing general care due to bias and fears of social repercussions.^[29]
- b. Most retail outlets, public places, demographic forms, government offices and buildings have toilets, shower rooms, queues, etc. with specific designated “Male” and “female” locations. Most government forms which collect personal or demographic data, all laboratory results of hormonal assays, all identifying surveys that collect results of research studies have gender binary boxes or blanks. The number of places which make the “non-conformist” invisible is too long a list to include here. The invisibilization of individuals who are gender non-conforming or have diverse sexual orientation occurs in the way the entire structure of the above tools is conceptualized and is highlighted due to its absence.
- c. Incorrect name and pronoun use: Often, even after “coming out”, the incorrect use of pronouns continues to be trivialized/dismitted.

These examples outlined lead to a subtle yet intense sense of alienation, or invisibilization and marginalization. Such experiences of pervasive social exclusion prove erosive to the self-esteem of the individual and can cause immense anticipatory fear and anxiety in both the child growing up, and the family.

Possible solutions: Creating respectful language and awareness regarding the importance of inclusion of diversity in all aspects outlined above.

6. Identified psychosocial determinant:

Continuing marginalization in many areas and social structures;
Examples of some absences and inequity as follows

- 6a. Fewer employment opportunities
- 6b. Role of policies- e.g., Trans Act, legalization of same-sex marriages etc.
- 6c. Protection in law: Freedom of choice for the individual to identify and live freely and safely in their chosen gender, should be enshrined in law and include all rights available to other citizens, including the right to work in their field of interest, marry and have children (biological or adopted).
- 6d. Intersection with class/caste/sex/language/gender
 - The role of societal structures in a patriarchy needs to be addressed.
 - Gender: focus on female sexual health as well as male sexual health not just the latter. (refer to relevant section of the guideline)
7. The premise that existing as an individual identifying with the LGBTQIA community, within the current social structures in the present India, limits healthy expression, exploration and therefore the opportunity of fulfilling the potential of human existence and growth in the individual. This aspect seeks to highlight the limiting nature of possibilities for progress and growth rather than just an established adverse impact of an external or internal factor.

For example:

- Limited social circle and difficulty to date and make friends.
- Othering and marginalization becoming an anticipated and expected part of social interface leading to avoidance of exploration.

- Internalization of shame and hate which often could limit exploration of possibility and own potential.
8. In case of development of resilience and the ability to express and assert—impact on mental health.

Biomedical Care

Psychosocial determinant:

The prevalent medicalization/pathologisation of the LGBTQIA population within prevailing medical services and professionals

Possible Solutions: Policies to provide gender-transition related services and sensitive management of intersex variation are needed. Free or subsidized gender transition services, including hormonal therapy and gender-affirmative surgeries, for trans people, and sensitive surgeries, if required, for intersex people need to be provided in government hospitals after proper informed consent – at least in tertiary level government hospitals to start with. (Please refer to relevant section of guidelines for actual recommendations.)

Possible mental healthcare related solutions

Mental Healthcare vulnerabilities and patterns that are historically known to exist via research in our as well as other countries need further study and need to be studied and better known. Identification and looking out for these determinants may in themselves lead to better and efficacious solutions. Studying guidelines like the WPATH guidelines and its evolution and wisdom base may be truly beneficial, if we are able to in parallel understand and truly apply the cultural and local wisdom of prevailing narratives and practices.

Some of these knowledges and patterns are outlined below with citations.

1. STI related mental illness
 - a. HIV and greater risk of STDs and consequential mental health issues
 - b. HIV prevalence among India's transgender community is 26 times higher than the national rate
 - c. HIV prevalence in men who have sex with men is higher
 - d. BUT important to differentiate that not all LGBTQ people in this category are at risk— role of participation and self determination

2. Transition related care for trans individuals who seek it.
 - a. Government has been offering free gender affirming surgery since 2009. However, it is important to remember that this is not available everywhere and NOT all trans people want it.
 - b. Gender affirming treatment associated adjustment to transition are: voice, body image, hormonal changes etc. The availability of this also impacts the sense of hope and possibility that has the potential to alleviate mental distress and consequent ill health.
 - c. No set length of time for psychotherapy, in order to facilitate support and referral to transition services in a timely way
 - d. Those who are transgender are significantly more likely to be diagnosed with anxiety disorders or depression than the general population.
 - e. Self-harm/ mutilation: The vulnerability towards this is likely to increase, especially in the absence of accessible and affordable healthcare and safe procedures.
 - f. Post transition sense of loss, regret, recalibrating expectations. There is emerging research-based evidence for this.
3. Non-transition related care for trans people
 - a. Not all transgender people seek gender affirming treatment.
 - b. Perceived “need” for surgery to be identified as trans. The narrative of trans individual who do not prefer gender affirming surgery may impact the owning of gender identity for some.
 - c. Re-learning autonomy through gender expression
4. Reproductive care for queer cis women
 - a. Polycystic ovaries and infertility were identified as being more common amongst lesbians than heterosexual women. The associated mental health morbidity may need to be looked for specifically.
(refer to relevant section in guidelines)
5. Comorbidities with other mental health problems
 - a. Depression, mood and anxiety disorders are 2–3 times higher than the general population.
 - b. Transgender youth are far more likely than their non-transgender peers to experience depression – nearly four times the risk, according to one study (Reisner 2015). Similarly,

- LGBTQ teens experience significantly more depression symptoms than their heterosexual peers (Marshal 2011).
- c. In a 2016-2017 survey from HRC, 28 percent of LGBTQ youth – including 40 percent of transgender youth – said they felt depressed most or all of the time during the previous 30 days, compared to only 12 percent of non-LGBTQ youth (HRC Foundation 2017).
 - d. High rates of suicide, and self-harm
 - i. LGBTQ young people are more than twice as likely to feel suicidal, and over four times as likely to attempt suicide, compared to heterosexual youth (Kann 2016); the rates may be especially high for bisexual teens (Marshal 2011). According to one study, a third of transgender youth have seriously considered suicide, and one in five has made a suicide attempt (Reisner 2015).
 - ii. Basic issues like restroom access have a profound effect on transgender youth well-being. For instance, one study showed that transgender students denied access to gender appropriate facilities on their college campuses were 45 percent more likely to try to take their own lives (Seelman 2016).
 - iii. According to the CDC's 2015 Youth Risk Behavior Survey, 60 percent of LGBTQ youth reported being so sad or hopeless they stopped doing some of their usual activities (Kann 2016).

Psychosocial care targeting family:

In a collectivist culture like ours where the individual and family is often more closely intertwined than in other more individualist cultures, the “coming out” process, too, is not the individual's alone. It happens in stages and at various levels, the “coming out” to oneself, then the family, and then the family as a unit “coming out” to society at large.

As such, the ripples, challenges and struggles of this process, and the resolution thereof, cannot be seen as an individual process alone. The mental health consequences and challenges of the non-conforming journey, as well responsibility and standards of care, need to address the needs of the familial system just as much as the individual.

Therefore, mental health care practice in India, needs to mindfully include (with the individual's consent) the family.

This also means that recognizing the vulnerable members in the family,

and the adverse impact on the family especially siblings and parents and supporting them in their journey is an essential component of the “care”.

1. Addressing the anxieties and fears within the family:

When a family accompanies or is made aware, or approaches a mental health professional, the ability to discern the needs of the family and answering their doubts and questions is important. To also help them understand their potential role in the affirming journey and address not just their role as caregivers but be alert to the possibility of anxiety disorders or depression or stress related disorders within the members of the family is advised.

Therefore, involving and being able to include the family is an essential ingredient in the mental health practice.

2. The need to balance individuality with the often-unexpressed wish to be accepted within the family.

- a. The Mental Health Practitioner should be willing to balance and respect the need for an individual’s confidentiality with the attempt at creating acceptance within the family.
 - b. Often, the anticipatory fear and the knowledge of the importance of social image to the family is part of the stress on the individual and may contribute to the avoidance of sharing their identity within their family. The MHP needs to remain sensitive and alert to Identifying the appropriate time in the journey of the individual where involvement of the family is possible and may become beneficial.
 - c. The stigma, the shame and potential “letting down” the family - that is often feared but also associated with the context of Indian families and how a child or adolescent represents not just themselves , but as legacy carriers of the entire clan/ family which in turn carries the legacy of the community they identify with is a remarkable cultural factor that needs to be acknowledged and addressed by mental health practitioners and needs to be addressed and located firmly in context and local wisdom.
3. Many of the solutions and advocacy for the community ultimately resides in and is grown by family and allies. Therefore, identifying potential advocates and encouraging colleagues, friends and family members to spread further awareness may also be something that an MHP would be able to do given their vantage point.

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Section 2
Gender Affirmative Care: Pediatrics

Indian Standards of Care for Gender Incongruent Children and Adolescents

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Introduction

Gender perception of a person is something which is very personal. The conventional orthodox thinking that gender is a binary entity is very far from the actual concept of gender. Being trans or gender diverse is a part of the natural spectrum of biological human neurodiversity in the dimension of one's perception of maleness or femaleness. It is, however, commonly accompanied by significant gender dysphoria (GD), which is the distress that arises from incongruence between a person's gender identity and their sex assigned at birth due to lack of understanding and support from the social milieu of that person which includes family in inner proximity circle and society in outer proximity circle.

Trans and gender diverse individuals are at increased risk of harm because of discrimination, social exclusion, bullying, physical assault. (1) Psychiatric comorbidities are seen frequently in children and adolescents who identify themselves as gender diverse. Studies of the mental health of trans young people have found very high rates of them being diagnosed with depression, anxiety, post-traumatic stress disorder, a personality disorder, psychosis or an eating disorder, self-harming and attempting suicide. (2) Increasing evidence demonstrates that early supportive and gender affirming care during childhood and adolescence, can significantly improve mental health and wellbeing outcomes in this group. (3,4, 5) Despite advancements in public awareness and rights of children, trans and gender diverse individuals continue to face disparities from inequitable laws and policies, societal discrimination, and a lack of access to quality health care, including mental health care. Such challenges are often more pronounced for youth who are naive to social expectations and norms regarding gender and may start experiencing gender minority stress. Pediatricians are increasingly encountering such children and adolescents, who are often brought to their clinics by well-meaning and more often than not misinformed parents or guardians or care providers, seeking medical advice and interventions. The lack of the formal training about the care and support of transgender and gender diverse individuals further complicates the issue. Goal of this document is to prime the primary care providers about the approach to this essentially normal manifestation of human neurodiversity.

Nomenclature and definitions

For a better clarification and understanding, a familiarity with the evolving terminology in context of transgender persons is of utmost importance to ensure use of respectful language during communication. It should be ensured that the person is given the opportunity to express and decide their individual preferences.

Sex is a label which is assigned by the medical professional/doctor at birth on the basis of the anatomical phenotype and/or genotype reinforced by the family and society without any say of the child. Most of the time it corroborates with the gender of the child. However, in contrast to the sex assigned, the gender affirmed lies in the personal domain.

Gender identity is the internal perception of the person of his or her maleness or femaleness irrespective of the biological phenotypic sex. Gender can't be conceptualized as binary with one pole as male and the other as female, a whole spectrum does exist in between these two entities with a blend of masculine and feminine identities. Self-recognition of gender identity evolves over time and though most children affirm their gender identity at an early age, however, some may remain undecided or fluid even way beyond adolescence. This is known as **gender fluidity**.

How a person exhibits their inner perception of gender to others by way of pretend play, body language, preferences for toys and trinkets, manner of clothing, hair styles, mannerism etc. is known as **Gender expression**. The objective perception of the gender expression i.e. e. the way others interpret this expression is referred as **Gender perception**.

Sometimes gender expression by the child may not fit in the usual frame of gender perception by the family and society. This *incongruence* between the assigned and affirmed eventually leads to discomfort and progresses to **Gender dysphoria** in the child.

Gender diverse is a blanket term used to describe a plethora of labels which people may apply when their gender identity and/or expression does not conform to the norms and stereotypes as per the expectations of the society. **Transgender Person** is an individual whose gender identity does not match their assigned sex and generally remains persistent and consistent over a significant duration of time. (6)

Table 1: Terminologies and definitions pertinent to gender care.

Terms	Definitions
Sex assigned at birth (SAB)	Sex is assigned at the time of birth, as male or female, based on the appearance of external genital anatomy, internal gonads and chromosomes
Gender identity	A person's inner concept of self being a male, female, mix of both or neither. It can be the same or different from their sex assigned at birth.
Gender expression	How a person wants to celebrate their gender, the external expression of one's gender, in the form of one's name, clothing, behaviour, hairstyle or voice, and which may or may not fit to usual frame of socially defined behaviors and character associated with being either masculine or feminine.
Gender perception	The objective interpretation of a person's gender expression
Gender diverse person	people who do not conform to their society or culture's expectations for males and females. Being transgender is in a way is gender diverse, but not all gender diverse people are transgender.
Transgender person	When someone's gender identity is incongruent with their sex assigned at birth.
Cisgender person	A congruence in gender identity and sex assigned at birth.
Agender person	A person who does not identify self as having a particular gender.
Gender fluid person	A person whose gender identity varies over a period of time.
Non-binary person	A person who doesn't identify exclusively as male or female.
Transwoman	A term to describe someone who was assigned male at birth who identifies as a female.
Transman	A term to describe someone who was assigned female at birth who identifies as a male.

Magnitude of the issue

Questioning and open discussions about gender issues are like the dark side of the moon, less often discussed. In epidemiological surveys, questions related to gender identity are rarely asked, making it difficult to assess the size and characteristics of the population matrix of transgender individuals. Indian census recognized the third gender for the first time while collecting census data in 2011. Data of transgender persons was collected based on details related to their employment, literacy and cast. In India total population of transgender persons as per 2011 census was recorded as around 4.88 lakh with highest number

in Uttar Pradesh. (7) It is a grossly underestimated and skewed data given the stigma regarding those who openly identify themselves as transgender and the difficulty in defining “**transgender**” in the way that is inclusive of all gender-diverse identities.

Taking into account that the recorded prevalence of nonconformity of gender expression in medical text is almost 7% in girls and 5 % boys shows that we have probably not even touched the proverbial tip of the iceberg, the actual figures would certainly be much higher than the 2011 census data of India.

Children become aware of their gender identity at an early age however may not disclose the same till they are older. The average age of disclosure may be as late as 10 years of age. (8)

Understanding gender dysphoria; Biological basis

The term *gender identity disorder* has been replaced by *gender dysphoria*. (9) This change of terminology from disorder to dysphoria draws attention to the stresses caused by the incongruity between an individual’s perceived gender identity and assigned sex, rather than suggesting that the individual’s perception is in itself the result of a disorder. This is a positive step towards de-pathologizing Gender Incongruence.

A label of gender dysphoria should be given to a person who experiences marked discomfort due to difference between the individuals expressed or experienced gender and the gender assigned by others to him or her, and it must continue for a duration of at least six months. When dealing with a gender dysphoric individual, it is important to note that not all individuals express their gender identity in the same way, in fact it is a spectrum of normal biodiversity and each individual may be different.

Biological basis of gender dysphoria

Older theory that early childhood experiences are determining factors in whether someone would become trans or gender diverse is largely refuted due to lack of scientific evidence. A more widely accepted hypothesis that differences in neurological development contribute to establishing a person’s gender identity regardless of the biological sex and is something which is really hardwired in the brain, being a manifestation of neuro diversity.

A study has shown that the white matter of Transgender female (MTF) individuals is more like that of biological females, while the white matter of Transgender male (FTM) individuals is more like that of

biological males. (10) there are multiple studies but till now nothing concrete have surfaced which can clarify this biological variation.

Does the fault lie at the level of society or individual?

Gender diversity is now considered as a normal spectrum of biological variation but due to lack of awareness a disparity in sex and gender of an individual is largely perceived as a social stigma. This raises a question whether it is the society which is “incongruent” with the individual or is it the other way around? Well the answer lies in the fact that it is simply a matter of poor communication and understanding between the individual and society, which will need a lot of effort from supportive groups and health care providers, and can be resolved by acceptance, accommodation and understanding of this issue. Early gender affirmative care by the family and caregiver can help in sorting out the issue and may help in promoting congruence between society and the individual.

Early pointers: red flag signs

Role of the pediatrician and primary care physician is to pick up the signs of gender incongruence at an early stage so that child can be spared of undue and unnecessary emotional trauma and adjustment issues by offering help and support well in time. Certain behavioral patterns may give clue to the early diagnosis of gender dysphoria and may be told or noticed by the parents. Early intervention can be advantageous as gender affirmative care and support can be given early to prevent dysphoria.

Young children and adolescents: signs of gender Incongruence

Signs of gender Incongruence mentioned here are based on observations recorded in the existing literature. These are mere indicators and are influenced by the culture and gender cues. These are seen to be changing gradually over time as the line of demarcation between classical masculine and feminine roles is fading away. Younger children usually express their gender by role play, preference for toys and clothing, hair style and mannerism though there is no clear-cut demarcation or way of expressing the gender identity. Furthermore, the child may not exhibit what is not appreciated by the care giver and closet their true self.

Gender incongruence may manifest in children as:-

- Consistently insisting that they are a different gender – for example, they might say ‘I’m a girl, not a boy’

- Showing signs of unusual anxiety or avoiding being a part of activities which do not match their affirmed gender.
- Getting upset or angry if they're misgendered, called a brother or sister, or boy or girl anything else which does not match with their affirmed gender.
- Showing discomfort in using the washroom of the assigned sex.
- Insisting to be called by a different name and use pronouns which match their affirmed gender.
- A wish to "get rid of" their genitals. Desire to have the genitals of their perceived gender.
- Voicing concerns about their body or expected gender roles.
- Showing signs of anxiety especially in social situations.
- Self-harm like cutting or suicidal ideation
- Rejecting assigned gender roles and showing a fascination with or preference for clothing and activities typically associated with their perceived gender and rejection of the toys, games, clothing and activities associated with his/her assigned sex.
- Portraying the perceived gender roles during Role play / fantasy enactment.
- Puberty is a stressful phase for transgender children and the changes occurring in their body can be extremely distressing to a child with gender Incongruence and it often unmask and enhances gender dysphoria

Mental health support in transgender children and adolescents

Transgender children, adolescents and adults have been documented to have higher rates of depression, anxiety, eating disorders, self-harm, and incidence of suicide. Transgender children may face prejudice and discrimination, which can create or exacerbate emotional and behavioral problems. They often resort to high risk behaviour and substance abuse putting them at risk to lifestyle disorders, physical and sexual abuse and violence. (11)

Studies have reported that up to 56% of youth with a label of transgender reported previous suicidal ideation, 31% reported a previous suicide attempt, in comparison to 20% and 11% among matched youth who identified as cisgender, respectively. (12) A study in transgender persons from the age group 12 -24 showed that 35% had symptoms of depression and almost >50% had suicidal thoughts. (13) Origin of mental illness in transgender is multifactorial, budding from internal conflict between

one's appearance and identity, which is further aggravated by low access to health care providers. This conglomerate causes a feeling of rejection and isolation. (14) Studies have shown that gender nonconforming children (3–9 years of age) have a higher prevalence of anxiety and attention deficit disorders in comparison to their cisgender counterparts. (15)

These all may lead to impairment in peer and family relationships, scholastic performances and an emotional closet formation in the child, a state where he/she no longer shares his psychological world with any other person. It is important to give gender affirmative and participative care from an early age to the gender diverse child by interacting with the caregivers in order to ensure a nurturing environment conducive to the attainment of mental, physical, social and spiritual wellbeing. The pediatrician needs to step into the role of custodian by taking ownership, facilitating delivery of care in accordance to child's perception, helping both the child and caregivers make informed decisions to navigate the nuances of gender and orientation, taking care to prevent/mitigate dysphoria in their turbulent journey through childhood and adolescence with the help of the Gender Affirmation Team consisting of the primary care providers, parents/guardians, educators, mental health professionals, pediatric endocrinologist and social workers.

Role of Pediatrician in early detection support and intervention

Pediatricians in their practice should be careful not to make assumptions about gender identity and sexual orientation, but rather ask how they would describe themselves. A coordinated, multidisciplinary team approach is needed for the delivery of care for the children with gender incongruence and those with differences in sexual development and/or orientation.[16] This gender affirmation team ideally includes trained clinicians with expertise in the disciplines of pediatrics, child and adolescent psychiatry, clinical psychology, adolescent medicine, pediatric endocrinology, gynecology, fertility services, and speech therapy. Ideally the primary care provider should take ownership and facilitate care in accordance to the direction and quantum of care desired by the child, helping them make informed choices for mitigating dysphoria. [17]

Individualized care

Every child or adolescent who presents with concerns regarding their gender will have a unique clinical presentation and their own individual needs. Understanding and using a person's preferred name and pronouns

is vital to the provision of affirming and respectful care of all children and adolescents. Options for intervention that are appropriate for one person might not be helpful for another. Consistent with the above, decision making should be driven by the child or adolescent. The pediatrician teams with the care givers to facilitate the gender affirmation process which includes medical and social transition for both the child and the family/care givers. Pediatrician should utilize the family support groups as a resource and make them a part of the gender affirmation team.

Guiding Principles for affirmative care

- Believe the narrative
- Be sensitive and facilitate
- Mitigate Dysphoria
- Look two decades forwards- address fertility and companionship issues
- Inform – do not scare
- Don't get carried away or overwhelmed by the information overload
- Involve the Gender Affirmation Team – do not do it alone – participative care
- Know the law
- Advocacy is important – Become the voice for the child's rights

Barriers to care in Gender Incongruent pediatric population

Limited access to gender affirming care

Prejudice/ misunderstanding of care givers

Expensive, Transgender Healthcare available mostly in the private institutions

Off-label use of drugs and use of street hormones

No medical insurance and little Government support (barring a few states)

Relatively few clinical programs

Lack of structured training

Lack of Legal support

Importance of early affirmative care

It has been documented that children who have been provided affirmative care from an early age have less mental health issues and less high risk behaviour as compared to those in whom affirmative care is not provided.

Pediatricians should be aware of the practices undertaken by the gender diverse persons to help them pass in their affirmed gender role so that they can assist them and also educate them regarding the risks. The adolescent with gender Incongruence and body image issues may employ makeup, use chest binders, do tucking, use prosthesis and corsets. Safe binding practices include use of a properly fitting binder, limiting their frequency (e.g. by having 'off-days'), and avoiding inflexible or adhesive tape which can cause skin irritability, pain and limitation of chest movement. Chest and axillary infections are described with unsafe practices. [18] [19]

Basic principles for supporting gender incongruent children and adolescents

- Individualize care
- Use respectful and affirming language
- Avoid causing harm.
- Consider sociocultural factors
- Consider legal requirements
- Primary care and creation of the comfort zone
- Referral Chain and support group

Approaches that are not recommended – Approaches that are not recommended and potentially harmful include, redirection, and reparative (conversion) therapy because negative reinforcement (e.g., shaming the child) has substantial mental and social health consequences. [20]

Role of the Gender Affirmation Team in creating nurturing environment for the child with Gender Incongruence and/or differences in sexual development/Orientation

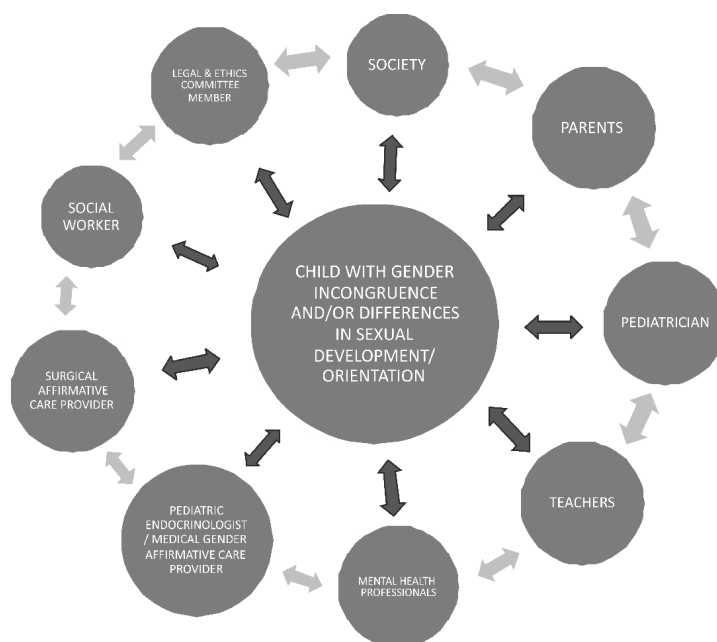


Figure 1: Stakeholders in gender affirmative care team

Creating Social acceptance

The multi-disciplinary/Gender affirmation team identifies how stigma, intolerance, discrimination and aggression has an impact on the health and welfare of trans-children and adolescents [21]

Gender-nonconforming children and adolescents may struggle with a number of general behavioral problems which may stem from minority stress. They are found to be prone to anxiety, have negative emotions and a higher stress response. They are rated lower in self-worth, social competence, and psychological well-being. Often subject to ostracism and bullying from peers, which may negatively impact their psychosocial adjustment and lead to social isolation, loneliness, depression, low self-esteem, behavioral problems, self-harm and suicide. [22] Gender-nonconforming children have more peer relationship difficulties than controls. Children predominantly internalize (anxious and depressed) rather than externalize behavioral difficulties. To assist children and families, individual stigma management strategies, as well as interventions to change the environment, can be offered.

Creating nurturing environment in schools

Evidence states that gender nonconforming children are subjected to bias varying from minor to severe when accessing, school health care services and other social needs.

These children and adolescents are at higher risk of being subjected to discrimination and violence in educational set-up.[27] A large number drop out from schools due to harassment and violence by peers. The gender nonconforming adolescents should be offered psychological care which involves an all-inclusive assessment of early development history, emotional behaviour, peer and social bonding and family support. Legal assistance maybe required to prevent harm.

Creating Family acceptance

Guideline –*Acceptance of thenonconforming children and adolescents by the family has a positive impact on their health.*

Many gender nonconforming children and adolescents are subjected to emotional, mental and physical abuse by family members who reject their narrative. A large number of them leave their natal families and seek support from community members and sects such as the Hijra, Kinnar, Jogtaetc who offer them acceptance. Lack of social support makes them vulnerable to abuse, increased prevalence of substance abuse, high risk behavior, sexually transmitted diseases and violence leading to decreased life expectancy. It has been documented that adolescents with a caring family and a nurturing environment fare well. The adolescent and their parents or caregivers gain from an early evaluation and support by mental health professional / clinical psychologist. [28]

Siblings can be of great help in the management of the child with gender incongruence, especially if the bond between them is strong. More often than not, they become the bridge between the parent and the child who finds it difficult to communicate with parents and other adults. They also become a bridge between the child and the peer group and neighborhood, protecting them from getting bullied. The Pediatrician should try to involve them in the care of the child. Parent Support groups such as **“Sweekar: The Rainbow parents”** can also help by becoming bridges between the care providers, the families and society, helping them cope with the situation.

Creating School acceptance

Guideline - *The multidisciplinary team/Gender affirmation team should understand the need to encourage social reforms that reduces the negative effects of stigma on the health and well-being of gender nonconforming children and adolescents.*

Schools or educational institutions are an integral part of childhood. Every child deserves safe school atmosphere that encourages the learning and healthy development of all students. Psychologists and counsellors play a key role in solving dilemmas related to gender identity. Gender education modules can be introduced for schoolteachers. RCI certified school counsellors who are trained in gender affirmation health care can counsel gender nonconforming children. Schools need to implement stringent policies such as “No Bullying due to Gender”, working closely with the students would be a collaborative approach involving counsellors, social workers, nurses which would offer support to school administrators in creating a safe environment for gender nonconforming children and adolescents. This would be beneficial in reducing the dropping out and prevention of high risk behaviour in adolescents.

Social transition - Individual

Guideline - *The multidisciplinary team/Gender affirmation team should understand that the social transition happens both at the individuals and care-givers level.*

Social transition implies that the individual lives in the gender role which is in harmony with one's gender identity. This includes using pronouns and wearing outfits appropriate to their affirmed gender. Social transition when initiated by the child should be supported by the family. Social transition is beneficial in reducing emotional stress and curtails negative experiences [29].

There are reports which show that gender non-conforming kids who have socially transitioned, demonstrate lesser rates of depression, anxiety and poor self-worth [30]. The Pediatrician plays a key role in making the parents understand the social transition.

Social transition - Care giver

Adolescents may enter into a conflict with and encounter resistance from their parents and siblings when they come out to them with a diverse gender identity or sexual orientation [31]. The parents are informed, they sense the change as sudden and require some time to understand. But the adolescents are experiencing this change for quite a lot of time. The multi-disciplinary team has to have a dual approach

of devoting time for parental support as well as work for the adolescent to evolve a shared understanding between the two.

Guideline – The multidisciplinary team works on speech therapy and voice coaching in trans-adolescents

Voice is a crucial constituent of gender expression. In gender incongruence voice and communication are contrasting between gender identity and style. The multi-disciplinary team should have trained speech therapists and voice coach who can train adolescents to converse in a way which is in harmony with their gender identity [32]. Speech therapy and voice coaching has been beneficial in reducing the dysphoria.

Legal Aspects

Guideline –The multidisciplinary team should safeguard the legal rights of the gender nonconforming individuals

The Government of India has enacted the ‘Transgender Persons Protection of Rights Act 2019’ and published the “Transgender Persons Protection of Rights Rules 2020”.

This lays down process for change of gender markers and enumerates the provisions for delivery of social justice to the transgender persons.

Role of Bioethicist in the Gender affirmation team

Guideline –The multidisciplinary team can consider advice from Bioethicist with respect to conflicting views on management.

Bioethicists can offer advice to gender affirmation team on request to strengthen decision making during a complicated clinical scenario or ethical dilemmas during management. Clinical scenarios like the adolescent has developed dysphoria and yet underaged for taking hormonal therapy. In such scenarios, Bioethicists can give opinion with respect to adolescent’s capacity to give informed consent.

Bioethics and how curriculum can be made gender tolerant

Guideline – Training undergraduate medical students in bioethics modules with respect to gender education and health care

The educational system has to become more inclusive and considerate towards gender congruence. MBBS students should become aware of the fact that stigma does exist. The surrounding pressures of competitive world may contribute in a large way towards the stigma. There are serious consequences of stigma on health issues. Training in medical

ethics aims at grooming a medical student to use moral judgement in testing clinical situations. The need of teaching bioethics to undergraduate medical students by including ethics training into medical curriculum is uniformly recognized all over the world. It is also vital that medical professionals cultivate social and communicative skills in an organized manner to identify and evaluate the unique demands of the gender nonconforming group and avoid hurtful situations that could lead to physical and psychological suffering.

Gaining of these set of life skills, as well as good clinical professional practices, occur mainly in the medical college environment. According to recent guidelines in Competency based curriculum, foundation course would include a module on professionalism and ethics. But in the current times, the curriculum should have modules on gender sensitization. This would immensely benefit the medical students in sensitizing them towards handling complex clinical situations or ethical dilemmas.

Gender Affirmative Medical Intervention in Adolescents presenting with Gender Incongruence

Gender incongruent children and adolescents do not require karyotyping or other genetic tests on a routine basis. Assessment of height, weight, blood pressure, general physical examination, sexual maturity rating (SMR) is done. Investigations like Complete blood picture (CBP), liver function tests (LFT), renal function tests (RFT), blood glucose, lipid profile, hormonal tests like LH, FSH, Testosterone, Estradiol, Prolactin, TSH are done, as required. Extensive hormonal workup is not advised routinely.

Baseline investigations before starting pubertal suppressive intervention

Routine investigations	CBP, LFT, RFT, HbA1C, Lipid Profile
Hormonal profile	LH, FSH, Estradiol, Testosterone, Prolactin, TSH

The medical management of gender incongruent adolescents consists of two tiers of intervention - the suppression of puberty and the induction of pubertal changes of the affirmed gender.

Pubertal suppressive Intervention:

Pubertal suppression is the only intervention that is done till the gender incongruent individual attains the age of consent for gender affirmative hormone intervention. It reduces mental distress associated with the

development of secondary sexual characteristics in gender diverse adolescents. It provides time for the adolescents and their family to explore gender identity, approach psychosocial supports, develop various coping skills, and helps in defining appropriate intervention goals. Prevention of certain irreversible features such as male pattern baldness, protrusion of Adam's apple, voice change, growth of facial bones, etc. ameliorates the need for later surgery. [32]

Pubertal suppression is started after the Tanner stage 2 pubertal status has been achieved. This can be confirmed by the presence of breast buds(B2) or increased testicular volume (≥ 4 ml) (G2), and elevation of Luteinising Hormone, LH to ≥ 0.5 IU/L.

Tanner stages of Puberty(34)

Tanner stages for breast development

1. Prepubertal
2. Breast and papilla elevated as small mound; areolar diameter increased
3. Breast and areola enlarged, no contour separation
4. Areola and papilla form secondary mound
5. Mature; nipple projects, areola part of general breast contour

Tanner stages for penis and testes

1. Prepubertal, testicular volume < 4ml
2. Slight enlargement of penis; enlarged scrotum, pink, texture altered, testes 4-6ml
3. Penis longer, testes larger (8-12 ml)
4. Penis and glans larger, including increase in breadth; testes larger (12-15ml), scrotum dark
5. Penis adult size; testicular volume > 15ml

Eligibility criteria for pubertal suppression [21]

Adolescents are eligible for pubertal suppression intervention (GnRH agonist) if:

1. A qualified MHP has confirmed that:

- the adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria (whether suppressed or expressed),
- gender dysphoria worsened with the onset of puberty,
- any coexisting psychological, medical, or social problems that could interfere with intervention, (e.g., that may compromise adherence to intervention) have been addressed, such that the adolescent's situation and functioning are stable enough to start intervention,
- the adolescent has sufficient mental capacity to give informed consent to this (reversible) intervention,

2. The adolescent:

- has been informed of the effects and side effects of intervention (including potential loss of fertility if the individual subsequently continues with sex hormone intervention) and options to preserve fertility,
- has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the intervention and are involved in supporting the adolescent throughout the process,

3. A pediatric endocrinologist or other clinician experienced in pubertal assessment

- agrees with the indication for pubertal suppression (GnRH agonist) intervention,
- has confirmed that puberty has started in the adolescent (Tanner stage \geq G2/B2),
- has confirmed that there are no medical contraindications to GnRH agonist intervention.

Gonadotrophin-releasing hormone analogues (GnRH analogues) can be used in adolescents with gender incongruence to suppress the development of secondary sexual characteristics. They act by suppressing the secretion of pituitary gonadotrophins and thereby, gonadal steroids. They cause regression of secondary sexual characteristics that have already developed, and later, the puberty gets arrested. The breast tissue becomes atrophic and menses will stop. Virilization will stop and testicular volume may decrease. Some studies reported low bone mineral density (BMD) in individuals on GnRH analogues while others showed no association. The individuals should be given adequate calcium supplementation, advised adequate physical activity, and vitamin D deficiency, if associated, should be treated. Body weight, height and Blood pressure should be recorded in every visit as arterial hypertension can be a side effect of GnRH analogues.

Progestin preparations like depot medroxyprogesterone can be a reasonable option for individuals who cannot afford GnRH analogues or have needle phobia. They are not as effective as GnRH analogues and may be associated with side effects. In post pubertal adolescents receiving gender affirmative feminizing intervention, androgen receptor blockers like spironolactone can be given if GnRH analogues are not available. [35]

Early pubertal suppression may compromise fertility and these issues must be discussed before starting pubertal suppression therapy. Pubertal suppression may cause lower self-esteem in some adolescents as the puberty gets delayed beyond their peer group. According to Some experts, underdevelopment of genitalia due to pubertal suppression may limit some potential reconstructive options. [36] However, compared with starting gender-affirming hormone intervention in the late stages of puberty, early pubertal suppression may be associated with better psychological and physical outcomes.

Pubertal suppressive intervention

Resource rich setting (first line therapy)	GnRH analogues	More effective	Expensive Injectable
Resource poor setting	Medroxyprogesterone acetate	Less effective	Economical Oral/injectable

Baseline and follow up monitoring during pubertal suppression [37]

Every 3–6 months

Anthropometry: height, weight, sitting height, blood pressure, Tanner stages

Every 6–12 months

Laboratory: LH, FSH, E2/T, 25OH vitamin D

Every 1 –2 years

Bone density using DXA

Bone age on X-ray of the left hand (if clinically indicated)

DXA - Dual-energy X-ray absorptiometry

Induction of secondary sexual characteristics of the affirmed gender (Gender Affirmative Hormonal Intervention)

The hormonal intervention done to gender incongruent individuals, to better align gender expression with their gender identity is Gender affirmative hormonal intervention.

In India, the legal age limit for informed consent is above 18 years. So, Gender affirmative hormonal intervention is started after the age of 18 years.

It mainly consists of giving sex steroids in the form of Estrogen to feminize adolescents and Testosterone to masculinize adolescents for the development of secondary sexual characteristics.

Eligibility criteria for Gender affirmative hormonal intervention in adolescents [21] *

Adolescents are eligible for subsequent gender affirmative hormonal intervention if:

1. A qualified MHP has confirmed:

- the persistence of gender dysphoria,
- any coexisting psychological, medical, or social problems that could interfere with intervention (e.g., that may compromise adherence to intervention) have been addressed, such that the adolescent's situation and functioning are stable enough to start gender affirmative hormonal intervention,
- the adolescent has sufficient mental capacity (which most adolescents have by age 16 years) to estimate the consequences of this (partly) irreversible intervention, weigh the benefits and risks, and give informed consent to this (partly) irreversible intervention,

2. The adolescent:

- has been informed of the (irreversible) effects and side effects of intervention (including potential loss of fertility and options to preserve fertility),
- has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the intervention and are involved in supporting the adolescent throughout the process,

3. A pediatric endocrinologist or other clinician experienced in pubertal induction:

- agrees with the indication for gender affirmative hormonal intervention,
- has confirmed that there are no medical contraindications to gender affirmative hormonal intervention

*Though the literature uses the word treatment, we prefer the term interventionm

Gender affirmative feminizing interventions in adolescents

Oral estrogen preparation like 17 β -estradiol or estradiol valerate is started at a lower dose and titrated up gradually, every 6 months, till the adult dosage is reached. Transdermal 17 β -estradiol may be an alternative but is not used because of poor availability and higher cost associated. Also, the absence of low dose estrogen patches is a problem. The individuals may need to cut patches to achieve appropriate dosing. [38]

When puberty is initiated with estrogen at low doses, the initial levels will not be adequate to suppress endogenous testosterone secretion and can interfere with the effectiveness of estrogen treatment. Hence, GnRH analogue treatment is continued until gonadectomy. However, if the individual wants to discontinue GnRH analogue treatment, an antiandrogen like spironolactone can be added.

Gender affirmative masculinizing interventions in adolescents

Testosterone injections are given intramuscularly or subcutaneously, starting with a low dose and gradually titrating up the dose every 6 months, till the adult dose is reached. Transdermal preparations of testosterone are available too. GnRH analogue treatment can be discontinued once an adult dose of testosterone has been reached and the individual is well virilized. [5]

In every visit, the individual should be monitored for height, weight, blood pressure, and secondary sexual characteristics. Ideally, specific growth charts for gender incongruent children would be better; given the lack of availability/ possibility of having one, the pediatrician should be gender inclusive while interpreting the growth charts to those children or their families.

Protocol for induction of puberty [37]

Induction of female puberty with oral 17 β -estradiol, increasing the dose every 6 months:

5 μ g/kg/d

10 μ g/kg/d

15 μ g/kg/d

20 μ g/kg/d

Adult dose = 2–6 mg/d

In postpubertal adolescents, the dose of 17 β -estradiol can be increased more rapidly:

1 mg/d for 6 months

2 mg/d

Induction of female puberty with transdermal 17 β -estradiol, increasing the dose every 6 months (new patch is placed every 3.5 d):

6.25–12.5 mg/24 h (cut 25-mg patch into quarters, then halves)

25 mg/24 h

37.5 mg/24 h

Adult dose 50–200 mg/24 h

Adjust maintenance dose to mimic physiological estradiol levels (100–200 pg/ml)

Induction of male puberty with testosterone esters increasing the dose every 6 months (IM or SC):

25 mg/m²/2 wk (or alternatively, half this dose weekly, or double the dose every 4 wk)

50 mg/m²/2 wk

75 mg/m²/2 wk

100 mg/m²/2 wk

Adult dose = 100–200 mg every 2 wk

In post pubertal adolescents, the dose of testosterone esters can be increased more rapidly:

75 mg/2 wk. for 6 months

125 mg/2 wk.

Adjust maintenance dose to mimic physiological testosterone levels (400–700 ng/dl)

Baseline and follow up monitoring of pubertal induction [37]

Every 3–6 months

- Anthropometry: height, weight, sitting height, blood pressure, Tanner stages

Every 6–12 months

- Gender affirmative masculinizing intervention: hemoglobin/hematocrit, lipids, testosterone, 25OH vitamin D
- Gender affirmative feminizing intervention: prolactin, estradiol, 25OH vitamin D

Every 1–2 years

- Bone Mineral Density (BMD) using DXA
- Bone age on X-ray of the left hand (if clinically indicated) BMD should be monitored into adulthood (until the age of 25–30 y or until peak bone mass has been reached).

Surgical management

Genital surgery is not commonly performed before the age of 18 years due to the irreversibility of the process, with impact on the adolescent's future sexual function and reproductive potential. It should be performed by a surgeon with expertise and experience in the field.

Follow up and transition to adult care

After having treated in a pediatric setting for several years, transition to adult healthcare services can be a source of significant anxiety for gender incongruent adolescents and their family. The pediatrician should discuss with them regarding the need for transition of care, apriori. For adolescents who have associated psychiatric disorders or who are at high risk of self-harm or suicide, ongoing care from a mental health professional is required.

CONCLUSION

Each family has its unique dynamics and the pediatrician needs to understand them in order to give affirmative and participative care, which in light of current medical evidence and available standards of care, is what is expected from a medical professional.

Points to remember:

- 1 Early recognition
 - Individualized care
 - Use respectful affirmative language
 - Avoid causing harm
 - Assessment of co morbidities
- 2 Support
 - Psychological support
 - Gender affirming approach
 - Supportive and safe home environment
- 3 Education
- 4 Advocacy on behalf of child and family
- 5 Coordinate team efforts
- 6 Consider socio-cultural and legal factors
- 7 Facilitate social transition as early as possible

- 8 Proper and timely referrals for hormonal Intervention and/or surgery

Follow the LEADER Strategy

Pediatrician should ideally take the lead and employ the mnemonic **LEARN**.

L - Look, Listen and Learn from the child, the child's gender identity

E - Educate- self, parents and society

A - Advocate - the rights of the child - Home & Educational institution

R - Resource - for parents' children and society

N - be Non-judgmental

Since it is an evolving field, the Pediatricians need to be up to date with the current medical evidence.

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Section 3
Gender Affirmative Medical Care:
Hormonal Intervention

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Recommendations for Those Involved in the Gender-Affirming Hormonal Intervention of Individuals with GD/Gender Incongruence

Criteria for hormonal intervention

1. Persistent, well-documented Gender Dysphoria
2. Capacity to make a fully informed decision and to consent for intervention
3. Age of majority in a given country
4. If significant medical or mental health concerns are present, they must be reasonably well controlled [1]

Competency of Hormone-Prescribing Physicians

Primary care clinicians can learn to safely and effectively provide hormonal interventions, preventive care, and surgical follow-up through basic training and practice. Despite common concerns that transgender health care is complicated, it is in fact as straightforward as managing common chronic diseases.

The general approach to gender-affirming hormonal intervention first requires counseling individuals on the benefits and potential risks of intervention, including options for fertility preservation. Typically, the next step involves delivering estradiol for feminization, or testosterone for masculinization. Intervention may also consist of an additional medication to suppress endogenous hormones, particularly in the case of feminization. Once intervention has begun, clinicians track progress toward desired effects and monitor for potential side effects.

Sometimes a core team (eg, a physician, nurse, and mental health clinician) initially trains together and then meets regularly to discuss cases. A program can also begin with a single clinician who gradually trains others within the organization through shadowing opportunities, consultation, and didactic learning.

Feminizing/masculinizing hormonal intervention is best undertaken in the context of a complete approach to health care that includes comprehensive primary care and a coordinated approach to psychosocial issues. Many of the screening tasks and management of comorbidities associated with long-term hormone use, such as cardiovascular risk factors and cancer screening, fall more uniformly within the scope of primary care rather than specialist care.

While psychotherapy or ongoing counseling is not required for the initiation of hormonal intervention, if a therapist is involved, then regular communication among health professionals is advised.

Given the multidisciplinary needs of transsexual, transgender, and gender-nonconforming people seeking hormonal interventions, as well as the difficulties associated with fragmentation of care in general, WHO / WPATH strongly encourages the increased training and involvement of primary care providers in the area of feminizing/masculinizing hormonal interventions. If hormones are prescribed by a specialist, there should be close communication with the individual's primary care provider. Conversely, an experienced hormone provider or endocrinologist should be involved if the primary care physician has no experience with this type of hormonal replacement or if the individual has a pre-existing metabolic or endocrine disorder that could be affected by endocrine interventions.

Although only a handful of clinical training programs offer transgender health care within their existing standardized curricula. While formal training programs in transgender medicine do not yet exist, hormone providers have a responsibility to obtain appropriate knowledge and experience in this field. Clinicians can increase their experience and comfort in providing feminizing/masculinizing hormones by co-managing care or consulting with a more experienced provider. Because this field of medicine is evolving, clinicians should become familiar and keep current with the medical literature and discuss emerging issues with colleagues.

Responsibilities of Hormone-Prescribing Physicians

In general, clinicians who prescribe hormones should engage in the following tasks:

1. Perform an initial evaluation that includes discussion of a transgender individual's physical transition goals, health history, physical examination, risk assessment, and relevant laboratory tests.
2. Confirm that individuals have the capacity to understand the risks and benefits of intervention and are capable of making an informed decision about medical care.
3. Discuss with them the expected effects of feminizing/masculinizing medications and the possible adverse health effects. These effects can include a reduction in fertility

4. Provide ongoing medical monitoring, including regular physical and laboratory examination to monitor hormone effectiveness and side effects.
5. Communicate as needed with an individual's primary care provider, mental health professional, and surgeon.

Staff Training and Competencies

It is very important for all transgender individual-facing staff (clinical and nonclinical) to receive a foundational level of training in cultural sensitivity and effective communication with transgender and gender-diverse individuals.

Key competencies include

1. Using individuals' correct names and pronouns
2. Maintaining confidentiality of gender identities,
3. Avoiding assumptions about gender
4. Being open to non-binary gender identities
5. Avoiding questions not pertinent to care

If hiring new staff, programs should aim to hire transgender and gender-diverse employees, some of whom may identify themselves during the needs-assessment process. At the same time, programs ought to take caution against unconsciously tokenizing or outing transgender and gender-diverse staff or expecting these staff to educate their colleagues or become public spokespersons unless they wish to serve in this role.

Referral for Feminizing/Masculinizing Hormonal interventions

Hormones can be initiated with referral from two qualified MHPs (Although the WPATH SOC 7th version recommends referral from one MHP, but regional medical experts suggest two referrals, as mentioned earlier). One of the two MHPs should be a qualified Psychiatrist as the medical experts suggest. It is also preferable, if the first referral is from the individuals psychotherapist/Psychiatrist, the second referral be from an MHP who has only had an evaluative role with the client. Two separate letters, or one letter signed by both (e.g., if practicing within the same clinic) may be sent. MHPs who refer for hormonal intervention share the ethical and legal responsibility for that decision with the physician who provides the service but should not be held responsible for any physical complication arising out of hormonal interventions.[2]

Informed Consent

The effects of hormonal interventions are not always reversible. Feminizing/masculinizing hormones may lead to irreversible physical changes. Therefore, care should be taken before taking decision about undergoing hormonal interventions and it should be provided only to those who are legally able to provide informed consent. Comprehensive information has to be provided about relevant aspects of the hormonal interventions, possible benefits and risks. Obtaining informed consent for hormonal intervention is an important task of health providers to ensure that transgender individuals understand the psychological and physical benefits and risks of hormonal interventions as well as its psychosocial implications.[3]

Physical Effects of Hormonal interventions

Feminizing/masculinizing hormones will induce physical changes that are more congruent with an individual's gender identity. Most physical changes, whether feminizing or masculinizing, occur over the course of two years. There is a great deal of variability between individuals, as evidenced during physiological pubertal development. The initiation of intervention should be preceded by a detailed discussion about the hormonal regimen, the possible physical changes expected, and the duration taken for the changes to appear especially in a resource limited setting like ours.

In FtM individuals, the following physical changes are expected to occur: - deepened voice, clitoral enlargement, growth in facial and body hair, cessation of menstrual cycle, atrophy of breast tissue, and decreased percentage of body fat compared to muscle mass.

In MtF individuals, the following physical changes are expected to occur: - breast growth, facial hair reduction, decreased erectile function, decreased testicular size, and increased percentage of body fat compared to muscle mass. [2]

Tables 1a and 1b outline the approximate time course of these physical changes

Masculinizing hormone effects timeline

Effect	Expected Onset	Expected maximum effect	Reversibility
Acne/ oily skin	1-6 months	1-2 years	Likely
Cessation of menstrual cycles	2-6 months	NA	Likely
Body fat redistribution	3-6 months	2-5 years	Likely
Facial and body hair growth	3-6 months	3-5 years	Unlikely
Deepening of voice	3-12 months	1-2 years	Not possible
Clitoral enlargement	3-6 months	1-2 years	Unlikely
Vaginal atrophy	3-12 months	1-2 years	Unlikely
Scalp hair loss	>12 months	Variable	Unlikely
Increased muscle mass & strength	6-12 months	2-5 years	Likely

The onset of effects from hormone treatment may take months to occur with the maximum effect taking years to achieve. Changes are partly dependent on the type and dose of medications, route of administration and the medical risk profile of the individual. In Feminizing hormonal intervention, facial and body hair growth and scalp hair loss are highly dependent on age and inheritance while muscle strength is significantly dependent on the amount of exercise.

Feminizing hormone effects timeline

Effect	Expected Onset	Expected maximum effect	Reversibility
Decreased libido and spontaneous erections	1-3 months	6 months -2 years	Likely
Breast growth	3-6 months	2-3 years	Not possible
Skin softening	3-6 months	2-3 years	Likely
Decreased testicular volume	3-6 months	2-3 years	Unknown
Body fat redistribution	3-6 months	2-5 years	Likely
Decreased muscle mass & strength	3-6 months	1-2 years	Likely
Decreased body and facial hair	6-12 months	>3 years	Possible
Scalp hair regrowth	Loss stops in 1-3 months	1-2 years	Likely
Decreased spermproduction	Variable	Variable	Unknown

Complete removal of facial and body hair by feminizing hormonal intervention is not possible; it requires additional procedures like electrolysis, laser etc. Over a long period of time, the prostate gland and testicles will undergo atrophy. Clear expectations for the extent

and timing of sex hormone-induced changes may prevent the potential harm and expense of unnecessary procedures.

Baseline Laboratory Tests

(Before starting intervention)

Hormone provider clinicians should be knowledgeable about routine monitoring of hormone levels. Before initiating hormones, selected laboratory tests are recommended. Baseline gonadal hormones, biochemical parameters and bone mineral density are done for future reference. Many medical conditions can be exacerbated by hormone depletion and many by cross-sex hormones. Laboratory tests are done at baseline and on follow up to address these issues. The current recommendation for baseline evaluation is congruent with the guidelines published by professional bodies, namely The Endocrine Society, The World Professional Association for Transgender Health (WPATH) and Integrated Diabetes and Endocrine Academy (IDEA), India.[3]

Recommendation

Transfeminine (MtF):	
Concise: (Resource limited setting)	Estradiol, testosterone, lipid profile, fasting plasma glucose, liver enzymes, prolactin, electrolytes, creatinine, thyroid function test, follicle-stimulating hormone (FSH), luteinizing hormone (LH), hepatitis B surface antigen (HbsAg)
Additional tests: (Resource rich setting)	Complete blood count, HbA1c, Karyotyping, coagulation profile, anti-Hepatitis C antibody, VDRL, tests for human immunodeficiency virus (HIV), prostate-specific antigen (PSA), bone mineral density using DXA
Transmasculine (FtM):	
Concise: (Resource limited setting)	Estradiol, Testosterone, Lipid profile, fasting glucose, complete blood count, liver enzymes, creatinine, thyroid function test, follicle-stimulating hormone (FSH), luteinizing hormone (LH), hepatitis B surface antigen (HbsAg)
Additional tests: (Resource rich setting)	HbA1c, Karyotyping, anti-Hepatitis C antibody, VDRL, tests for human immunodeficiency virus (HIV), bone mineral density using DXA.

Feminizing hormonal intervention

The hormonal intervention in gender incongruent males is complex as estrogen alone is not enough to suppress endogenous testosterone production. Hence, there is a need for concomitant anti androgens or GnRH analogues in most individuals. Anti-androgenic

drugs used are spironolactone, 5 α reductase inhibitors, GnRH agonists and Cyproterone acetate. They also minimize the dosage of Estrogens needed; thereby reducing the risks associated with high dose exogenous Estrogens. [5,6]

Estrogen is required in supraphysiological doses, and estrogen requirement is more in those who are not receiving GnRH and in those who have not undergone gonadectomy. The dose is gradually up titrated to keep balance between the clinical response on one hand and risk of side effect on the other. Use of progestins is controversial because of its beneficial role in feminization process, optimisation of breast maturation, increase in bone formation and possible cardiovascular health benefits. But it does not lower the serum testosterone levels and is associated with many side effects. Below table shows different preparations of oral estrogens available in India.[3]

Estrogen preparations	Dose	Advantages	Limitations
Oral Estradiol valerate	2-8 mg/day	Levels can be monitored Less risk of VTE	Risk of VTE
Oral 17 beta Estradiol	1-6 mg/daily	Inexpensive Levels can be monitored	High risk of VTE
Conjugated equine estrogen	1.25 – 5 mg / day	Widely available	Levels cannot be monitored High risk of VTE Expensive
Parenteral Estradiol valerate ¹	0-20 mg IM every 1-2 week	Levels can be monitored Less risk of VTE	Injectable

	Anti-androgens	Feminizing Hormones	Ancillary therapy
Resource poor setting	Spironolactone + Finasteride/Dutasteride	Oral /Parenteral Estradiol valerate	Laser Eflornithine
Resource rich setting	GnRHa + Spironolactone + Finasteride/Dutasteride	Oral /Parenteral Estradiol valerate	Laser Eflornithine

Regimens for Masculinizing Hormonal intervention (FtM)

Testosterone generally can be given orally, transdermally, or parenterally (IM), although buccal and implantable preparations are also available. Because intramuscular testosterone cypionate or enanthate are often administered every 2-4 weeks, some individuals may notice cyclic variation in effects as well as more time outside the normal physiologic levels. This may be mitigated by using a lower but more frequent dosage schedule or by using a daily transdermal preparation. Intramuscular testosterone undecanoate maintains stable, physiologic testosterone levels over approximately 12 weeks and has been effective in both the setting

of hypogonadism and in FtM individuals. There is evidence that transdermal and intramuscular testosterone achieve similar masculinizing results, although the timeframe may be somewhat slower with transdermal preparations. Progestins, most commonly medroxyprogesterone, can be used for a short period of time to assist with menstrual cessation early in hormonal intervention. GnRH agonists can be used similarly, as well as for refractory uterine bleeding in individuals without an underlying gynaecological abnormality.

Targets of hormonal intervention:

The Endocrine Society guidelines as well as the WPATH guidelines have fixed the target levels of testosterone and estradiol necessitating their measurement at specified intervals during follow up of cross hormonal intervention. The UCSF website and a prescribing guideline from Australia, a publication by Gardener et al as well as the Sappho guidelines also have similar guidelines:

MtF: A practical target for hormonal intervention for transgender women (MTF) is to decrease testosterone levels to the normal female range (30–100 ng/dl) without supra- physiological levels of estradiol (<200 pg/ml) by administering an antiandrogen and estrogen.

The target for hormones:

- A. Serum testosterone levels should be <55 ng/dl.
- B. Serum estradiol should be 100- 200pg/ml

FtM: A practical target for transgender men (FTM) is to increase testosterone levels to the normal male physiological range (300–1000 ng/dl) by administering testosterone. Doses can be adjusted to target trough total testosterone levels in the lower end of the male reference interval. For people requiring masculinizing hormones for gender dysphoria, can use similar guidelines as for “androgen deficiency due to an established testicular disorder”.

Transgender adolescents in Tanner stage 2-5 usually have stable gender identities and can be given GnRH analogues to suppress puberty until they can proceed with hormonal intervention as early as age 18.

Risks of hormonal interventions

No medical interventions are free of risks. Cross-sex hormones confers the same risks associated with sex hormone replacement therapy in biological males and females. The probability of an adverse event is dependent on several factors like the medication dose, route of

administration, age of the individual, associated comorbidities, family history, and health habits of the person. With feminizing hormones there are increased risks of venous thrombo-embolism (VTE), gallstones, elevated liver enzymes, hypertriglyceridemia, hyperprolactinemia, weight gain, increased incidence of migraine and cardiovascular disease. The most serious adverse effect of estrogen is VTE and increasing age and bodyweight are two important factors that increase the risk of VTE with estrogen use. Cessation of tobacco use should be strongly encouraged in MTF transsexual persons to avoid increased risk of thromboembolism and cardiovascular complications.

Whereas masculinizing hormones carries the risk for polycythemia, acne, androgenic alopecia, dyslipidemia, hypertension and cardiovascular disease. There is no conclusive evidence that hormonal intervention increases the risk for various cancers.

Risk level	Feminizing hormones	Masculinizing hormones
High	Venous thromboembolism Hypertriglyceridemia Gall stone disease Liver enzyme elevation Weight gain	Acne Androgenic alopecia Polycythemia Weight gain Sleep apnea
Possible increased risk	Hypertension Hyperprolactinemia Type 2 Diabetes Cardiovascular disease	Hyperlipidemia Liver enzyme elevation Hypertension Type 2 Diabetes PCOS Cardiovascular disease Destabilization of psychiatric disorders
No/inconclusive risk	Breast cancer	Osteoporosis Breast, uterine, cervical, ovarian cancer

Contraindications

Estrogen is absolutely contraindicated in 3 settings

1. Subjects with previous history of venous thrombotic events
2. History of estrogen-sensitive neoplasm
3. End-stage chronic liver disease
4. Hypertriglyceridemia is a relative contraindication

Clinicians should particularly attend to tobacco use, as it is associated with increased risk of venous thrombosis, which is further increased with estrogen use. Absolute contraindications to testosterone include

1. Pregnancy
2. Unstable coronary artery disease

3. Untreated polycythemia with a hematocrit of 55% or higher
4. History of breast or other estrogen dependent cancers.

Drug interactions

Enzyme inducing anti-epileptic drugs (AEDs) may interact with the hormones used for gender affirmation. AEDs increase the level of SHBG in the blood thereby decreasing active free testosterone, estrogen and progesterone. Therefore, serum monitoring of testosterone levels for dosing should be performed by measuring free levels in transmen on AEDs. AEDs increase the hepatic metabolism of estradiol and subsequently lower the effective systemic dose of estrogen which could lead to a reversal of the feminizing characteristics in transwomen. Hence non inducing AEDs could be tried as first line in transwomen to avoid this interaction. Since estrogen is proconvulsant, when a transwoman with epilepsy is initiated on estrogen, an exacerbation of seizure activity is to be expected and dose of AED is to be modified.

Follow-up:

In the first year of intervention, 3-monthly monitoring is suggested to review clinical effects, sex steroid levels, mood changes and adverse effects, and provide general preventive screening. Mental health and spiritual and peer support can be beneficial during transition. Evaluate the individual every 3monthly in the first year and then every 6-12 months' time per year to monitor for appropriate signs of feminization/masculinization and for development of adverse reactions. The clinical and biochemical monitoring must be done in 3-6 month interval to evaluate efficacy and safety of treatment regimen. Once stable, individuals can be reviewed less frequently (6-12 monthly). Cancer screening should be individualized based on the presence of organs, not gender identity or hormonal intervention status.

Clinical Monitoring During Hormonal intervention for Efficacy and Adverse Events

The purpose of clinical monitoring during cross hormonal intervention is to assess the degree of feminization / masculinization and the possible presence of adverse effects of medication. Cross hormones for transgender males and females confer many of the same risks associated with sex hormone replacement therapy in non -transgender persons. The risks arise from and are worsened by inadvertent or intentional use of supra physiologic doses of sex hormones, as well as use of inadequate doses of sex hormones to maintain normal physiology. Monitoring of any

long-term medication including cross hormones should take place in context of comprehensive health care. In the absence of comorbidities, one can prioritize monitoring risks that are either likely to be increased by cross hormones or possibly increased but clinically serious in nature. Subjects with comorbid medical conditions may need more frequent monitoring in contrast to healthy individuals specially in remote or resource-poor areas may have less frequent monitoring with assistance from telehealth or general practitioner or nurses. Cancer screening should be individualized based on the presence of organs, not gender identity or hormonal intervention status.

The Endocrine Society guidelines as well as the WPATH guidelines have fixed the target levels of testosterone and estradiol necessitating their measurement at specified intervals during follow up of cross hormones. The best assessment of hormonal intervention is clinical response. Weight gain may occur when commencing hormones and lifestyle advice is recommended. Smoking cessation should be encouraged. Clinicians evaluate transgender persons treated with hormones for cardiovascular risk factors using fasting lipid profiles, diabetes screening, and/or other diagnostic tools. Clinicians obtain bone mineral density (BMD) measurements when risk factors for osteoporosis exist, specifically in those who stop sex hormones after gonadectomy. Transgender persons who have undergone gonadectomy may choose not to continue consistent sex steroid replacement after hormonal and surgical sex reassignment, thereby becoming at risk for bone loss. There have been no studies to determine whether clinicians should use the sex assigned at birth or affirmed gender for assessing osteoporosis (e.g., when using the FRAX tool). Although some researchers use the sex assigned at birth (with the assumption that bone mass has usually peaked for transgender people who initiate hormones in early adulthood), this should be assessed on a case-by-case basis until there are more data available. Sex for comparison within risk assessment tools may be based on the age at which hormones were initiated and the length of exposure to hormones. In some cases, it may be reasonable to assess risk using both the male and female calculators and using an intermediate value. When transgender subjects undergo normal pubertal development, with known effects on bone size, reference values for birth sex may be used were used for all participants.

Efficacy and Risk Monitoring During Feminizing Hormones (MtF)

The best assessment of hormone efficacy is clinical response: feminization of body while minimizing masculine characteristics, consistent with that individual's gender goals. To ascertain cross hormone dosages

required to achieve clinical response, suppress testosterone levels to below upper limit of normal female range and estradiol levels within premenopausal female range but well below supra physiologic levels. Efficacy monitoring should include:

1. Physical monitoring:

- a. Breast growth.
- b. Growth of body and facial hair.
- c. Libido and erectile function.
- d. Testicular size.
- e. Softening of skin.

2. Biochemical monitoring: Measure serum testosterone and estradiol every 3 months.

- a. Testosterone: target in the female testosterone range: 30 – 100 ng/dL; median: 50 ng/dL.
- b. Estradiol: Serum estradiol should be in physiologic range: 100–200 pg/mL, peak estradiol <200 pg/mL

Monitoring for adverse events should include both clinical and laboratory evaluation. The Women's Health Initiative a large prospective study looking at 8506 women taking estrogen showed a 26% increase in breast cancer and 37 % reduction in colon cancers whereas there was no impact on endometrial cancer. The Breast Cancer Detection Demonstration Project demonstrated an increased risk of ovarian cancer in women taking estrogen therapy. Hence, subjects with a history of estrogen hormone sensitive neoplasm were restrained from estrogens. Estrogen being hepatotoxic, advanced stages of chronic liver disease was considered to be another cause of absolute contraindication for initiating hormonal intervention. Follow up should include careful assessment for signs of cardiovascular impairment and venous thromboembolism (VTE) through measurement of blood pressure, weight, and pulse; heart and lung exams; and examination of the extremities for peripheral edema, localized swelling, or pain. Laboratory monitoring should be based on the risks of hormonal intervention and comorbidities and risk factors, and the specific hormone regimen itself. Safety monitoring should include:

1. Monitoring for venous thromboembolism: Venous thromboembolism is a major complication of estrogen although the extent of risk varies according to the route of administration
2. Liver function test: Hepato-toxicity and acute liver injury needs to be looked into

3. For individuals on spironolactone, serum electrolytes, particularly potassium, should be monitored every 3 months in the first year and annually thereafter.
4. Routine cancer screening for prostate, breast and colon: The presence of estrogen receptors in breast and prostate cancer tissue obviates the need of breast and prostate cancer screening in individuals receiving feminisation but the modalities for screening and the frequency of screening has not been laid down by the existing guidelines
5. Prostate: Transgender females treated with estrogens follow individualized screening according to personal risk for prostatic disease and prostate cancer.
6. Breast: Transgender females with no known increased risk of breast cancer follow breast-screening guidelines recommended for non-transgender females.
7. Colon: HRT has been proved to be protective for colon cancer, hence do we really require colonoscopy in the follow up protocol remains a question.
8. Monitor Prolactin and triglycerides before starting hormones and at follow-up visits.
9. Bone mineral density (BMD) testing: The evidence from a meta-analysis states that the BMD increases in individuals receiving feminisation and the UCSF guidelines clearly state that there is insufficient evidence to recommend BMD as a routine follow up investigation.
 - a. If high risk for osteoporotic fracture - at baseline and every 3 year
 - b. If low risk for osteoporotic fracture - at age 60 and every 3 year

Efficacy and Risk Monitoring During Masculinizing Hormonal intervention (FtM)

The best assessment of hormone efficacy is clinical response: masculinization of body while minimizing feminine characteristics, consistent with that individual's gender goals. To ascertain testosterone dosage and frequency by maintaining testosterone levels within the normal male range while avoiding supra physiological levels. For individuals using intramuscular (IM) testosterone cypionate or enanthate, one can check trough levels or mid cycle levels. Efficacy monitoring should include:

1. Monitor serum testosterone at follow-up visits every 3 months until levels are in normal physiologic male range (300 – 1000 ng/dl). Peak levels for individuals taking parenteral testosterone can be measured 24 – 48 h after injection. Trough levels can be measured immediately before injection.
2. For testosterone enanthate/cypionate injections, testosterone level should be measured midway between injections, target level is 400–700 ng/dL. Alternatively, measure peak and trough levels to ensure levels remain in the normal male range.
3. For parenteral testosterone undecanoate, testosterone should be measured just before the following injection, target level is 400 ng/dL, to adjust dosing interval accordingly.
4. For transdermal testosterone, the testosterone level can be measured no sooner than after 1wk of daily application (at least 2 h after application).

Monitoring for adverse events should include both clinical and laboratory evaluation. Follow-up should include careful assessment for signs and symptoms of excessive weight gain, acne, uterine break-through bleeding, and cardiovascular impairment, as well as psychiatric symptoms in at risk individuals. Physical examinations should include measurement of blood pressure, weight, and pulse; and heart, lung, and skin exams. Laboratory monitoring should be based on risks of hormonal intervention, comorbidities/ risk factors, and specific hormone regimen. Safety monitoring should include:

1. Measure hematocrit or hemoglobin at baseline and every 3 months for the first year and then one to two times a year. Hemoglobin levels should be compared with the male reference interval. Hematocrit (PCV) target is < 0.5.
2. Monitor weight, blood pressure, and lipids at regular intervals.
3. Cervix or breasts should be screened appropriate to guidelines in females. Conduct sub- and peri areolar annual breast examinations if mastectomy
4. Screening for osteoporosis should be conducted in those who stop testosterone replacement or are not compliant with hormones: BMD screening before starting hormones for individuals at risk for osteoporosis. Otherwise, screen at age 60 or earlier if sex hormone levels are consistently low.
5. Ovariectomy can be considered after completion of hormone transition.

Test	Comments	Baseline	3 months	6 months	12 months
RFT, K+	Only if spironolactone is used	Y	Y	Y	Y
Lipids	Use clinical discretion	Y		Y	Y
Estradiol		Y		Y	
Testosterone		Y	Y	Y	Y
Hemoglobin		Y		Y	Y

Long-Term Care:

While rigorous long-term studies are required, retrospective cohort studies suggest that short term gender-affirming hormonal intervention is safe, and significant benefits on mental health outweigh potential risks. Mental health and spiritual and peer support can be beneficial during transition. Once stable, individuals can be reviewed less frequently (6–12 monthly). Weight gain may occur with hormones and lifestyle advice is recommended. Smoking cessation should be encouraged.

Clinicians should monitor weight and blood pressure, conduct physical exams, and assess routine health questions, such as tobacco use, symptoms of depression, and risk of adverse events such as deep vein thrombosis/pulmonary embolism and other adverse effects of sex steroids. Clinicians evaluate transgender persons treated with hormones for cardiovascular risk factors using fasting lipid profiles, diabetes screening.

In an Austrian gender clinic, administering gender affirming hormones to transgender females and 89 transgender males was not associated with VTE, despite an 8.0% and 5.6% incidence of thrombophilia. Numerous studies have demonstrated the effects of sex hormone replacement on the cardiovascular system. Long-term studies may suggest no increased risk for cardiovascular mortality. Future research is needed to ascertain the potential harm of hormonal therapies. Clinicians should manage emerging cardiovascular risk like glucose, lipid metabolism and blood pressure regularly according to established guidelines.

Obtain BMD measurements if risk factors for osteoporosis: specifically, in those who stop sex hormones after gonadectomy. Fracture data in transgender males and females are not available suggesting need for further research.

Feminizing Transition (MtF):

Standard monitoring plan for transgender females include avoiding supra physiologic doses or blood levels of estrogen that may lead to increased risk for thromboembolic disease, liver dysfunction, and

hypertension. Clinicians should monitor serum estradiol levels using laboratories with good quality control, as measurements of estradiol in blood can be erroneous.

VTE may be a serious complication. Use of synthetic estrogens (ethinyl estradiol) and conjugated estrogens is undesirable because of inability to regulate doses by measuring serum levels and increased risk of thromboembolic disease. Thrombophilia screening of transgender persons initiating hormonal intervention should be restricted to those with a personal or family history of VTE. Monitoring D-dimer levels during is not recommended.

Favorable changes in lipid parameters with increased high-density lipoprotein and decreased low-density lipoprotein concentrations seen in n transgender females. However, increased weight, blood pressure, and markers of insulin resistance may attenuate favorable lipid changes. In a meta-analysis, only serum triglycerides were higher without increase in cardiovascular mortality despite of tobacco use. Thus, there is limited evidence to determine whether estrogen is protective or detrimental on lipid and glucose metabolism in transgender females.

Transgender females: In aging males, studies suggest that serum estradiol more positively correlates with BMD than testosterone and is more important for peak bone mass. Estrogen preserves BMD in transgender females who continue on estrogen and antiandrogen therapies.

Transgender females with no known increased risk of breast cancer follow breast-screening guidelines recommended for those designated female at birth. Studies suggest that estrogen does not increase the risk of breast cancer in the short term (20 to 30 years). Long-term studies are required to determine the actual risk, as well as the role of screening mammograms. Regular examinations and gynecologic advice should determine monitoring for breast cancer.

Periodically monitoring prolactin levels in transgender females treated with estrogens as they can increase growth of pituitary lactotroph cells. Up to 20% of transgender females treated with estrogens may have elevations in prolactin levels associated with enlargement of the pituitary gland. In most cases, the serum prolactin levels will return to the normal range with a reduction or discontinuation of the estrogen or discontinuation of cyproterone acetate. Clinicians should measure prolactin levels at baseline and then at least annually during the transition period and every 2 years thereafter. Major presenting findings of microprolactinomas (hypogonadism and sometimes gynecomastia) are not apparent in transgender females, clinicians may perform radiologic

examinations of the pituitary in those individuals whose prolactin levels persistently increase despite stable or reduced estrogen levels. Some transgender individuals receive psychotropic medications that can increase prolactin levels.

Transgender females treated with estrogens follow individualized screening according to personal risk for prostatic disease and prostate cancer. Prostate cancer is very rare before the age of 40, especially with androgen deprivation. Adult castration reverses benign prostate hypertrophy (BHP). BHP reported in transgender females treated with estrogens for 20 to 25 years. Few prostate carcinomas reported in transgender females. Transgender females may feel uncomfortable scheduling regular prostate examinations. Gynecologists are not trained to screen for prostate cancer or to monitor prostate growth. Thus, it may be reasonable for transgender females who transitioned after age 20 years to have annual screening digital rectal examinations after age 50 years and prostate-specific antigen tests consistent with Guidelines.

Masculinizing Transition (FtM)

Standard monitoring plan for transgender males on testosterone include maintaining testosterone levels in the physiologic normal male range and avoiding adverse events resulting from excess testosterone, particularly erythrocytosis, sleep apnea, hypertension, excessive weight gain, salt retention, lipid changes, and excessive or cystic acne. Because oral 17-alkylated testosterone is not recommended, serious hepatic toxicity is not anticipated with parenteral or transdermal testosterone use.

Administering testosterone to transgender males results in a more atherogenic lipid profile with lowered high-density lipoprotein cholesterol and higher triglyceride and low-density lipoprotein cholesterol value. Studies of the effect of testosterone on insulin sensitivity have mixed results. A randomized, open-label uncontrolled safety study of transgender males treated with testosterone undecanoate demonstrated no insulin resistance after 1 year.

Polycythaemia with testosterone: Hemoglobin levels should be compared with the male reference interval. If the hematocrit level is >0.5 , exclude alternative causes (e.g. smoking) and consider decreasing the testosterone dose or increasing the dosing interval.

Persistent menstruation on testosterone: Menstrual suppression usually occurs within 1–6 months of testosterone, but menses can continue beyond 12 months. If menses result in significant dysphoria, options include increasing testosterone levels, oral progestins or progestin-releasing Intrauterine devices.

Baseline bone mineral measurements in transgender males are generally in the expected range for their preintervention gender. Adequate dosing of testosterone is important to maintain bone mass in transgender males. The protective effect of testosterone may be mediated by peripheral conversion to estradiol, both systemically and locally in the bone. Serum LH levels were inversely related to BMD, thus LH levels in the normal range may serve as an indicator of the adequacy of sex steroid administration to preserve bone mass.

In transgender males has expected rate of breast cancers found in cisgender females, however breast cancer can occur even after mastectomy specially in subareolar tissue

Although aromatization of testosterone to estradiol in transgender males has been suggested as a risk factor for endometrial cancer, no cases have been reported. When transgender males undergo hysterectomy, the uterus is small and there is endometrial atrophy. Studies have reported cases of ovarian cancer. Although there is limited evidence for increased risk of reproductive tract cancers in transgender males

Acne with testosterone: Acne peaks at 6 months and gradually improves over time. Topical retinoids or retinoid-benzoyl peroxide combinations are useful for mild to moderate acne. Moderate to severe acne may require oral antibiotics or isotretinoin.

Different clinical scenarios for Hormonal intervention

Guidelines for hormonal intervention among gender incongruent individuals are mostly extrapolations from recommendations that currently exist, namely The Endocrine Society, The World Professional Association for Transgender Health (WPATH) and Integrated Diabetes and Endocrine Academy (IDEA), India. [3]

1. Hormonal intervention for hormone and surgery naive gender incongruent individuals:

The major goals of hormonal intervention are: 1) to suppress the secondary sex characteristics of the individual's biological or genetic gender and 2) to replace endogenous sex hormone levels with those of the reassigned gender. The timing at which to begin intervention for gender-affirming hormones is determined in collaboration with both the person pursuing sex reaffirmation and the mental health professional who performed psychological evaluation.

Transfeminine persons:

The hormone regimen for transfeminine individuals is complex and anti-androgen in conjunction with an estrogen is commonly advised. Estrogen feminizes the individual by changing fat distribution, inducing breast formation, and reducing male pattern hair growth. Exogenous estrogen also suppresses the gonadotropin secretion from the pituitary gland and reduce androgen production.

Estrogen can be given orally (ethinyl estradiol, estradiol valerate, 17β-estradiol and conjugated estrogens), transdermally (17β Estradiol gel) or parenterally (estradiol valerate). Though Ethinyl estradiol is cheap and very effective for estrogen-directed therapies however limitation is increased incidence of deep venous thrombosis. 17β-estradiol is a commonly used formulation with low possibility of venous thrombosis and can easily be measured with commercial estrogen assay. No robust comparative evaluation of the efficacy and safety of the different estrogen formulations are available. As the possibility of venous thrombosis increases with advancement of age, transdermal formulations are better after the age of 40. Parenteral estradiol valerate is also a preferred formulation as the possibility of venous thrombosis is low.

Ideally androgen levels should be maintained that found in adult biological women. Estrogen alone is often not enough to achieve the desirable androgen suppression, and additional anti-androgens are often necessary.

Four categories of medications have shown to be effective to reduce production or block endogenous androgen:

- 1) gonadotropin-releasing hormone agonists,
- 2) progestins with anti-androgen activity,
- 3) spironolactone
- 4) Finasteride.

GnRH agonist in combination with estrogen is very effective in reducing testosterone levels and safe with low incidence of adverse reactions. However, use of GnRH agonist is limited in our country due to its prohibitive cost.

Cyproterone acetate, an anti-androgenic progesterone is widely used. Possible adverse effects include liver enzyme elevation and depression. Cyproterone acetate is not available in recommended strength in India.

Spironolactone is commonly used as part of the feminizing regimen because of its anti-androgenic properties. It inhibits the androgen binding

to the androgen receptor. Adverse effects include hyperkalemia and hypotension.

Finasteride is a 5-alpha-reductase inhibitor and block the conversion of testosterone to the more potent dihydrotestosterone (DHT) and is a commonly used medication in transfeminine persons. Possible adverse effects include mood disturbance.

Progestins, like GnRH agonists, can suppress gonadotropins and help in optimisation of breast maturation. They are not recommended as the data is inconclusive regarding the benefit[4] and as they are associated with an elevated risk of cardiovascular disease and breast cancer.

Recommendation

Hormone and surgery naive transfeminine persons to be treated with an anti-androgen in conjunction with an estrogen.

Routine use of progestin is not beneficial.

Transmasculine persons:

Testosterone is the mainstay of intervention for transmasculine individuals. It is used to masculinize the person. Testosterone also suppress female secondary sex characteristics. Testosterone is available as oral preparation (testosterone undecanoate), as transdermal preparations (testosterone gel) and parenteral preparations (testosterone propionate, testosterone enanthate, testosterone undecanoate). Oral testosterone undecanoate are used but associated with concerns about first-pass metabolic effects from the drug. Some parental testosterone (enanthate and propionate) are usually administered weekly or with higher doses two weekly. As the testosterone undecanoate is a long-acting preparation, that can be administered every 12 weeks but associated with increased risks of pulmonary oil micro embolism and anaphylaxis. Subcutaneous administration is better as target levels are easily achieved than intramuscular injections. Transdermal options are also good alternatives but associated with risk of transfer to partner and skin reactions. All androgen preparations have demonstrated the efficacy to induce masculinization. No comparative data is available suggesting relative superiority of any specific testosterone preparation. However, target levels are easily achieved with parenteral route and more uniformly achieved with transdermal route.

Androgens result in increased muscle mass and decreased fat mass, increased facial hair and acne, male pattern baldness, increased libido, virilization and, usually, cessation of menses.[6] If menses continue

few months with testosterone replacement, addition of another strategy may be considered. Depot medroxyprogesterone or endometrial ablation are two further options.

Recommendation

Hormone and surgery naive transmasculine persons to be treated with testosterone

If menses continue few months with testosterone addition of depot medroxyprogesterone or endometrial ablation may be considered

2. Hormonal intervention for gender incongruent individuals after gonadectomy without prior hormone:

In the absence of endogenous gonadal hormones adequate replacement of sex hormone with those of the reassigned sex is the goal. The timing at which to begin this intervention is again determined in collaboration with both the person pursuing sex reaffirmation and the mental health professional who performed psychological evaluation.

Transfeminine persons:

Many transfeminine persons undergo crude and radical removal of external genitalia without prior hormonal interventions. They are mostly from the “hijra” community, the largest gender incongruent community of India. These poorly supervised mutilating surgeries are mostly done by medically unqualified persons.[8]

Recommendation

Transfeminine persons who had had her gonads removed without prior hormone to be treated with estrogen only.

Routine use of progestin is not beneficial.

Transmasculine persons:

Seeking for transmasculine hormonal interventions after gonadectomy is rare. Testosterone is the mainstay for masculinizing effect. As the person is amenorrhoeic due to the absence of gonadal hormones, additional treatment with depot medroxyprogesterone or endometrial ablation to stop menses are not required.

Recommendation

Transmasculine persons who had had his gonads removed without prior hormone to be treated with testosterone only.

Depot medroxyprogesterone is not required.

3. Hormonal intervention for gender incongruent individuals during and after gender reaffirmation surgery:

Genital sex reassignment surgery, removal of the gonads and breast surgery (augmentation or removal) may be considered for gender reassignment and is often medically necessary. Optimization of risk reduction with modification of the medical intervention is the goal for preoperative evaluation.

Transfeminine persons:

Venous thrombosis leading to pulmonary embolism is the major perioperative concern among transfeminine persons on estrogen. Events are related to immobility and thrombotic effects of estrogen. The prospect of thromboembolism is very low if significant immobility can be avoided in perioperative period. However, it is prudent to discontinue hormones 2-4 weeks prior to surgery and to restart four weeks after surgery. Transdermal preparations instead of oral, may be used if complete withdrawal cause distressing impact on the individual. The surgeon and endocrinologist should discuss with the individual in reaching a mutual decision regarding the withdrawal of hormones during perioperative period and reinitiation after surgery.

Recommendation

- Stop estrogen four weeks before surgery
- Shift to transdermal preparations if complete withdrawal of estrogen is not acceptable
- Restart estrogen four weeks after surgery when the individual is completely ambulatory
- Re-evaluate the need of further hormones after surgery:
- GnRH and spironolactone to be stopped
- Estrogen dose may be reduced to half after breast augmentation surgery
- Only transdermal estrogen to be started if venous thrombosis encountered during perioperative period.

Transmasculine persons

Testosterone may have detrimental effect during the perioperative period. But stopping the testosterone for longer periods, can result in reversal of the masculinizing effects and resumption of menses. Despite the assumption of an increased perioperative cardiovascular risk, transmasculine individuals on testosterone are not at risk of increased cardiovascular events. However, other important adverse effects such as erythrocytosis, liver dysfunction, lipid level changes may complicate the perioperative period.

Recommendation

Stop testosterone four weeks before surgery

Restart testosterone four weeks after surgery when the individual is completely ambulatory

4. Hormonal interventions for gender incongruent individuals after age 50 (Initiation or continuation):

Gender incongruent individuals, who have transitioned, are at risk for unintended systemic biological effects from long term pharmacological use of hormones. Quality data assessing morbidity, mortality and cancer incidence among transgender people above age 50 and benefit on long term hormonal intervention are not available. [7]

Transfeminine persons:

Long term intervention with estrogens particularly in combination with progestins, are possibly associated with increased risk of developing cardiovascular disease and venous thrombosis among transfeminine individuals. Reduction in the dose of estrogens with aging or shift to probably safer transdermal preparations must be considered⁴. Long-term cross-sex hormones for transfeminine individuals produce reduction in bone mineral density also.

Recommendation

Re-evaluate the need of further hormones after age 50

Begin and continue with transdermal preparations for new initiation

Shift from oral or injectable to transdermal preparations for continuation among the individuals who are already on hormone

Transmasculine persons

Long term testosterone administration to transmasculine individuals may increase little risk for cardiovascular disease and cancer. But testosterone appears safe in most long-term studies. A dose optimization may be needed with a high hematocrit or with cardiovascular disease. Breast cancer may occur in residual mammary tissue in transmasculine individuals. Though rare, tumors of the prostate, meninges and pituitary also have been demonstrated with long term follow up. However, it appears initiation of cross-sex hormone intervention in elderly subjects is without disproportionate risks.

Recommendation

- Begin and continue with standard dose of testosterone for new initiation
- Continue with standard dose of testosterone for continuation among the individuals who are already on hormone
- Reduce 25-50% dose of testosterone in individuals who have high hematocrit (more than 50%) or cardiovascular disease.

5. Hormonal intervention for gender incongruent children and adolescents:

Transgender children and adolescents are understudied population and only limited data available in this field. In most gender incongruent children, the dysphoria does not persist into adolescence and hence the diagnosis can reliably be made only after the first signs of puberty. Given the high rate of remission after the onset of puberty, gender-affirming hormones are not recommend in prepubertal gender incongruent children. Depending on the child's level of distress, gender transition can help manage the discomfort in prepubertal children. Gender transition means taking steps to affirm the gender that feels comfortable to the child. It consists of social changes like name, pronoun and gender expression. [8,9,10]

Gender incongruent adolescents considers that the pubertal physical changes are unbearable and source of dysphoria. Early medical intervention may prevent this psychological harm and gender incongruent young adolescents may be treated with GnRH analogue, a puberty-suppressing medication. For persons who cannot afford this costly intervention, cheap depot medroxyprogesterone is an alternative. However, GnRH analogues are superior in efficacy and safety. Pubertal suppression

is a relief from dysphoria and associated with better psychological and physical outcome.

Pubertal developments are the result of maturation of the hypothalamo-pituitary gonadal axis with increase in rhythm of gonadotropins secretion. In girls the first physical sign of puberty is the start of budding of the breasts and in boys the first physical change is testicular growth. A testicular volume equal to 4 ml is usually taken a cut off value for the start of puberty and intervention.[1] Longitudinal studies demonstrated that those individuals who were first identified as gender incongruent at early puberty are likely to be transgender as adults. The recent evidence demonstrated the benefits of early intervention for phenotypic gender transition compared to puberty suppression with gonadotropin-releasing hormone agonists only. Till date most guideline suggest to start gender-affirming hormones at age 16, as at this age most adolescents are possibly able to make complex cognitive decisions. Intervention with GnRH analogues may be continued with gender-affirming hormones. The combination will help in suppressing the endogenous sex steroid secretion and in reducing the gender-affirming hormone dose requirement. GnRH analogue may be continued until gonadectomy.

Recommendations

Children who fulfil the diagnostic criteria for gender incongruence may undergo gender transition depending on the child's level of distress

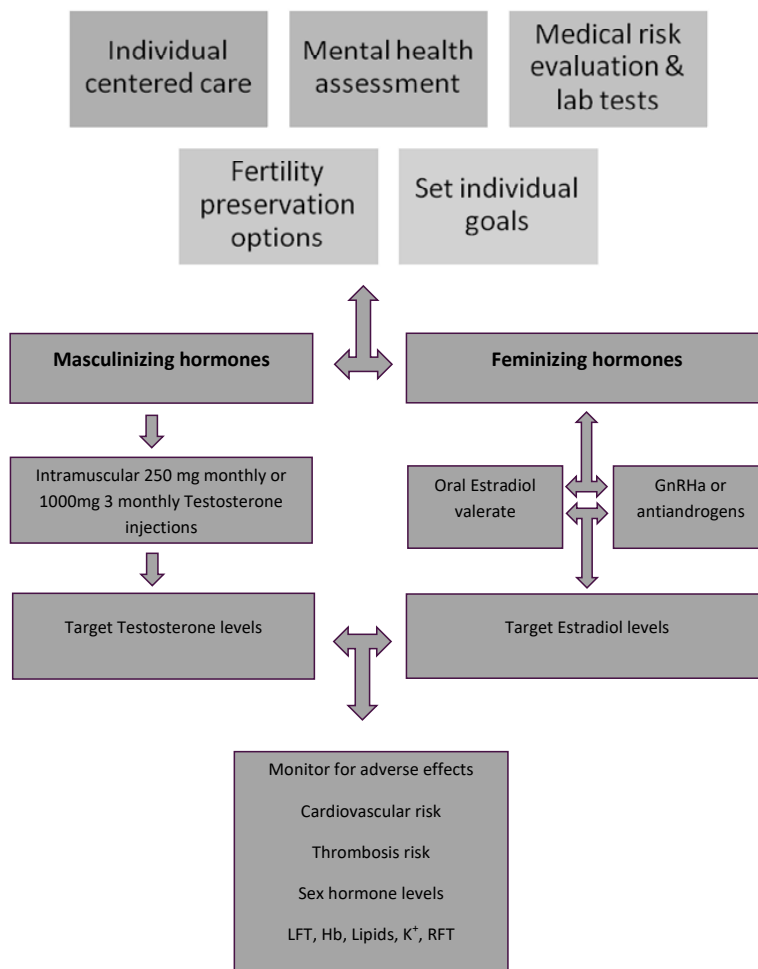
Adolescents who fulfil the diagnostic criteria for gender incongruence may undergo intervention to suppress pubertal development.

Suppression of pubertal hormones start when girls first exhibit budding of the breasts (Tanner stages 2) and boys first exhibit testicular volume equal to or above 4 ml (Tanner stages 2).

Gender-affirming hormone administration for phenotypic gender transition to begin at age 16 after reconfirmation of the diagnosis.

GnRH analogues may be continued with gender-affirming hormones until gonadectomy.

Regimen for Gender affirming hormonal Intervention



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Section 4

Gender Affirmative Surgical Care

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Surgical Management of Gender Incongruence

Physical 'sex' of a person is determined by the phenotype and is assigned at birth usually by parents and the physician. On the other hand, the word 'Gender' refers to our psychological identification of self and its expression. Normally, our physical sex and 'gender' are in alignment. In a few individuals, there is a noticeable and persistent incongruence between 'sex' and 'gender' to an extent, that the individual wishes to get rid of one's primary and/or secondary sexual characteristics and acquire the characteristics of a gender, which is different from that of assigned (birth) sex/ gender (DSM5)¹. The need to express one's desired gender and for the society to accept them in this role, and their treatment by the society gives rise to a deep seated pain referred to as 'Gender Incongruence' (ICD11)², (previously dysphoria (DSM5)). Genital and non- genital gender affirmative surgery helps in alleviation of gender incongruence and the associated conditions such as anxiety and depression. It is important to work as part of a gender team for the purpose of shared decision making and comprehensive management under one roof. Generally, in India, individuals seek information about professionals through social media and from persons, who have undergone gender affirmative care. Around 50% of the individuals at presentation are unsure, regarding how to proceed further, Remaining individuals wish to know about specific procedures and the results. Almost all individuals wish to know the costs involved at the outset. Around 25 years ago, individuals used to present in clinics with their partners/ friends/ cousins and were in late twenties and thirties. These days most individuals present in their teens or early twenties and are accompanied by their parents. This represents a significant shift in Indian people's attitude to gender incongruent persons, and a more trans friendly environment. As per law, any irreversible intervention such as surgery can be only be carried out after the age of legal majority, which is 18 years in India.

Ideally, the Gender Identity Clinic should be in a discrete area of the hospital and have dedicated entry and exit. The registration area for these should be separate from general patients and there should be a provision in hospital information system (HIS) to include individual's desired name and gender in all documents. The hospital documents may include the above as well as name and gender as per legal identity proofs, for medicolegal purposes. The washrooms should be gender neutral and clinic staff should be gender sensitized. One should ask the individual regarding the preferred pronoun, as well as which sexed

chaperone should be present with the examining surgeon. After the interview, individual should be given a definite algorithm to follow for achieving a smooth transition. Our current algorithm is broadly based on 7th version of Standards of Care for the health of transsexual, transgender and gender nonconforming people (7th SOC's³) published by the World Professional Association for Transgender Health (WPATH), modified by our (the Indian) experience. 7th SOC's recommend one referral from a board- certified mental health professionals working in this field prior to any breast surgery and two such referrals prior to genital surgery. The letters of recommendation should include the individual's demographic data, results of psychological assessment including diagnosis, the duration of evaluation and therapy, a statement that any underlying mental health issues have been addressed, the individual is well informed about the irreversible nature of surgery and informed consent has been taken, that the criteria for recommending surgery have been met and that the mental health professional is available for any coordination of care. It's also important to contact the individual's mental health professional for validation of referral prior to performing surgery. Generally, for breast surgery (reduction in case of transmen and augmentation in case of transwomen), letter from only mental health professional is required. Also, only one letter is required for initiation of hormone therapy. However, we prefer to obtain both recommendations at the outset, as we feel that it makes the path to individual's transition smoother and there is a higher certainty in diagnosis. We also prefer to take these letters of recommendation from two different mental health teams, though it is not mandatory. If one such teams is from our hospital, then we prefer the other referral letter from a team outside the hospital to remove any iota of bias. As most of the individuals are from out of state, it suits them to take such letters from a mental health professional in their state, as it avoids unnecessary expenditure of time and money. We have a pool of mental health professionals in the Association for Transgender Health in India (ATHI) and Indian Professional Association for Transgender Health (IPATH) family with interest in this field, who provide the necessary mental health analysis, diagnosis, therapy, referrals and are available for professional interaction.

Hormonal Intervention plays an important role in the management of gender incongruence. It eases the individual's transition into the desired gender role. Deepening of voice, growth of beard and moustache hair, shifts in body fat distribution to masculine and better definition and development of musculature goes a long way in adapting a transman, who was otherwise a biologic woman, in the desired male gender role. Likewise, development of breasts, shifts in body fat resulting in feminine curves, smoother skin, reversal of male pattern baldness with better scalp hair growth help the transition of a transwoman, who was otherwise

a biologic man, in a female gender role. Post orchidectomy in transwomen, the hormone therapy also plays an important role in bone health. In effect, hormone therapy provides a real-life experience for gender incongruent persons, as a partially reversible intervention, prior to surgery. Hence, 7th SOC's recommend hormone therapy for 12 months prior to genital surgery for both transmen and transwomen, unless the individual is unwilling to take it, or it is medically contraindicated. It is also recommended for 12 months as an optional criterion, prior to breast augmentation in transwomen, as after 12 months, there is little if any further increase in breast size, and the individual can realistically assess the need for further surgical breast augmentation. However, we feel that we should inform the individual regarding the pros and cons of hormone therapy in their particular case and keep it as an optional intervention only, because many individuals are reluctant to take hormones for fear of side effects in spite of 6 monthly endocrine follow-up. It is also important to stop oral estradiol therapy 2-4 weeks prior to any surgery, to obviate the increased risk of venous thromboembolism.

Although the procedure of informed consents is well established, and there is a legal precedence in the form of Bidhan Baruah Judgment⁴, when a division bench of Mumbai High Court observed that- "...there is no law which prohibits sex change operation and an adult (>18years) can undergo sex change operation without the need of parental consent", the gender affirmative surgeries still involve removal of normal organs. There have been instances in the past, when the surgeons were sued by the individuals, pleading that the individual had not understood the consent or, the surgery was forced upon them. Hence in India, we prefer to involve the court in the form of a notarized affidavit on a Rs 100/- stamp paper, called 'Waiver of Liability Affidavit'⁵, in which the individual promises not to sue the treating team for undertaking the individual's surgeries. The affidavit explains the individual's circumstances and releases the operating team for removing the individual's normal sexual organs, causing irreversible loss of current sexual functioning and fertility. In case the individual is married, a spousal release affidavit may also need to be notarized for extra caution, though it is not legally necessary. Although these affidavits cause some extra expense to the individual, and the added discomfort of having to visit courts, these also go a long way in smoothening the relationship with the doctor. These affidavits also imply that the state has been informed and the individual has had adequate opportunity and time to think about the implications of gender affirmative surgeries.

In India, a large set of third gender/ transgender persons consist of biologic males with feminine gender expression, who have been castrated either before or after development of secondary sexual characteristics.

These individuals have often undergone penectomy, orchidectomy and scrotoectomy at the hands of unqualified persons in a ceremony called 'Nirvan'. They often present in GICs with absent external genitalia or a shallow vaginal pit, with desire for corrective surgeries such as vaginoplasty or breast augmentation. The standard requirements for trans persons do not apply in such cases, as there are no normal tissues to be removed and any surgery undertaken is likely to be a corrective surgery. Hence, consults and referrals or recommendation letters from mental health professionals and waiver of liability affidavits are not required in such situations.

It is important for the surgeon to educate the individuals and devise a customized algorithm in their quest for surgical transition to the desired gender role. Living in a gender congruent role for at least 12 months, as mentioned in 7th SOC's is very important for the individual, before undergoing genital surgery such as Phalloplasty/ Metaidoioplasty or Vaginoplasty. This provides a real- life experience of living in desired gender role in all seasons, gaining a first- hand experience, and resolving any conflicts regarding gender expression and sexuality prior to undergoing the irreversible genital transformation, thus decreasing the chances of regret. Surgeons should also inform the individuals about success rates and complications of various procedures, so that they get adequate time and opportunity to make informed choices regarding their transition. For example, phalloplasty is a complex and long procedure with a significant incidence of urinary complications such as stricture (narrowing of urinary stream or blockage) or fistula (leakage of urine). While metaidoioplasty, which consists of enlargement of clitoris and advancement of urethra (urine pipe) to clitoral tip is a relatively simple procedure with less urinary complications, enables orgasm but does not enable the individual to engage in penetrative sexual intercourse, or to void urine in a standing position in all cases. An informed individual can thus select either procedure depending on expense, number of stages, time duration, complications and need for corrective surgeries. Another example is the type of phalloplasty. Two of the commonest methods of neo-penis reconstruction are free Radial forearm free flap phalloplasty (fRAFFp) and pedicled Anterolateral thigh flap phalloplasty (pALTp). Most of the transmen at first presentation in our experience have already decided on getting operated by one of these methods. Phalloplasty is usually the last major core procedure in transition to the male gender role. Hence, those individuals who opt for fRAFFp are advised to preserve the veins in non- dominant forearm, and not allow blood sampling or venous cannulation during preceding procedures such as top surgery and the surgery for removal of uterus, tubes, ovary and vagina (HSOV). This helps to keep the superficial venous system in that forearm uninjured, and hence facilitates the final procedure. In

those opting for pALTp, we often harvest vaginal mucosa during HSOV and prelamine the designated donor thigh with mucosa during this procedure. When phalloplasty is carried out few months later, the phallus already has a mucosa lined mature urethral tube.

Generally, core procedures are those, which are carried out in all gender incongruent persons, while ancillary procedures are the ones, that are carried out on demand. Ancillary procedures do not require any letters of recommendation from mental health professionals, and some may be carried out before the core procedures. The procedures are detailed in table 1⁶

Table 1

Core surgical procedures for transwomen	orchidectomy penectomy vaginoplasty clitoroplasty labiaplasty and vulvoplasty. breast augmentation.
Core surgical procedures for transmen	reduction mammoplasty (the top surgery) hysterectomy and bilateral salpingo-oophorectomy vaginectomy phalloplasty or metaidoioplasty scrotoplasty urethroplasty placement of testicular prosthesis and placement of an erectile implant/ penile prosthesis
Ancillary procedures for both transmen and transwomen	Hair transplants advancement of hairline/ forehead reduction Pectoral/ Calf implants facial feminizing/ masculinizing/ harmonizing surgery rhinoplasty thyroid chondroplasty and voice affirmative surgery Thoracic shaping Abdominoplasty, liposuction, high definition body contouring. Non-invasive aesthetic procedures.

Surgical Procedures in gender incongruent people:

1) Core surgeries in transwomen:

- i) **Breast augmentation:** Breast development occurs once the individual initiates feminizing hormone therapy. However, after a 12- month period on feminizing hormones, there is little if any increase. Also, this enlargement is hemispherical and conical, and without distinctive feminine curves or natural ptosis.

Therefore, many transwomen opt for surgical breast augmentation, often without waiting for this 12- months period. There are two common methods for breast augmentation-

- a) **Autologous fat grafting-** In this procedure, fat is harvested from an area in which there is excess- such as abdomen, love handles, thighs etc. under low suction pressure. This fat is then filtered, centrifuged, gravity sedimented and decanted or otherwise processed in Operation Theatre itself to obtain the infiltrate, which has been shown to consists of purified fat cells, stromal vascular fraction, and adipose derived stem cells. This infiltrate is then injected into the appropriate area on chest wall for breast development. 1-4 sittings may be required, at intervals of 4-6 weeks each for optimum breast development to take place.
 - b) **Breast augmentation with implant-** Cohesive silicone gel implants are used for augmentation, commonly via inframammary or axillary approach. In contrast to transwomen, biologic women have extra mammary fat overlying the origins and insertions on muscles in chest wall and axilla, thus softening the contours. Also, their thorax is shorter and more conical. As a result, to compensate for this, transwomen generally opt for larger size implants.
- ii) **Vaginoplasty, clitoroplasty, labiaplasty, vulvoplasty, corporectomy and feminizing urethroplasty:** The goals of the procedure are to create a perineo-genital complex, which is aesthetic and as feminine as possible, free of scars and painful neuromas, a vagina of adequate depth and dimensions, and lined by self- lubricating, elastic and hairless epithelium, sensate and with correct axis. The urinary stream should be downwards in a sitting position. Unlike neovaginoplasty (NVP) in biologic women, this procedure is more difficult in transwomen, on account of differences as enumerated in Table 2. Initial steps, which are common to all procedures are- careful dissection of the neovaginal cavity between urinary bladder and rectum, avoiding injury to these important organs. This cavity then needs to be lined by a skin flap or skin graft to prevent its collapse. Otherwise the body will treat it like any other injury or wound and close it in a few days. Currently, the commonest methods for lining the NV cavity are a)**use of penile and/or perineoscrotal skin flaps for lining** b)**the use of an intestinal segment such as sigmoid colon for vaginal lining** c) **Laparoscopic peritoneal vaginoplasty.** Authors advise self- dilatation of NV cavity by the individual, for 3 months or till the time of initiating regular vaginal intercourse.

- iii) **Ancillary procedures:** These are carried out as per the need, and many transwomen do not require these procedures. If the person suffers from male pattern baldness or receding hairline, this can be readily corrected to approximate a feminine hairline by hairline advancement procedures or hair transplants. Thyroid chondroplasty can be done to reduce Adam's apple. Voice can be feminized by a procedure on larynx, like the tightening of guitar/ violin strings, in a few minutes, under local anaesthesia. A male forehead, which is more prominent with bulging supraorbital ridges, a wide chin, excessively prominent wide cheek bones, square jaws and nasal hump or convex nose, all of these can be feminized by facial feminization surgery and rhinoplasty. Removal of lower floating ribs can be done to mimic the shorter and conical feminine thorax and a narrow waist. Body contouring procedures such as liposuction and abdominoplasty can also be used as per requirement.

Table 2: Differences between Neovaginoplasty in Transwomen and Biologic Women

NVP comparison	NVP in biologic females	NVP in transsexuals	Implications
Differences in pelvic soft tissues	Pelvis is roomier, with greater space in rectovesical area	There is no rectovesical space. There is just a septum.	Easier dissection. Greater success for techniques such as Vecchietti, Lap Vecchietti and Lap assisted balloon NVPs in biologic females.
Differences in bony pelvis (Fang, 2003)*	IIRD 5.2+/- 0.36cms. As bony pelvis is wider, relatively thicker flaps may be used, especially in NVPs for malignant resections.	IIRD 3.95+/- 0.25cms. Chances of bony compression of neovagina, even if a long cavity is created, preventing sexual intercourse.	Only thinnest flaps can be used for transsexual NVPs, such as penile, scrotal skin and grafts.
Differences in pudendal organs	Pudendal organs such as clitoris, labia majora and minora are present. These were sometimes used for reconstructing neovagina.	Pudendal organs also require reconstruction	In transwomen, nearly entire penile tissue except corpora cavernosa is used for reconstruction of pudendal organs. This tissue is often missing in those with castration.

*Fang⁷

2) Core surgeries in transmen:

- i) **Breast reduction ('the top surgery')-** This is usually the first surgery carried out in transmen. Reduction of the breast mounds enables them to easily pass off as men, while wearing shirts or T shirts, and thus helps alleviate GD. It also frees them from the difficult and painful practice of breast binding and wearing loose fitting shirts. The common methods for breast reduction surgery are **a) inferior periareolar**, if the breasts are relatively small in size, **b) concentric circular**, if these are moderately large, and **c) Excision and free nipple grafting (FNACG)**, if the breasts are really large and ptotic.
- ii) **Hysterectomy, bilateral salpingo-oophorectomy and vaginectomy (HSOV)-** This procedure differs from the normal gynecological procedure of hysterectomy in the fact, that in biologic women, the vagina is not removed. Additionally, in the HSOV procedure, the authors reconstruct proximal and distal pars fixa urethra, lengthening the female urethra by 5-8cms so that the neo urinary meatus lies anteriorly, almost near pubic bone. This facilitates the urethral anastomosis in subsequent surgeries. Sometimes, the authors also graft the vaginal mucosal lining to form urine pipe or urethra in the future flap, which will be used to form penis at a later stage and date, a process called prelamination. This is especially required in pALTp and sometimes in fRAFFp if the forearm circumference at lower border of flap is less than 15cms or the ulnar aspect of forearm is hairy. Additionally, authors also mobilize bilateral labia majora at this sitting, to form neo-scrotum. This not only provides an additional waterproofing tissue covering over the newly formed urethra, but also enables them to close the perineum completely, as even a small residual pit at the location of obliterated vaginal opening propagates the feeling of gender dysphoria in these individuals.
- iii) **Phalloplasty/metaidoioplasty, urethroplasty, scrotoplasty, -** The goal of masculinizing genitoplasty is – to construct or reconstruct genital organs, which aesthetically match the biologic male genitalia, allow the transman to easily micturate in erect position in a male washroom without soiling himself, and to enable him to function as a male partner in penetrative sexual intercourse. In this operative procedure, usually, the most complex of the core surgeries, penis is reconstructed most commonly from **a) the tissues of forearm (free Radial**

artery forearm flap or fRAFFp), b) thigh (pedicled Anterolateral thigh flap or pALTp) or c) back (free Musculocutaneous latissimus dorsi flap or fMLDp). Other flaps and sites are used uncommonly. The thigh flap can be transferred directly, but other two procedures require microsurgical free tissue transfer. fRAFFp is still the commonest procedure for phalloplasty, and provides excellent aesthetic result with good sensation, as two nerves are anastomosed, one for general touch and the other for erogenous sensation. However, many transmen do not opt for this procedure, as the skin grafted forearm donor site may be readily visible in short sleeved clothing and could be a giveaway for those conversant with the procedure. The authors carry out glansplasty at the same sitting in fRAFFp. The resultant neopenis looks like a circumcised erect penis. Urethra is also reconstructed at the same time, by using a part of flap skin rolled inside the outer part (tube in tube method) or using previous prelamination. This penile urethra is anastomosed to the previously advanced urinary meatus to restore the urethral continuity. Previously reconstructed scrotum is now sutured to the ventral proximal edge of neo-penis, thus also providing a waterproofing layer over urethral anastomosis. After the implantation of erectile device 6 months later, the individual can engage in penetrative sexual intercourse, has good erogenous sensation and is able to micturate in erect position without soiling himself. The complication rate of urethral fistula and stricture is close to 40% after phalloplasty. As a result, few individuals do not opt for phalloplasty, and instead opt for enlargement of clitoris (Metaidoioplasty). In this procedure, the natural clitoral chordee is released and urethra is advanced to the tip of clitoris. Though this procedure does not enable the individual to engage in penetrative sexual intercourse in most cases, it allows for excellent erogenous sensation and orgasm, and in some cases, allows the individuals to micturate in erect position.

- iv) **Ancillary procedures:** As there is no other erectile tissue in the body like penile corpora, a reconstructed penis is made in erect size. However, it still lacks the necessary rigidity, to allow vaginal penetration necessary for a sexual intercourse. For this purpose, erectile devices may be implanted in neopenis, (similar to the devices used in biologic male impotence), usually 6 months after penile reconstruction, when necessary

protective sensation has returned. The device can be a malleable rod with hinge, or inflatable prosthesis. Mandibular implants, genioplasty, rhinoplasty etc. can help masculinize a face. Laryngeal surgery can masculinize the voice. Pectoral implants in addition to top surgery can help masculinize the chest. Hi-definition body contouring procedures and 'six pack plasty' can help produce an aesthetic masculine abdominal appearance.

Conclusion

Gender incongruence and variance is a universal and culturally diverse phenomenon. Those persons requiring affirmative procedures should be managed by multidisciplinary teams (GIC's) comprising of various specialists, who are well versed in providing gender sensitive healthcare. Surgical management is a part of the comprehensive management of such persons and helps in alleviating gender incongruence. Not all individuals require every surgical procedure. The surgical care of these individuals needs to be customized to the individual's requirements and a customized algorithm needs to be devised for the purpose early in the treatment. The goal of Gender Affirmation Surgery is to allow these individuals to freely express their gender and perfectly blend in their desired gender role.

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Surgical Consent Forms

1) CONSENT FOR BREAST AUGMENTATION SURGERY WITH AUTOLOGOUS FAT IN MALE TO FEMALE GENDER INCONGRUENT INDIVIDUALS

GENERAL INFORMATION

While many gender-incongruent individuals find comfort with their gender identity, role, and expression without surgery, for many others surgery is essential and medically necessary to alleviate their gender incongruence. For the latter group, relief from gender incongruence cannot be achieved without modification of their primary and/or secondary sex characteristics to establish greater congruence with their gender identity and expression.

Usually feminizing hormonal therapy will stimulate breast growth, but a subset of individuals may not be satisfied with this growth alone and may opt for surgical breast augmentation procedure.

As this operation is completely cosmetic elective, a detailed consultation is essential so that you are educated about the procedure. For some trans women (male to female transitioning individuals), feminizing surgery is a natural step, and important to their sense of self. However, many choose not to have surgery. Transgender individuals relate to their bodies differently and need to make individual choices that best fit their requirements.

This is an informed-consent document that has been prepared to educate and inform you regarding augmentation mammoplasty surgery with autologous (own) body fat injections, its risks, as well as alternative treatment(s).

It is important that you read this information carefully and completely.

Preconditions and requirements prior to transfeminine augmentation mammoplasty

1. Persistent, well-documented gender incongruence.
2. Referral letter for surgery from one mental health professional
3. Capacity to make a fully informed decision and to give consent for treatment.

4. Age of majority (18years or more in India)
5. If significant medical or mental health concerns are present, these must be reasonably well controlled.
6. Recommended (not obligate) criterion- 12 months of feminizing hormone therapy prior to this procedure. This results in realistically the maximum breast growth that can occur by non-surgical means, allowing you to take a better decision whether or not to opt for further surgical breast augmentation.

Information regarding autologous fat breast augmentation procedure

Prior to this procedure, external tissue expansion systems like Brava may be prescribed by your surgeon. These devices need to be worn for 10-12 hours daily, for around 4 weeks prior to surgery. Such devices cause temporary expansion of tissues in the area of application (breast), so that more fat graft can be accommodated by breast, and the recipient bed is better prepared to ensure fat graft survival. During the procedure, one's own body fat tissue is harvested with the help of thin cannulae and low-pressure liposuction procedure. The donor site of fat graft is any area with excessive superficial fat, especially lower abdomen, thighs, flanks, and hip area. The harvested fat is then washed with saline and refined by one of the various methods in operation theatre, such as filtration, centrifugation, gravity sedimentation and decantation, fat refining systems etc leading to removal of contaminants such as saline, oil, cell debris, non-fat tissue etc. The refined fat is then injected into the breast area in subcutaneous, and subglandular/ prepectoral locations to build up the breast volume. Over a period, part of injected fat takes up as a graft and part of it gets absorbed, gets necrosed, forms cyst or gets calcified. At one sitting, only a limited amount of fat can be injected. The fat injection sittings may be repeated at intervals of 4-6 weeks. A total of 1-4 sittings may be required to augment the breast size. Your surgeon will make a few small incisions to insert the cannulae for harvesting fat. There will also be a few small incisions on and around the breast for entry of needles and thin cannulae for injecting fat.

Despite multiple sittings, only moderate breast augmentation (one cup size) is usually achievable by autologous fat injection technique. You should also not be excessively slim, otherwise there will not be sufficient available fat donor area. It may take upto 6 months for final result to appear. Alternatives to this procedure may be silicone gel or saline filled silicone breast implant augmentation. Breast augmentation can also be done with the help of flap transfer of tissues like subcutaneous

tissue and muscle into the breast area. You may also, opt, not to undergo breast augmentation.

Risks associated with autologous fat breast augmentation surgery

Note: The listed risks and complications are not all inclusive.

Every surgical procedure has some degree of unavoidable risk. Problems associated with autologous fat breast augmentation procedure, the injected tumescent solution or anaesthesia. It is important that you understand these risks and the possible complications associated with them.

The most common risks associated with injectable fat breast augmentation surgery are as follows:

Bleeding: Very little blood is lost at the time of surgery. It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain the accumulated blood. When a significant amount of blood collects at the surgical site it is called a “hematoma” and will likely need return to operating room to be drained. Hematoma can occur at any time following surgery or any form of injury to the breast and may contribute to infection or other problems. It is very important to stay off all blood thinning medications for two weeks before and after surgery. Do not take aspirin or any anti-inflammatory medications before or after surgery, as this may increase the risk of bleeding. Non-prescription “herbs” and dietary supplements can increase the risk of surgical bleeding. Vitamin E, untested supplements, a variety of other prescription and over the counter medications should be avoided. After surgery, the risk of bleeding can be reduced significantly by not straining or exerting yourself for at least four weeks, and by keeping your arms at your sides as much as possible for that period. Small amounts of bleeding can be absorbed by the body but can still impact healing.

Infection: Bacteria live on the skin and within the ducts of the breast. You will be given antibiotics through your intravenous line at the time of surgery and will require to take oral antibiotics following surgery. Although infection is unusual after this type of surgery, it may appear in the immediate post-operative period or at any time following the procedure. Should an infection occur, treatment including antibiotics, possible drainage, or additional surgery may be necessary.

Seroma: Fluid may accumulate around the implant following surgery, trauma, or vigorous exercise. Additional treatment may be necessary

to drain fluid accumulation around breast or fat donor areas. This may contribute to infection or other problems.

Asymmetry: It is unusual to find a person with perfectly symmetric breasts. Because the body is not completely symmetric and most people have a dominant upper extremity, there is usually a small amount of asymmetry following this type of surgery. Differences in terms of breast and nipple shape, size, or symmetry may also occur after surgery. These small degrees of asymmetry need to be accepted. Large degrees of asymmetry may be improved with additional surgery.

Calcification, cysts and swellings: Calcium deposits can form in and around the areas of fat graft which did not take up. In mammography, these can present as thin walled calcifications around oil cysts or coarse irregular calcifications. These can usually be differentiated from clusters of pleomorphic calcifications, which occur in early breast cancer. On ultrasound examination, liponecrotic cysts often appear as anechoic areas. On MRI, necrotic area of fat has lower signal intensity than normal fat. With the help of these investigations, the persistent areas of fat necrosis can usually be differentiated from breast cancer. However, in cases of persistent symptoms and inability to differentiate, additional surgery may be necessary to remove and examine these areas.

Pain: Expect some pain and discomfort for around one month. This will improve gradually. Severe pain is not expected, and you should present yourself for examination if there is a problem. Gentle massage may help alleviate pain in fat donor area.

Change in Nipple and Skin Sensation: Nerves that provide sensation to the nipple come from branches through the ribs and around the side of the breast. During the procedure, these nerves may be stretched, and sometimes even cut. Uncommonly, people will experience a decrease in nipple sensation following this type of surgery, although some become hypersensitive. It may take a year before maximal return is seen. In rare cases, nipple numbness can be permanent.

Risk of cancer: Autologous fat grafting to breast is not known to stimulate cancerous growth in the breast. In-fact this surgery is also carried out in some biologic women, who have undergone resection for breast cancer. Studies also show an increased risk of breast cancer in trans women compared with cisgender men, probably due to the feminizing hormone therapy. Therefore, transwomen undergoing autologous fat augmentation of breasts should undergo regular follow-up for monitoring as advised by the physician, including MRI and mammograms. The absolute overall risk of breast cancer in transgender people remains low and therefore

it seems sufficient for transgender people using hormone treatment to follow screening guidelines as for cisgender women.

Problems with Healing: Wound disruption or delayed wound healing is possible. Some areas of the breast skin or nipple region may not heal normally and may take a long time to heal. Risk factors for tissue breakdown or necrosis include a depressed immune system, steroid use, smoking, history of radiation, and exposure to extreme temperatures. The incision sites may become hypertrophic. Bruising, hyperpigmentation and unevenness may persist in the donor area. Smokers have a greater risk of wound healing complications.

Sutures: Incisions are likely to be small, typically less than one cm. These may or may not be sutured as per the surgeon preference and situation. You may notice these sutures after your surgery. Sutures may spontaneously poke through the skin, become visible or produce irritation that requires suture removal.

Poor Appearing Scars: All surgery leaves permanent scars. In some cases, these are more visible than others. Although a normal wound healing is expected after a surgical procedure, sometimes abnormal scars/keloid may occur within the skin and deeper tissues. There are many things that you will be required to do and be advised after surgery to improve the appearance of the scars. These may include application of various creams, gels, gel sheets, pressure garments and intra scar injections. It may take upto a year for the final/ long term appearance of scars to emerge. Surgery for scar revision may rarely be required.

Stretch marks: Individuals on feminizing hormonal therapy have higher propensity for developing stretch marks on the breast skin which might be dark colored. It might settle with time; however complete resolution of the stretch marks is unusual.

Dissatisfaction with Cosmetic Results: The lipoinjection volume for your surgery will be decided according to how much breast tissue you have, the ptosis, the size of your rib cage, laxity of your skin, your body shape, and finally, your target cup size. The take of injected fat graft is variable. Typically, around 40-60% of fat graft takes, and the remaining fat absorbs or necroses. You may require multiple sittings to achieve your target cup size. The augmentation with this method is at most one cup size or moderate. If you desire significant augmentation of more than a cup size, then you should look for alternate technique such as implant augmentation.

Risks of Surgery and Anesthesia: There are additional risks associated with having surgery, including medication reactions, and complications

from anesthesia. Both local and general anesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anesthesia or sedation. Other risks include pneumonia, deep venous thrombosis (blood clot in the leg), and pulmonary embolus (clot and rarely fat that travels to the lung), and allergic reactions. In rare cases, local allergies to tape, suture material and glues, blood products, topical preparations or injected agents have been reported. Serious systemic reactions including anaphylaxis may occur in response to drugs used during surgery and prescription medicines. These are rare but are possible with any type of surgery.

Cardiac and Pulmonary Complications: Pulmonary complications may occur secondary to both blood clots (pulmonary emboli), fat deposits (fat emboli) or partial collapse of the lungs after general anesthesia. Pulmonary emboli can be life-threatening or fatal in some circumstances. Cardiac complications are a risk with any surgery and anesthesia, even in individuals without symptoms. Should any of these complications occur, you may require hospitalization and additional treatment. If you experience shortness of breath, chest pains, or unusual heart beats after surgery, seek medical attention immediately.

Photographs: Pre-operative and post-operative photos will be taken to help with surgical planning and to document results. Your photos (which never include your face) may also be used for teaching purposes to help doctors or other individuals.

Long-Term Results: Subsequent alterations in breast shape may occur as the result of aging, weight loss, weight gain, or other circumstances not related to your augmentation mammoplasty. Breast sagging after augmentation may normally occur.

INDIVIDUAL COMPLIANCE

Preoperatively, feminizing hormone therapy should be withheld for a period as advised by the endocrinologist/ physician.

Post operatively, follow all physician instructions carefully; this is essential for the success of your outcome. It is important that the surgical incisions are not subjected to excessive force, swelling, abrasion, or motion during the time of healing. Personal and vocational activity needs to be restricted. Protective dressings and drains should not be removed unless instructed by your plastic surgeon.

Successful post-operative function depends on both surgery and subsequent care. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation and the need for

return to surgery. It is wise to refrain from intimate physical activities after surgery until your physician states it is safe. It is important that you participate in follow-up care like topical applications, massage therapy, pressure garments, wearing supportive bra etc. You should return for postoperative checks and aftercare, and thus actively promote your recovery after surgery.

FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges for the services provided. The total includes in-facility charges, fees charged by your surgeon, the cost of surgical supplies, anaesthesia, laboratory tests, and miscellaneous hospital charges, depending on where the surgery is performed. You will be provided an approximate written estimate of charges before surgery. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered.

The fees charged for this procedure do not include-

- 1) Charges after the discharge such as consults and dressings.
- 2) Charges for medicines, gels, ointments, gel-sheets, pressure garments, supporting bra etc.
- 3) Any potential future costs for additional procedures that you elect to have or require to revise, optimize, or complete your outcome.
- 4) Additional costs may occur should complications develop from the surgery. Secondary /additional surgeries, investigations or hospital stay, and surgery charges involved with revision surgeries would also be your responsibility.
- 5) The costs for physiotherapy or any supportive therapy if required.

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

1. I hereby authorize Dr _____ and such assistants as may be selected to perform the following procedure or treatment: **AUGMENTATION MAMMOPLASTY with autologous fat injections.**
2. I recognize that during the surgical procedure and medical treatment or anaesthesia, unforeseen conditions may necessitate different procedures than those specified above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or

her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.

3. I consent to the administration of such anaesthetics considered necessary or advisable. I understand that all forms of anaesthesia involve risk and the possibility of complications, injury, and sometimes death.
4. I understand what my surgeon can and cannot do, and I understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All my questions have been answered, and I understand the inherent (specific) risks of the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.
5. I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
6. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
7. I consent to the utilization of blood products should these be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
8. I understand that the surgeon's fees are separate from the anaesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
9. I realize that not having the operation is an option.
10. The procedure has been explained to me in a way that I understand:
 1. The above treatment or procedure to be undertaken
 2. There may be alternative procedures or methods of treatment
 3. There are risks to the procedure or treatment proposed

I consent to the treatment or procedure and the above listed items (1-10). I have fully discussed all aspects of the procedure, possible complication, aftercare, need for additional/ secondary/ revisional procedures and expenses to my satisfaction.

Name of Individual.....Signature of Pt.....

Date.....

Name of the Witness.....

Relationship.....

Signature of witness.....

Date.....

Name of doctor.....

Designation.....

Signature.....

Date.....

2) INDIVIDUAL INFORMATION AND INFORMED CONSENT FOR FEMINIZING GENITOPLASTY INCORPORATING ILEAL SEGMENT

While many gender-incongruent individuals find comfort with their gender identity, role, and expression without surgery, for many others surgery is essential and medically necessary to alleviate their gender incongruence. For the latter group, relief from gender incongruence cannot be achieved without modification of their primary and/or secondary sex characteristics to establish greater congruence with their gender identity and expression. Vaginal, clitoral, labial and vestibular reconstruction is of major importance for the psychological and sexual well-being and quality of life in transgender women. The advantages of intestinal vaginoplasty are providing sufficient vaginal depth, self-lubricating, and a lesser tendency to shrink.

This is an informed-consent document that has been prepared to help inform you about male to female sex reassignment genital surgery, its risks, and alternative treatments. This document consists of two parts- the first part is detailed information regarding the procedure and the next is procedure specific consent. Please go through the entire document before consenting to the procedure.

Part 1- Individual information

Introduction**1) Preconditions for surgery:**

- a) Firm diagnosis of Gender Incongruence, as per ICD-11/ DSM5 by two different mental health professionals.
- b) The reference letters from mental health professionals should include the parameters as mentioned in 7th SOC's, mainly the diagnosis, individual's mental competence to give consent for surgery and hormone therapy and the fact that all co-existing mental health conditions are currently well controlled.
- c) The individual has completed 12 months of hormone therapy under guidance from a hormone specialist/ gender team unless individual is unwilling to take hormones/ unable to take hormones or the hormone therapy is medically contraindicated. (In India many individuals, especially MTF, are however well adapted in their desired gender role and are unwilling to take hormone therapy).
- d) The individual has experienced living in desired gender role for a period of 12 months.
- e) A legally notarized waiver of liability affidavit on stamp paper, waiving the gender team's liability for removing individual's healthy organs, permanent loss of current sexual functioning and reproductive ability.

2) Preoperative Requirements:

- a) Stopping health supplements such as omega, fish oils, herbal products, garlic, green tea etc from 2 weeks prior to surgery.
- b) Stop smoking from 4 weeks prior to surgery.
- c) Limit/ stop alcohol intake 4 weeks prior to surgery.
- d) Hormone therapy should be stopped/ adjusted for 3-4 weeks prior to surgery as per advice of treating physician.
- e) Stop blood thinners if feasible, from 5 days prior to surgery with permission from individual's cardiologist.
- f) Liquid diet from 48 hours prior to surgery. Clear liquids only on the day prior to surgery.
- g) Bowel wash will be started 1pm on the day prior to surgery.

3) Pre-operative Investigations:

- a) Complete blood counts, coagulation profile, Blood sugar fasting and PP, LFT, RFT, TSH, viral markers for hepatitis B, C and

HIV, EKG, Chest x ray. Ultrasound whole abdomen. Other specific investigations if required for co-existing conditions and as per current guidelines.

4) Options for the proposed surgical procedure and details

Other surgical options are penile and augmenting flaps lined vaginoplasty, skin graft vaginoplasty, sigmoid segment vaginoplasty and peritoneal vaginoplasty. The pros and cons of all the options have been explained. In these cases, the method/tissue for lining the neovaginal cavity is different. Most other steps are similar. Another alternative could be to opt for reconstruction of only external organs, without creating a vaginal cavity.

5) Procedure specific information:

- a) General individual identifiers, names of admitting surgeons, individual's and witness's signatures, permission for photo and videography etc are usually part of general hospital consent and also may be a part of this consent. Higher risk due to some co-existing condition and anaesthesia consents are separate.
- b) Trimming of hair / Shaving of the private parts and abdomen will be done.
- c) The procedure will be laparoscopic with or without a short abdominal incision in addition to laparoscopic ports.
- d) The average duration of surgery is expected to be around 7-8 hours. It can vary in the individual case.

6) Surgical Technique

The procedure as described below may be varied and all steps may not be carried out. If needed, extra steps may be carried out and the procedure may be varied from the below description if operative situation so demands or as per surgeon's discretion.

1. The individual is placed in the lithotomy position laparoscopy ports are inserted. A suitable segment of ileum is mobilized, and mesentery is inspected for vascular pattern (under transillumination in fatty mesentery). Part of ileum will be isolated depending on the vascular pattern.
2. The segment of the ileum is divided at proximal and distal sites. The proximal end of the flap is closed making it the dome of neo-vagina.

3. Vaginal cavity (pelvic and perineal dissection): Cavity for future neo vagina is created between bladder and rectum by sharp and blunt pelvic dissection. About 1 cm from anus, a posteriorly based perineal/scrotal flap is raised and a cavity is created between urethral bulb and rectum. The perineal and pelvic parts of dissection are connected with careful bimanual palpation and dissection.
4. The ileal loop is delivered gently in the created cavity avoiding any kink of the pedicle. The distal end of the ileum is sutured with invaginated penile and scrotal flaps. The abdominal surgeon performs the ileal anastomosis. The abdomen is closed in layers.
5. Bilateral Orchiectomy: Both testes are removed. Cords may also be removed, or cord tissue may be used to augment labia majora as per requirement.
6. Penile skin degloving: Penile skin is degloved superficial to Buck's fascia all the way except a small flap of inner preputial skin which is left attached to the glans for purpose of forming clitoral hood.
7. Dissection of glanulo-preputial island flap: The dorso-lateral part of glans with attached preputial skin flap, underlying neurovascular bundles, with or without Bucks fascia and dorsal tunica albuginea is dissected, till the base of penis. The glans wings are sutured to themselves to create the neo clitoris.
8. Corpora are separated from urethra till just under the pubic symphysis, transected and resected.
9. Urethra is dissected to base, the bulbocavernosus muscle is removed to expose bare bulb. If the urethra is not being used for augmentation of penile skin flap, excess urethra is removed and the opening in bulb is widened. The margins are everted to form new urinary meatus.
10. Slit is made in proximal part of penile skin flap for exposing the neoclitoris and urethral meatus. These structures are now sutured in place.
11. The distal end of penile skin flap is sutured to anterior edge of ileal segment in a staggered manner.
12. Remnants of scrotal skin flaps are sutured to penile skin flap, to form labia majora. Medial aspects of penile skin flaps around the slits may be fashioned to form labia minora.

13. A pack is usually placed in neovaginal cavity to maintain it. A dressing is then applied.

7) **Postoperative Course:**

At the end of operation, you will have:

1. Dressing over the perineum and left abdomen
2. Urinary catheter
3. Epidural catheter
4. Blood pressure cuff over the arm to measure your blood pressure (you will feel pressure over the arm intermittently)
5. Pulse Oximeter to monitor your pulse rate and oxygen saturation
6. DVT pump over lower limbs, you will feel intermittent pressure over the lower limbs. Usually kept for initial 24 to 48 hrs to prevent clotting in the leg veins.
7. Intravenous cannula- to administer antibiotics, IV fluids and other medicines.
8. Need for post op procedures- like dressings, dilation, drain removal and urinary catheter removal (catheter may be reinserted in case of urinary retention and may be kept for couple of weeks)
9. Position change – gentle guided side-turn allowed after 24 hrs.
10. Ambulation- usually 3rd to 7th day.
11. Dilation -dilation is usually started on 5th to 7th day.
12. Diet- You will be kept nil orally till the wind breaks (passing flatus). Once you pass flatus, you will be given clear fluid followed by liquid diet. Liquid to very soft diet is recommended till 4 weeks. After that you can resume normal diet.
13. Duration of hospital stay – 7 to 10 days

8) **Complications** -

Note: The listed risks and complications are not all inclusive.

While majority of individuals have an uneventful surgery and recovery, few cases may be associated with complications. These are seen infrequently and not all the ones listed below are applicable to one individual. However, it is important that you are aware of the complications/risks that may arise out of this procedure which are as below:

- a) Bleeding- It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain accumulated blood or blood transfusion. You should reveal all the medications that you have been taking to the surgeon so that medicines that can cause bleeding can be stopped or its dose adjusted before the surgery.
- b) Infection- Bacteria live on the skin and near the perineal area. You will be given antibiotics through your I.V. at the time of surgery and will be required to take oral antibiotics following surgery and after discharge. Although infection is unusual after this type of surgery, it may appear in the immediate post-operative period or at any time following the surgery. Should an infection occur, treatment including antibiotics, or additional surgery may be necessary.
- c) Vascular compromise- though rare, there are chances of failure of operation due to vascular problems of ileum. If so, then one of the alternate procedures as detailed above may be required.
- d) Injury to nearby structures- urethra (1.2%), ureters, bladder and rectum (2.3%-2.5%) leading to Recto vaginal fistulas (0.6%-1.1%) or urethra neovaginal fistula (1.7%-2%)
- e) Necrosis - clitorio-labial complex partial or complete (0.5% - 24%)
- f) Paralytic ileus and bowel obstruction can occur (0.8%-3.6%) which may necessitate prolonged fasting and nasogastric aspiration, and in some cases repeat surgery.
- g) Altered bowel habits might occur
- h) Urinary issues (retention/incontinence/infection (1.3%-14%). Urethral meatus stenosis might occur which might need dilatation and possibly surgery
- i) Mucorrhea- Excessive mucus discharge (6.2%-28.6%) might occur
- j) Prolapse of the ileal segment might occur. (1.5%)
- k) Corpus spongiosum protrusion- (6.1%-15.6%)
- l) Introital or Vaginal stenosis (1.5%- 22.5%)
- m) Decreased/absent sensations with possible absence of orgasmic capabilities (3.3%)
- n) Wound healing issues (5.4%)

- o) Scarring/hypertrophic scar/keloid over abdomen and perineum
- p) Ileal anastomotic leak with possible need for creation of a stoma(ileostomy or colostomy).
- q) Abdominal hernia
- r) Possible Touch up procedures/surgical corrections (for aesthetic improvement, vaginal stenosis, corpus spongiosum correction etc.
- s) Pulmonary embolism—sometimes blood clot in the leg vein can travel up to lungs and cause difficulty in breathing. We use DVT pump and proper IV fluids to prevent. But rarely, deaths have been reported
- t) The procedure is irreversible. There will be permanent loss of ability to serve as a male partner in penetrative sexual intercourse.
- u) There will be loss of fertility due to removal of testes. This procedure will not grant you the ability to conceive.
- v) The procedure in itself does not provide any guarantees to you about successful sexual intercourse or success in marriage or relationship.
- w) **Unsatisfactory result-** You may be disappointed with the result of the surgery. It may be necessary to perform additional surgery to improve your results.
- x) **Allergic reactions-** In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions which are more serious may occur to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.
- y) **Surgical anaesthesia-** Both local and general anaesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anaesthesia or sedation.
- z) **Additional surgery necessary-** There are many variable conditions that may influence the long-term result of male to female genital gender affirmation surgery. Should complications occur, additional surgery or other treatments may be necessary. Besides the cited complications, other complications and risks can occur but are even more uncommon. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.

- 9) Discharge instructions- vary individual to individual and will be explained to you at the time of discharge.

10) Post-operative follow-up

Special precautions to be taken at home

- a) Diet- liquid to soft diet for 4 weeks.
- b) Local cleaning and dressing as explained. Need to wear a clean pad.
- c) Have bath regularly.
- d) Dilation schedule to be followed as instructed for at least 6 months, and later on if required.
- e) Exercise and Sexual activities- usually after 8 weeks
- f) Scar care explained.
- g) Urinary catheter care if individual is discharged with catheter and need of catheter removal in local area or during follow up
- h) Possible need of touch procedures explained

Follow up every month till 6 months, at follow up special focus on dilation.

Follow up with Psychiatrist/psychologist and Endocrinologist as per their advice.

Financial responsibilities

The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of surgical supplies, laboratory tests, blood bank, anaesthesia, and hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered.

Additional costs may occur should complications develop from the surgery. Secondary /additional surgeries, investigations or hospital stay and surgery charges involved with revision surgeries would also be your responsibility.

PART 2: CONSENT FORM

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). The informed-

consent process attempts to define principles of risk disclosure that should generally meet the needs of most individuals in most circumstances.

However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information which is based on all the facts in your particular case and the state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

- a) I hereby authorize Dr _____ and such assistants as may be selected to perform the following procedure or treatment: **feminizing genitoplasty with incorporation of ileal segment for lining the neovaginal cavity.**
- b) I consent to the presence of OR staff of either sex to be present in OR during my surgery. I understand that they are present for the safe conduct of my surgery.
- c) I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
- d) I consent to the administration of such anaesthetics considered necessary or advisable. I understand that all forms of anaesthesia involve risk and the possibility of complications, injury, and sometimes death.
- e) I understand what my surgeon can and cannot do, and I understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks of the procedures

I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.

- f) I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
- g) For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
- h) I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
- i) I understand that the surgeon's fees are separate from the anaesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
- j) I realize that not having the operation is an option. **I understand that no guarantee has been made that the procedure will improve the condition and that the procedure may make my condition worse.**
- k) It has been explained to me in a way that i understand:
 - a. The above treatment or procedure to be undertaken
 - b. There may be alternative procedures or methods of treatment
 - c. There are risks to the procedure or treatment proposed

I consent to the treatment or procedure. I am satisfied with the explanation.

Name of Individual.....Signature of Pt.....

Date.....

Name of the Witness.....

Relationship.....

Signature of witness.....

Date.....

Name of doctor.....

Designation.....

Signature.....

Date.....

3) INDIVIDUAL INFORMATION AND INFORMED CONSENT FOR FEMINIZING GENITOPLASTY INCORPORATING PENILE SKIN FLAP AUGMENTED WITH PERINEAL- SCROTAL SKIN FLAPS FOR VAGINAL LINING

GENERAL INFORMATION

While many gender-incongruent individuals find comfort with their gender identity, role, and expression without surgery, for many others surgery is essential and medically necessary to alleviate their gender incongruence. For the latter group, relief from gender incongruence cannot be achieved without modification of their primary and/or secondary sex characteristics to establish greater congruence with their gender identity and expression. Vaginal, clitoral, labial and vestibular reconstruction is of major importance for the psychological and sexual well-being and quality of life in transgender women. Advantages of the procedure are less shrinkage compared to skin graft, no need of an abdominal procedure, no need of bowel surgery and hence, less morbidity and attainment of good vaginal depth.

This is an informed-consent document that has been prepared to help inform you about male to female gender affirming genital surgery, its risks, and alternative treatments. This document consists of two parts- the first part is detailed information regarding the procedure and the next is procedure specific consent. Please go through the entire document before consenting to the procedure.

Part 1- Individual information

Introduction

1) Preconditions for surgery:

- a) Firm diagnosis of Gender Incongruence, as per ICD-11/ DSM5 by two different mental health professionals.
- b) The reference letters from mental health professionals should include the parameters as mentioned in 7th SOC, mainly the diagnosis, individual's mental competence to give consent for surgery and hormone therapy and the fact that all co-existing mental health conditions are currently well controlled.
- c) The individual has completed 12 months of hormone therapy under guidance from a hormone specialist/ gender team unless individual is unwilling to take hormones/ unable to take hormones or the hormone therapy is medically contraindicated. (Many individuals in India, especially MTF, are however well

adapted in their desired gender role and are unwilling to take hormone therapy).

- d) The individual has experienced living in desired gender role for a period of 12 months.
- e) A legally notarized waiver of liability affidavit on stamp paper, waiving the gender team's liability for removing individual's healthy organs, permanent loss of current sexual functioning and reproductive ability.

2) Preoperative Requirements:

- a) Stopping health supplements such as omega, fish oils, herbal products, garlic, green tea etc from 2 weeks prior to surgery.
- b) Stop smoking from 4 weeks prior to surgery.
- c) Limit/ stop alcohol intake 4 weeks prior to surgery.
- d) Hormone therapy should be stopped/ adjusted for 3-4 weeks prior to surgery as per advice of treating physician.
- e) Stop blood thinners if feasible, from 5 days prior to surgery with permission from individual's physician/ cardiologist.

3) Pre-operative Investigations:

Complete blood counts, coagulation profile, Blood sugar fasting and PP, LFT, RFT, TSH, viral markers for hepatitis B, C and HIV, EKG, Chest x ray. Other specific investigations if required for co-existing conditions and as per current guidelines.

4) Alternative Options for the proposed surgical procedure

Other surgical options are skin grafting, ileal vaginoplasty, sigmoid segment vaginoplasty and peritoneal vaginoplasty. In these cases, the method/ tissue for lining the neovaginal cavity is different. Most other steps are similar. Another alternative could be to opt for reconstruction of only external organs, without creating a vaginal cavity.

5) Procedure specific information:

- a) General individual identifiers, names of admitting surgeons, individual's and witness's signatures, permission for photo and videography etc are usually part of general hospital consent and, also may be a part of this consent. Higher risk due to some co-existing condition and anaesthesia consents are separate.
- b) Trimming of hair / Shaving of the private parts and abdomen will be done.
- c) The average duration of surgery is expected to be around 4-5 hours. It can vary in the individual case.

d) Surgical Technique

The procedure as described below may be varied and all steps may not be carried out. If needed, extra steps may be carried out and the procedure may be varied from the below description if operative situation so demands or as per operating surgeon's discretion.

- i) The individual is placed in the lithotomy position.
- ii) Bilateral Orchiectomy: Both testes are removed. Cords may also be removed, or cord tissue may be used to augment labia majora as per requirement.
- iii) Penile skin degloving: Penile skin is degloved superficial to Buck's fascia all the way except a small flap of inner preputial skin which is left attached to the glans for purpose of forming clitoral hood.
- iv) Dissection of glanulo-preputial island flap: The dorso-lateral part of glans with attached preputial skin flap, underlying neurovascular bundles, with or without Bucks fascia and dorsal tunica albuginea is dissected, till the base of penis. The glans wings are sutured to themselves to create the neo clitoris.
- v) Corpora are separated from urethra till just under the pubic symphysis, transected and resected.
- vi) Urethra is dissected to base, the bulbocavernosus muscle is removed to expose bare bulb. If the urethra is not being used for augmentation of penile skin flap, excess urethra is removed and the opening in bulb is widened. The margins are everted to form new urinary meatus.
- vii) Vaginal cavity (pelvic and perineal dissection): Cavity for future neo vagina is created between bladder and rectum by sharp and blunt pelvic dissection.
- viii) Additional vaginal cavity lining flaps: Additional flaps may be dissected from central perineal skin, scrotum and/or urethra to augment the penile skin flap in order to create a deeper lined vaginal cavity.
- ix) Penile skin flap is now used on it's own, or joined to scrotal flap/ perineal flap/ urethral flap/ scrotal skin graft to create vaginal lining.
- x) Slit is made in proximal part of penile skin flap for exposing the neoclitoris and urethral meatus. These structures are now sutured in place.

- xi) Suture may be taken from penile skin flap to either one or both sacrospinous ligaments for preventing postoperative vaginal prolapse. The neovaginal lining is now inserted into dissected cavity and sacrospinous ligament sutures tied.
- xii) Remnants of scrotal skin flaps are sutured to penile skin flap, to form labia majora. Medial aspects of penile skin flaps around the slits may be fashioned to form labia minora.
- xiii) A pack is usually placed in neovaginal cavity to maintain it. A dressing is then applied.

6) Postoperative Course:

At the end of operation, you will have:

- a) Dressing over the perineum.
- b) Urinary catheter
- c) Epidural catheter
- d) Blood pressure cuff over the arm to measure your blood pressure (you will feel pressure over the arm intermittently)
- e) Pulse Oximeter to monitor your pulse rate and oxygen saturation
- f) DVT pump over lower limbs, you will feel intermittent pressure over the lower limbs. Usually kept for initial 24 to 48 hrs to prevent clotting in the leg veins.
- g) Intravenous cannula- to administer antibiotics, IV fluids and other medicines.
- h) Need for post op procedures- like dressings, dilation, drain removal and urinary catheter removal (catheter may be reinserted in case of urinary retention and may be kept for couple of weeks)
- i) Position change – gentle guided side-turn allowed after 24 hrs.
- j) Ambulation- usually 3rd to 7th day.
- k) Dilation -dilation is usually started on 5th to 7th day.
- l) Duration of hospital stay – 4-6 days

7) Complications -

Note: The listed risks and complications are not all inclusive.

While majority of individuals have an uneventful surgery and recovery, few cases may be associated with complications. These are seen infrequently and not all the ones listed below are applicable to one individual. However, it is important that you are aware of the

complications/risks that may arise out of this procedure which are as below:

- a) Bleeding- It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain accumulated blood or blood transfusion. You should reveal all the medications that you have been taking to the surgeon so that medicines that can cause bleeding can be stopped or its dose adjusted before the surgery.
- b) Infection- Bacteria live on the skin and near the perineal area. You will be given antibiotics through your I.V. line at the time of surgery and will be required to take oral antibiotics on discharge. Although infection is unusual after this type of surgery, it may appear in the immediate post-operative period or at any time following the surgery. Should an infection occur, treatment including antibiotics, or additional surgery may be necessary.
- c) Vascular compromise- though rare, there are chances of failure of operation due to vascular problems of the penile or augmenting skin flap. If so, there may be loss of vaginal depth. To restore vaginal depth, you may require alternative procedure at a later date.
- d) Injury to nearby structures- urethra (1.2 %), ureters, bladder and rectum (2.3 %-2.5 %) leading to Recto vaginal fistulas (0.6 %- 1.1 %) or urethra neovaginal fistula (1.7 %-2 %) may occur.
- e) There may be loss of blood supply to clitorio-labial complex partial or complete (0.5 % -24 %) resulting in necrosis and subsequent loss of these structures.
- f) Urinary issues (retention/incontinence/infection (1.3 %-14 %). Urethral meatus stenosis might occur which might need dilatation and possibly surgery
- g) Corpus spongiosum protrusion may occur in some cases leading to interference with vaginal intercourse- (6.1 %-15.6 %)
- h) Introital or Vaginal stenosis (1.5 %- 22.5 %) may occur.
- i) Decreased/absent sensations with possible absence of orgasmic capabilities may occur in around 3.3 % cases.
- j) Wound healing issues may occur in around 5.4% cases leading to delayed healing.
- k) Possible hair growth may occur in neovagina. This may require the use of epilating creams.

- l) There may be chances of abnormal/ hypertrophic scarring, as in any surgery.
- m) Possible Touch up procedures/surgical corrections may be required for aesthetic improvement and above conditions.
- n) Pulmonary embolism—sometimes blood clots in the leg vein can travel up to lungs and cause difficulty in breathing. We use DVT pump and proper IV fluids to prevent. But rarely, deaths have been reported
- o) The procedure is irreversible. There will be permanent loss of ability to serve as a male partner in penetrative sexual intercourse.
- p) There will be permanent loss of fertility due to loss of testicles. This procedure will not grant you the ability to conceive.
- q) The procedure in itself does not provide any guarantees to you about successful sexual intercourse or success in marriage or relationship success.
- r) Unsatisfactory result- You may be disappointed with the result of the surgery. It may be necessary to perform additional surgery to improve your results.
- s) Allergic reactions- In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions which are more serious may occur to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.
- t) Surgical anaesthesia- Both local and general anaesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anaesthesia or sedation.
- u) Additional surgery may be necessary- There are many variable conditions that may influence the long-term result of male to female genital gender affirmation surgery. Should complications occur, additional surgery or other treatments may be necessary. Besides the cited complications, other complications and risks can occur but are even more uncommon. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.
- 8) Discharge instructions-vary individual to individual and will be explained to you at the time of discharge.
- 9) Post-operative follow-up

Special precautions to be taken at home

- a) Local cleaning and dressing as explained. Need to wear a clean pad.
- b) Have bath regularly.
- c) Dilation schedule to be followed as instructed for at least 3 months, and to be continued later if required.
- d) Exercise and Sexual activities may be permitted usually after 8 weeks
- e) Initial wound and later scar care may be advised with specific topical applications.
- f) Urinary catheter care if individual is discharged with catheter and need of catheter removal in local area or during follow up
- g) Possible need of touch procedures explained

Follow-up may be required with decreasing frequency and increasing interval.

Follow up with Psychiatrist/psychologist and Endocrinologist as per their advice.

Financial responsibilities

The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of surgical supplies, laboratory tests, blood bank, anaesthesia, and hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered.

Additional costs may occur should complications develop from the surgery. Secondary /additional surgeries, investigations or hospital stay and surgery charges involved with revision surgeries would also be your responsibility.

PART 2: CONSENT FORM**DISCLAIMER**

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). The informed-consent process attempts to define principles of risk disclosure that

should generally meet the needs of most individuals in most circumstances.

However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information which is based on all the facts in your particular case and the current state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

- a) I hereby authorize Dr _____ and such assistants as may be selected to perform the following procedure or treatment: **feminizing genitoplasty with use of penile skin flap augmented with perineal- scrotal skin flaps for lining the neovaginal cavity.**
- b) I consent to the presence of OR staff of either sex to be present in OR during my surgery. I understand that they are present for the safe conduct of my surgery.
- c) I recognize that during the course of the operation and medical treatment or anaesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
- d) I consent to the administration of such anaesthetics considered necessary or advisable. I understand that all forms of anaesthesia involve risk and the possibility of complications, injury, and sometimes death.
- e) I understand what my surgeon can and cannot do, and I understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered,

and I understand the inherent (specific) risks of the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.

- f) I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
- g) For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
- h) I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
- i) I understand that the surgeon's fees are separate from the anaesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
- j) I realize that not having the operation is an option. **I understand that though it is expected to, but no guarantee has been made that the procedure will improve the condition and that the procedure may make my condition worse.**
- k) It has been explained to me in a way that I understand:
 - a. The above treatment or procedure to be undertaken
 - b. There may be alternative procedures or methods of treatment
 - c. There are risks to the procedure or treatment proposed

I consent to the treatment or procedure. I am satisfied with the explanation.

Name of Individual.....Signature of Pt.....

Date.....

Name of the Witness.....

Relationship.....

Signature of witness.....

Date.....

Name of doctor.....

Designation.....

Signature.....

Date.....

4) Individual Information and Informed Consent for feminizing genitoplasty incorporating Sigmoid segment vaginal lining

GENERAL INFORMATION

While many gender-incongruent individuals find comfort with their gender identity, role, and expression without surgery, for many others surgery is essential and medically necessary to alleviate their gender incongruence. For the latter group, relief from gender incongruence cannot be achieved without modification of their primary and/or secondary sex characteristics to establish greater congruence with their gender identity and expression. Vaginal, clitoral, labial and vestibular reconstruction is of major importance for the psychological and sexual well-being and quality of life in transgender women. The advantages of intestinal vaginoplasty are providing sufficient vaginal depth, self-lubricating, and a lesser tendency to shrink.

This is an informed-consent document that has been prepared to help inform you about male to female sex reassignment genital surgery, its risks, and alternative treatments. This document consists of two parts-the first part is detailed information regarding the procedure and the next is procedure specific consent. Please go through the entire document before consenting to the procedure.

Part 1: Individual information

Introduction

1) Preconditions for surgery:

- a) Firm diagnosis of Gender Incongruence, as per ICD-11/ DSM5 by two different mental health professionals.
- b) The reference letters from mental health professionals should include the parameters as mentioned in 7th SOC, mainly the diagnosis, individual's mental competence to give consent for surgery and hormone therapy and the fact that all co-existing mental health conditions are currently well controlled.
- c) The individual has completed 12 months of hormone therapy under guidance from a hormone specialist/ gender team unless individual is unwilling to take hormones/ unable to take hormones or the hormone therapy is medically contraindicated. (Many individuals in India, especially MTF, are however well adapted in their desired gender role and are unwilling to take hormone therapy).

- d) The individual has experienced living in desired gender role for a period of 12 months.
- e) A legally notarized waiver of liability affidavit on stamp paper, waiving the gender team's liability for removing individual's healthy organs, permanent loss of current sexual functioning and reproductive ability.

2) Preoperative Requirements:

- a) Stopping health supplements such as omega, fish oils, herbal products, garlic, green tea etc from 2 weeks prior to surgery.
- b) Stop smoking from 4 weeks prior to surgery.
- c) Limit/ stop alcohol intake 4 weeks prior to surgery.
- d) Hormone therapy should be stopped/ adjusted for 3-4 weeks prior to surgery as per advice of treating physician.
- e) Stop blood thinners if feasible, from 5 days prior to surgery with permission from individual's physician/cardiologist.
- f) Liquid diet from 48 hours prior to surgery. Clear liquids only on the day prior to surgery.
- g) Bowel wash will be started 1pm on the day prior to surgery.

3) Pre-operative Investigations:

Complete blood counts, coagulation profile, Blood sugar fasting and PP, LFT, RFT, TSH, viral markers for hepatitis B, C and HIV, EKG, Chest x ray, Ultrasound whole abdomen. Other specific investigations if required for co-existing conditions and as per current guidelines.

4) Options for the proposed surgical procedure and details

Other surgical options are penile and augmenting flaps lined vaginoplasty, skin graft vaginoplasty, ileal segment vaginoplasty and peritoneal vaginoplasty. The pros and cons of all the options have been explained. In these cases, the method/ tissue for lining the neovaginal cavity is different. Most other steps are similar. Another alternative could be to opt for reconstruction of only external organs, without creating a vaginal cavity.

5) Procedure specific information:

- a) General individual identifiers, names of admitting surgeons, individual's and witness's signatures, permission for photo and videography etc are usually part of general hospital consent and, also may be a part of this consent. Higher risk due to

some co-existing condition and anaesthesia consents are separate.

- b) Trimming of hair / Shaving of the private parts and abdomen will be done.
- c) Location and length of incision and future scar- The procedure will be laparoscopic with or without a short lower abdomen transverse incision. Sometimes the incision will be made in the Left lower abdomen (left Pfannenstiel) or midline incision (open approach). At the end of the surgery, stitches are applied which are removed after 10-15 days.
- d) The average duration of surgery is expected to be around 7-8 hours. It can vary in the individual case.

6) Surgical Technique

The procedure as described below may be varied and all steps may not be carried out. If needed, extra steps may be carried out and the procedure may be varied from the below description if operative situation so demands.

- a) The individual is placed in the lithotomy position and an open or a laparoscopic approach is used. Recto-sigmoid colon is mobilized, and mesentery is inspected for vascular pattern (under transillumination in fatty mesentery). Part of rectosigmoid colon will be isolated based either on proximal or on distal pedicle depending on the vascular pattern.
- b) The segment of the colon is divided at proximal and distal sites. The proximal end of graft is closed (distal end in cases of distal pedicle) making it the dome of neo-vagina.
- c) Vaginal cavity (pelvic and perineal dissection): Cavity for future neo vagina is created between bladder and rectum by sharp and blunt pelvic dissection. About 1 cm from anus, a posteriorly based triangular perineal/scrotal skin flap (4 cm base width x 6 cm length) is raised and a cavity is created between urethral bulb and rectum. The perineal and pelvic parts of dissection are joined with careful bimanual palpation and dissection.
- d) The colon graft is delivered gently in the created cavity avoiding any kink of the pedicle. The distal end of the colon is sutured with invaginated perineal-scrotal flap completing posterior vaginal wall. The abdominal surgeon performs the colon anastomosis. An abdominal drain is placed (surgeon's decision as per requirement) and the abdomen is closed in layers.

- e) Bilateral Orchiectomy: Both testes are removed. Cords may also be removed, or cord tissue may be used to augment labia majora as per requirement.
- f) Penile skin degloving: Penile skin is degloved superficial to Buck's fascia all the way except a small flap of inner preputial skin which is left attached to the glans for purpose of forming clitoral hood.
- g) Dissection of glanulo-preputial island flap: The dorso-lateral part of glans with attached preputial skin flap, underlying neurovascular bundles, with or without Bucks fascia and dorsal tunica albuginea is dissected, till the base of penis. The glans wings are sutured to themselves to create the neo clitoris.
- h) Corpora are separated from urethra till just under the pubic symphysis, transected and resected.
- i) Urethra is dissected to base, the bulbocavernosus muscle is removed to expose bare bulb. If the urethra is not being used for augmentation of penile skin flap, excess urethra is removed and the opening in bulb is widened. The margins are everted to form new urinary meatus.
- j) Slit is made in proximal part of penile skin flap for exposing the neoclitoris and urethral meatus. These structures are now sutured in place.
- k) The distal end of penile skin flap is sutured to anterior edge of sigmoid colon in a staggered manner.
- l) Remnants of scrotal skin flaps are sutured to penile skin flap, to form labia majora. Medial aspects of penile skin flaps around the slits may be fashioned to form labia minora.
- m) A pack is usually placed in neovaginal cavity to maintain it. A dressing is then applied.

7) Postoperative Course:

At the end of operation, you will have:

- a) Dressing over the perineum and left abdomen
- b) Urinary catheter
- c) Abdominal drain
- d) Epidural catheter
- e) Blood pressure cuff over the arm to measure your blood pressure (you will feel pressure over the arm intermittently)

- f) Pulse Oximeter to monitor your pulse rate and oxygen saturation
- g) DVT pump over lower limbs, you will feel intermittent pressure over the lower limbs. Usually kept for initial 24 to 48 hrs to prevent clotting in the leg veins.
- h) Intravenous cannula- to administer antibiotics, IV fluids and other medicines.
- i) Need for post op procedures- like dressings, dilation, drain removal and urinary catheter removal (catheter may be reinserted in case of urinary retention and may be kept for couple of weeks)
- j) Position change – gentle guided side-turn allowed after 24 hrs.
- k) Ambulation- usually 3rd to 7th day.
- l) Dilation -dilation is usually started on 3rd to 5th day.
- m) Diet- You will be kept nil orally till the wind breaks (passing flatus). Once you pass flatus, you will be given clear fluid followed by liquid diet. Liquid to very soft diet is recommended till 4 weeks. After that you can resume normal diet.
- n) Duration of hospital stay – 7 to 10 days

8) Complications -

Note: The listed risks and complications are not all inclusive.

While majority of individuals have an uneventful surgery and recovery, few cases may be associated with complications. These are seen infrequently and not all the ones listed below are applicable to one individual. However, it is important that you are aware of the complications/risks that may arise out of this procedure which are as below:

- a) Bleeding- It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain accumulated blood or blood transfusion. You should reveal all the medications that you have been taking to the surgeon so that medicines that can cause bleeding can be stopped or its dose adjusted before the surgery.
- b) Infection- Bacteria live on the skin and near the perineal area. You will be given antibiotics through your I.V. at the time of surgery and will be required to take oral antibiotics following surgery and after discharge. Although infection is unusual

after this type of surgery, it may appear in the immediate post-operative period or at any time following the surgery. Should an infection occur, treatment including antibiotics, or additional surgery may be necessary.

- c) Vascular compromise- though rare, there are chances of failure of operation due to vascular problems of sigmoid colon segment (0.5%). If so, then one of the alternative procedures as detailed above may be required.
- d) Injury to nearby structures- urethra (1.2%), ureters, bladder and rectum (2.3%-2.5%) leading to Recto vaginal fistulas (0.6%-1.1%) or urethra neovaginal fistula (1.7%-2%)
- e) Necrosis - Clitorio-labial complex partial or complete (0.5% - 24%) resulting in loss of these structures.
- f) Paralytic ileus and bowel obstruction can occur (0.8%-3.6%) which may necessitate prolonged fasting and nasogastric aspiration, and in some cases repeat surgery.
- g) Altered bowel habits might occur
- h) Urinary issues (retention/incontinence/infection (1.3%-14%). Urethral meatus stenosis might occur which might need dilatation and possibly surgery
- i) Mucorrhoea- Excessive mucus discharge (6.2%-28.6%) might occur
- j) Prolapse of the sigmoid segment might occur. (1.5%)
- k) Corpus spongiosum protrusion- (6.1%-15.6%)
- l) Introital or Vaginal stenosis (1.5%- 22.5%)
- m) Decreased/absent sensations with possible absence of orgasmic capabilities (3.3%)
- n) Wound healing issues (5.4%)
- o) Scarring/hypertrophic scar/keloid over abdomen and perineum
- p) Colonic Anastomotic leak with possible need for creation of a stoma (ileostomy or colostomy).
- q) Abdominal hernia
- r) Possible Touch up procedures/surgical corrections (for aesthetic improvement, vaginal stenosis, corpus spongiosum correction etc.
- s) Pulmonary embolism—sometimes blood clot in the leg vein can travel up to lungs and cause difficulty in breathing. We

use DVT pump and proper IV fluids to prevent. But rarely, deaths have been reported

- t) The procedure is irreversible. There will be permanent loss of ability to serve as a male partner in penetrative sexual intercourse.
 - u) There will be loss of fertility due to removal of testes. This procedure will not grant you the ability to conceive.
 - v) The procedure in itself does not provide any guarantees to you about successful sexual intercourse or success in marriage or relationship.
 - w) **Unsatisfactory result-** You may be disappointed with the result of the surgery. It may be necessary to perform additional surgery to improve your results.
 - x) **Allergic reactions-** In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions which are more serious may occur to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.
 - y) **Surgical anaesthesia-** Both local and general anaesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anaesthesia or sedation.
 - z) **Additional surgery necessary-** There are many variable conditions that may influence the long-term result of male to female genital gender affirmation surgery. Should complications occur, additional surgery or other treatments may be necessary. Besides the cited complications, other complications and risks can occur but are even more uncommon. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.
- 9) Discharge instructions- vary individual to individual and will be explained to you at the time of discharge.
- 10) Post-operative follow-up
- Special precautions to be taken at home
- a) Diet- liquid to soft diet for 4 weeks.
 - b) Local cleaning and dressing as explained. Need to wear a clean pad.
 - c) Have bath regularly.

- d) Dilation schedule to be followed as instructed for at least 6 months, and later on if required.
- e) Exercise and Sexual activities- usually after 8 weeks
- f) Scar care explained.
- g) Urinary catheter care if individual is discharged with catheter and need of catheter removal in local area or during follow up
- h) Possible need of touch procedures explained

Follow up every month till 6 months, at follow up special focus on dilation.

Follow up with Psychiatrist/psychologist and Endocrinologist as per their advice.

Financial responsibilities

The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of surgical supplies, laboratory tests, blood bank, anaesthesia, and hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered.

Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day-surgery charges involved with reversionary surgery would also be your responsibility.

PART 2: CONSENT FORM

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most individuals in most circumstances.

However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information which is based on all the facts in your particular case and the state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

- 1) I hereby authorize Dr _____ and such assistants as may be selected to perform the following procedure or treatment: **feminizing genitoplasty with incorporation of sigmoid colon segment for lining the neovaginal cavity.**
- 2) I consent to the presence of OR staff of either sex to be present in OR during my surgery. I understand that they are present for the safe conduct of my surgery.
- 3) I recognize that during the course of the operation and medical treatment or anaesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
- 4) I consent to the administration of such anaesthetics considered necessary or advisable. I understand that all forms of anaesthesia involve risk and the possibility of complications, injury, and sometimes death.
- 5) I understand what my surgeon can and cannot do, and I understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks of the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.
- 6) I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.

- 7) For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
- 8) I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
- 9) I understand that the surgeon's fees are separate from the anaesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
- 10) I realize that not having the operation is an option. **I understand that no guarantee has been made that the procedure will improve the condition and that the procedure may make my condition worse.**
- 11) It has been explained to me in a way that I understand:
 - a. The above treatment or procedure to be undertaken
 - b. There may be alternative procedures or methods of treatment
 - c. There are risks to the procedure or treatment proposed

I consent to the treatment or procedure. I am satisfied with the explanation.

Name of Individual.....Signature of Pt.....

Date.....

Name of the Witness.....

Relationship.....

Signature of witness.....

Date.....

Name of doctor.....

Designation.....

5) INDIVIDUAL INFORMATION AND CONSENT FOR GENDER AFFIRMING BILATERAL BREAST REDUCTION IN FEMALE TO MALE GENDER INCONGRUENT INDIVIDUALS (The top surgery)

Instructions

This is an informed-consent document that has been prepared to help inform you about female to male gender affirmation chest surgery, its risks, and alternative treatments. It is important that you read this information carefully and completely.

General information

While many gender-incongruent individuals find comfort with their gender identity, role, and expression without surgery, for many others surgery is essential and medically necessary to alleviate their gender incongruence. For the latter group, relief from gender incongruence cannot be achieved without modification of their primary and/or secondary sex characteristics to establish greater congruence with their gender identity and expression.

Gender affirmation is a long process which takes place with counselling and treatment by primary care doctors, mental health professionals, endocrinologists and surgeons. Surgery takes place as a part of this process and must be carefully considered. The best candidates are those who are mature enough to understand the procedure, related complications and have realistic expectations about the results.

Criteria for transmasculine breast reduction surgery

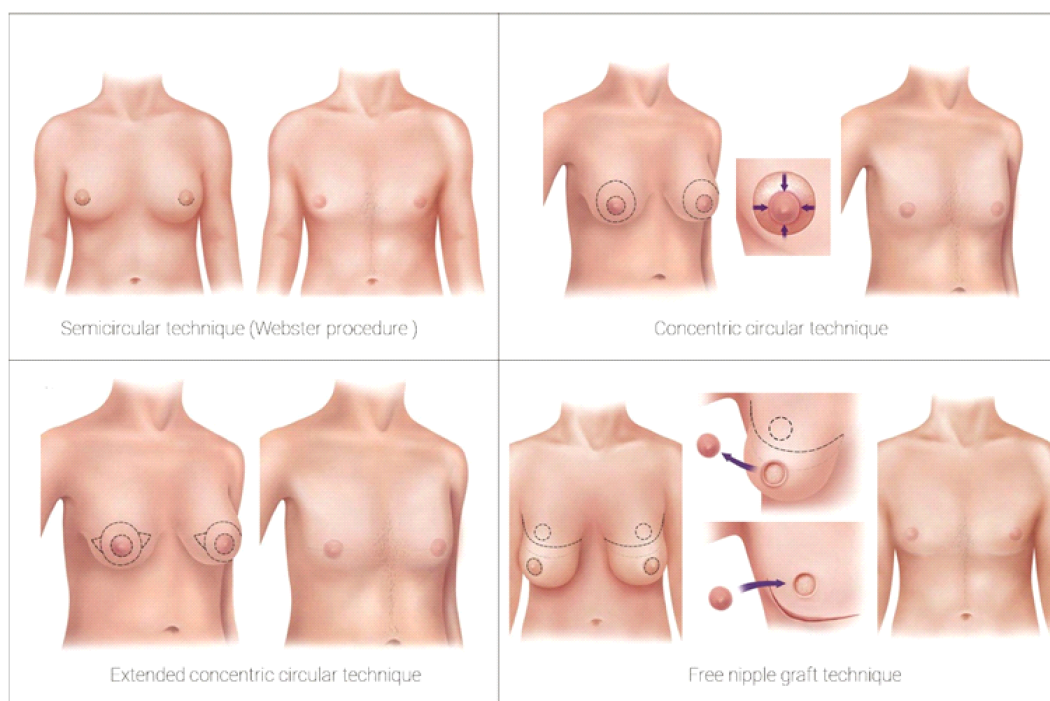
1. Persistent, well-documented gender incongruence.
2. Referral letter for surgery by one mental health professional.
3. Capacity to make a fully informed decision and to give consent for treatment.
4. Age of majority in that country (>18 years in India).
5. If significant medical or mental health concerns are present, they must be reasonably well controlled.

Hormone therapy is not a prerequisite.

There are a variety of different surgical techniques used to reduce and reshape the female chest to have a male appearance, depending on many factors including, but not limited to, the size of the breasts, nipple size and position, sagging of the breasts, previous use of chest binders or bandages.

These include:

1. Semicircular technique, (Nipple sparing mastectomy/ Webster procedure), commonly known as Key-Hole Surgery. Incision for breast tissue removal is made in the lower half of areolar breast skin junction. As a result, the post- surgical scar is around lower half of nipple areola complex (NAC), at junction of dark and light skin.
2. Concentric circular mastectomy. This is carried out in larger or saggy breasts than above technique. Incision is given in two concentric circles. The inner and outer circle incisions are superficial. The outer circle incision is deep in one area, to facilitate breast tissue removal. The skin between these two incisions is removed in superficial plane. As a result, the required skin tightening is achieved. This results in circular scar at the periphery of nipple areola complex (NAC).
3. Extended concentric circular mastectomy. This is carried out in larger or saggy breasts than above technique. In addition to the skin between concentric circles, additional triangular areas of skin are removed on either side of NAC. This results in circular scar at periphery of nipple areola complex (NAC) as well as on scars on either side of NAC on both sides of chest.
4. Double incision mastectomy with free nipple areola graft technique. This technique is carried out in very large or saggy breasts. Long incisions on lower aspects of both breasts help in removal of large amounts of skin and breast tissue. The NAC is removed and reappplied in desired location as full thickness skin graft. This results in long scars on both sides of chest, as well as scars around nipple areola complex (NAC).



Your surgeon will discuss various options and a consensus will be reached as to which technique would be most ideal for you.

Alternative treatment

Gender affirmation surgery is an elective surgical operation. Alternative treatment would consist of not undergoing the surgical procedure or wearing garments/ binders to hide the developed breasts.

Risks of Female to Male Gender Affirming breast reduction Surgery

Note: The listed risks and complications are not all inclusive.

Every surgical procedure involves a certain amount of risk. It is important that you understand the risks involved with surgery. An individual's choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. Although most individuals do not experience the following complications, you should discuss each of them with your surgeon to make sure you understand the risks, potential complications and consequences of female to male gender affirmation surgery.

Despite the rather low complication rate, about one third of individuals will require an additional procedure to improve aesthetic results.

Bleeding: It is possible, though unusual, to experience a heavier than

expected bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain the accumulated blood, despite the presence of drains. When a significant amount of blood collects at the surgical site it is called a “hematoma” and will likely need return to operating room be drained. Hematoma can occur at any time following surgery or any form of injury to the breast. It is very important to stay off all blood thinning medications for two weeks before and after surgery. Do not take aspirin or any anti-inflammatory medications before or after surgery, as this may increase the risk of bleeding. Non-prescription “herbs” and dietary supplements can increase the risk of surgical bleeding. Vitamin E, untested supplements, a variety of other prescription and over the counter medications should be avoided. After surgery, the risk of bleeding can be reduced significantly by not straining or exerting yourself for at least four weeks, and by keeping your arms at your sides as much as possible for that period. Small amounts of bleeding can be absorbed by the body but can still impact healing.

Infection- Bacteria live on the skin and within the ducts of the breast. You will be given antibiotics through your I.V. at the time of surgery and will take oral antibiotics following surgery. Although infection is unusual after this type of surgery, it may appear in the immediate post-operative period or at any time following the surgery. Should an infection occur, treatment including antibiotics, or additional surgery may be necessary.

Change in nipple and areola skin - You may experience a change in the sensitivity of the nipples and the skin of your breast. Permanent loss of nipple sensation can occur after chest surgery in one or both nipples. Nipple areola sensation may be lost if nipple areola graft techniques are used for the top surgery (breast reduction surgery in transmen). Pigment changes resulting in unusually light or dark skin colour may also occur. Due to variation in skin graft take, there may be some asymmetry in NAC on either side.

Skin scarring- All surgical incisions produce permanent scarring. This is how human bodies heal the wounds. The quality of these scars is unpredictable. Abnormal, hypertrophic and *keloid* scars may occur within the skin and deeper tissue. In some cases, scars may require surgical revision or other treatments. Some scars are limited to the border of the nipple, but individuals with larger breasts may require scars which extend outside of the nipple area. Such scars are more noticeable. Every effort will be made to minimize scars.

Lax Skin- Especially in procedures in which skin is not removed, such as Webster and sometimes in other procedures, loose skin may remain. The individuals are advised to wear a pressure garment for 6-12 weeks, and then wait for upto a year, to allow this loose skin to shrink. However, at the end of this period, some individuals require revisional surgery with consequent scars and the necessary expense to cover this.

Unsatisfactory result- You may be disappointed with the result of the surgery. It may be necessary to perform additional surgery to improve your results. Sometimes, it may not be possible to give a satisfactory result even with revisional surgery.

Pain- Abnormal scarring in skin and the deeper tissues may produce pain. This is a rare complication.

Firmness- Excessive firmness of the chest can occur after surgery due to internal scarring or fat necrosis. The occurrence of this is not predictable, but it is usually temporary. If an area of fat necrosis or scarring appears, this may require additional surgical treatment.

Delayed healing- Wound disruption or delayed wound healing is possible. Some areas of the breast skin or nipple region may not heal normally and may take a long time to heal. It is even possible to have loss of skin or nipple tissue. This may require frequent dressing changes or further surgery to remove the non-healed tissue. Complete loss of the NAC would necessitate later NAC reconstruction or tattooing. Smokers have a greater risk of skin loss and wound healing complications.

Asymmetry- Some chest asymmetry naturally occurs in most men. Often the muscles of the chest on the side of an individual's dominant upper limb are larger. Differences in nipple shape, size, or symmetry may also occur after surgery. Additional surgery may be necessary to revise asymmetry after chest surgery. Some asymmetries may also be non-correctable.

Breast disease- Breast disease and breast cancer can occur independently of a gender affirmation surgery. It is unlikely that the entire breast tissue will be removed after this surgery, and some tissue (around 6% or more) remains. If you have a family history of breast cancer, then you should undergo regular chest area examination. It is recommended that you seek professional care should a breast lump be detected. Such occurrences are rare and usually occur after the teenage years. Top surgery decreases the risk of breast cancer substantially but does not eliminate it.

Allergic reactions- In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions which are more serious may occur to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.

Surgical anaesthesia- Both local and general anaesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anaesthesia or sedation. You will get an opportunity to discuss these issues with the anaesthesiologist during pre-anaesthesia check-up. A separate consent will be taken by the anaesthesiologist.

Additional surgery necessary- There are many variable conditions that may influence the long-term result of female to male gender affirming breast reduction surgery (Top Surgery). Secondary surgery may be necessary to perform additional skin tightening or repositioning of the nipples. Should complications occur, additional surgery or other treatments may be necessary. Other complications and risks can occur but are even more uncommon. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.

Reversal of surgery

It is imperative that you carefully consider the decision to have your breasts removed. The surgery is irreversible. Although in case of regret (you regret the decision to undergo the gender affirming breast reduction surgery), it may be possible to reconstruct the breasts by implants, fat grafting or flaps in the future, these are not specialized breast tissue. You will never be able to breast feed a child. Also, these additional procedures may necessitate their own costs and may have their own set of complications.

Financial responsibilities

The cost of surgery involves several charges for the services provided. The total includes all facility charges ie fees charged by your doctors, the cost of surgical supplies, laboratory tests, blood bank, anaesthesia, and hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered.

Additional costs may occur should complications develop from the surgery. Secondary surgery, investigations or hospital stay, and surgery charges involved with revision surgeries would also be your responsibility.

After the procedure—Follow up with the operating surgical team, Mental health professional and Endocrinologist as per their advice.

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most individuals in most circumstances.

However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information which is based on all the facts in your specific case and the state of current medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined based on all of the facts involved in a specific case and are subject to change as scientific knowledge and technology advances and as surgical practice patterns evolve.

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

- a) I hereby authorize Dr _____ and such assistants as may be selected to perform the following procedure or treatment: **Gender Affirming breast reduction surgery (Top Surgery).**
- b) I recognize that during the course of the operation, anesthesia and medical treatment, unforeseen conditions may necessitate different procedures than those described above. I therefore authorize the above surgeon and assistants or designees to perform any other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my doctor at the time the procedure is begun.

- c) I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
- d) I understand what my surgeon can and cannot do, and I understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All my questions have been answered to my satisfaction, and I understand the inherent (specific) risks of the procedures I wish to undergo, as well as those additional risks and complications, benefits, and alternatives. I have had ample opportunity to understand the above through this document as well as consultations with my operating team. Having understood all the aspects of my procedure, I chose to proceed with the surgery.
- e) I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed in these media.
- f) For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
- g) I consent to the utilization of blood products should these be deemed necessary by my surgical team and their appointees, and I am aware that there are potential significant risks to my health with their utilization.
- h) I understand that the surgeon's fees are separate from the anaesthesia and hospital charges, and the charges are agreeable to me. If a secondary or a revisional procedure is necessary, further expenditure will be required.
- i) I realize that not having the operation is an option.
- j) It has been explained to me in a way that I understand:
 - a. The above treatment or procedure to be undertaken
 - b. There may be alternative procedures or methods of treatment, including not undergoing the procedure.
 - c. There may be risks and complications related to the procedure or treatment proposed and I have understood these.

Having understood the above details both in writing as well as verbally in my language of choice by my operating team, I consent to the procedure of Top Surgery (Gender affirming breast reduction surgery for transmen).

Name of Individual.....Signature of Pt.....

Date.....

Name of the Witness.....

Relationship.....

Signature of witness.....

Date.....

Name of doctor.....

Designation.....

Signature.....

Date.....

6) CONSENT FOR BREAST AUGMENTATION SURGERY WITH IMPLANT IN MALE TO FEMALE GENDER INCONGRUENT INDIVIDUALS

GENERAL INFORMATION

While many gender-incongruent individuals find comfort with their gender identity, role, and expression without surgery, for many others surgery is essential and medically necessary to alleviate their gender incongruence. For the latter group, relief from gender incongruence cannot be achieved without modification of their primary and/or secondary sex characteristics to establish greater congruence with their gender identity and expression.

Usually feminizing hormonal therapy will stimulate breast growth, but a subset of individuals may not be satisfied with this growth alone and may opt for surgical breast augmentation procedure.

As this operation is completely cosmetic elective, a detailed consultation is essential so that you are educated about the procedure. For some trans women (male to female transitioning individuals), feminizing surgery is a natural step, and important to their sense of self. However, many choose not to have surgery. Transgender individuals relate to

their bodies differently and need to make individual choices that best fit their requirements.

This is an informed-consent document that has been prepared to educate and inform you regarding augmentation mammoplasty surgery with silicone gel-filled implants, its risks, as well as alternative treatment(s).

It is important that you read this information carefully and completely.

Preconditions and requirements prior to transfeminine augmentation mammoplasty

- 1) Persistent, well-documented gender incongruence.
- 2) Referral letter for surgery from one mental health professional
- 3) Capacity to make a fully informed decision and to give consent for treatment.
- 4) Age of majority (18years or more in India)
- 5) If significant medical or mental health concerns are present, these must be reasonably well controlled.
- 6) Recommended (not obligate) criterion- 12 months of feminizing hormone therapy prior to this procedure. This results in realistically the maximum breast growth that can occur by non- surgical means, allowing you to take a better decision whether or not to opt for further surgical breast augmentation.

Information regarding breast implants and the procedure

Breast enlargement is accomplished by inserting a breast implant either behind the breast tissue, or partially or completely under the chest muscles. Incisions are made to keep scars as inconspicuous as possible. Individuals undergoing breast augmentation surgery must consider the following:

Breast augmentation may not be a one-time surgery. Breast implants of any type are not considered lifetime devices. They cannot be expected to last forever. You will likely require future surgery for implant replacement or removal.

Breast implants are manufactured in a variety of shapes, sizes, and with either smooth or textured surfaces. They are made of medical grade silicone rubber and filled with cohesive silicone gel. The method of implant selection and size, along with surgical approach for inserting and positioning breast implants, will depend on your preferences, your specific anatomic features and your surgeon's recommendation.

Your surgeon will make incisions 1) Below the breast (inframammary) or 2) Around the areola (periareolar) or 3) Near the armpit (axillary) locations to insert the implant. Next, your surgeon will place the silicone gel implants either in front of or behind the pectoral muscles. Alternatively, you could have your own body fat graft (multiple stages), muscles or tissue from other parts of your body transplanted into your breasts.

Risks associated with breast augmentation surgery

Note: The listed risks and complications are not all inclusive.

Every surgical procedure has some degree of unavoidable risk. Problems associated with breast implants can be inherent to this type of implanted medical device or relate to complications of a surgical procedure. It is important that you understand these risks and the possible complications associated with them.

The most common risks associated with Breast Augmentation surgery are as follows:

Bleeding: Very little blood is lost at the time of surgery. It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain the accumulated blood. When a significant amount of blood collects at the surgical site it is called a “hematoma” and will likely need return to operating room be drained. Hematoma can occur at any time following surgery or any form of injury to the breast, and may contribute to capsular contracture, infection, or other problems. It is very important to stay off all blood thinning medications for two weeks before and after surgery. Do not take aspirin or any anti-inflammatory medications before or after surgery, as this may increase the risk of bleeding. Non-prescription “herbs” and dietary supplements can increase the risk of surgical bleeding. Vitamin E, untested supplements, a variety of other prescription and over the counter medications should be avoided. After surgery, the risk of bleeding can be reduced significantly by not straining or exerting yourself for at least four weeks, and by keeping your arms at your sides as much as possible for that period. Small amounts of bleeding can be absorbed by the body but can still impact healing.

Infection: Bacteria live on the skin and within the ducts of the breast. You will be given antibiotics through your intravenous line at the time of surgery and will require to take oral antibiotics following surgery. Although infection is unusual after this type of surgery, it may appear

in the immediate post-operative period or at any time following the insertion of a breast implant. Should an infection occur, treatment including antibiotics, possible removal of the implant, or additional surgery may be necessary. The biggest problem in trying to treat an infection is that the body cannot re-sterilize the implant if an infection is present. The implant must be removed. Replacement of the implant should not occur ideally before three months from the time of explanation.

Seroma: Fluid may accumulate around the implant following surgery, trauma, or vigorous exercise. Additional treatment may be necessary to drain fluid accumulation around breast implants. This may contribute to infection, capsular contracture, or other problems.

Asymmetry: It is unusual to find a person with perfectly symmetric breasts. Because the body is not completely symmetric and most people have a dominant upper extremity, there is usually a small amount of asymmetry following this type of surgery. Differences in terms of breast and nipple shape, size, or symmetry may also occur after surgery. These small degrees of asymmetry need to be accepted. Large degrees of asymmetry may be improved with additional surgery.

Capsular Contracture: Your body knows that a large piece of foreign material, such as an implant, does not belong there. As a part of healing process, everyone will develop a layer of scar tissue, which is called a “capsule,” internally around the implant. This capsule may tighten immediately or over time, causing hardening of the breast, distortion, and even pain. A very mild contracture (where one breast is slightly firmer than the other) is common. As this does not cause pain or significant degree of breast distortion, it can be treated with massage. More severe contractures require a surgical procedure to remove the scar tissue from around the implant with removal and/or replacement of the implants. Your operating team will advise you to massage your breasts to move the implants within their cavities, which will help reducing the chances of capsular contracture.

Calcification: Calcium deposits can form in the scar tissue surrounding the implant and may cause pain, firmness, and be visible on mammography. These deposits must be identified as different from calcium deposits that are a sign of breast cancer. Should this occur, additional surgery may be necessary to remove and examine calcifications.

Pain: Expect some pain and discomfort for around one month. This will improve gradually. Severe pain is not expected, and you should present yourself for examination if there is a problem. Implants that are too large for your frame, nerve entrapment, and severe capsular contractures can result in chronic pain.

Change in Nipple and Skin Sensation: Nerves that provide sensation to the nipple come from branches through the ribs and around the side of the breast. When a pocket for the implant is created, these nerves are stretched, and sometimes even cut. Most people will experience a decrease in nipple sensation following this type of surgery, although some become hypersensitive. Approximately 15% will lose sensation and it may take a year before maximal return is seen. In some cases, nipple numbness can be permanent.

Risk of cancer: Though extremely rare, breast implant associated-anaplastic large cell lymphoma, (BIA-ALCL) is a lymphoma associated with textured implants. To reduce the risk of development of this disease, surgeons all over the world have switched from textured to smooth or nanotextured breast implants. BIA-ALCL can also occur in transwomen. Thus, all individuals, including transwomen, should be monitored for development of this disease.

Studies also show an increased risk of breast cancer in trans women compared with cisgender men, probably due to the feminizing hormone therapy. Therefore, transwomen undergoing breast implants should do undergo regular follow-up for monitoring as advised by the physician, including MRI and mammograms. The absolute overall risk of breast cancer in transgender people remains low and therefore it seems sufficient for transgender people using hormone treatment to follow screening guidelines as for cisgender people.

Problems with Healing: Wound disruption or delayed wound healing is possible. Some areas of the breast skin or nipple region may not heal normally and may take a long time to heal. There could be problems with healing due to infection, seroma (fluid collection), or tissue breakdown (necrosis) at the surgical site. Lack of adequate tissue coverage or infection may result in exposure and extrusion of the implant through the skin. Risk factors for tissue breakdown or necrosis include a depressed immune system, steroid use, smoking, history of radiation, and exposure to extreme temperatures. If tissue around the implant does not heal and the implant becomes exposed to the outside world, it will need to be removed. In some cases, incision sites fail to heal normally. Permanent scar deformity may occur. Smokers have a greater risk of skin loss and wound healing complications.

Sutures: Most surgical techniques use deep sutures. You may notice these sutures after your surgery. Sutures may spontaneously poke through the skin, become visible or produce irritation that requires suture removal.

Poor Appearing Scars: All surgery leaves permanent scars. In some cases, these are more visible than others. Although a normal wound healing is expected after a surgical procedure, sometimes abnormal scars/keloid may occur within the skin and deeper tissues. Scars may be unattractive, raised, or depressed, and of different color than the surrounding skin tone. Scar appearance may also vary within the same scar. Scars may be asymmetrical (appear different on the right and left side of the body). There are many things that you will be required to do and be advised after surgery to improve the appearance of the scars. These may include application of various creams, gels, gel sheets, pressure garments and intra scar injections. It may take up to a year for the final/ long term appearance of scars to emerge. Surgery for scar revision may rarely be required.

Palpable Implants or Visible Skin Wrinkles/Ripples: Visible and palpable wrinkling of implants and breast skin can occur post-operatively. Some wrinkling is normal and expected with breast implants. Lesser the soft tissue covers over the implant (i.e. smaller breasts, thinner individuals, and implants placed above the muscle), more palpable the implant will be. Also, the larger the implant, more easily you will be able to feel it.

Implant Rupture or Deflation: Breast implants are exposed to daily forces that can create wear and tear, and at some point, these may actually rupture. Rupture can also occur as a result of an injury, from no apparent cause (silent rupture), or during mammography. It is also possible to damage an implant at the time of surgery. Damaged or ruptured implants cannot be repaired. These require replacement or removal. Silicone implant rupture may not be obvious to the individual or physician. MRI studies may be necessary to evaluate the possibility of implant rupture, yet it may not be 100% accurate in diagnosing implant integrity. Implant companies recommend MRI's at 3 years post-op and every 2 years after that.

Implant Malposition or Displacement and Tissue Stretching: Displacement, rotation, or migration of a breast implant may occur from its initial placement and can be accompanied by discomfort and/or distortion in breast shape (visible rippling of the skin). Implants are in their ideal position when these are evenly centered under the nipple. Unfortunately, most breasts are not symmetric, and sometimes the nipples are low on the breast. The type of bra worn post-operatively can also influence the positioning of the implant (i.e. sports bras and push-up bras can force the implants too close together; no bra, or those with poor support can allow these to drop too low). The ultimate positioning

of the implants can end up slightly too high or low, too close together or far apart, and the breasts may still have some degree of ptosis. Heavier implants will also continue to stretch the skin over time, just like naturally large breasts. Additional surgery may be necessary to correct this problem. It may also, not be possible to resolve this problem once it has occurred.

Stretch marks: Individuals on feminizing hormonal therapy have higher propensity for developing stretch marks on the breast skin which might be dark colored. It might settle with time; however complete resolution of the stretch marks is unusual.

Dissatisfaction with Cosmetic Results: The sizes recommended for your surgery are decided according to how much breast tissue you have, the size of your rib cage, laxity of your skin, your body shape, and finally, your target cup size. Implants that are either too large or too small based on the overall picture can result in a poor cosmetic result. In order to achieve the most natural breast shape and good long-term result, the final implant choice may end up being either larger or smaller than your personal ideal.

Deformity if the Implant is Removed: Over time, you may want to have your implants removed. The implants cause pressure in the chest wall and breast tissue over time, and there may be some atrophy resulting in smaller or droopier breasts once the implants are removed. Some individuals look much better after their implants are removed.

Risks of Surgery and Anesthesia: There are additional risks associated with having surgery, including medication reactions, and complications from anesthesia. Both local and general anesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anesthesia or sedation. Other risks include pneumonia, deep venous thrombosis (blood clot in the leg), and pulmonary embolus (clot that travels to the lung), and allergic reactions. In rare cases, local allergies to tape, suture material and glues, blood products, topical preparations or injected agents have been reported. Serious systemic reactions including anaphylaxis may occur in response to drugs used during surgery and prescription medicines. These are rare but are possible with any type of surgery.

Cardiac and Pulmonary Complications: Pulmonary complications may occur secondary to both blood clots (pulmonary emboli), fat deposits (fat emboli) or partial collapse of the lungs after general anesthesia. Pulmonary emboli can be life-threatening or fatal in some circumstances. Cardiac complications are a risk with any surgery and anesthesia, even in individuals without symptoms. Should any of these complications

occur, you may require hospitalization and additional treatment. If you experience shortness of breath, chest pains, or unusual heart beats after surgery, seek medical attention immediately.

Photographs: Pre-operative and post-operative photos will be taken to help with surgical planning and to document results. Your photos (which never include your face) may also be used for teaching purposes to help doctors or other individuals.

Long-Term Results: Subsequent alterations in breast shape may occur as the result of aging, weight loss, weight gain, or other circumstances not related to your augmentation mammoplasty. Breast sagging after augmentation may normally occur.

INDIVIDUAL COMPLIANCE

Preoperatively, feminizing hormone therapy should be withheld for a period as advised by the endocrinologist/ physician.

Post operatively, follow all physician instructions carefully; this is essential for the success of your outcome. It is important that the surgical incisions are not subjected to excessive force, swelling, abrasion, or motion during the time of healing. Personal and vocational activity needs to be restricted. Protective dressings and drains should not be removed unless instructed by your plastic surgeon.

Successful post-operative function depends on both surgery and subsequent care. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation and the need for return to surgery. It is wise to refrain from intimate physical activities after surgery until your physician states it is safe. It is important that you participate in follow-up care such as breast massage and movement of implant in pocket, wearing supportive bra topical applications, dressings etc. You should return for aftercare as advised and promote your recovery actively after surgery.

FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges for the services provided. The total includes infacility charges, fees charged by your surgeon, the cost of surgical supplies, anaesthesia, laboratory tests, and miscellaneous hospital charges, depending on where the surgery is performed. You will be provided an approximate written estimate of charges before surgery. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered.

The fees charged for this procedure do not include-

- 1) Charges after the discharge such as consults and dressings.
- 2) Charges for medicines, gels, ointments, gel-sheets, pressure garments, supporting bra etc.
- 3) Any potential future costs for additional procedures that you elect to have or require to revise, optimize, or complete your outcome.
- 4) Additional costs may occur should complications develop from the surgery. Secondary /additional surgeries, investigations or hospital stay, and surgery charges involved with revision surgeries would also be your responsibility.
- 5) The costs for physiotherapy or any supportive therapy if required.

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

- a) I hereby authorize Dr _____ and such assistants as may be selected to perform the following procedure or treatment: **AUGMENTATION MAMMAPLASTY WITH IMPLANT.**
- b) I recognize that during the surgical procedure and medical treatment or anaesthesia, unforeseen conditions may necessitate different procedures than those specified above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
- c) I consent to the administration of such anaesthetics considered necessary or advisable. I understand that all forms of anaesthesia involve risk and the possibility of complications, injury, and sometimes death.
- d) I understand what my surgeon can and cannot do, and I understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All my questions have been answered, and I understand the inherent (specific) risks of the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.

- e) I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
- f) For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
- g) I consent to the utilization of blood products should these be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
- h) I understand that the surgeon's fees are separate from the anaesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
- i) I realize that not having the operation is an option.
- j) The procedure has been explained to me in a way that I understand:
 - a. The above treatment or procedure to be undertaken
 - b. There may be alternative procedures or methods of treatment
 - c. There are risks to the procedure or treatment proposed

I consent to the treatment or procedure and the above listed items (1-10). I have fully discussed all aspects of the procedure, possible complication, aftercare, need for additional/ secondary/ revisional procedures and expenses to my satisfaction.

Name of Individual.....Signature of Pt.....

Date.....

Name of the Witness.....

Relationship.....

Signature of witness.....

Date.....

Name of doctor.....

Designation.....

Signature.....

Date.....

7) Individual Information and Informed Consent for pedicled Anterolateral Thigh Flap Phalloplasty

While many gender-incongruent individuals find comfort with their gender identity, role, and expression without surgery, for many others surgery is essential and medically necessary to alleviate their gender incongruence. For the latter group, relief from gender incongruence cannot be achieved without modification of their primary and/or secondary sex characteristics to establish greater congruence with their gender identity and expression. Phalloplasty (penile reconstruction) inclusive of urethral lengthening and scrotoplasty is of major importance for the psychological and sexual well-being and quality of life in transgender men. Pedicled Anterolateral thigh flap phalloplasty (pALTp) is a procedure which avoids a donor scar in forearm, often considered a giveaway for free Radial artery forearm flap phalloplasty (fRAFFp) in the transgender community. This is the most common indication for pALTp. The donor area for flap is either thigh. As thigh tissue contains thicker fat layer compared to forearm, often the neophallus is bulkier compared to fRAFFp. On the contrary, greater phallic length can be achieved if desired. Flap sensation is inferior to fRAFFp as only one sensory nerve is available for anastomosis. Also, due to increased bulk, tube in tube urethral reconstruction is often not possible in pALTp, with need for prelamination of urethra in thigh with the help of skin graft/ vaginal mucosa graft or buccal mucosa graft. An erectile implant or stiffener is required around 6 months after the procedure, once the sensation is regained, to enable the individual to engage in sexual intercourse.

This is an informed-consent document that has been prepared to help inform you about female to male sex reassignment genital surgery, its risks, and alternative treatments. This document consists of two parts- the first part is detailed information regarding the procedure and the next is procedure specific consent. Please go through the entire document before consenting to the procedure.

Part 1: Individual information

Introduction

1) Preconditions for surgery:

- a) Firm diagnosis of Gender Incongruence, as per ICD-11/ DSM5 by two different mental health professionals.
- b) The reference letters from mental health professionals should include the parameters as mentioned in 7th SOC, mainly the

diagnosis, individual's mental competence to give consent for surgery and hormone therapy and the fact that all co-existing mental health conditions are currently well controlled.

- c) The individual has completed 12 months of hormone therapy under guidance from a hormone specialist/ gender team unless individual is unwilling to take hormones/ unable to take hormones or the hormone therapy is medically contraindicated. (Many individuals in India, especially MTF, are however well adapted in their desired gender role and are unwilling to take hormone therapy).
- d) The individual has experienced living in desired gender role for a period of 12 months.
- e) A legally notarized waiver of liability affidavit on stamp paper, waiving the gender team's liability for removing individual's healthy organs, permanent loss of current sexual functioning and reproductive ability.

2) Preoperative Requirements:

- a) Stopping health supplements such as omega, fish oils, herbal products, garlic, green tea etc from 2 weeks prior to surgery.
- b) Stop smoking from 4 weeks prior to surgery.
- c) Limit/ stop alcohol intake 4 weeks prior to surgery. Hormone therapy should be adjusted as per advice of treating endocrinologist.
- d) Stop blood thinners if feasible, from 5 days prior to surgery with permission from individual's physician/ cardiologist.

3) Pre-operative Investigations:

- a) Complete blood counts, coagulation profile, Blood sugar fasting and PP, LFT, RFT, TSH, viral markers for hepatitis B, C and HIV, EKG, Chest x ray. Other specific investigations if required for co-existing conditions.
- b) Colour Doppler (Duplex scan) is usually not required if Allen's test confirms the hand perfusion with either radial or ulnar artery.

4) Options for the proposed surgical procedure and details

Other surgical options/alternatives like metoidioplasty, RAFFp, musculocutaneous latissimus dorsi flap, fibula flap, deltoid flap, lateral arm flap and combined flap phalloplasties etc. are used less often. The pros and cons of these options have been explained to me. I understand that in view of inferior sensation compared to RAFFp, and often the inability to form a tube in tube urethra

in ALTp with necessity of additional procedures and increased chances of urinary complications, individuals often opt for RAFFp rather than this procedure.

5) Procedure specific information:

The procedure as described below may be varied and all steps may not be carried out. If needed, extra steps may be carried out and the procedure may be varied from the below description if operative situation so demands or as per surgeon's discretion.

- a) General individual identifiers, names of admitting surgeons, individual's and witness's signatures, permission for photo and videography etc are usually part of general hospital consent and, also may be a part of this consent. Higher risk due to some co-existing condition and anaesthesia consents are separate.
- b) The perforator vessels of flap are auscultated, and flap marking is done in the designated thigh.
- c) Shaving of genital area, thighs and forearm will be carried out just prior to the surgery. A urinary catheter will be inserted. The surgery is generally done sequentially on perineum and then on thigh. In lithotomy position, the surgical team first removes the vaginal lining and closes the vagina, lengthens the urethra, reconstructs the scrotum and transposes the clitoris to pubic area. A drain is often left in the obliterated vaginal cavity. Many a times, this procedure has already been done earlier at the time of hysterectomy and salpingo-oophorectomy.
- d) After this in supine position, the thigh is dissected, and previously marked ALT flap is raised (with prelaminated urethra/ tube in tube urethra/ no urethra). The flap is tubed to form a neophallus and shifted to pubic area, where it's base is inset over the transposed clitoris. If a phallic urethra is present, it may or may not be anastomosed to previously or just extended fixed part of urethra at this time. If the urethral anastomosis is done, a diverting cystostomy may or may not be done.
- e) The lateral cutaneous nerve of forearm present in flap is anastomosed to one of the recipient nerves.
- f) Skin graft harvested from the other thigh is applied to the ALT donor thigh, and secured with staples, sutures, dressing and slab.

g) All wounds are now closed leaving behind drains as required. Dressings are done in a manner permitting ready examination of neophallus for monitoring of circulation.

- 6) **Postoperative Course:** After ALT phalloplasty 4-5 days stay may be required in ward/ room. During the period of stay my vital signs will be monitored and initially, neophallus circulation will be monitored frequently by various methods. I may be put on blood thinners which may increase my risk of bleeding and necessity of blood transfusion. My epidural anaesthesia may be continued for 3-4 days for facilitating analgesia and lowering the dose of analgesics. Thrombo-embolic deterrent stockings will be on for a period of 4-5 days. Even so, I will be required to carry out regular ankle movements. I will be expected to avoid movements at that hip, which is the donor site of flap. I will be mobilized and expected to start walking on day 4/5, with expected discharge from hospital. I will be expected to carry out instructions and take medicines regularly and will come for follow-up as advised. I will be expected to stay in town for around one month from the day of admission. My urinary catheter will be removed at around 2-3 weeks depending on healing and recovery. If a cystostomy has been done, it may be removed at 3-6 weeks from day of surgery. Sensations are typically gained in neophallus at around 6 months, at which time an erectile implant/ stiffener may be inserted in neophallus, together with silicone testicles in neoscrotum.

7) **Complications** -

Note: The listed risks and complications are not all inclusive.

While majority of individuals have an uneventful surgery and recovery, few cases may be associated with complications. These are seen infrequently and not all the ones listed below are applicable to one individual. However, it is important that you are aware of the complications/risks that may arise out of this procedure which are as below:

- a) **Bleeding-** It is possible, though unusual, to experience a bleeding episode during or after surgery and may require blood transfusion. Should post-operative bleeding occur, it may require emergency treatment to stop bleeding, drain accumulated blood or give a blood transfusion. You should reveal all the medications that you have been taking to the surgeon so that medicines that can cause bleeding can be stopped or its dose adjusted before the surgery.

- b) **Infection-** Bacteria live on the skin and near the perineal area. You will be given antibiotics through your I.V. at the time of surgery and postoperative period and will be required to take oral antibiotics on discharge. Although infection is unusual after this type of surgery, it may appear in the immediate post-operative period or at any time following the surgery. Should an infection occur, treatment including antibiotics, or additional surgery may be necessary.
- c) **Skin graft related complications-** The skin graft applied over the thigh might not survive completely, which can necessitate prolonged dressings or sometimes repeat grafting. As the skin graft is thin compared to normal skin, it graft might break down post operatively or can result in unstable scars which might require additional procedures. The skin graft can also have a different colour and texture compared to surrounding normal skin.
- d) **Neophallus related complications-** During surgery, an abnormal course of perforators can lead to abandonment of the procedure (very rare).
- e) After transfer of the flap to the groin, vascular (venous or arterial) thrombosis might occur at leading to flap congestion or failure-which requires immediate exploration and correction. Vascular (venous or arterial) thrombosis or compression may also present at any time after the procedure (with decreasing chances as time passes) leading to flap failure and loss of neophallus in spite of salvage procedures. Rarely, total loss of neophallus might occur, which may require later reconstruction using other surgical options.
- f) **Urinary complications-** Urinary fistulas (leakage of urine) or stenosis (partial or complete blockage of urine flow) can occur in the extended urethral segments immediately or some ime after surgery. Incidence of such complications can be up to 40%. These may require further investigations and surgery to correct or to divert the urine. Sometimes the urinary complications may not be correctable or may recur. In these instances, a permanent urinary passage may be created along the course of urethra.
- g) **Sensory deficit of neophallus-** Usually protective sensations return at around 6 months after surgery. Impairment of sensations or total lack of sensations might occur, though uncommon.
- h) **Donor thigh complications)-** You might develop swelling (oedema) and stiffness, nerve or vascular injury, altered/loss of sensations and movements, numbness, burning/shooting pain, hypertrophic scarring, contracture.

- i) **Skin scarring-** All surgical incisions and donor sites (forearm and thighs) produce permanent scarring. The quality of these scars is unpredictable. Abnormal and hypertrophic scars may occur within the skin and deeper tissue. In some cases, scars may require surgical revision or other treatments. Every effort will be made to minimize scars.
- j) **Unsatisfactory result-** You may be disappointed with the result of the surgery. It may be necessary to perform additional surgery to improve your results.
- k) **Delayed healing and prolonged hospital stay-** Wound disruption or delayed wound healing is possible and may result in prolonged hospital stay. Partial flap loss or skin graft loss might take a long time to heal. This may require frequent dressing changes or further surgery to remove the non-healed tissue. Smokers have a greater risk of skin loss and wound healing complications.
- l) **Allergic reactions-** In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions which are more serious may occur to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.
- m) **Anaesthesia related risks-** Both local and general anaesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anaesthesia or sedation.
- n) **Additional surgery necessary-** There are many variable conditions that may influence the long-term result of female to male genital gender affirmation surgery. Should complications occur, additional surgery or other treatments may be necessary. Complications and risks other than the cited ones can occur but are even more uncommon. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.
- o) **Vaginal closure together with phalloplasty will affect on a permanent bases, your current sexual functioning. You have been given no guarantees about successful sexual intercourse or success in marriage and relationships.**
- 8) **Post-operative follow-up –** Discharge instructions- vary individual to individual.
 - a) Local cleaning and dressing (if required) as explained.
 - b) Sutureline and scar care and regular physiotherapy.

- c) Urinary catheter care if individual is discharged with catheter and need of catheter removal in local area or during follow up.
- d) Possible need of touch up procedures/further procedures explained
- e) Need to reduce activities & take time off from work six to eight weeks or longer.
- f) Need for a support person in the post-operative period to assist with daily activities such as self-care & grooming, meal preparation, laundry, etc.
- g) Need for regular follow-up with care providers for 3-4 weeks as per given schedule during initial post-operative period and less frequently later.
- h) Follow up with mental health professional and hormone prescribing physician as per their advice.

Financial Responsibilities

The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of surgical supplies, laboratory tests, blood bank, anaesthesia, and hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered.

Additional costs may occur should complications develop from the surgery. Secondary /additional surgeries, investigations or hospital stay and surgery charges involved with revision surgeries would also be your responsibility.

PART 2: CONSENT FORM

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most individuals in most circumstances.

However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your

plastic surgeon may provide you with additional or different information which is based on all the facts in your particular case and the state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

- a) I hereby authorize Dr _____ and such assistants as may be selected to perform the following procedure or treatment: **pedicled anterolateral thigh flap phalloplasty.**
- b) I consent to the presence of OR staff of either sex to be present in OR during my surgery. I understand that they are present for the safe conduct of my surgery.
- c) I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
- d) I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
- e) I understand what my surgeon can and cannot do, and I understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks of the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.
- f) I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or

educational purposes, provided my identity is not revealed by the pictures.

- g) For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
- h) I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
- i) I understand that the surgeon's fees are separate from the anaesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
- j) I realize that not having the operation is an option.
- k) It has been explained to me in a way that i understand:
 - a. The above treatment or procedure to be undertaken
 - b. There may be alternative procedures or methods of treatment
 - c. There are risks to the procedure or treatment proposed

I consent to the treatment or procedure. I am satisfied with the explanation.

Name of Individual.....Signature of Pt.....

Date.....

Name of the Witness.....

Relationship.....

Signature of witness.....

Date.....

Name of doctor.....

Designation.....

Signature.....

Date.....

8) Individual Information and Informed Consent for Free Radial Artery Forearm Flap Phalloplasty

While many gender-incongruent individuals find comfort with their gender identity, role, and expression without surgery, for many others surgery is essential and medically necessary to alleviate their gender incongruence. For the latter group, relief from gender incongruence cannot be achieved without modification of their primary and/or secondary sex characteristics to establish greater congruence with their gender identity and expression. Phalloplasty (penile reconstruction) inclusive of urethral lengthening and scrotoplasty is of major importance for the psychological and sexual well-being and quality of life in transgender men. Free Radial artery forearm flap phalloplasty (fRAFFp) is considered the gold standard technique, against which all techniques are compared. Currently, the majority of phalloplasties world over are being done with this technique. This technique results in a near normal size and shape of penis, mimicking a circumcised erect penis. As there is currently no reconstructive technique which can provide a natural physiologic erection, the penis is reconstructed in erect size and a stiffener or erectile implant is inserted later to enable the individual to engage in penetrative sexual intercourse. In some cases, a segment of radius bone may be taken as stiffener at the time of flap elevation, thus avoiding the need of later surgery. This technique is known as osteocutaneous fRAFFp (ofRAFFp). fRAFFp also provides good sensations (touch and erogenous) as two nerves are available for anastomosis. The urethra in fRAFFp is formed with tube in tube technique from the hairless ulnar aspect of forearm.

This is an informed-consent document that has been prepared to help inform you about female to male sex reassignment genital surgery, its risks, and alternative treatments. This document consists of two parts- the first part is detailed information regarding the procedure and the next is procedure specific consent. Please go through the entire document before consenting to the procedure.

Part 1: Individual information

Introduction

The radial forearm free flap has become the most frequently used surgical technique for phalloplasty, because it meets the goals of creating a sensate neophallus with functioning urethra and allows penetrative intercourse. It can be a single stage or more commonly multi-staged procedure

1) Preconditions for surgery:

- a) Firm diagnosis of Gender Incongruence, as per ICD-11/ DSM5 by two different mental health professionals.
- b) The reference letters from mental health professionals should include the parameters as mentioned in 7th SOC, mainly the diagnosis, individual's mental competence to give consent for surgery and hormone therapy and the fact that all co-existing mental health conditions are currently well controlled.
- c) The individual has completed 12 months of hormone therapy under guidance from a hormone specialist/ gender team unless individual is unwilling to take hormones/unable to take hormones or the hormone therapy is medically contraindicated. (Many individuals in India, especially MTF, are however well adapted in their desired gender role and are unwilling to take hormone therapy).
- d) The individual has experienced living in desired gender role for a period of 12 months.
- e) A legally notarized waiver of liability affidavit on stamp paper, waiving the gender team's liability for removing individual's healthy organs, permanent loss of current sexual functioning and reproductive ability.

2) Preoperative Requirements:

- a) Stopping health supplements such as omega, fish oils, herbal products, garlic, green tea etc from 2 weeks prior to surgery.
- b) Stop smoking from 4 weeks prior to surgery.
- c) Limit/ stop alcohol intake 4 weeks prior to surgery. Hormone therapy should be adjusted as per advice of treating endocrinologist.
- d) Stop blood thinners if feasible, from 5 days prior to surgery with permission from individual's physician/ cardiologist.

3) Pre-operative Investigations:

- a) Complete blood counts, coagulation profile, Blood sugar fasting and PP, LFT, RFT, TSH, viral markers for hepatitis B, C and HIV, EKG, Chest x ray. Other specific investigations if required for co-existing conditions.
- b) Colour Doppler (Duplex scan) is usually not required if Allen's test confirms the hand perfusion with either radial or ulnar artery.

4) Options for the proposed surgical procedure and details

Other surgical options/alternatives like metatidoioplasty, anterolateral thigh flap, musculocutaneous latissimus dorsi flap, fibula flap, deltoid flap, lateral arm flap and combined flap phalloplasties etc. are used less often. The pros and cons of these options have been explained to me. I understand that there will be a visible scar/ grafted area in the donor forearm after RAFFp, which is often the reason why many individuals do not opt for this procedure.

5) Procedure specific information:

The procedure as described below may be varied and all steps may not be carried out. If needed, extra steps may be carried out and the procedure may be varied from the below description if operative situation so demands or as per surgeon's discretion.

- a) General individual identifiers, names of admitting surgeons, individual's and witness's signatures, permission for photo and videography etc are usually part of general hospital consent and also may be a part of this consent. Higher risk due to some co-existing condition and anaesthesia consents are separate.
- b) Shaving of genital area, thighs and forearm will be carried out just prior to the surgery. A urinary catheter will be inserted. The surgery is generally done with a two- team approach. While one surgical team works on the donor forearm for raising the flap together with blood vessels and nerves, reconstructing urethra, tubing the flap and sculpting the coronal sulcus and glans, the other surgical team operates on perineum, thighs and pubic area. This second team removes the vaginal lining and closes the vagina, lengthens the urethra, reconstructs the scrotum and transposes the clitoris to pubic area. Then, the recipient vessels and nerves are dissected in thigh and prepared for anastomosis. In many cases, the perineal part of procedure has been done earlier, at the time of hysterectomy and salpingo-oophorectomy (HSOV).
- c) The reconstructed phallus is now detached from forearm and attached to pubic area. It's blood vessels are joined to recipient structures so that the circulation can restart. The nerves are also joined. Clitoris is usually buried at the base of neophallus. The phallic urethra may be joined to extended fixed part of urethra now or at a later sitting. In case the urethra is joined,

a suprapubic cystostomy may be done to divert urine away from the healing urethral anastomosis.

- d) Skin graft harvested from thigh is applied to the forearm, and secured with staples, sutures, dressing and slab.
 - e) All wounds are now closed leaving behind drains as required. Dressings are done in a manner permitting ready examination of neophallus for monitoring of circulation.
- 6) **Postoperative Course:** As RAFF phalloplasty is a long and complicated procedure with potential for significant blood loss, 1-2 days stay in high dependency unit/ surgical intensive care unit might be needed followed by 5-7 days in ward/ room. During the period of stay my vital signs will be monitored and initially, neophallus circulation will be monitored frequently by various methods. I may be put on blood thinners which may increase my risk of bleeding and necessity of blood transfusion. My epidural anaesthesia may be continued for 3-4 days for facilitating analgesia and lowering the dose of analgesics. Thrombo-embolic deterrent stockings will on for a period of 4-7 days. Even so, I will be required to carry out regular ankle movements. I will be expected to avoid movements at that hip, which is the site for microvascular anastomosis. I will be mobilized and expected to start walking on day 6/7, with expected discharge from hospital on day 7-10. I will be expected to carry out instructions and take medicines regularly and will come for follow-up as advised. I will be expected to stay in town for around one month from the day of admission. My urinary catheter will be removed at around 2-3 weeks depending on healing and recovery. If a cystostomy has been done, it may be removed at 3-6 weeks from day of surgery. Sensations are typically gained in neophallus at around 6 months, at which time an erectile implant/ stiffener may be inserted in neophallus, together with silicone testicles in neoscrotum.

7) **Complications** -

Note: The listed risks and complications are not all inclusive.

While majority of individuals have an uneventful surgery and recovery, few cases may be associated with complications. These are seen infrequently and not all the ones listed below are applicable to one individual. However, it is important that you are aware of the complications/risks that may arise out of this procedure which are as below:

- a) **Bleeding-** It is possible, though unusual, to experience a bleeding episode during or after surgery and may require

blood transfusion. Should post-operative bleeding occur, it may require emergency treatment to stop bleeding, drain accumulated blood or give a blood transfusion. You should reveal all the medications that you have been taking to the surgeon so that medicines that can cause bleeding can be stopped or its dose adjusted before the surgery.

- b) **Infection-** Bacteria live on the skin and near the perineal area. You will be given antibiotics through your I.V. at the time of surgery and postoperative period and will be required to take oral antibiotics on discharge. Although infection is unusual after this type of surgery, it may appear in the immediate post-operative period or at any time following the surgery. Should an infection occur, treatment including antibiotics, or additional surgery may be necessary.
- c) **Vascular compromise (donor forearm)-** Loss of blood supply to donor forearm is a rare complication. It is usually detected and managed intraoperatively with vascular anastomosis, venous graft or in certain cases, abandoning the procedure.
- d) **Skin graft related complications-** The skin graft applied over the forearm might not survive completely, which can necessitate prolonged dressings or sometimes repeat grafting. As the skin graft is thin compared to normal skin, it graft might break down post operatively or can result in unstable scars which might require additional procedures. The skin graft can also have a different colour and texture compared to surrounding normal skin.
- e) **Neophallus related complications-** During surgery, poor arterial supply or venous outflow of neophallus while still attached to forearm can occur, leading to abandonment of the procedure (very rare).
- f) After transfer of the radial forearm flap to the groin, vascular (venous or arterial) thrombosis might occur at the site of anastomosis (leading to flap failure)- which requires immediate exploration and repair. Vascular (venous or arterial) thrombosis may also present at any time after the procedure (with decreasing chances as time passes) leading to flap failure and loss of neophallus in spite of salvage procedures. Rarely, total loss of neophallus might occur, which may require later reconstruction using other surgical options.
- g) **Urinary complications-** Urinary fistulas (leakage of urine) or stenosis (partial or complete blockage of urine flow) can occur

in the extended urethral segments immediately or sometime after surgery. Incidence of such complications can be up to 40%. These may require further investigations and surgery to correct or to divert the urine. Sometimes the urinary complications may not be correctable or may recur. In these instances, a permanent urinary passage may be created along the course of urethra.

- h) Sensory deficit of neophallus-** Usually protective sensations return at around 6 months after surgery. Impairment of sensations or total lack of sensations might occur, though uncommon.
- i) Donor site (upper limb Complications)-** You might develop swelling (oedema) and stiffness, nerve or vascular injury, altered/loss of sensations and movements, numbness, burning/shooting pain, scarring/keloid, contracture. Tourniquet related complications including ischemia and nerve injury.
- j) Skin scarring-** All surgical incisions and donor sites (forearm and thighs) produce permanent scarring. The quality of these scars is unpredictable. Abnormal and hypertrophic scars may occur within the skin and deeper tissue. In some cases, scars may require surgical revision or other treatments. Every effort will be made to minimize scars.
- k) Unsatisfactory result-** You may be disappointed with the result of the surgery. It may be necessary to perform additional surgery to improve your results.
- l) Delayed healing and prolonged hospital stay-** Wound disruption or delayed wound healing is possible and may result in prolonged hospital stay. Partial flap loss or skin graft loss might take a long time to heal. This may require frequent dressing changes or further surgery to remove the non-healed tissue. Smokers have a greater risk of skin loss and wound healing complications.
- m) Allergic reactions-** In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions which are more serious may occur to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.
- n) Anaesthesia related risks-** Both local and general anaesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anaesthesia or sedation.

- o) **Additional surgery necessary-** There are many variable conditions that may influence the long-term result of female to male genital gender affirmation surgery. Should complications occur, additional surgery or other treatments may be necessary. Complications and risks other than the cited ones can occur but are even more uncommon. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.
 - p) Vaginal closure together with phalloplasty will affect on a permanent bases, your current sexual functioning. You have been given no guarantees about successful sexual intercourse or success in marriage and relationships.
- 8) **Post-operative follow-up –** Discharge instructions- vary individual to individual.
- a) Local cleaning and dressing (if required) as explained.
 - b) Sutureline and scar care and regular physiotherapy.
 - c) Urinary catheter care if individual is discharged with catheter and need of catheter removal in local area or during follow up.
 - d) Possible need of touch up procedures/further procedures explained
 - e) Need to reduce activities & take time off from work six to eight weeks or longer.
 - f) Need for a support person in the post-operative period to assist with daily activities such as self-care & grooming, meal preparation, laundry, etc.
 - g) Need for regular follow-up with care providers for 3-4 weeks as per given schedule during initial post-operative period and less frequently later.
 - h) Follow up with mental health professional and hormone prescribing physician as per their advice.

Financial responsibilities

The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of surgical supplies, laboratory tests, blood bank, anaesthesia, and hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be

responsible for necessary co-payments, deductibles, and charges not covered.

Additional costs may occur should complications develop from the surgery. Secondary /additional surgeries, investigations or hospital stay and surgery charges involved with revision surgeries would also be your responsibility.

PART 2: CONSENT FORM

DISCLAIMER

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However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information which is based on all the facts in your particular case and the state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

- a) I hereby authorize Dr _____ and such assistants as may be selected to perform the following procedure or treatment: **free radial forearm flap phalloplasty.**
- b) I consent to the presence of OR staff of either sex to be present in OR during my surgery. I understand that they are present for the safe conduct of my surgery.
- c) I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under

this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.

- d) I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
- e) I understand what my surgeon can and cannot do, and I understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks of the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.
- f) I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
- g) For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
- h) I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
- i) I understand that the surgeon's fees are separate from the anaesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
- j) I realize that not having the operation is an option.
- k) It has been explained to me in a way that i understand:
 - a. The above treatment or procedure to be undertaken
 - b. There may be alternative procedures or methods of treatment
 - c. There are risks to the procedure or treatment proposed

I consent to the treatment or procedure. I am satisfied with the explanation.

Name of Individual.....Signature of Pt.....
 Date.....
 Name of the Witness.....
 Relationship.....
 Signature of witness.....
 Date.....
 Name of doctor.....
 Designation.....
 Signature.....
 Date.....

9) Individual Information and Informed Consent for Metaidoplasty

While many gender-incongruent individuals find comfort with their gender identity, role, and expression without surgery, for many others surgery is essential and medically necessary to alleviate their gender incongruence. For the latter group, relief from gender incongruence cannot be achieved without modification of their primary and/or secondary sex characteristics to establish greater congruence with their gender identity and expression. Phalloplasty (penile reconstruction) is of major importance for the psychological and sexual well-being and quality of life in transgender men. However, phalloplasty is a major surgery with significant morbidity. Also, many a times, it is done in multiple stages. Therefore, many transmen opt not to undergo this procedure and instead opt for metaidoplasty, which is a relatively minor, single staged procedure, with chances of less urinary complications, and preserving physiologic erection, natural sensation and orgasm. In a significant number of cases, metaidoplasty will not achieve the phallic length capable of penetrative sexual intercourse with a female partner or micturition in erect position with good stream. It is usually possible to proceed to phalloplasty, if you so desire, later.

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the first part is detailed information regarding the procedure and the next is procedure specific consent. Please go through the entire document before consenting to the procedure.

Part 1: Individual information

Introduction

1) Preconditions for surgery:

- a) Firm diagnosis of Gender Incongruence, as per ICD-11/ DSM5 by two different mental health professionals.
- b) The reference letters from mental health professionals should include the parameters as mentioned in 7th SOC's, mainly the diagnosis, individual's mental competence to give consent for surgery and hormone therapy and the fact that all co-existing mental health conditions are currently well controlled.
- c) The individual has completed 12 months of hormone therapy under guidance from a hormone specialist/ gender team unless individual is unwilling to take hormones/ unable to take hormones or the hormone therapy is medically contraindicated. (Many individuals in India, especially MTF, are however well adapted in their desired gender role and are unwilling to take hormone therapy).
- d) The individual has experienced living in desired gender role for a period of 12 months.
- e) A legally notarized waiver of liability affidavit on stamp paper, waiving the gender team's liability for removing individual's healthy organs, permanent loss of current sexual functioning and reproductive ability.

2) Preoperative Requirements:

- a) Stopping health supplements such as omega, fish oils, herbal products, garlic, green tea etc from 2 weeks prior to surgery.
- b) Stop smoking from 4 weeks prior to surgery.
- c) Limit/ stop alcohol intake 4 weeks prior to surgery. Hormone therapy should be adjusted as per advice of treating physician/ endocrinologist.
- d) Stop blood thinners if feasible, from 5 days prior to surgery with permission from individual's cardiologist.
- e) Depending on the protocol, you may be required to use a suction device and local application of testosterone analogues for 2-4 weeks prior to the procedure.

3) Pre-operative Investigations:

Complete blood counts, coagulation profile, Blood sugar fasting and PP, LFT, RFT, TSH, viral markers for hepatitis B, C and HIV, EKG, Chest x ray, Ultrasound whole abdomen. Other specific investigations if required for co-existing conditions.

4) Options and alternate procedures: Phalloplasty by various methods such as radial artery forearm flap, anterolateral thigh flap, musculocutaneous latissimus dorsi flap and others.**5) Procedure specific information:**

a) General individual identifiers, names of admitting surgeons, individual's and witness's signatures, permission for photo and videography etc are usually part of general hospital consent and, also may be a part of this consent. Higher risk due to some co-existing condition and anaesthesia consents are separate.

b) Shaving of genital area and thighs will be carried out just prior to the surgery. A urinary catheter will be inserted.

c) Surgical procedure:

Metaidoioplasty may be done in isolation or can be combined with hysterectomy, salpingo-oophorectomy, vaginectomy, urethroplasty and scrotoplasty (with or without testicular implants) in the same sitting.

In metoidioplasty the natural clitoral chordee is released and the suspensory ligaments are transected to straighten the phallus. Depending upon the type of metaidoioplasty (simple metaidoioplasty/ Ring metaidoioplasty/ Belgrade Metaidoioplasty) the surgeon might take mucosa from inside your mouth, or vaginal mucosa when done along with vaginectomy, or skin flap from the labia minora to extend the urethra (reconstruct the fixed part of male urethra) up to the tip or corona of clitoris. The skin closure is then carried out to complete the reconstruction.

Scrotoplasty can also be done in the same sitting to obtain a male-like appearance of the genitalia.

A supra pubic urinary catheter might be placed for around 3 weeks after surgery. Urethral stent might be placed in some cases which may be removed after 10 days. Alternatively, a Foleys catheter might be placed for 3 weeks.

- 6) **Postoperative Course:** After surgery, you will be having a urinary catheter for around 3 weeks. Hospital stay after surgery is usually for 3-7 days.

Depending on the protocol, you may require the post-operative use of vacuum pump or a syringe suction device, starting 3 weeks after surgery to maximize the result.

- 7) **Complications** -post operative complications can be minor (that can be managed without surgery) or major (those requiring additional surgery)

Minor complications: The minor complication rate ranges from 17.5% to 35%.

Bleeding- It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require drainage. You should reveal all the medications that you have been taking to the surgeon so that medicines that can cause bleeding can be stopped or its dose adjusted before the surgery.

Infection- Bacteria live on the skin and near the perineal area. You will be given antibiotics through your I.V. at the time of surgery and post operatively and will be required to take oral antibiotics on discharge. Although infection is unusual after this type of surgery, it may appear in the immediate post-operative period or at any time following the surgery.

Delayed healing- Wound disruption or delayed wound healing is possible. Partial flap loss might take a long time to heal. This may require frequent dressing changes or further surgery to remove the non-healed tissue. Smokers have a greater risk of skin loss and wound healing complications.

Major complications:

Urethral Fistula- urethral fistulas occur in around 7-15% of all metoidioplasty individuals and are repaired by excision of the fistula and overlaying with available local vascularised flaps.

Urethral stricture- urethral strictures occur in 2-3% of all individuals. Stricture plasty or buccal mucosal graft urethroplasty might be necessary to repair the stricture.

Testicular implant dislocation- in the event of a dislocated testicular implant, repositioning and fixation of the implant into proper position, along with creation of a new capsule are indicated.

Other complications:

Unsatisfactory result- You may be disappointed with the result of the surgery. It may be necessary to perform additional surgery to improve your results.

Allergic reactions- In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions which are more serious may occur to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.

Surgical anaesthesia- Both local and general anaesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anaesthesia or sedation.

Additional surgery necessary- There are many variable conditions that may influence the long-term result of female to male gender reassignment surgery. Should complications occur, additional surgery or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited are particularly associated with gender reassignment surgery. Other complications and risks can occur but are even more uncommon. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.

Financial Responsibilities

The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of surgical supplies, laboratory tests, blood bank, anaesthesia, and hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered.

Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day-surgery charges involved with reversionary surgery would also be your responsibility.

PART 2: CONSENT FORM**DISCLAIMER**

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). The informed-

consent process attempts to define principles of risk disclosure that should generally meet the needs of most individuals in most circumstances.

However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information which is based on all the facts in your particular case and the state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

- a) I hereby authorize Dr _____ and such assistants as may be selected to perform the following procedure or treatment: **Metaidoioplasty**
- b) I consent to the presence of OR staff of either sex to be present in OR during my surgery. I understand that they are present for the safe conduct of my surgery.
- c) I recognize that during the course of the operation and medical treatment or anaesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
- d) I consent to the administration of such anaesthetics considered necessary or advisable. I understand that all forms of anaesthesia involve risk and the possibility of complications, injury, and sometimes death.
- e) I understand what my surgeon can and cannot do, and I understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All my questions have been answered, and I understand the inherent (specific) risks of the procedures I seek,

as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.

- f) I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
- g) For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
- h) I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
- i) I understand that the surgeon's fees are separate from the anaesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
- j) I realize that not having the operation is an option.
- k) It has been explained to me in a way that i understand:
 - a. The above treatment or procedure to be undertaken
 - b. There may be alternative procedures or methods of treatment
 - c. There are risks to the procedure or treatment proposed

I consent to the treatment or procedure. I am satisfied with the explanation.

Name of Individual.....

Name of the Witness.....

Relationship.....

Signature.....

Signature.....

Date.....

Date.....

Doctor.....

Designation.....

Signature.....

Date.....

10) INDIVIDUAL INFORMATION AND INFORMED CONSENT FOR VOICE MODIFICATION

This is an informed-consent document that has been prepared to help inform you about voice modification surgery, its risks, and alternative treatments. This document consists of two parts- the first part is detailed information regarding the procedure and the next is procedure specific consent. Please go through the entire document before consenting to the procedure.

Part 1: Individual information

Introduction

Voice is a very important part of our identity, also of our gender identity and expression, because within seconds, most of us decide the gender of the person speaking. Individuals wishing to affirm the gender identity of their voice may benefit from surgical alteration of their sound-producing mechanism.

1) Indications

- a. Individuals who cannot alter their voice through therapy or practice who want to be perceived as female by sound alone, such as during a telephone conversation
- b. Individuals who can voluntarily alter their voice to sound female but wish to remove even the potential for inadvertently sounding male.
- c. Individuals whose speaking pitch and vocal range have dropped from the complication of vocal cord detachment after tracheal shave.

2) Contraindications

- a. Individuals who cannot tolerate the chance that surgery will not accomplish a pitch and/or resonance change; all surgeries have the risk of incomplete alteration of the voice from male to female
- b. Individuals who cannot tolerate a loss of maximal volume are not surgical candidates.

3) Preoperative Requirements:

- a. A voice recording might be made of the following vocal capabilities:
 - Comfortable speaking pitch reading a standard passage of several sentences

- Lowest pitch that can be produced
 - Highest pitch that can be produced.
 - Loud phonation, a robust yell, cough and a throat clearing
 - Soft singing of several words at high and low pitches, such as “Happy Birthday to You”
- b. Endoscopic examination with audio might be done for visualising the cords.
 - c. Stopping health supplements such as omega, fish oils, herbal products, garlic, green tea etc from 2 weeks prior to surgery.
 - d. Stop smoking from 4 weeks prior to surgery.
 - e. Limit/stop alcohol intake 4 weeks prior to surgery. Hormone therapy should be adjusted as per advice of treating endocrinologist.
 - f. Stop blood thinners if feasible, from 5 days prior to surgery with permission from individual’s cardiologist.

4) Pre-operative Investigations:

- a) Complete blood counts, coagulation profile, Blood sugar fasting and PP, LFT, RFT, TSH, viral markers for hepatitis B, C and HIV, EKG, Chest x ray.
- b) voice recordings and endoscopy might be done for medicolegal purposes. Other specific investigations if required for co-existing conditions.

5) Procedure specific information:

- a) General individual identifiers, names of admitting surgeons, individual’s and witness’s signatures, permission for photo and videography etc are usually part of general hospital consent and also may be a part of this consent. Higher risk due to some co-existing condition and anaesthesia consents are separate.
- b) Various surgical techniques are available including- cricothyroid approximation, LASER vocal cord thinning, vocal cord webbing, anterior commissure advancement, anterior partial laryngectomy and thyrohyoid elevation.

The most common procedures done are CTA (cricothyroid approximation) and vocal cord webbing and will be discussed here:

- 6) CTA surgery mimics the normal action of the cricothyroid muscle to lengthen the vocal cord. The vocal quality produced by this increase in tension of the vocal cord is called a falsetto. The

surgery can be done under general anaesthesia or under local anaesthesia.

- i) The skin incision is made in the neck near the cricothyroid space, with the individual supine and head extended.

The thyroid and cricoid cartilage are visualised, and these cartilages are approximated with a permanent suture.

The neck incision is closed

After the surgery, no voice rest is required, and the individual can take bath after 24 hours.

- ii) Vocal cord webbing is a procedure which shortens the effective length of the vocal cords so that the pitch is elevated. It is done with micro laryngoscopy under general anaesthesia. There will be no external incisions. the raw edges of the anterior vocal cords are sutured together. Individuals should rest their voice for 2 weeks after surgery.

6) Complications:

Note: The listed risks and complications are not all inclusive.

- a) **Fading of elevated pitch** over time- some individuals can experience an initial elevation in pitch that fade back to a baseline pitch over a few months (33%)
- b) Some individuals develop an **unnatural, hyper elevated** pitch ranging from an extreme falsetto to a mild falsetto quality
- c) **Bleeding-** It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain accumulated blood or blood transfusion. You should reveal all the medications that you have been taking to the surgeon so that medicines that can cause bleeding can be stopped or its dose adjusted before the surgery.
- d) **Infection-** Bacteria live on the skin. You will be given antibiotics through your I.V. at the time of surgery and will take oral antibiotics following surgery. Although infection is unusual after this type of surgery, it may appear in the immediate post-operative period or at any time following the surgery. Should an infection occur, treatment including antibiotics, or additional surgery may be necessary.
- e) **Skin scarring-** All surgical incisions produce scarring. The quality of these scars is unpredictable. Abnormal scars may occur within the skin and deeper tissue. In some cases, scars

may require surgical revision or other treatments. Every effort will be made to minimize scars.

- f) **Unsatisfactory result-** You may be disappointed with the result of the surgery. It may be necessary to perform additional surgery to improve your results.
 - g) **Allergic reactions-** In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions which are more serious may occur to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.
 - h) **Surgical anaesthesia-** Both local and general anaesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anaesthesia or sedation.
 - i) **Additional surgery necessary-** There are many variable conditions that may influence the long-term result of voice feminisation surgery. Should complications occur, additional surgery or other treatments may be necessary. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.
- 7) **Postoperative Course:** voice rest and speech therapy depend on the type of surgery performed. For cricothyroid approximation, no voice rest is required. individuals can take bath after 24 hours. For vocal cord webbing, voice rest for 2 weeks is necessary. After surgery, you'll have follow-up visits with a speech-language pathologist to make the most of your surgery, protect your vocal health and learn to use your changed voice.
- 8) **Financial responsibilities:** The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of surgical supplies, laboratory tests, blood bank, anaesthesia, and hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered. Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day-surgery charges involved with reversionary surgery would also be your responsibility.

PART 2: CONSENT FORM

DISCLAIMER

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However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your surgeon may provide you with additional or different information which is based on all the facts in your particular case and the state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

- a) I hereby authorize Dr _____ and such assistants as may be selected to perform the following procedure or treatment: **gender affirming voice surgery.**
- b) I consent to the presence of OR staff of either sex to be present in OR during my surgery. I understand that they are present for the safe conduct of my surgery.
- c) I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
- d) I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
- e) I understand what my surgeon can and cannot do, and I understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain

my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks of the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.

- f) I consent to be photographed, voice recorded or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
- g) For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
- h) I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
- i) I understand that the surgeon's fees are separate from the anaesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
- j) I realize that not having the operation is an option.
- k) It has been explained to me in a way that i understand:
 - a. The above treatment or procedure to be undertaken
 - b. There may be alternative procedures or methods of treatment
 - c. There are risks to the procedure or treatment proposed

I consent to the treatment or procedure. I am satisfied with the explanation.

Name of Individual.....Signature of Pt.....

Date.....

Name of the Witness.....

Relationship.....

Signature of witness.....

Date.....

Name of doctor.....

Designation.....

Signature.....

Date.....

11) Consent for voice recording / medical photography/ videography

I, _____ aged _____ years, Hospital ID _____, hereby grant Dr _____ or designee permission to take voice recordings and /or video of myself.

I understand that photographs/ voice recordings/ video may be taken before, during and after my procedure(s) as a routine part of my medical care. I am aware that the photographs may be used for any lawful purpose including, but not limited to the hospital/doctor's website, social media accounts, promotional materials, either digital or in print, in perpetuity.

I authorize the use of my photographs and voice recordings for doctor's photo gallery to help future individuals understand and see outcomes from surgery/treatment. I understand that the information may be used in my medical records, for purposes of medical teaching, or for publication in medical journals.

By consenting to these voice recordings and photography, I understand that I will not receive payment from any party. Refusal to consent to photographs will in no way affect the medical care I receive. I release and discharge above mentioned doctor and the hospital from all rights that I may have in the photographs/voice recordings/ video and from any claim that I may have relating to such use in publication, including any claim for payment in connection for distribution or publication of the photographs.

I understand that I will not be identified by name in any use of these photographs/videos (unless I state my name). I understand that in some circumstances the photographs may portray features which make my identity recognizable. Jewelry, tattoos, distinctive clothing / other features may also reveal my identity.

By signing this consent, I authorize doctor and the hospital to edit, alter, share, remix, tweak, build upon or in any way alter the photographs/voice recordings/ video mentioned above.

I am more than 18 years of age. I understand the scientific facts that have been discussed with me as well as the contents of this consent form. I have been given the opportunity to discuss regarding the treatment plan. I also had the opportunity to ask questions and have received satisfactory answers in a language I understand.

I have signed this consent voluntarily it of my free will without any compulsion and in my full senses.

Name of Individual.....Signature of Pt.....
Date.....

Name of the Doctor.....Designation.....
Signature.....
Date.....

Section 5

Sexual and Reproductive Health

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Cancer Screening in Transgender persons

LGBTQIA is the inclusive queer term which stands for lesbian, gay, bisexual, transgender, queer and/or questioning, intersex and asexual and/or allies.

Cancer screening: It is preventive way to detect cancer. Clinicians noted that trans persons' eligibility status was often misclassified¹. Providing appropriate cancer screening services to them can be particularly challenging, as appropriateness depends on an individual's natal and current anatomy, as well as where individuals are at with regard to their gender transition.

Prostate cancer: Discussion regarding risks and benefits of screening should start at age of 50years. Palpation of prostate by rectal or transvaginal route if neovagina has been created. PSA testing should be performed (upper limit of normal range is 1 ng/ml). Removal of gonads in addition to estrogen exposure likely reduces risk for prostate cancer and benign prostatic hypertrophy.

Testicular cancer: Routine testicular cancer screening is not recommended in cisgender men and there is no evidence to perform screening in transgender women. Transgender women adherent to therapeutic doses of estrogen plus an androgen blocker, and with persistent testosterone elevations, should be evaluated for testicular tumors by physical exam, as well as human chorionic gonadotropin (hCG), alpha-fetoprotein (AFP) and lactic dehydrogenase (LDH) levels, and possibly a scrotal ultrasound.

Transwomen Cancer Screening Guidelines

Type of Cancer	Screening needed?	When to start	Modality of Screening	Frequency
Breast	Yes, when over age 50 years and after at least 5 years of Feminizing Hormonal intervention	No earlier than age 50 years	Mammography	Every two years (USPSTF Guidelines)
Prostate	No, same as cisgender person*	N/A	N/A	N/A
Testicles	No, same as cisgender person	N/A	N/A	N/A

*Transwomen are believed to have lower risk of prostate cancer from estrogen therapy and orchiectomy

Transmen Cancer Screening Guidelines

Type of Cancer	Screening needed?	When to start	Modality of Screening	Frequency
Breast	In case of Bilateral Mastectomy: No clear guideline	Age 50 years	Ultrasound or MRI	Unclear
	In case of breast reduction surgery: same as non-transgender individuals	Age 50 years	Mammogram	Every two years (USPSTF Guidelines)
Cervix	Same as cisgender individuals, discontinue after total Hysterectomy*	Age 21 years**	PAP Smear***	Every three years
Ovary	Not indicated	N/A	N/A	N/A
Uterus	Not indicated, unless new unexplained vaginal bleeding	As needed	Endometrial biopsy	As per clinical status

*Unless history of CIN II/III. In that event, continue screening for 20years after hysterectomy.

** If HIV positive then first PAP smear should be within first one year of diagnosis.

***Consider using pediatric speculum with lubrication, oral benzodiazepine pre-examination or vaginal estrogen for a week prior to collection.

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5. Allison M. Puechl, MD Beverly A. Gray, M

Contraceptive Needs of Transgender Persons

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Introduction

Transgender men who have not had their pelvic organs removed will need contraceptive advice to prevent pregnancy. This need is never requested by the person, but the physician needs to assess this need by direct questioning. If the pelvic organs have not been removed this issue should be discussed. Sexual abuse by male partners may lead to an unwanted pregnancy.

Desirable Choices

Reversible methods (LARC)

Long term contraception is required. Progesterone has been found to be safe for use in both adult and adolescent transitioning transgender people. Moreover, it does not interfere with testosterone use and contributes to amenorrhea as well. Pills are not a good choice due to compliance issues in the long term and its recurring cost.

- Subdermal implants may be used
- Depo-Provera® injection popularly known as DMPA is a cost effective non-invasive and widely available preparation in India. This is an excellent choice for adolescents as it produces reversible amenorrhea and gives time for detailed psychological assessment. It does cause some reduction in bone mineral density, between 3-7% in the first two years of use but this is completely reversible after its use is discontinued. For detailed discussion on this issue the reader is referred to the position paper of the society of Adolescent medicine published in 2006. (see ref 5,6 below)

Classically puberty is suppressed with the use of depot GnRH agonists in this population. The cost as well as the bone mineral density reduction is greater with injections of GnRH agonists if used long term in this population. Hence, they should be used for the shortest duration possible. Follow up DEXA Scans are recommended to check bone mineral density in this population.

- It is also ideal to insert an Intrauterine device for such individuals. The Copper IUD may be inserted but the hormonal levonorgestrel intrauterine device (LNG-IUS) is suitable as it prevents breakthrough bleeding. The only disadvantage is that it is an invasive procedure.

Insertion will require short anaesthesia as pelvic examination is uncomfortable due to vaginal atrophy as well as it can trigger gender dysphoria.

Permanent Methods

- Sterilization by the laparoscopic route is a suitable form of permanent contraception but is invasive.
- Ensure device placed hysteroscopically to occlude the tubal ostia is also a desirable alternative
- Hysterectomy with bilateral salpingo oophorectomy may be opted for by some to get rid of the menace of undesirable breakthrough bleeding

Undesirable choices

- Oral Contraceptive pills are not an option because they may cause withdrawal bleeding and moreover these individuals are on testosterone intervention.
- Barrier Contraceptives are uncomfortable to use and have a high failure rate. Hence, they are not a desirable choice.

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1. Light A, Wang LF, Zeymo A, Gomez-Lobo V. Family planning and contraception use in transgender men. *Contraception*. 2018 Oct;98(4):266-269. doi: 10.1016/j.contraception.2018.06.006.
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Recommendations for Fertility Preservation in Transgender Individuals in India

Contributing Author

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Introduction

Transgender person denotes an individual whose sense of personal identity and gender does not correspond with their sex assigned at birth. The term 'Gender dysphoria' is often used to explain the emotional struggle such individuals undergo to deal with their gender identity- a discordance between sex (external appearance of genitalia) and gender (psychological recognition of self). (Ahuja and Bhattacharya 2001) Intersex individuals on the other hand have anatomy that is ambiguous at birth. Transgender individuals can be offered Gender-affirming intervention (GAI) which could be surgical - gonadectomy (removal of testes or ovaries) and/or gender affirmative hormonal intervention. These interventions invariably lead to loss of reproductive potential making it mandatory to have a discussion on fertility preservation before initiation of GAI. The number of persons having Gender Incongruence in India has increased in the past 5 years and many of them are seeking Gender Affirming Surgery (GAS). (Gupta et al 2017)

In recent years, transgender issues are coming to the fore in children and adolescents. Psychological evaluation and counselling are essential before they are given GAI which includes pubertal suppression and gender affirming hormones. Fertility preservation options should be discussed by the Gender Affirmation Team with the child and parents / guardians before starting intervention since they are the decision makers, raising considerable ethical concerns. A major worry being the inability of a young child to fully comprehend the consequences of their decision. The Endocrine Society therefore recommends that only pubertal suppression using GnRH analogues should be offered till the age of 16 years (Hembree et al 2017). GnRH agonists induce a reversible arrest of germ cell maturation and development of secondary sex characteristics.

The preservation of fertility or reproductive capacity developed initially for cancer persons needing gonadotoxic intervention (Chemo intervention/ radio intervention) or gonadal surgery, has been extended to many other person groups at risk of infertility due to medical, surgical and genetic causes, as well as age related ovarian insufficiency. The need for fertility preservation (FP) in the transgender group of individuals has also been acknowledged by medical professionals. Studies show that more than 50% persons want to have children and between 37-76% would opt for fertility preservation, though the actual number who finally undergo the procedure is small 3.1% (transmen) to

9.6%(transwomen) (Neblett et al 2019). The rate of FP amongst transgender youth is reported to be 3-5% (Nahata et al 2017)

Barriers to fertility preservation from the transgender person's perspective include undesired side effects of hormones or apprehension about invasiveness of procedure and a delay in their GAI. Lack of awareness, availability, cost and efficacy of fertility preservation procedures are major barriers on the physician front, particularly in India. (Mahajan et al 2016) Paucity of literature on management of transsexual people in India (Gupta and Morarka 2009) precludes the possibility of assessing the level of discussions on fertility preservation.

In India, the Transgender Persons (Protection of Rights) Bill was passed in July 2019. It includes trans-men, trans-women, persons with intersex variations, gender-queer, and persons with socio-cultural identities, such as kinnar and hijra (Ministry of Social Justice and Welfare)

This bill protects such individuals from discrimination and gives them equal rights to health, education, employment, state welfare and comprehensive medical insurance schemes. Certificate of identity for a transgender person indicates gender as transgender. A revised certificate can be acquired only after Gender Affirming Surgery (GAS). This long-awaited bill has come as a huge relief to both individuals wanting GAS and doctor performing the surgery, as it affords legal protection.

A list of FP procedures and the recommendations offered, for Indian transgender persons contemplating GAI are extrapolated from FP recommendations for onco-fertility procedures promulgated by The Fertility Preservation Society (India)-(FPSI) with inputs from leading Oncology and Reproductive Medicine experts in the country, keeping in mind social, ethnic and religious differences.

Fertility preservation options include sperm and testicular tissue cryopreservation for males and oocyte, embryo and ovarian tissue cryopreservation (OTC) for females. Oocytes need to undergo ICSI with donor sperm when the individual wants to have a child. All the above procedures except OTC are widely available in India in the private sector and some government hospitals.

Fertility Preservation Recommendations (FPSI)

- A. FP counselling** should be done prior to GAI in all transgender people desirous of future fertility.
- B. Consent** - Detailed consent for procedure should be taken. For children and adolescent consent of parents and assent of child

is required. Consent for posthumous use/disposal of gametes/tissue should also be taken.

C. Post pubertal Males (Sex assigned at birth) (MtF)

1. Semen cryopreservation (CP) is recommended. Preferably 2-3 samples of semen should be cryopreserved.
2. Collection of ejaculate can be through masturbation. Vibrators – mechanical or electrical, can be used if person is unable to produce a masturbated sample.
3. TESA (Testicular sperm aspiration) can be offered to post-pubertal males when semen collection is not possible.
4. Semen can be used for IUI or IVF to achieve pregnancy. ICSI (intra cytoplasmic sperm injection) is required in case testicular sperm is to be used.

D. Post pubertal Females (Sex assigned at birth) (FtM)

1. FP procedures include oocyte, embryo and ovarian tissue CP.
2. Oocyte cryopreservation (CP) is the procedure of choice.
3. Embryo freezing is an established technique and may be offered. Donor sperm would be required for fertilization
4. Ovarian tissue cryopreservation (OTC) involves surgical retrieval of ovarian tissue and transplantation subsequently when pregnancy is desired.
5. Oocyte and embryo CP necessitates ovarian stimulation (OS) with gonadotrophins for 9-10 days and an approximate delay of 6 – 8 weeks is expected for undergoing GAS and 3-4 weeks for gender affirmative hormonal intervention.
6. Safety of OS in FP has been established.
7. Efficacy: For cryopreserved oocytes - 10-16 oocytes ensure a reasonable chance of reproductive success in young women. An oocyte-to-baby rate of 6.5% has been estimated (Cobo et al., 2015), probability of live birth increases progressively till number of used oocytes reaches 25.

OTC- is no longer considered experimental. Many births have been reported worldwide after transplantation of CP thawed ovarian tissue.

8. There is no increased risk of birth defects or genetic diseases in infants delivered from CP oocytes, embryos or OTC.

E. FP options in children and adolescents

Pre-pubertal boys: Spermatogenesis occurs at approximately 13 years and can precede testicular growth and development of pubic hair. Experimental techniques such as immature testicular tissue (ITT) and spermatogonial stem cell (SSC) cryopreservation followed by transplantation or in vitro maturation can be performed. No pregnancies have been reported in humans so far.

Post pubertal boys: semen and testicular tissue can be preserved. Masturbation is generally possible even in young adolescents provided testicular volume is more than 5 mL. (Hagenas et al 2010)

Pre-pubertal females: ovarian tissue cryopreservation is an option. Ovarian tissue needs to be transplanted for restoration of endocrine function and ovulation. Transgender boys (FtM) may not be keen on this. Alternatively, in-vitro maturation (IVM) of oocytes can be performed.

F. Pregnancy can be achieved through surrogacy in both MtF and FtM cases. Pregnancy in self is feasible in FtM after stopping testosterone intervention and has been reported. Uterine transplantation may be a future option in MtF individuals but currently it is experimental.

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Hysterectomy and Bilateral Salpingo-oophorectomy

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Many transmen opt for definitive surgery, which is performed in stages. Hysterectomy should be offered along with bilateral salpingo-oophorectomy. Vaginectomy and Genital reconstruction surgery can be performed at another sitting.

Criteria for hysterectomy and salpingo-oophorectomy in FtM persons and for orchiectomy in MtF persons:

1. Persistent, well-documented gender dysphoria.
2. Capacity to make a fully informed decision and to consent for intervention.
3. Age of majority in a given country.
4. If significant medical or mental health concerns are present, they must be well controlled.
5. Twelve continuous months of gender affirmative hormonal intervention as appropriate to the person's gender goals (unless hormones are not clinically indicated for the individual).
6. Recommendation by a mental health specialist

The laparoscopic Total Abdominal Hysterectomy is the preferred method in Transgender individuals.

The options of future fertility should be discussed with the individual prior to embarking on this procedure. Transmen have successfully born children and this option should definitely be discussed. Some may opt out of it for some time and some may not afford this surgery or avoid it for other reasons. They need to be counseled for contraceptive use as well as appropriate screening for cervical, ovarian and endometrial cancers.

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Reproductive Options

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Presently there are no laws in our country that talk about parenting rights of the transgender population. The bill drafted in 2019 does not discuss this issue. Marriages between transmen and trans or cis women have been reported with increasing frequency and the need for parenting does arise.

Pregnancy may occur in transmen if the uterus and ovaries are present even while taking cross gender affirmative hormonal intervention. Gender affirmative hormonal intervention should be stopped as soon as pregnancy is achieved or in the pre pregnancy counseling clinic. People can experience feelings of loneliness and isolation during pregnancy, caused by gender dysphoria. Effective communication and inclusive language in the work has suggested using the term 'pregnant people' instead of 'expectant mothers' so as to include pregnant intersex men and transmen.

Although pregnancy may increase the dysphoria, many transmen continue the pregnancy and welcome a genetic offspring. They shy the public eye and hence antenatal appointments are not attended regularly. From the obstetrician's point of view, Antenatal Care and delivery follow general obstetric principles. Many may request elective cesarean section as compared to vaginal delivery. Chest feeding is also possible, and a testosterone intervention is re-instated post breast feeding.

Conversely some transmen may seek *Assisted reproductive technologies* (ART) to help them achieve a pregnancy. The commonly performed procedure is *Intrauterine Insemination* (IUI) of partner/donor sperms to achieve a pregnancy. If *In vitro fertilization* (IVF) is required, oocytes may be retrieved after ovarian stimulation, fertilized by partner sperms and embryos can be formed. Transwomen partners may opt for sperm retrieval by testicular sperm aspiration (TESA) and intracytoplasmic injection in the oocyte. (ICSI). Embryos thus formed may be replaced in transmen or frozen for future use.

Surrogacy is banned in India for transgender and same sex couples.

Adoption by transgender individuals is not legal in India. However, several transwomen adopt children outside the legal framework. Often very poor children are left uncared for and transwomen are known to take care of them. Gauri Sawant made history by publicly adopting a girl child of an HIV positive sex worker.

If an accidental pregnancy is undesirable, termination can be offered by medical /surgical means. Contraception options should be discussed and implemented prior to discharge from care.

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Monitoring Gender Affirmative Hormonal Intervention

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Commencement

Prior to commencing hormone intervention, confirm criteria for starting gender affirmative hormonal intervention. A thorough counselling of person for time required for expecting physical response of either feminization or masculinization and possibilities of adverse effects should be discussed. A risk assessment and if required modifications should be done in hormonal regimens, physical examination including blood pressure monitoring and baseline blood tests to assess suitability for the start of the intervention. Blood tests include full blood count, renal profile, liver function tests, fasting blood glucose levels, lipid profile, thyroid function and hormone assay of oestrogen, testosterone and prolactin levels. Reproductive gametes cryopreservation should be considered before initiating gender affirmative hormonal intervention (Refer to section below)

Monitor every 3 months for first year, 6 months for 3 years, then yearly

Monitoring for assessing response and evaluation for any adverse events should include both clinical and laboratory evaluation. Follow-up should include careful assessment for signs and symptoms of excessive weight gain, acne, uterine break-through bleeding, and cardiovascular impairment, as well as psychiatric symptoms in at risk persons. Physical examinations should include general physical exam including measurement of heart rate, blood pressure, weight, as well as systemic, heart, lung, and skin exams. Laboratory monitoring should be individualised based on the risks of gender affirmative hormonal intervention, and person's individual comorbidities and risk factors.

Target hormone level

- For hormone (testosterone) intervention for transgender men (FTM) target is to increase testosterone levels to the normal male physiological range (300–1000 ng/dl).
- For gender affirmative hormonal intervention (administering an antiandrogen and estrogen) for transgender women (MTF) is to decrease testosterone levels to the normal female range (30–100 ng/dl) without supra- physiological levels of estradiol (<200 pg/ml).

Monitoring for transgender men (FTM) on gender affirmative hormonal intervention:

1. Monitor for virilizing and adverse effects every 3 months for first year and then every 6 – 12 months.
2. Monitor serum testosterone at follow-up visits with a target in the male range (300 – 1000 ng/dl).
3. Monitor hematocrit and lipid profile before starting hormones and at follow-up visits.
4. Bone mineral density (BMD) screening before starting hormones for persons at risk for osteoporosis and in others at age 60 years onwards or earlier if sex hormones are consistently low.
5. FTM persons with cervixes or breasts should be screened for malignancy from age 40-65 years at regular intervals.

Monitoring for transgender women (MTF) on gender affirmative hormonal intervention:

1. Monitor for feminizing and adverse effects every 3 months for first year and then every 6– 12 months.
2. Monitor serum testosterone and estradiol at follow-up visits with a target in the female range (testosterone 30 – 100 ng/dl; E2 <200 pg/ml).
3. Monitor prolactin and triglycerides before starting hormones and at follow-up visits.
4. Monitor potassium levels if the person is taking spironolactone.
5. BMD screening before starting hormones for persons at risk for osteoporosis. Otherwise, start screening at age 60 or earlier if sex hormone levels are consistently low.
6. MTF persons should be screened for breast and prostate cancer appropriately.

Risks /Adverse effects/Complications:**MTF**

One should be watchful of following complications like

- potential risk of *venous thromboembolism (VTE)* associated with estrogen use, transdermal estrogen confers a lower thromboembolic risk
- increased incidence of *gallstones and liver dysfunction* and

- increased incidence of *breast cancer* while using estrogen intervention, same as the background rate of breast cancer in males.

Some absolute contraindications of estrogen intervention includes previous venous thrombotic events related to an underlying hypercoagulable condition, history of estrogen-sensitive neoplasm, and end-stage chronic liver disease.

FTM

Complications of female to male (FTM) include

- *Vaginal atrophy* due to long term testosterone intervention,
- *Menstrual related problems* because of long term GnRH and testosterone replacement, onset of menstrual bleeding in those previously amenorrhoeic on testosterone, or any abnormal bleeding, should prompt consideration of endometrial hyperplasia as an underlying pathology, Progestogens such as norethisterone or medroxyprogesterone are used to abolish menses if ovarian activity is not adequately suppressed by testosterone intervention alone.
- Testosterone intervention is associated with cortical and thecal thickening of the ovary leading to polycystic ovary metabolic profile and acne.
- Few published reports of *ovarian cancer* in transmen. Earlier surgical recourse in the form of hysterectomy may be indicated , as delay can be detrimental to the person.
- Testosterone induces the production of erythropoietin, serious risk *polycythaemia*.
- Polycythaemia can predispose to a *cerebrovascular accident*.
- Elevated liver enzymes and hyperlipidemia are also possible risks.

Absolute contraindications to testosterone intervention include pregnancy, unstable coronary artery disease, and untreated polycythemia with a hematocrit of 55% or higher. Because the aromatization of testosterone to estrogen may increase risk in persons with a history of breast or other estrogen dependent cancers

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Management of Uterine Bleeding

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Introduction

Uterine bleeding can be a source of distress in those for whom their gender identity is incongruent. Clinical experience shows that depressive symptoms and self-harming behaviors may peak during menstrual bleeding. Menstrual cycling is typically suppressible with gender affirmative hormonal intervention, although in a significant proportion of individuals it may persist.

Testosterone

For those adolescents who have met criteria for gender affirming hormone use, testosterone (T) is typically highly effective for induction and maintenance of amenorrhea within 6 months of its initiation, although it may be effective as early as 1 month. Greater than 90% of transmen using either bi-weekly intramuscular or weekly subcutaneous forms of testosterone achieve amenorrhea within 6 months.

Testosterone acts directly on the endometrium, causing both endometrial and vaginal atrophy as shown by examination of the endometria of transmen who had been on androgen intervention for at least 6 months. Histological analysis of endometrial samples of transmen on testosterone for at least 1 year is similar to that of post-menopausal women. Both groups expressed similar levels of Ki-67, a marker of endometrial proliferation. However, some studies also show an active endometrium and hypertrophic myometrium in some individuals.

While the effects of testosterone on the uterus itself are fairly clear, less is understood about its effects on the hypothalamus and pituitary. There are reports of unplanned pregnancies while on testosterone support due to lack of inhibition of ovulation in at least some individuals.

There does appear to be a dose-dependent amenorrhea response to T, which supports a trial of increased dose or frequency in cases of persistent bleeding. The recommended therapeutic range for testosterone levels is 350–700 ng/dL. However, in conditions in which the sex hormone binding globulin levels may be low (e.g., obesity and polycystic ovarian syndrome) total testosterone levels may appear subtherapeutic while free testosterone levels are in the normal range for adult males. Current guidelines recommend monitoring total testosterone levels only.

Progestogens

Progestogens comprise of natural, micronized progesterone and synthetic progestins. They are an important class of medications for induction of amenorrhea in the transmen and non binary adolescent. They may be considered in the post-menarchal adolescent who is not yet ready for masculinizing hormones but may be less effective in inducing amenorrhea than combined oral contraceptive pills that contain estrogen. Progesterone and progestins are available in different formulations, including oral, injectable, implantable, and intrauterine. In our practice we typically start with norethindrone or norethindroneacetate.

Progestogens exert most of their effects peripherally at the level of the endometrium primarily through changes in angiogenesis. Systemic forms at higher doses may also suppress the hypothalamic-pituitary-gonadal axis by inhibiting GnRH activity and therefore induce hypothalamic amenorrhea. Both forms counteract the effects of estrogen by inhibiting the proliferation of the endometrium and reducing the mitotic rate of the glands and stromal tissue, through reduction of the estrogen receptors on the glands. Prolonged use typically leads to endometrial atrophy. Oral medroxyprogesterone has been used historically to suppress the hypothalamic-pituitary-gonadal axis and may be a more cost-effective option.

Intrauterine levonorgestrel (LNG-IUS) is a very effective method of inducing long term amenorrhea in transmen who have not undergone hysterectomy. It leads to partial suppression of ovulation but is thought to act more locally at the endometrium. There is less concern for bone health as compared with injectable medroxyprogesterone. With any of the progestogens, irregular and unpredictable bleeding can occur, and this will lead to discontinuation of the agent.

Aromatase Inhibitors

These agents inhibit Cytochrome P450 aromatase enzyme that converts testosterone to estradiol and androstenedione to estrone. This enzyme is active in peripheral tissues throughout the body, including skin, bone, brain, and adipose tissue. They are also effective at increasing testosterone levels in transmen. In the pediatric population they have been used in hypoestrogenic states such as McCune-Albright syndrome, hyperandrogenic states such as familial male-limited peripheral puberty, pubertal gynecomastia, short stature, and/or pubertal delay in cis-gendermales.³⁷

Third-generation AIs, including anastrozole and letrozole are the most potent, selective, and least toxic AIs available. These agents may be of

particular benefit in the obese person, as aromatase is highly expressed in adipocytes. In many obese transpersons with low T, increasing the T levels may only serve to be converted to estradiol in adipocytes.

Selective Estrogen Receptor Modulators

These agents interact with intracellular estrogen receptors in target organs as estrogen receptor agonists or antagonists in a tissue-specific manner. Tamoxifen, the oldest member of this class, is a competitive inhibitor of estrogen at the breast, but an agonist in the endometrium. For this reason, there is a risk of endometrial hyperplasia, polyps, carcinoma, and uterine sarcoma as well as ovarian cysts, which is thought to be highest in post-menopausal ciswomen. Other side effects may include menopause like symptoms and increased risk of thrombosis. For these reasons, these are not commonly used in the intervention of uterine bleeding in transmen.

GnRH Agonists (GnRHa)

GnRHa mimic the hypothalamic hormone GnRH; when given continuously they act as an inhibitor of the pituitary gonadotropins LH and FSH. In practice, this is a highly effective way to halt production of estradiol or testosterone. GnRHa are available in intramuscular 1-, 3-, and 6-month formulations. GnRHa are typically used in pediatrics for intervention of central precocious puberty. In the transgender population, they are commonly referred to as “puberty blockers” as they are used to halt and/or prevent development of secondary sexual characteristics of the assigned gender. Side effects are primarily concerns about bone health as this has been shown to decline in both trans girls and trans boys on GnRHa. When used in a precocious puberty population, there seem to be no long-term consequences on fertility or bone health. In an individual who has already experienced puberty, and sex steroids (gender affirming or endogenous) are not present, people may experience symptoms similar to those seen in menopause such as hot flashes. We do not recommend routine use in persons who desire a prolonged agonadal state; the lack of sex steroids in these individuals is detrimental to bone health, as inferred by the observation that men without estrogen receptors and those with very delayed puberty have poor bone health.

Hysterectomy

Performed with or without salpingectomy/oophorectomy, this is a definitive option for the elimination of uterine bleeding. Hysterectomy

may be performed abdominally, laparoscopically, robotically, or trans vaginally. Current guidelines set forth by the World Professional Association for Transgender Health recommend persistent, well-documented gender dysphoria, the capacity to make a fully informed decision and consent to intervention, well-controlled mental health or medical concerns if significant, and 1 year of gender-affirming hormones unless not desired or medically contraindicated for the individual. Additionally, it is recommended that the person be the age of majority and have two letters of referral from mental health professionals. The Endocrine Society Practice Guidelines recommend the risks and benefits be evaluated by the individual. In the National Transgender Discrimination Survey, 21% of transmen surveyed had undergone hysterectomy, 58% desired a hysterectomy at sometime in the future, and 21% had no desire for a hysterectomy.

Conclusion

Management of uterine bleeding is vital for the mental health of the transmasculine or non binary person who desires amenorrhea. Progestogens may be initiated early in medical transition if they are not ready for or not desiring testosterone. For long term progestogen use the LNG-IUS is preferred in transmen with a uterus. If while on testosterone intervention, amenorrhea is not achieved, a trial of an increased dose or change in dose frequency is usually the first step. For persistent bleeding, particularly in the obese individual, a trial of an AI may be beneficial. GnRH agonist are only utilized as a temporary measure while other options take effect. Hysterectomy remains a viable, but the decision must be the result of an informed discussion and consent between the treating physician and person.

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Section 6

Public Health Approach to Gender in Congruence

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Introduction

Gender incongruence is defined as the mismatch an individual feel as a result of the discrepancy experienced between their gender identity and the gender assigned at birth. The discomfort associated with this incongruence is described as gender dysphoria (Gires, 2019).

The term 'Gender Incongruence' has been introduced as a condition under 'Conditions related to Sexual Health' in the latest International Statistical Classification of Diseases and Related Health Problems (ICD-11), released by the World Health Organization on 18th June 2018 (M. Fernández Rodríguez, 2018). These changes of ICD-11 represent a breakthrough and a great sense of freedom for transgender people. This step, which undoubtedly reflects the progressive mindset of the Medical Fraternity, will go down in the annals of the history of Modern Medicine as the turning point. Henceforth the existence of the Gender Spectrum has been validated and a platform prepared for addressing the issues arising out of nonconformity to the populist binary view of gender held by the society at large without the attached stigma of Mental Illness. Though the debate on the appropriateness of the label of Gender Incongruence continues to rage among the academicians and several other wrinkles also need to be ironed out, it is nevertheless a positive step towards delivery of healthcare to this marginalized and oft-neglected subset of society. Another significant step is the complete removal of Homosexuality from the ICD 11, which validates the current scientific stand that 'Sexual orientation' is a matter of personal choice and not a medical issue.

'Gender' is the pedestal on which the construct of 'I' or 'Self' stands. It is the foundation of 'Identity', what one sees oneself as and what one desires to project to the environment irrespective of the genotype inherited or phenotype exhibited. Gender is by and large a social construct and has cultural relevance. Gender Identity and Sexual orientation are recognized as separate entities and are not binary. Gender is a multifaceted spectrum manifested by the self-assigned role and expression which cannot be limited to Male or Female.

There have been a few studies to enumerate transgender population; however, no such enumeration is available for Gender Incongruence. Transgender is an umbrella term used to describe a wide range of identities whose appearance and characteristics are perceived as gender-atypical –including transsexual people, cross-dressers (sometimes referred to as "transvestites"), and people who identify as the third gender (UNFE, Definitions, n.d.). A study published in *The Lancet* in June 2016 estimates 25 million people, or 0.3 to 0.5% of the global

population, as Transgender (Balakrishnan, 2016). Perhaps this is the only accurate estimation available for the worldwide population of Transgender. In the same article, the author cites significant health inequities leading to inaccessible health services because of their social and economic marginalisation. The findings on the health aspect were published by Reisner and his colleagues in *The Lancet*. A GAP report from UNAIDS cites that estimates from countries indicate that the transgender population could be between 0.1% and 1.1% of reproductive age adults (UNAIDS, 2014). As per Census 2011 in India, there are approx. 4.9 Lakhs people in the Others category (which includes Transgender) in the country.

There are very few estimates available for gender incongruence. Two recent population studies have aimed to estimate the prevalence of people who identify as such. Kuyper & Wijsen (2014) examined self-reported gender identity and dysphoria in a large Dutch population sample, and found that 1.1% of people assigned male at birth and 0.8% of people assigned female at birth reported an 'incongruent gender identity', defined as stronger identification with other sex as with sex assigned at birth (Lisette Kuyper, 2014). Similarly, Van Caenegem et al. (2015) reported results based on two population-based surveys in Belgium. In the general population, gender incongruence was found in 0.7% of men and 0.6% of women. In sexual minority individuals, the same was 0.9% in men and 2.1% in women (Van Caenegem E, 2015).

Census, an exercise to count the population in India, never recognised Hijra/ Transgender until 2011. In 2011, for the first time, it collected data of Transgender with details related to their employment, literacy, and caste. As per this, out of the total estimated population of 1.247 billion, people who have identified themselves as transgender persons, constitute 4,87,303 (Mandal, n.d.). Though Census 2011, mentions above number in the "Others" category (GoI, 2019), various other literature hints towards a higher figure of about 5-6 million eunuchs in India (Mal, 2018).

Even if the census gives a figure of the transgender population, we do not know how many people with gender incongruence are there, or how many of them experience a need for health care, which poses a big problem for healthcare planners. The first challenging task for the survey researcher in this area will be to decide whom to count and by what means in the upcoming census.

Gender identification is the stepping stone for psychosocial development. Gender recognition, though starting very early in childhood, may remain

fluid through a large portion of the growing years before gender affirmation finally crystallizes. This fluidity, in some cases, may extend right through adolescence into adulthood. A conflict arising as a result of incongruity between assigned sex and desired gender leads to dysphoria and non-resolution may distort psychosocial development, thereby manifesting as deviant behaviour, delinquency, mental ill-health, high-risk behaviour and conditions related to sexual health. This is further compounded by the insensitive callous attitude of the cisgender majority looking at them through the narrow prism of their own preconceived notions, perpetuating an environment of mistrust and intolerance and threat of ostracization, thus forcing the gender incongruent child/adolescent to solicit advice through the unmonitored electronic media exposing themselves to further harm at the hands of unscrupulous professionals who peddle street hormones and offer unscientific 'quick fix' procedures.

It has been documented that early recognition of gender incongruence, provisioning of a gender-sensitive environment for psychosocial development and early access to Healthcare services when coupled with social support, especially acceptance by parents, markedly reduces dysphoria, incidence of mental illness, risk-taking behaviour and sexual health issues. Hence it is of paramount importance that a multipronged proactive approach is adopted for the management of gender incongruence. The stakeholders need to acquire and share knowledge, facilitate the delivery of multispecialty healthcare, empower through advocacy and implement strong legislation for getting these outliers of society into the mainstream as productive citizens.

Discussion

A holistic public health approach needs to be adopted by all agencies working to ensure equity in the delivery of healthcare. Existing policies, designed to address the problem, need to be reworked to address the cause rather than manage the outcomes. The task is compounded by not only the binary viewpoint and inadequate understanding of the "Transgender Experience" by the agencies, both Governmental and Non-Governmental, entrusted with the task of giving succor, but also the inherent mistrust by the community of the cis population. To make matters worse, the majority of the transgender persons have poor health-seeking behaviour. The misinformed impressionable "client" is drawn to "Procedures" being offered in an unethical, covert manner to a privileged few who can afford the high costs. The non-existence of Indian Standards of Care and non-adherence to existing protocols lead

to further harm. The absence of recognized Centers of Excellence adhering to the norms laid down by national and/or international professional bodies in the country capable of providing Training, Certification and Continuing Medical Education to the professionals desirous of / working in the field of Transgender Medicine and Surgery, adds fuel to the fire by promoting the growth of self-styled experts, who assume the role of gatekeepers, ready to cut corners and flaunt rules for financial gains. Their demand for unnecessary affidavits designed to absolve them of any legal action for procedures carried out over and above the minimum documentation needed for the protection of the interests of the transgender person, further adds to the dysphoria and make the journey of transitioning more arduous. Non-availability of trained manpower working in the Government Sector and absence of the much-needed Government aid / Political will and infrastructure puts affordable healthcare out of reach of this misunderstood, marginalized and often ostracized subset of society. Thus, denying them the fundamental human rights and opportunities to live with dignity as bestowed upon each citizen by the Constitution of India and reinforced by the various international fora of which India is a signatory.

Concerted efforts are needed to bring together, the professionals already working in the field of Transgender Health, educationists, academicians and social workers, on a common platform, wherein, they can step out of their silos, interact with each other and share their experiences to undertake formulation of Indian Standards of Care and work towards provisioning of a holistic and affordable Healthcare to all human forms, irrespective of their self-affirmed gender identity or sexual orientation. Dissemination of knowledge regarding Gender to the Primary Care Providers is essential for early recognition and prevention of gender dysphoria. Development of a progressive society mandates provisioning of a robust, customized healthcare infrastructure which addresses the unique needs and a nurturing, inclusive, social environment which seeks to harness the full potential of this often neglected vibrant human resource by encouraging empowerment and mainstreaming.

Recommendation

It is important to nurture and promote collaboration between academic institutions, implementing structures and international bodies working on or with the Transgender communities to not only fill the lacunae in Primary, Secondary and Tertiary Healthcare but also to lay down the benchmarks in the delivery of standardized healthcare to the Transgender community in India.

The following action plan, based on a Public Health approach resting on the four domains of Knowledge, Healthcare, Empowerment and Mainstreaming, is proposed.

The domain of Knowledge:

1. Setting up of a “Centre of Excellence in Transgender Health” at an academic institution

As the first step in the multipronged approach, it is recommended to set up a “Centre of Excellence in Transgender Health” at one of the top Universities of India having on its campus all the requisite departments needed for imparting education in the Medical, Nursing, Paramedical, Social, and Legal fields, but also houses a Pharmacy and a Hospital.

The Centre shall function as the seat of academic excellence imparting training and education to the professionals from the Medical, Nursing, Paramedical, Legal and Social streams in the best practices in Transgender Health in collaboration with WPATH (World Professional Association for Transgender Health). It shall promote evidence-based care, education, research, advocacy and public policy in Transgender Health and set the benchmark for the delivery of Transgender Healthcare in the country. Taking a cue from the current Standards of Care developed by WPATH, the Centre shall, in light of the Indian cultural context, set the Indian Standards of Care. It shall formulate a curriculum specific to the Indian cultural context to enable proficiency in the implementation of the current Indian Standards of Care for delivery of healthcare to the Transgender and Gender nonconforming persons.

The Centre shall run Short term courses starting with a foundation course followed by Advance Courses leading to a Certification course in Transgender Medicine and Surgery.

The short term training courses shall include a Foundation Course in interdisciplinary Transgender Healthcare, Advanced Courses in Mental Health, Advanced Course in Non- Surgical Gender Affirmation Therapies, Advanced Course in Surgical Gender Affirmation Therapies, Advanced Child and Adolescent Transgender Healthcare Course, Course in Transgender Health Planning and Documentation and a Course in Law and Ethics in Transgender Health.

The Centre shall also conduct Continuing Medical Education Workshops containing highly specialized 4-8-hour interactive and/or case-based sessions focused on specific areas of interest for professionals who have completed the Foundations in Transgender Health course. Topics would

include - Working with Children and Adolescents; Planning and Documenting for Medical Transition; Ethical Considerations; Pre and Post-Operative Surgical Care; Voice and Communication.

The Centre of Excellence shall also run an outreach programme for sensitization of the primary caregivers, schoolteachers, parents and employers regarding gender-related issues and help them develop gender-friendly safe spaces

The long-term goal is to create a faculty of international standing who shall mentor professionals to excel in the field of Transgender Health and pioneer research aligned to meet the needs of the community.

2. Conduct intensive IEC activities

Intensive IEC activities need to be conducted for raising awareness and among all stakeholders for mitigating the risk of communicable and non-communicable diseases as a result of the high vulnerability of the community members. For running innovative IEC campaigns, the involvement of national and international agencies with prior knowledge and expertise will be required.

The domain of Healthcare:

3. Setting up of a Gender Clinic at the Hospital

Provisioning of affordable and accessible primary, secondary and tertiary care to the community members will be made possible by setting up a Gender Clinic at the Hospital. The gender clinic shall not only provide a hands-on training ground to the students but also allow them to closely interact with and develop a deeper understanding of the community.

4. Develop a Department of Transgender Medicine and Surgery at Medical College

Introduction of Transgender Medicine and Surgery as a separate subject in the Medical curriculum is needed to ensure that every Medical student is aware of the special needs of the Transgender and Gender Nonconforming Persons and issues such as sexual and reproductive health, care of the aging transgender person and preventive healthcare can be addressed by professionals having sound knowledge and proper training. Role of National Medical Council and the Ministry of Health and Family Welfare is supreme for achieving this goal.

The domain of Empowerment:**5. Setting up of a Gender Ethics Committee and Legal Cell**

It is of paramount importance to set up an ethics committee and legal cell at the University, to prevent gatekeeping and unethical practices. This cell will work closely with the Gender Team to protect the interests of the Transgender persons and also that of the professionals providing care.

6. Providing Health Insurance cover and Government Support for Gender affirming therapies

Gender Affirming therapies for affecting transition, though considered essential for reducing/preventing dysphoria, are not covered by Medical Insurance/government health schemes. The exorbitant price of treatment in private institutes makes it inaccessible for the large majority. A dialogue with the Insurance sector to address this issue and engagement with the Government to include gender-affirming therapies under the purview of the Government Health Schemes such as Ayushman Bharat will be required to move ahead.

7. Provisioning of a Single Window for change of Gender in official documents

Change of name and gender in official documents such as Aadhar Card, PAN Card, Driving License, Voter ID card, Passport, educational qualifications etc. is an integral part of social transitioning. The Transgender person is often harassed and their dysphoria increases, as he is forced to come face to face with insensitive and prejudiced officials. It is proposed that a single window be set up by the Government for change of name and gender in all official documents.

Domain of Mainstreaming**8. Reservation and Social protection as regards Education, Housing and avenues for earning a livelihood.**

It is recommended that all State Governments should act in accordance to the directions of the Honorable Supreme Court by engaging with the community and form the Transgender Welfare Boards to address the felt needs as regards Education, Housing and avenues for earning a livelihood.

Conclusion

The vision of an all-inclusive society, wherein, all forms of gender

identity and expression are nurtured and celebrated, where, new abilities emerging as a result of scientific progress permit all form of the human to live in harmony with dignity, embracing diversity and enjoying equal rights and privileges, as bestowed by the constitution, can indeed be converted into reality by making a concerted and coordinated effort, harnessing the time tested strengths and expertise of the various national and international agencies working with or assisting the Government in providing Social Justice and Health for All.

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Section 7
Parents Support Group

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How Parent Support Groups Can Help Improve Healthcare for Transgender Youngsters

As a parent, one often wonders as to whether one is doing parenting right. At the best of times parenting is a challenging job. It's a non-stop, relentless 24/7 job. Most of us struggle even when times are good, and the going is all along a beaten path. When it comes to supporting transgender children, the job gets infinitely more complex. There is no help, no guidance because no one around us knows anything. With little to no societal guidance or help, parents of transgender children are often helpless and are on the lookout for help, support and guidance. Internet may help but it is not reliable. In matters pertaining to trans issues, the internet may actually even be a bit problematic. The authenticity of information available and also the quality of it can very well be suspect. Most of it comes from western sources and is therefore not quite what works in our sociocultural milieu. Even the medical info available is mostly of western origin and therefore can be a bit off context for our country. How can we develop a support system for parents of transgender children? Where do the parents of trans kids go, when they need moral support and guidance?

Our country has lacked support groups for almost everything. Unlike the west, support groups have not existed in our country, in general. But things are beginning to change. Support groups have recently come up to help parents find support from other parents who have similar lived experiences. I am myself, a member of Sweekar. The Rainbow Parents group. It's a group of parents of Indian origin from across the globe. All of us in this group are parents of LGBTQIA+ children. The group provides a safe space for parents where they can find support from other parents having similar lived experiences. The group has been a source of much needed moral support and often beyond. Here, I have met many parents of LGBTQIA+ children. We all share the same concerns and challenges and have all been the source of great help for each other. Moral support that we offer to each other is priceless. And, it's not just that. The very fact that we see other parents proudly standing up for their children gives us hope courage and strength. So far however, our role has been to support each other and to provide advocacy for the cause of LGBTQIA+ communities. Through this write up, I plan to suggest a more comprehensive role for such groups (PSGs from now), especially in the context of transgender children and their

specific needs. Let me highlight some areas where parents support groups (PSGs) can be of great help.

The bridge between medical care givers and families of transgender children

Transgender children and their families have this difficult challenge of finding the right medical care givers. Trans kids require many different medical interventions. They need psychiatric treatments and counselling to mitigate their dysphoria and distress related with social issues they face. They need endocrinologists to supervise their feminizing/masculinizing hormone therapies. Also, many if not all need surgeries to alter their primary and secondary sex characteristics. In addition, they might require medical interventions to help them with other medical conditions. PSGs can help children to develop an understanding of the medical procedures and their realistically expected outcomes. Also, the help that such PSGs can provide in identifying competent and gender friendly medical professionals would be simply priceless. Such medical care providers are rare and therefore hard to find. PSGs can therefore be that much needed bridge between medical professionals and trans youngsters.

Help parents of transgender children understand their medical needs

Transgender children have a lot of needs that are specific to them. These require parental support. For instance, they need to be their 'authentic self.' They have to explore their true identity to get to know themselves. It may be very difficult for parents of a child they have brought up say, as a boy, to explore their feminine side. It is however of existential importance to the child. Parents often need to be counselled and should seek help from professional counsellors. They need to be convinced to reach out to counsellors for their own mental health and that of the child. The PSGs can easily provide this guidance and convince parents to take the right steps in this direction. Here a PSG can be the ideal bridge between mental healthcare professionals/counsellors and families of trans children.

Watchdogs

PSGs also have an important role in guiding parents in avoiding medical procedures that are detrimental for children. A lot has been discussed in this regard in the IPATHCON conferences. This is of special importance in case of surgeries that are performed on intersex children before they attain the age of consent. Any lifelong body alterations must wait

till the child has attained maturity and is capable of understanding their gender identity and expression. Such surgeries have been performed routinely in the past and the practice must stop. PSGs can easily be the watchdogs and help the parents of intersex children avoid such catastrophes. There is also the need to stop other malpractices like DIY hormone therapy tried out by children. Such instances are very common in countries like the UK, where there is a three to four year waiting list for appointments at NHS gender clinics. In such instance's parents must guide children and their families to find professional help where it's available before taking up any treatment. Any and every treatment must be under medical supervision, by appropriate medical professionals. PSGs can easily act as watchdogs in this regard and safeguard the children.

Here, I would also like to make two important points regarding practices by young trans children. One is the practice of using breast binders by young transmen to 'pass' as men. This is fine if done occasionally. However, if it's done on a regular basis for prolonged periods of time, it starts to alter the nature of tissues creating problems for appropriate surgeries later. The exact same caveats can be made for the practice of 'tucking' the genitals by young transitioning transwomen. This too causes similar problems for surgeons performing gender affirming surgeries later. Parents must make themselves aware of these issues and help their children avoid these practices.

Ensuring a conducive environment for diverse children in schools and educational institutions

There is a huge need for parents to find representation in the PTAs of schools to guide school managements to have policies in place so that children who belong to the LGBTQIA+ spectrum have their needs taken care of. Such children are often bullied and therefore end up deprived of the education they deserve.

For instance, transgender and intersex children have a need for gender neutral bathrooms in schools. Schools need to be made aware of this need. PSGs can do the job here. They can help schools in ensuring inclusive policies and practices for LGBTQIA+ children.

Bring in policy changes at the government level for ensuring equity

According to some recent research, as much as 15% of the population belongs to the LGBTQIA+ spectrum. Hence, they are not the miniscule minority as was the belief earlier. There is a need for activism to ensure

political representation for such communities. Here, PSGs can be the activists to ensure policy changes at the level of government to make our country truly inclusive. PSGs can be the harbingers of change at the highest levels of government.

Be the change

The last but not the least. Parents can be the change agents in the society by being the change themselves. By proudly supporting their children and being the example for the society, parents of transgender children can be the agents of change.

When we saw other parents in our parents support group, we felt that we are not alone. To see other parents like ourselves, supporting their children, was a great source of strength and courage for us. Here lies the single most important role that the PSGs can play. To all parents who are struggling with the challenges faced by them we offer a hand of help. As parents and PSGs we promise to be the paradigm for the world at large. We appreciate the work being done by **ATHI** in association with **Jamia Hamdard**. These are stellar organizations and the work being done by them must be recognized. Let us all stand together and be the agents of positive change.

When it comes to being the change agents, parents of transitioning trans children do need advice from those with experience. Therefore, to give parents a helping hand, we have compiled an ABC of parenting checklist. I would suggest parents of transitioning young children to go through this and benefit from it. So here it goes.

The Alphabet of parenting a Transgender child

Accept

Be an ally, not an adversary

Confidence of the child is very fragile, maintain it.

Do not be afraid, and do not be in a denial

Embrace the child wholeheartedly

Follow the lead given by the child

Get rid of guilt, and get information, arm yourself.

Happiness of the child is paramount, get Help if needed.

Ignore all kinds of negativity, whether from relatives or friends.

Judging a person on the basis of their preferences or gender is never right. Your child deserves this consideration.

Knowledge is power, educate yourself

Laws are there to protect you and your family. Know the legality.

Mental health professionals are needed only to dispel dysphoria, seek medical help when required.

Not an illness, No treatment can “cure” gender incongruence.

Be Open in communication, not opinionated.

Professional help for hormonal/surgical treatment should be sought when necessary

Question/ queries often help getting you on the right path. Ask continuously.

Raise happy children

Support groups are helpful. Get in touch with similar minded people.

It's a Teamwork where the leader is the child.

Understand the child's viewpoint

Variation is part of nature, accept it.

“Why me?” is to be replaced with “Yay me”.

Xpress yourself positively.

You are the chosen one to bring about a change.

Embrace your calling with a Zeal.

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