

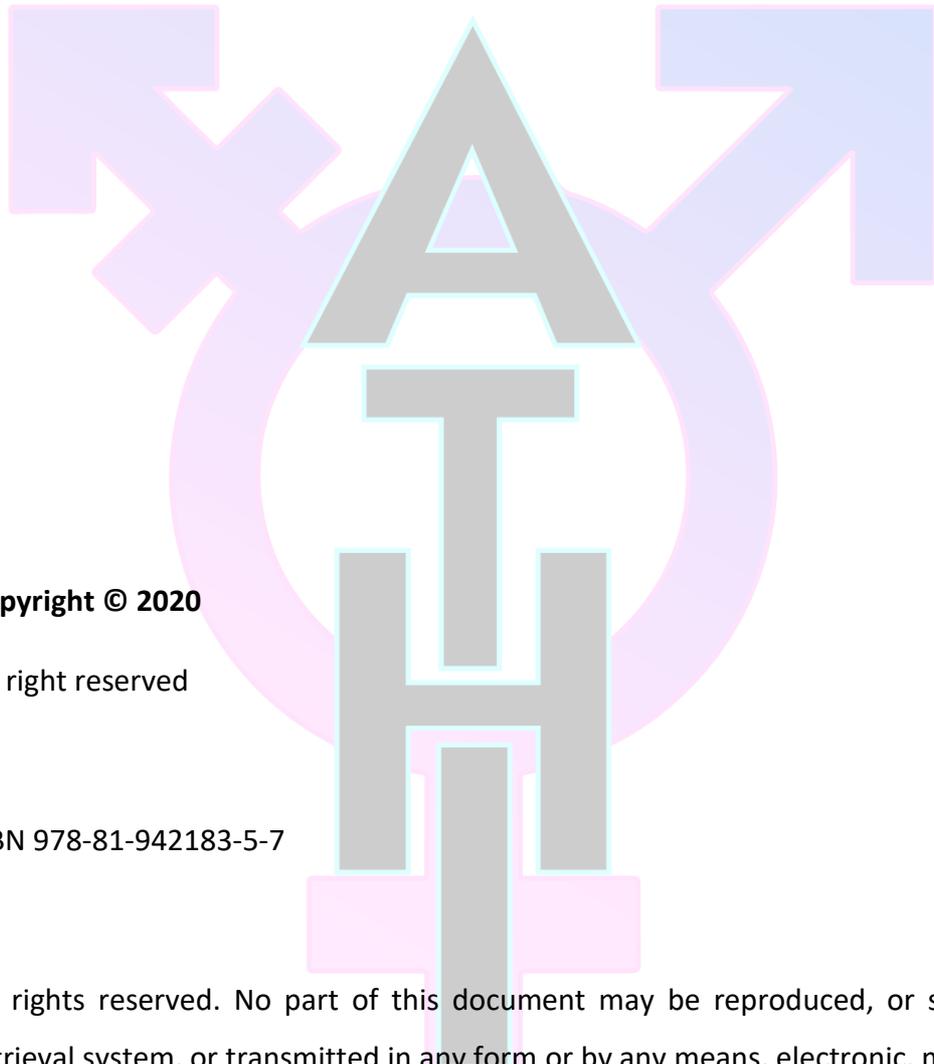
ISOC 1

Indian Standards of Care

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



Association for
Transgender Health
in India



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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 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.

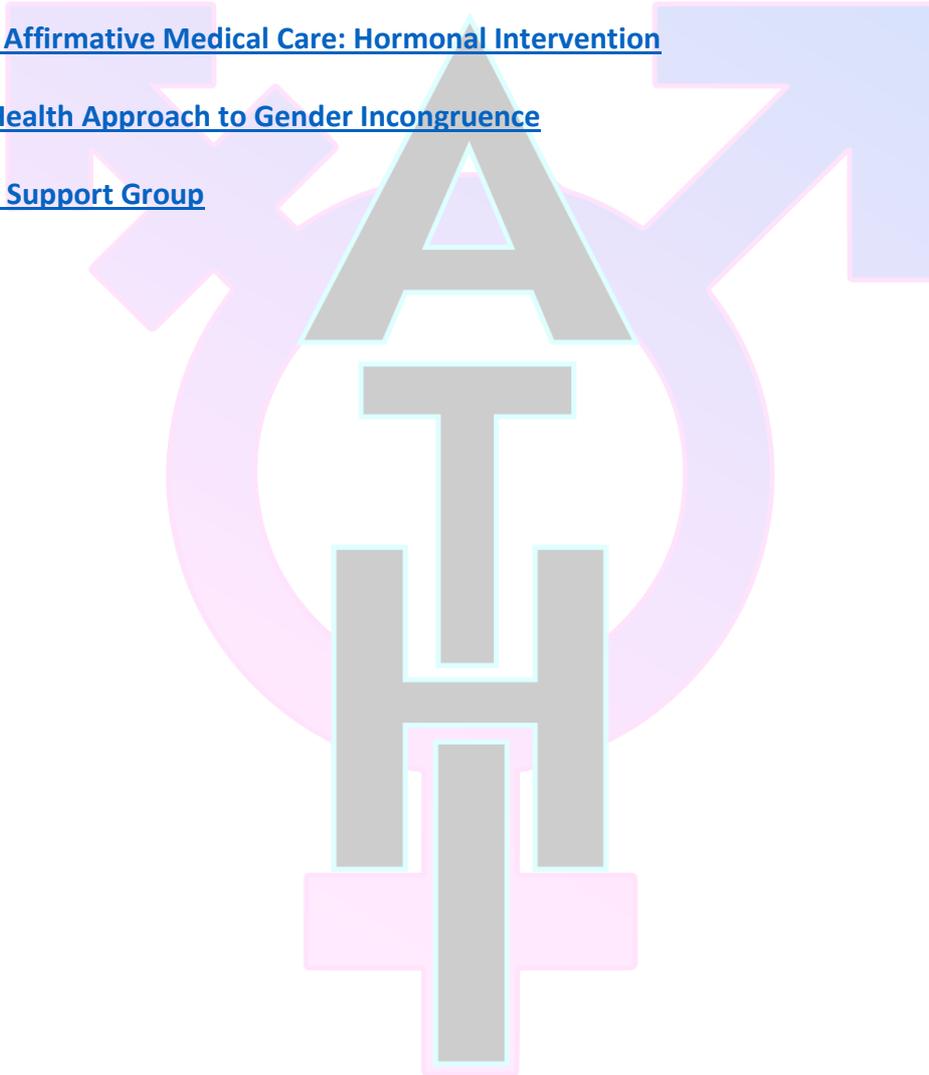
ISOC-1 seeks to be a dynamic document, constantly evolving and stimulating the professionals working in the field of Transgender Health, educationists, academicians, social workers, and community members to step out of their silos, interact with each other, undertake research and share their experiences 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", with a stylized flourish extending from the end.

Air Cmde (Dr) Sanjay Sharma (Retd)
CEO & Managing Director
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Gender Affirmative Medical Care: Hormonal Intervention

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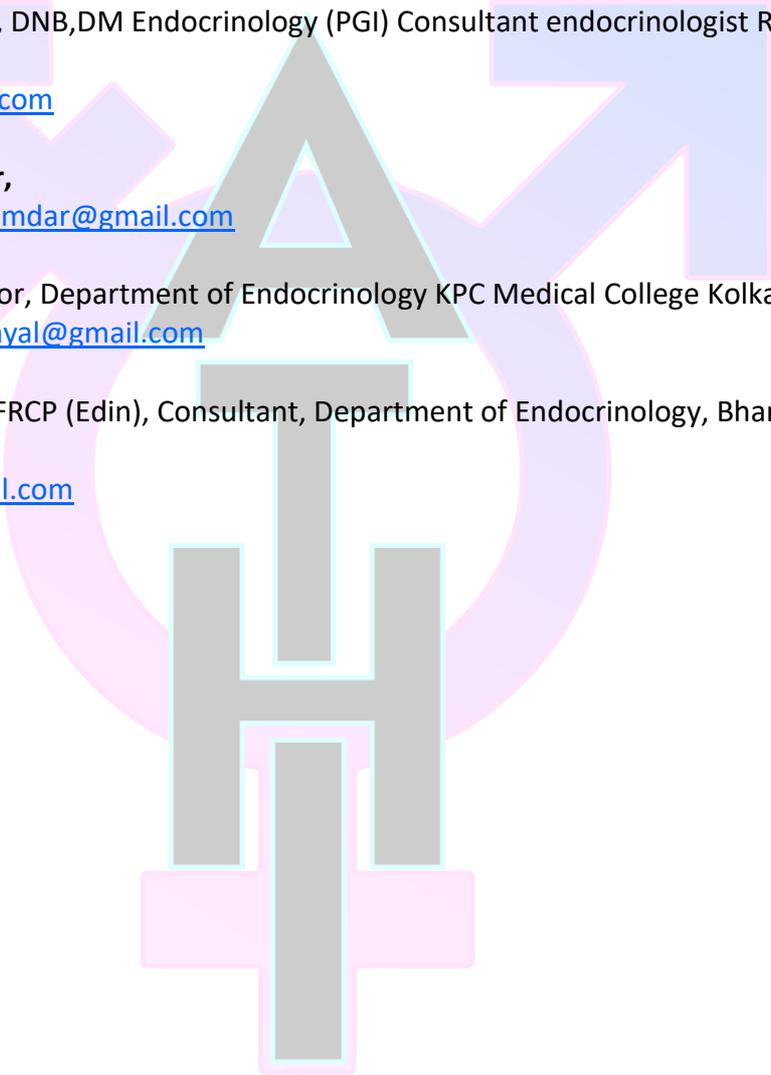
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Recommendations for Those Involved in the Gender-Affirming Hormonal Intervention of Individuals with GD/Gender Incongruence:

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 FTM 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 sperm production	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 mo.

- 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 prostatic hypertrophy (BPH). BPH 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). Ethinyl estradiol is a cheap and very effective for estrogen-directed therapies but limited with 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-α-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 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 results 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 recommended 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 consider 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 as 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 guidelines 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

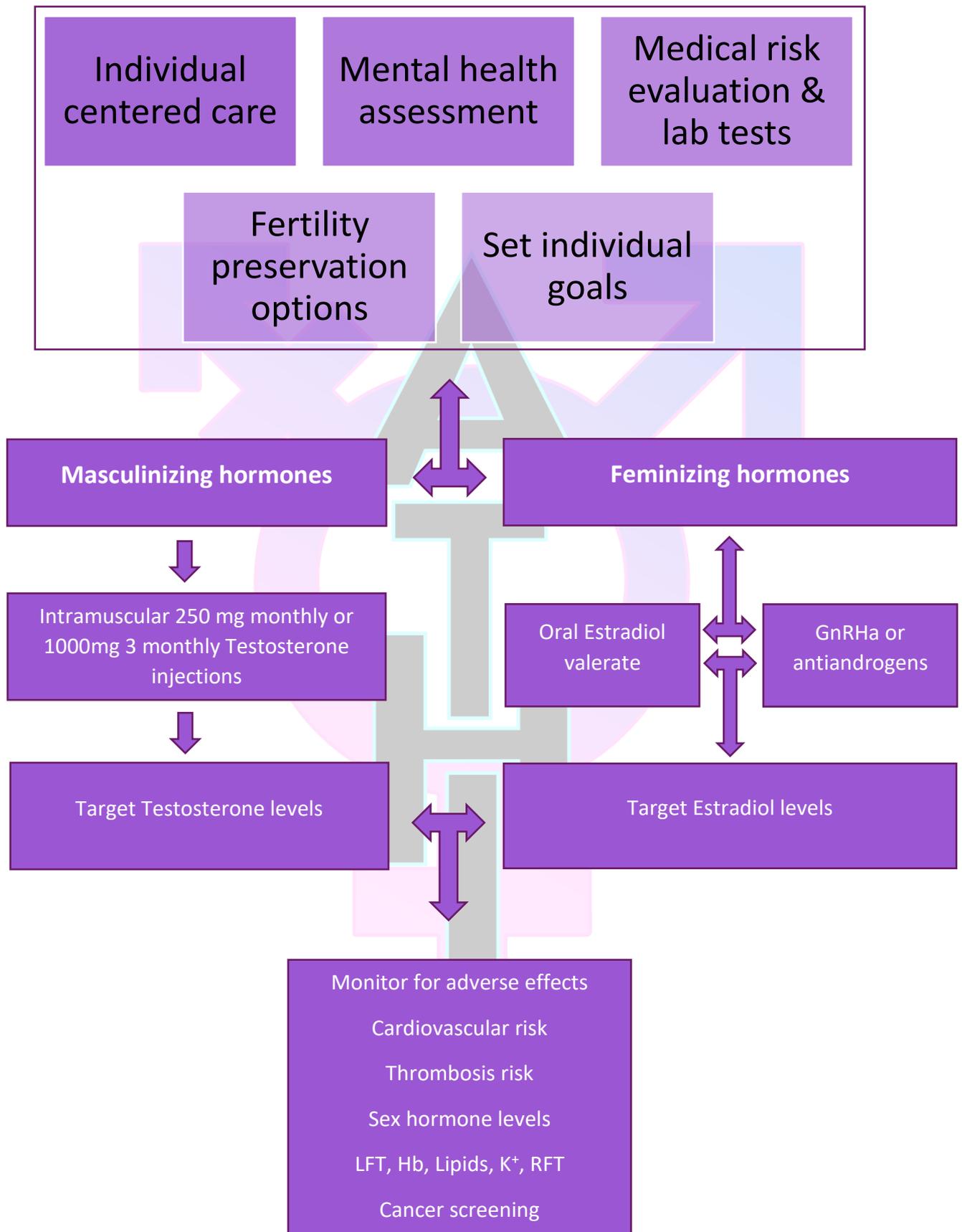
Adolescents who fulfil the diagnostic criteria for gender incongruence may undergo intervention to suppress pubertal development.

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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Public Health Approach to Gender Incongruence

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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 & Wijzen (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 (Gol, 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 steppingstone 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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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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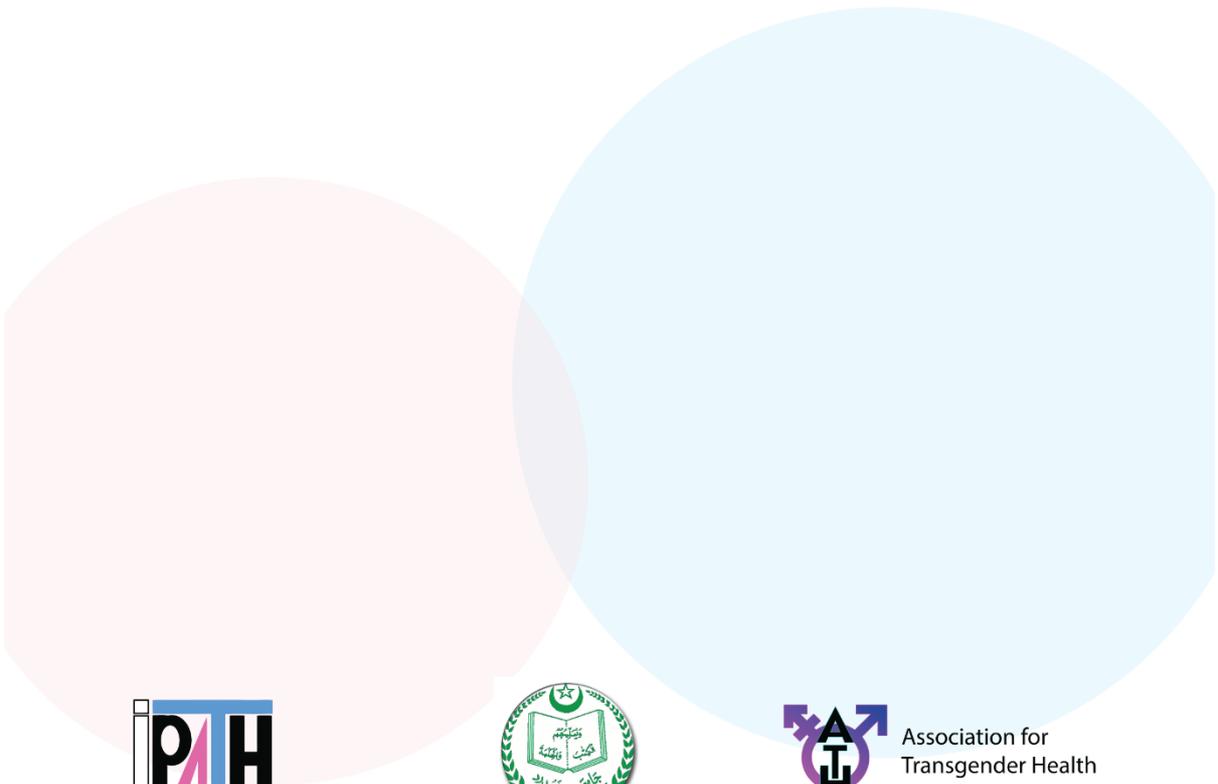
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Indian Standards of Care



Association for
Transgender Health
in India