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Govt. of India
M/o Health & Family Welfare
Dte. General of Health Services

Nirman Bhawan, New Delhi.
Dated the August, 2024

Subject: Standard Operating Procedures for medical treatment of transgender persons

Sir/Ma'am

The Dte. GHS has prepared Standard Operating Procedures for medical treatment of transgender persons. The same is being enclosed for your information and wider dissemination.

This issues with the approval of competent authority.

Enclosure as above.

Yours sincerely

Signed by
Amita Bali
Date: 03-09-2024 16:09:30

(Dr Amita Bali)
Dy. Director General (Planning)

To

1. Secretary (Health) all States/UTs
2. Director, AIIMS, New Delhi
3. Director/EDs of all AIIMS.
4. Director LHMC and Associated hospitals, New Delhi.
5. Medical Superintendent, ABVIMS & RML Hospital, New Delhi.
6. Medical Superintendent, VMMC and Safdarjung Hospital, New Delhi.

Copy to-

1. PSO to Secretary (H)
2. PSO to DGHS

Standard Operating Procedures for

Medical Treatment of Transgender Persons

Gender dysphoria is defined as a marked incongruence between one's experienced or expressed gender and gender assigned at birth. This state can be understood as a misalignment between 'biological sex' (typically understood as sexual organ and genetic characteristics) and 'gender identity'. Gender dysphoria might occur at various developmental stages, but commonly escalates with development of secondary sexual characteristics.

As per ICD-11, **Gender Incongruence** is characterised by a marked and persistent incongruence between an individual´s experienced gender and the assigned sex, which often leads to a desire to 'transition', in order to live and be accepted as a person of the experienced gender, through hormonal treatment, surgery or other health care services to make the individual´s body align, as much as desired and to the extent possible, with the experienced gender.

Multidisciplinary input can improve outcomes when treating patients with gender incongruence. In this context, a multidisciplinary team commonly includes mental healthcare providers, sexual healthcare physicians, general practitioners (GPs), endocrinologists and surgeons (Urology, Plastic Surgery, General Surgery, Obstetrics and Gynaecology).

Gender Affirmation Surgery has an important role in the treatment of gender incongruence. Various surgical options are available to transgender individuals, which include facial reconstructive surgery, vocal surgery, chest or 'top' surgery, and genital or 'bottom' surgery.

The terms **Gender Incongruence and Gender Affirmation Surgery** are preferred to the terms Gender Dysphoria and Sex Reassignment Surgery respectively and will be used henceforth in the document.

Role of Mental Health Professionals (Psychiatrists and/or Clinical Psychologist as per availability)

The primary role of the mental health professionals would include assessment for gender incongruence, as per the current diagnostic system followed by World Health organization, and certification for the same. Before endocrinology treatment, certificate from one Psychiatrist is required. Before Gender Affirmation Surgery, 2 certificates are required- 1 by a Psychiatrist and 1 by a Clinical Psychologist/Psychiatrist.

Apart from that, the mental health professional would also assess for distress and co-morbid mental and/or substance use disorders and provide management of the same.

They would also provide support or therapy, if needed, to cope with issues related to gender incongruence, including participation in integrated cross-disciplinary care and intersectoral collaboration (as required) for clients and caregivers (if appropriate). The support would be provided pre-hormonal therapy/gender assignment surgery, during the period as well as post-surgery, if need be.

Endocrine Treatment Protocol

1. Once the patient presents to the hospital, they/he/she would be referred to the departments of psychiatry/ psychology and Endocrinology.
2. The Endocrinologist would take relevant history (including history of intake of hormones or any previous surgeries), evaluate the individual and perform the necessary hormonal and biochemical investigations including metabolic profile, glucose, lipids LFT, KFT, and blood pressure. The hormones assessed would include a panel of gonadal sex steroids, gonadotropins and thyroid hormones.
3. They need to regularly meet a mental health professional during the hormonal therapy.
4. Individuals would be given hormonal therapy for a period of 1 year before planning for surgery.
5. Before initiating hormonal therapy, subjects would be explained regarding the adverse effects of hormones. They would be screened for obesity, hypertension, diabetes and dyslipidemia and treated accordingly.
6. Feminizing Therapy will include initiation of antiandrogens and estrogens (preferably estradiol valerate) or GnRH therapy (if needed). Masculinising therapy would include intramuscular testosterone therapy. During this period subjects would be monitored for adverse effects. Lipid profile and glucose would be assessed. Blood pressure and weight would be assessed at each visit.
7. Individuals would be in Endocrine follow up post surgery for long term hormonal therapy.
8. A certificate of being stable on endocrine treatment for 1 year and suitability for surgical procedure is required before Gender Affirmation Surgery

SOP for Gynecologist

All health professionals use language that upholds the principles of safety, dignity, and respect. Also, they should enquire as to how the patient wishes to be addressed as in terms of name, and pronoun. The patient may be referred to the Obstetrics and Gynecology department for the purpose of Hysterectomy and bilateral salpingectomy/salpingoopherectomy.

1. A detailed history and examination is done in the OPD along with opportunistic pap's smear screening.
2. Patient is investigated for fitness for surgery and PAC performed.
3. Ultrasound Whole abdomen and pelvis done to to rule out any abdominal and pelvic pathology.
4. Consent to be taken for risks and consequences of the surgery including irreversibility of the procedure.
5. Total Hysterectomy, salpingectomy /salpingoopherectomy performed laparoscopically or by laparotomy depending on patient's suitability.
6. Patient kept under follow up for 6weeks or longer if need be.

Patient will need lifelong hormonal therapy for bone health. They should also undergo medical screening which is appropriate for their age. Post Total hysterectomy and Bilateral salpingoopherectomy no cervical screening is needed. Lifelong monitoring is needed for evaluating hormone effectiveness and for side effects. They need to be made aware of need for active weight bearing exercise, healthy diet, calcium, and vitamin D supplementation.

Fertility Preservation in Transgenders (Female to Male)

Established method for fertility preservation includes cryopreservation of embryo and oocytes for females. Ovarian tissue cryopreservation is also a successful technique for fertility preservation and no longer experimental, however, has limited availability and is possible only after attaining puberty. Transgender patient wishing for TAH and salpingoopherectomy should be informed about the option of fertility preservation and informed decision for surgery may be taken thereafter. Fertility preservation should be as per prevailing law/ Assisted Reproductive Technology (ART) Act. Transgender and gender diverse people with a uterus who wish to carry a pregnancy should undergo preconception care and prenatal counselling regarding need to stop temporarily gender affirming hormones like testosterone, labor delivery breast feeding and postpartum support. Contraception methods for those who engage in sexual activity that can result in pregnancy should be discussed.

STD Clinics and Care

- There is a need to make STD clinics friendly to Gender Diverse patients
- Clinics should document gender identity and sex *assigned at birth* for all patients to improve sexual health care for transgender and gender nonbinary persons.
- Primary care providers should take a comprehensive sexual history, including a discussion of STI screening, HIV PrEP and PEP, behavioral health, and social determinants of sexual health.
- Clinicians can improve the experience of sexual health screening and counseling for transgender persons by asking for their choice of terminology or modifying language (e.g., asking patients their gender pronouns) to be used during clinic visits and history taking and examination.
- Options for fertility preservation, pregnancy potential, and contraception options should also be discussed, if indicated.
- The majority of transgender women have not undergone genital-affirmation surgery and therefore might retain a functional penis; in these instances, they might engage in insertive oral, vaginal, or anal sex as well as receptive oral or anal sex.
- Transgender women- Providers should have knowledge about the type of tissue used to construct the neovagina, which can affect future STI and HIV preventive care and screening recommendations. Transgender women who have had a vaginoplasty might engage in receptive vaginal, oral, or anal sex. Neovaginal STIs have infrequently been reported in the literature and include HSV and HPV/genital warts , *C. trachomatis N. gonorrhoeae*
- Transgender Men- The few studies of HIV prevalence among transgender men indicated that they have a lower prevalence of HIV infection than transgender women. Recent data from the STD Surveillance Network demonstrated higher prevalence of gonorrhea and chlamydia among transgender men, similar to rates reported among cisgender. Transgender men who have not chosen to undergo hysterectomy with removal of the cervix remain at risk for cervical cancer. High-risk HPV testing using a swab can be considered; self-collected swabs for high-risk HPV testing has been reported to be an acceptable option for transgender men.

Screening Recommendations

The following are screening recommendations for transgender and gender diverse persons:

- Because of the diversity of transgender persons regarding surgical gender-affirming procedures, hormone use, and their patterns of sexual behavior, providers should remain aware of symptoms consistent with common STIs and screen for asymptomatic infections on the *basis of the patient's sexual practices and anatomy.*
- Gender-based screening recommendations should be adapted on the basis of anatomy (e.g., routine screening for *trachomatis* and *N. gonorrhoeae)* as recommended for all sexually active females aged <25 years on an annual basis and should be extended to transgender men and nonbinary persons with a cervix among this age group.
- HIV screening should be discussed and offered to all transgender persons. Frequency of repeat screenings should be based on level of risk.
- For transgender persons with HIV infection who have sex with cisgender men and transgender women, **STI screening** should be conducted at least annually, including syphilis serology, HCV testing, and urogenital and extragenital NAAT for gonorrhea and chlamydia.
- Transgender women who have had vaginoplasty surgery should undergo routine STI screening for all exposed sites (e.g., oral, anal, or vaginal). The usual techniques for creating a neovagina do not result in a cervix; therefore, no rationale exists for cervical cancer screening.
- If transgender men have undergone metoidioplasty surgery with urethral lengthening and have not had a vaginectomy, assessment of genital bacterial STIs should include a cervical swab because a urine specimen will be inadequate for detecting cervical infections.
- Cervical cancer screening for transgender men and nonbinary persons with a cervix should follow current screening guidelines

Requirements for Gender Affirmation Surgery

Gender affirmation surgery requires considered multidisciplinary input over a minimum of 1 year. An ideal candidate for referral to a reconstructive surgeon would:

- be psychologically stable; absence of psychosis, depression, alcoholism and intellectual disability
- have a strong support network
- have a clear idea of their desired type of surgery
- have begun or planned hormonal transition. Current recommendation is a minimum of 1 year prior surgery

- have undergone optimisation of modifiable surgical risk factors, including smoking cessation (recommended six months minimum), weight management (optimal body mass index [BMI] 21–29) and diabetes stabilisation. Elevated BMI is not an absolute contraindication to surgery, but would require a careful discussion of risks and benefits with the patient.

Criteria for Gender affirming surgery

All of the following criteria to be met:

A. The individual is at least 18 years of age; **and**
B. The individual has capacity to make fully informed decisions and consent for treatment; **and**
C. The individual has been diagnosed with gender incongruence; **and**
D. For individuals without a medical contraindication or intolerance, the individual has undergone a minimum of 1 year of continuous hormonal therapy when recommended by a mental health professional and provided under the supervision of an endocrinologist/physician*; **and**
E. Stable on their gender affirming hormonal treatment regime certified by the treating Endocrinologist/Physician (which may include at least 1 year of hormone treatment or a longer period if required to achieve the desired surgical result, unless hormone therapy is medically contraindicated); and
F. Understands the effect of gender-affirming surgical intervention on reproduction and they have explored reproductive options**; and**
G. If the individual has significant medical or mental health issues present, they must be stable on treatment. If the individual is diagnosed with severe psychiatric disorders and impaired reality testing (for example, psychotic episodes, bipolar disorder etc.), an effort must be made to improve these conditions with psychotropic medications and/or psychotherapy before surgery is contemplated; **and**
H. Two referrals from qualified mental health professionals who have independently assessed the individual. Two separate letters, or one letter signed by both (for example, if practicing within the same setup) are required. The letter(s) must have been signed within 12 months of the request submission.

**Physician should be MD Medicine with adequate knowledge of the subject. This provision is kept due to the limited numbers of Endocrinologists and an Endocrinologist may not be available at all centres.*

Role of Nodal Officer/ Coordinating person

The various departments involved in the process of Gender Affirmation procedures (medical/surgical) should identify nodal officer from their respective department who will facilitate the coordination with other departments.

Role of Gender Affirmation Surgery Board

Before going for Gender Affirmation Surgery, the centers have an option to create a medical board, if required, which would comprise of a minimum of-

- 2 Mental Health Professionals (at least one Psychiatrist),
- one Endocrinologist,
- one Specialist from concerned surgery departments and
- one representative from Hospital administration (MS/AMS)

List of Gender Affirmation Surgeries

I. Gender Defining Surgeries

A. Genital Surgery (MALE TO FEMALE)-

i. Orchidectomy
ii. Modified Penile Inversion Vaginoplasty including Labioplasty, Clitoroplasty, Penectomy, Vestibuloplasty
iii. Feminizing urethroplasty
iv. Sigmoid vaginoplasty
v. Peritoneal vaginoplasty

B. Mammoplasty with implants

C. Genital Surgery (FEMALE TO MALE)-

i. Metoidioplasty and similar procedures with urethral lengthening and scrotoplasty
ii. Radial artery forearm flap and free phalloplasty
iii. Anterolateral thigh (ALT) and similar procedures
iv. Testicular prosthesis
v. Open/ Lap- Hysterectomy, salphingo- oophorectomy and vaginectomy
vi. Hysterectomy + oophorectomy + vaginectomy+ perineal procedures+
vii. urethroplasty+ clitoral transposition

D. Mastectomy

II. Gender refining surgeries/ Ancillary Procedures

A. Aesthetic procedures (MALE TO FEMALE)-

i. Forehead Feminization
ii. Feminizing rhinoplasty
iii. Cheek feminization
iv. Lip lift
v. Chin feminization
vi. Lipofilling of breast up to 5 sitting
vii. Facial bone reduction
viii. Blepharoplasty/ rejuvenation of lids

B. Lower jaw contouring- V line surgery
i. V line soft tissue jaw angle (Masseter reduction) under chin liposuction, buccal fat pad removal
ii. V line surgery (bone contouring)

C. Laser therapy# (only for facial hair removal per year)

D. Hair transplantation (small, medium and large)

E. Aesthetic Procedures (FEMALE TO MALE)
i. Pectoral implants
ii. Blepharoplasty/ rejuvenation of lids

F. Hair Transplantation (small, medium and large)

G. Beard Hair Transplant

 # Hair removal with appropriate anti androgen therapy in TG female will have inadequate effect. Hence, a Laser hair removal procedure should be advised only after adequate therapy to reduce the end organ hypersensitivity that is seen in TG female. Also the frequency of hair removal will depend on the anagen growth phase which may necessitate frequent sitting in the absence of anti-androgen therapy

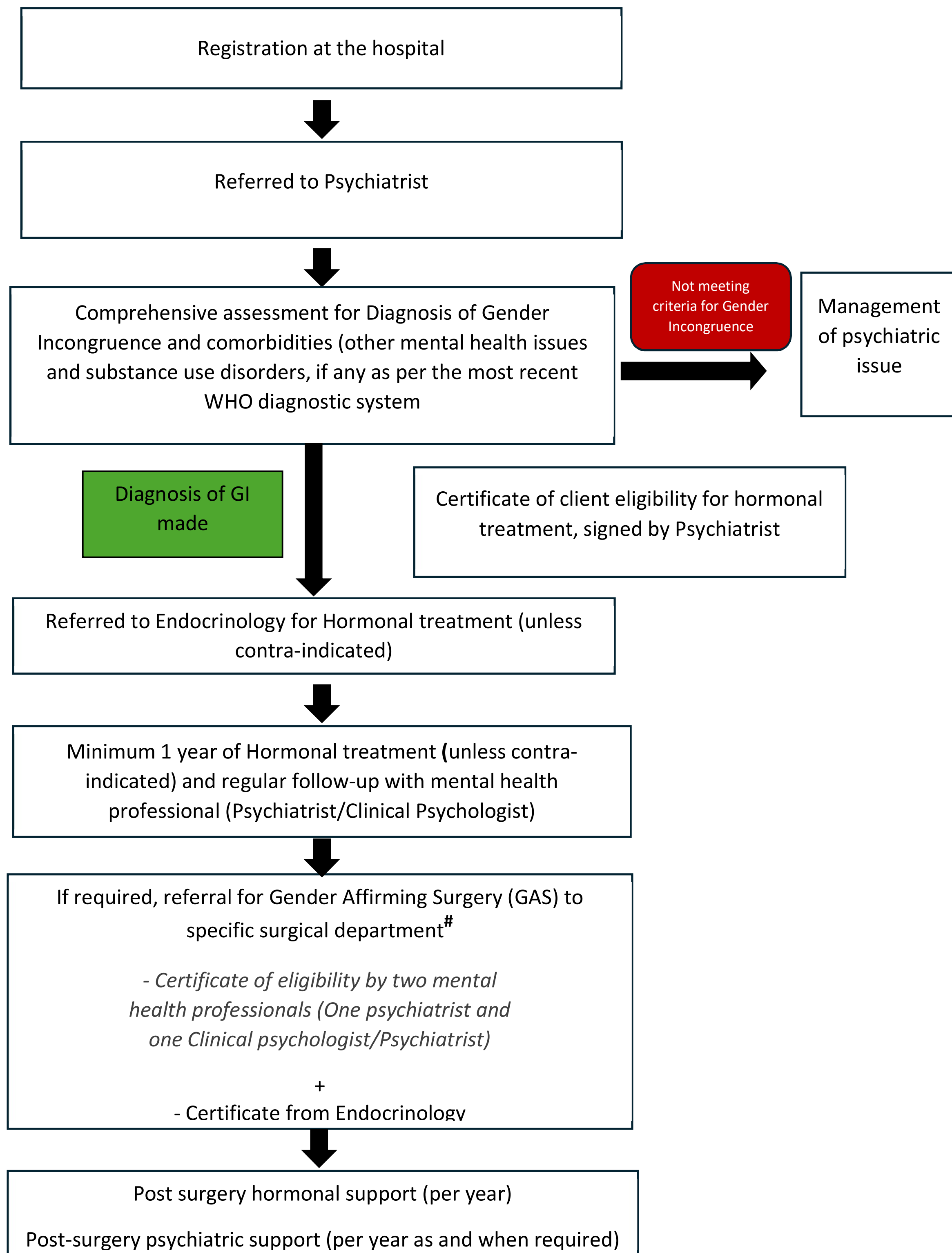
List of Endocrine/Hormonal Treatments

A. Hormone Therapy (Pre Surgical for 1 years)
B. Hormone Therapy (Post Surgical per year)

List of Mental Health Procedures

A. Assessment of Gender Incongruence including Psychological Testing (if required)
B. Psychological/Psychiatric support/therapy (Pre Surgical for 1 year)
C. Psychological/Psychiatric support/therapy (Post Surgical per year)

RECOMMENDED THERAPEUTIC FLOW



Option to create a Gender Affirmation Surgery medical board if required

SAMPLE CERTIFICTAE

{Insert logo of the Institute}

[Name of Department, Institute and Address]

Certificate of Gender Incongruence for Hormonal Treatment

This is to certify that ______________________________ {name of client}, age __________________ {years} has been under the follow-up of the Department of Psychiatry, _______________________ {name of hospital} since _______________ {date of first registration}. Comprehensive clinical assessment confirm the diagnosis of Gender incongruence as per ICD-11 and the same has been duly documented (Ref.: ________________________ {File no./UHID/Identifying Number}.

The assessment reveals patient's desire to live and be accepted as a Male/Female, including the need to transition to the desired gender. They/he/she has been living sometimes/mostly/all the time in their desired gender role.

Patient has been provided with necessary and relevant information to enable them/him/her to understand that their/his/her environment will be different after hormonal treatment. They/he/she are fully aware of the effects, risks and consequences of such treatment at a physical, emotional and social level and have the capacity to make informed healthcare decisions. There is no evidence of any external coercion on their/his/her decision.

In my clinical opinion, _____________________________ {Name of client} meets the requirement for hormonal treatment and is psychologically ready for the same.

Signature: Date: ______________ Place: ______________

Name of the Psychiatrist: ______________________________

Designation: ____

Department/Institute: _________________________________

____

Registration No.: _____________________________________

SAMPLE CERTIFICTAE

{Insert logo of the Institute}

[Name of Department, Institute and Address]

Certificate of Gender Incongruence for Gender-affirming Surgery (GAS)

With regard to desire of ________________________________ {name of client}, age ___________________ {years}, to undergo Gender-affirming surgery, it is certified that they/he/she has been under the follow-up of the Department of Psychiatry, ________________________ {name of hospital} since _______________ {date of first registration}.

Comprehensive clinical assessment confirm the diagnosis of Gender incongruence as per ICD-11 and the same has been duly documented (Ref.: _________________________ {File no./UHID/Identifying Number}.

The assessment reveals patient's desire to live and be accepted as a Male/Female, including the need to transition to the desired gender. They/he/she has been living sometimes/mostly/all the time in their desired gender role.

They/he/she have undergone ____________________ {months} of Hormonal Therapy under the care of ____ {Name of treating Endocrinologist} in Department of Endocrinology, _________________________ __________________________ {Name of Institute}.

The patient has been provided with necessary and relevant information to enable them/him/her to understand that their/his/her environment will be different post-surgery. They/he/she are fully aware of the effects, risks and consequences of such treatment at a physical, emotional and social financial level and have the capacity to make informed healthcare decisions. There is no evidence of any external coercion on their/his/her decision.

In my clinical opinion, _______________________________ {Name of client} meets the requirement for Gender affirming surgery and is psychologically ready for the same.

Signature: Date: _______________ Name of the Psychiatrist: ________________________________ Designation: _____________________________________ Department/Institute: ___________________________________ ______________________________________ _________________ Registration No.: _____________________________________	Signature: Date: _______________ Name of the Clinical Psychologist/ Psychiatrist: ________________________________ Designation: _____________________________________ Department/Institute: ___________________________________ ______________________________________ _________________ Registration No.: _____________________________________

(The certificate may be combined or separate for the two mental health professionals.)

<u>SAMPLE CERTIFICTAE</u>

{Insert logo of the Institute}

[Name of Department, Institute and Address]

Certificate of Hormonal treatment

This is to certify that ________________________________ {name of client}, age ____________________ {years} has been under the follow-up of the Department of Endocrinology, _________________________ {name of hospital} since ________________ {date of first registration}.

The patient has received maculinising / feminising hormones for a period of one year strating from ________ to ________. Patient's current hormonal profile and physical changes are in consonance with regular hormonal treatment for a period of one year. Patient has also also undergone psychological evaluation during this period. Patient wishes to continue with the desired gender and Gender Affirmation Surgery for the same. Patient is cleared for Gender Affirmation surgery from Endocrine viewpoint.

Signature: Date: _______________ Place: _______________

Name of the Endocrinologist: _________________________________

Designation: ____

Department/Institute: ____________________________________

____

Registration No.: ____

Sub- committees involved in formulating the SOP

Dte. GHS

1. Dr. Atul Goel, DGHS
2. Dr. Amita Bali, DDG (P)
3. Dr. Bhavuk Garg, Associate Professor Psychiatry, LHMC

Psychiatry & Clinical Psychology

1. Dr. Pratap Sharan, Head of Department Psychiatry, AIIMS New Delhi
2. Dr. Mina Chandra, Head of Department Psychiatry, RMLH
3. Dr. Shiv Prasad, Head of Department Psychiatry, LHMC
4. Dr. Pankaj Verma, Head of Department Psychiatry, VMMC/SJH
5. Dr. Swati Kedia Gupta, Assistant Professor, Cl. Psychology, AIIMS New Delhi
6. Ms. Satyam, Assistant Professor, Cl. Psychology, RMLH.

Urology

1. Dr. Hemant Goyal, Head of Department, RMLH
2. Dr. Abhishek Johari, Assistant Professor VMMC/SJH
3. Dr. Sridhar P, Assistant Professor AIIMS Delhi

Obstetrics & Gynaecology

1. Dr. Reena, Head of Department, LHMC
2. Dr. Ashok Kumar, Head of Department, RMLH.
3. Dr. Bindu Bajaj, Head of Department, VMMC/SJH

Plastic Surgery

1. Dr. Sameek Bhattacharya, Head of Department, RMLH
2. Dr. Sujata Sarabhai, Head of Department, VMMC/SJH
3. Dr. Manish Singhal, Head of Department, AIIMS

General Surgery

1. Dr. Shivani B Paruthy, Head of Department, VMMC/SJH.
2. Dr. Sunil Chumber, Head of Department, AIIMS, New Delhi

Endocrinology

1. Dr. Krishna Biswas, Head of Department, VMMC/SJH
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Dermatology

1. Dr. Vibhu Mendiratta, Head of Department, LHMC
2. Dr. Kabir Sardana, Head of Department, RMLH
3. Dr. Sanchita Karmalkar, Head of Department, VMMC/SJH