स्वास्थ्य एवं
परिवार कल्याण मंत्रालय
MINISTRY OF
HEALTH AND
FAMILY WELFARE

National AIDS Control Organisation

National Technical Guidelines on Sexually Transmitted Infections and Reproductive Tract Infections 2024

National AIDS and STD Control Programme
Ministry of Health & Family Welfare
Government of India

National Technical Guidelines on Sexually Transmitted Infections and Reproductive Tract Infections

2024

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NACO, MoHFW, GoI, 2024

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Foreword

The National AIDS and STD Control Programme (NACP) aims to strengthen provisioning of quality services for prevention and management of STI and RTI across the country. The NACP Phase V's Goal 3 is to intensify efforts for attainment of dual elimination of vertical transmission of HIV and Syphilis, while Goal 4 specifically aims at provisioning of universal access to quality STI and RTI services to at-risk and vulnerable population across the country.

Aligned with the above, the National Guidelines on STI and RTI required to be updated to provide the technical guidance to the country as per the latest trends while adopting and adapting the evidence-based approaches for holistic interventions across the country. Therefore, the National Technical Guidelines on STI and RTI was reviewed and revised by NACO following a detailed, rigorous and consultative process. The National Technical Guidelines on STI and RTI (2024) is enriched with the inputs received from various critical stakeholders including National Health Programs and Divisions under MoHFW, bilateral and multilateral organizations, subject experts, legal experts, community representatives and professional medical associations.

This document provides the latest recommendations for screening, diagnosis, and management of various STI and RTI prevalent in the country. These guidelines while retaining its focus on the at-risk population, also prioritizes inclusivity in healthcare by addressing the needs of marginalized population such as transgender persons and other high-risk and vulnerable groups and people living with HIV. It also provides stepwise procedures for clinical and behavioral assessment of clients, latest recommendations on laboratory diagnosis, updated algorithms for syndromic case management and regimens for management of STI and RTI including the management of complicated and treatment failure cases.

These guidelines will not only improve the provisioning of quality healthcare services for prevention, management and control of STI and RTI under NACP but will also augment the STI and RTI services at all levels of public health systems and private health settings. I believe that these guidelines will act as a reference document for clinical decision making by healthcare providers and support in capacity building of the staff engaged in provisioning of STI and RTI services. It will also act as a crucial guide for the program managers in effective implementation of standardized and effective STI and RTI services, thus ensuring a sustained public health response to STI and RTI in the country.

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Preface

The National AIDS and STD Control Programme is an evidence-driven and community-centric programme working towards prevention and control of HIV and STI across India. The Phase V of NACP is intensively working towards provisioning of quality services for prevention, management, and control of STI and RTI in the country.

There has been a continuous shift amongst the scientific fraternity on the technical recommendations for provisioning of clinical and preventive services for STI and RTI. Not only has the burden of STI and RTI and sexual dynamics of populations at-risk of STI and RTI changed over the years, but also the technical and operational standards for their screening, diagnosis, and management have evolved significantly since the release of last National Guidelines on STI and RTI. Therefore, the National Technical Guidelines on STI and RTI have been revised by NACO to promote evidence-based and high quality STI and RTI services under the program and in the country.

The document while retaining its focus on the updated Syndromic Case Management algorithms also provides guidance on the detailed clinical procedures, latest diagnostics, and treatment recommendations for management of these infections. These guidelines also form an effective resource material for providing the technical as well as managerial training to all levels of healthcare staff engaged in provisioning of STI and RTI Services.

The guidelines provide a basket of evidence-based approaches to guide diagnosis and treatment at all levels of public health system aligned with the availability of the resources. These guidelines are designed in manner, where it can be effectively implemented in the public health system, programmatic interventions, and private healthcare settings to efficiently guide patient management and program implementation for STI and RTI services. I am confident that this document will be suitably used by clinicians and other healthcare providers for treatment decision-making and program managers to guide the implementation of program towards the attainment of our goals of providing universal access to quality STI and RTI services across the country.

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Message

India is committed to providing universal access to quality STI and RTI services to at-risk and vulnerable populations across the country under NACP Phase V. There is necessity to build capacities of healthcare providers on STI and RTI to ensure proper assessment and appropriate management of STI/RTI to achieve cure (wherever possible) and reduce infectiousness and risk of developing complications.

There has been a significant change in the epidemiology, sexual dynamics and high-risk behaviour of populations in the country. This warrant strengthening of STI and RTI services through implementation of evidence-based approach, technical recommendations and capacity building of healthcare providers to deliver effective STI and RTI services. Taking this into effect, the National Technical Guidelines on STI and RTI is, thus, revised to strengthen quality STI and RTI services across the country. The guideline is developed under the leadership of NACO and in close guidance of other National Health Programs and Divisions from MoHFW, various Senior Public Health, Programmatic and STI experts, academicians, developmental organizations, community experts, and representatives from key populations and professional medical associations.

This document outlines the latest recommendations for the screening, diagnosis, and management of prevalent STIs and RTIs in India. Emphasizing syndromic management (SCM) as a critical component in India's public health response, the guideline offers rapid, effective treatment solutions for resource-limited settings, while addressing the challenges of India's geographic and infrastructural diversity. Alongside SCM, the guideline underscores the importance of etiological diagnosis wherever feasible, as precise treatment can mitigate antimicrobial resistance and enhance patient outcomes. The document provides detailed protocols for clinical and behavioural assessments, updated laboratory diagnostic procedures, syndromic case management algorithms, and treatment regimens for complex and treatment resistant STI and RTI cases. Prioritizing inclusivity, the guideline addresses the healthcare needs of marginalized populations, such as transgender persons, high-risk groups, and people living with HIV, while emphasizing procedures to strengthen partner notification and management.

This document is a ready reckoner for clinicians and other healthcare providers, public health experts, program managers and academicians on provision of quality services for management of STI and RTI. It will ensure capacity building of healthcare providers and program managers towards effective management and deliver of high-quality care and support services in a stigma-free, gender-sensitive and community friendly manner.

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Acknowledgement

The 'National Technical Guidelines on Sexually Transmitted Infections and Reproductive Tract Infections (2024)' is an evidence-based and standardized document, meticulously developed to guide provisioning of quality STI and RTI services across the country. The document has been developed through an extensive, consultative approach with involvement of technical and programmatic experts under the National Technical Resource Group – STI (NTRG-STI), National Working Group – STI/RTI (NWG-STI/RTI) and National Technical Working Group – Dual RDT (NTWG-Dual RDT). The document has been developed in close consultation with officers from NACO and other National Health Programs, representatives from communities, civil society organizations and professional medical associations.

We extend our deepest gratitude to Ms. V. Hekali Zhimomi (Additional Secretary & Director General, NACO) for her dynamic leadership and guidance in development of the guidelines. We are grateful for the invaluable guidance and continued support provided by Shri Nikhil Gajraj (Joint Secretary, NACO) in the completion of this document.

We would also like to acknowledge the leadership of Dr Anoop Kumar Puri, (DDG – IEC & MS, NACO) and Dr Chinmoyee Das (HoD-CST, SI, IT & SCM, NACO) for providing all the necessary support in drafting this guideline. We are extremely thankful to Dr Uday Bhanu Das (HoD – PMR, Lab Services & GF, NACO) and Lab Services Team of NACO for their technical and timely inputs in finishing this document. We express our indebted gratitude to Dr Shobini Rajan (HoD – Prevention, BSD and STI, NACO) for conceptualization and her leadership in designing and development of these guidelines. The support received from Dte GHS, National Viral Hepatitis Control Programme, Maternal Health, Child Health, Family Planning and Adolescent Health Divisions from NHM and NP-NCD has been critical in the completion of this document.

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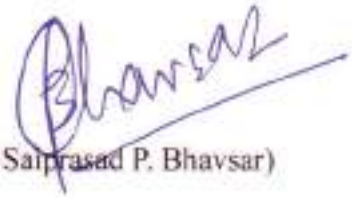
The list of contributors who have enriched this document by the virtue of their knowledge and experience is exhaustive and difficult to cover through this acknowledgement and is enclosed for kind reference. We sincerely believe that this document will enhance the ability of the program to prevent, effectively manage and control STI and RTI in India. We also acknowledge the support from WHO India for designing, editing, and printing of this document.



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Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
ARD	Ano-rectal Discharge
ARTC	Antiretroviral Therapy Centre
BP	Bridge populations
BV	Bacterial Vaginosis
C alb	Candida albicans
CHC	Community Health Centre
CS	Congenital Syphilis
CT	Chlamydia trachomatis
DARE	Digital ano-rectal examination
DH	District Hospital
DSRC	Designated STI/RTI Clinic
Dual RDT	HIV and syphilis dual rapid diagnostic test kits
ESCM	Enhanced Syndromic Case Management
FSW	Female Sex Worker
GC	General Client
GUD	Genital Ulcer Disease
H/TG	Hijra/ transgender
HAV	Hepatitis A Virus
HBV	Hepatitis B Virus
HCP	Healthcare providers
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HPV	Human Papilloma Virus
HRG	High Risk Groups
IB	Inguinal Bubo
IM	Intramuscular
IUD	Intrauterine Devices
KP	Key population
LAP	Lower Abdominal Pain
LWS	Link Workers Scheme
MC	Medical College
MG	Mycoplasma genitalium
NAAT	Nucleic Acid Amplification Test

NACO	National AIDS Control Organization
NACP	National AIDS and STD Control Programme
NG	Neisseria gonorrhoeae
NHM	National Health Mission
OSC	One Stop Centre
P&OCS	Prison and other closed settings
PEP	Post-Exposure Prophylaxis
PHC	Primary Health Centre
PID	Pelvic Inflammatory Disease
PLHIV	People living with HIV
POCSO	Protection of Children from Sexual Harassment Act, 2012
PrEP	Pre-Exposure Prophylaxis
PSS	Painful Scrotal Swelling
PT	Presumptive Treatment
PWID	People who inject drugs
RPR	Rapid Plasma Reagin
RRP	Recurrent respiratory papillomatosis
RTI	Reproductive Tract Infections
SC	Sub centre
SCM	Syndromic Case Management
SDH	Sub-district Hospital
SSS	Sampoorna Suraksha Strategy
STD	Sexually Transmitted Diseases
STI	Sexually Transmitted Infections
TI	Targetted Intervention
TV	Trichomonas vaginalis
UD	Urethral Discharge
VD	Vaginal Discharge
VDRL	Venereal Diseases Research Laboratory

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Chapter 1 Introduction and Overview of Sexually Transmitted Infections and Reproductive Tract Infections

Sexually transmitted infections (STI) and reproductive tract infections (RTI) pose a significant challenge to sexual and reproductive health and well-being. Sexually transmitted infections can be defined as infections that spread primarily through sexual contact. These infections can also be transmitted from an infected mother to her infant (vertical transmission) during pregnancy and childbirth and through blood products and tissue transfer. Moreover, majority of cases of all STI remain asymptomatic (without any symptom). Therefore, absence of signs/symptoms does not rule out the possibility of an STI. An asymptomatic infection can be transmitted to sexual partners and may be associated with sequelae and lead to complications. A person may also be infected with more than one STI at a time. The term 'STI' is usually used in place of 'STD' (refers to sexually transmitted diseases) to indicate that infections do not always result in a symptomatic disease.

The term reproductive tract infections (RTI) refer to any infection of the reproductive tract. In women, it includes infections of vagina, cervix, uterus, fallopian tubes and/or ovaries and may also involve external genitalia. In men, it may involve testes, epididymis and/or prostate but may also involve external genitalia. Some RTI are caused in the same way as STI. But RTI can also be caused due to overgrowth of normal organisms in the reproductive system (e.g., bacterial vaginosis) or they could be infections caused by improper medical procedures such as catheterization, termination of pregnancy or IUD insertion. Moreover, practices like vaginal douching, multiple sexual partners and inconsistent condom use are also associated with increased risk of RTI.

'Not all reproductive tract infections are sexually transmitted, and not all sexually transmitted infections are located in the reproductive tract.'

More than 30 microorganisms are associated with various STI and RTI and many others exclusively with RTI. Along with significantly increasing the risk of acquisition and transmission of HIV, these infections are responsible for serious sexual and reproductive morbidity (including infertility), adverse pregnancy outcomes and various cancers. These infections may manifest differently in people living with HIV (PLHIV) and can be associated with increased morbidity resulting in various complications and increased infectiousness of PLHIV. Hence, the prevention, management, and control of STI and RTI is important to prevent HIV transmission and ensure sound sexual-reproductive health and wellbeing of people.

1.1. Trends of STI in India

India demonstrates a large degree of heterogeneity in statistics of STI and RTI over the years. The burden of STI and RTI has declined with significant etiological shifts from bacterial and ulcerative infections to chronic viral STI (e.g., genital herpes, HPV) in 21st century[1]. The epidemiological studies conducted in 1990's demonstrated a limited control of STI in India with high prevalence rates of bacterial, and particularly ulcerative STI which were closely associated with HIV transmission especially in urban

1 Is it possible to reduce syphilis and gonorrhoea incidence by 90%? A review of STI control in the WHO South-East Asia Region with an eye on 2030 global targets. Available at: https://cdn.who.int/media/docs/default-source/searo/hiv-hepatitis/sear-sti-paper-journal-02jan20.pdf?sfvrsn=6b21f453_2

settings. The later studies (particularly after 2005) reported a significant decrease in the rates of STI with etiological shifts from bacterial and ulcerative infections to chronic viral STIs (genital herpes, HPV) with significant decline in Syphilis in the 2nd decade of 21st century[2]. However, the current programmatic data reports increasing trends of RPR seropositivity in STI clinics[3].

According to NFHS-5, five percent of women and 2.1% of men in the reproductive age group (15 - 49 years) who ever had sexual intercourse self-reported the presence of an STI in last 12 months. These figures rise up to 12.3% in females and 9.3% in males while self-reporting the presence of an STI/genital discharge/sore or ulcer in this population respectively[4]. The RPR seropositivity was reported to be 1.3%, 0.3% and 1.9% among males, females, and transgender/hijra population respectively in Designated STI/RTI Clinic (DSRC) in 2022-23. While the overall RPR positivity was reported to be 0.7%, the trend for RPR positivity at DSRC continues to rise in 2022-23 when compared with test positivity reported in 2020-21 (0.49%) and 2021-22 (0.60%). The seropositivity is also reported to increase among males and females when compared with previous FY. (The seropositivity among males and females was reported to be 1% and 0.28% respectively in 2021-22)[2]. The latest programmatic data on STI and RTI can be referred from Sankalak- National Report from National AIDS Control Organisation, India.

1.2. STI and RTI Services Delivery in India

The STI and RTI services at district level are provided through a network of DSRC (also branded as 'Suraksha Clinic') under National AIDS and STD Control Programme (NACP). These clinics are primarily located in district hospitals (DH) and medical colleges (MC). The services at district/sub-district level and below are provided at DH, sub-district hospitals (SDH), community health centres (CHCs), primary health centres (PHCs), and sub-centres (SCs) under National Health Mission (NHM) (Figure 1.1). DSRCs provide various STI and RTI services to general, high-risk and vulnerable populations and acts as a referral unit for cases referred from Targetted Interventions (TI)/ Link Worker Scheme (LWS)/ ART centres (ARTC) and other health facilities under NHM.

STI and RTI services are provided to high-risk groups or HRGs [Female Sex Workers (FSW), Men who have Sex with Men (MSM), People who inject drugs (PWID), Hijra/Transgender (H/TG)] including population under prison and other closed settings (P&OCS) and bridge populations (mainly migrants and transportation workers) through various modalities as provisioned under Targeted Interventions. Moreover, the screening of PLHIV for STI and RTI is also provisioned at ART centres.

The STI and RTI services are included as essential services under Sampoorna Suraksha Strategy (SSS) to cater to the needs of 'at-risk' population (populations at significant risk of HIV and STI and are defined under Sampoorna Suraksha Strategy) and One Stop Centres (OSC). The LWS covers HRGs, bridge population and PLHIV, including their spouses and partners, and other vulnerable population in rural areas. The STI and RTI services under LWS are mainly provided through referrals and linkages to NACP/ NHM facilities.

2 Is it possible to reduce syphilis and gonorrhoea incidence by 90%? A review of STI control in the WHO South-East Asia Region with an eye on 2030 global targets. Available at: https://cdn.who.int/media/docs/default-source/searo/hiv-hepatitis/sear-sti-paper-journal-02jan20.pdf?sfvrsn=6b21f453_2

3 National AIDS Control Organization (2023). Sankalak: Status of National AIDS Response (Fifth edition, 2023). New Delhi: NACO, Ministry of Health and Family Welfare, Government of India

4 International Institute for Population Sciences (IIPS) and ICF. 2021. National Family Health Survey (NFHS-5), 2019-21: India. Mumbai: IIPS

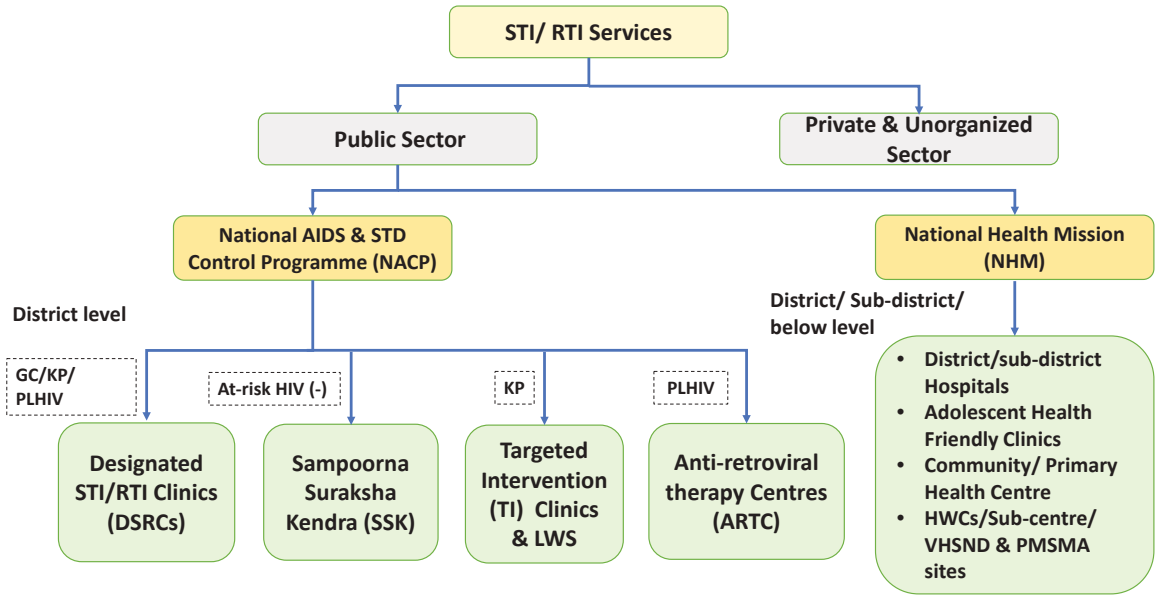

Figure 1.1. STI and RTI Services Delivery in India

GC: General Clients; KP: Key Population; PLHIV: People living with HIV: LWS; Link Workers Scheme

The syndromic approach is considered as the backbone of STI and RTI services in India along with optimum utilization of available on-site diagnostic facilities without delaying the prompt treatment of patients. The syndromic case management of STI and RTI is adopted as a universal strategy at all levels of the health care system to ensure access to a package of standardized STI and RTI services for the general population with an emphasis on women, adolescents, and key and other vulnerable populations.

STI color-coded kits: Under NACP, STI color-coded kits are distributed as a part of syndromic case management approach to streamline and simplify the diagnosis and management of common STI and RTI. Each kit consists of pre-packaged medications tailored for specific STI and RTI syndromes. The contents are determined based on the most common causative organisms and the recommended treatment protocols. Each kit is color-coded to correspond with specific STI and RTI syndrome, ensuring quick identification and appropriate use by healthcare providers. The STI color-coded kits have proven to be an effective strategy for controlling the spread of these infections and improving public health outcomes in India.

There is a network of STI laboratories under NACP supporting etiological diagnosis, syndromic validation, gonococcal antimicrobial susceptibility surveillance and quality assurance under the National Programme. The Regional STI Training, Research and Reference Laboratories (RSTRRLs) act as the nodal agency in their respective regions and each of these RSTRRLs is linked to State Reference Centers (SRCs); which are further linked to DSRCs, TIs and NHM health facilities[5] (Figure 1.2). There are currently 1133 DSRCs and, 10 RSTRRLs (including apex laboratory) and around 45 SRCs operating under the National Programme.

5 Operational Guidelines: Regional STI Training, Research and Reference Laboratories (2014) New Delhi: NACO, Ministry of Health and Family Welfare, Government of India.

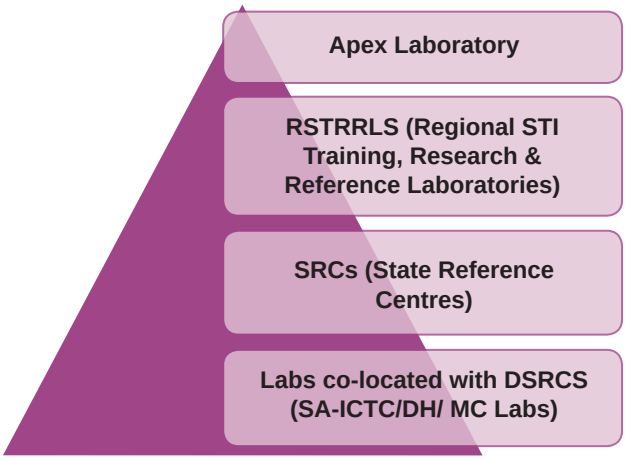

Figure 1.2 STI Laboratory Network

1.3 STI and RTI Services under NACP-V Strategy

India is committed to provide universal access to quality STI and RTI services to at-risk and vulnerable populations across the country under National AIDS and STD Control Programme (NACP Phase-V). While the Goal 3 of NACP-V is dedicated to intensifying efforts for attainment of dual elimination of vertical transmission of HIV & syphilis in India, the Goal 4 specifically aims towards providing universal access to quality STI and RTI services to at-risk and vulnerable population in the country[6]. The proposed strategies under NACP-V to achieve Goal 4 are mentioned below:

1. Strengthen the strategic information on STI through the complementary, action-oriented systems of programme monitoring, surveillance and research and evaluation.
2. Maintain the existing model of DSRCs while augmenting its role to anchor newer initiatives like Sampoorna Suraksha Strategy and integrated service delivery tailored to the local contexts.
3. Develop and implement integrated communication strategies on prevention, testing, and treatment of HIV and STI.
4. Dovetail HIV and Syphilis dual testing under HIV Counselling and Testing Services [including introduction and scale-up of use of HIV and syphilis dual rapid diagnostic test kits (referred as Dual RDT)]
5. Promote active case findings to facilitate early detections through social network-based and partner testing approaches.
6. Improve collaboration with NHM on STI and RTI services to scale-up preventive and management services for STI and linkages to quality diagnostics services and quality assurance systems
7. Strengthen and streamline private sector engagement on STI and RTI management
8. Suitably update the STI and RTI management guidelines periodically
9. Augment the laboratory capacities for STI and RTI
10. Strengthen the supply chain management through timely forecasting, procurement, and supply of STI and RTI commodities and implementation of IT-enabled supply-chain management information systems

6 National AIDS Control Organization (2022). Strategy Document: National AIDS and STD Control Programme Phase-V (2021-26). New Delhi: NACO, Ministry of Health and Family Welfare, Government of India

1.4 Sexual Health and Wellbeing

Sexual health is defined as "a state of physical, emotional, mental, and social well-being in relation to sexuality; it is not merely the absence of disease, dysfunction, or infirmity. Sexual health requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences, free of coercion, discrimination, and violence. For sexual health to be attained and maintained, the sexual rights of all persons must be respected, protected, and fulfilled."[7] Sexual health concerns are diverse and cover various aspects including the following:

- Sexual orientation, gender identity, sexual expression, relationships, and pleasure
- Adverse conditions such as infections like HIV, STI and RTI, which can lead to serious outcomes like cancer and infertility
- Unintended pregnancies and abortions
- Sexual dysfunction
- Sexual violence, and harmful practices such as female genital mutilation

The ability of a person to achieve the optimum level of sexual health and well-being depends on the following factors:

1. Access to comprehensive, good-quality information about sex and sexuality
2. Understanding and awareness about the risks associated with unprotected/risky sexual activity and their vulnerability to adverse sexual health outcomes
3. Access to quality, affordable, stigma-free, and inclusive sexual health care services
4. Positive and affirming environment that promotes sexual health.

Therefore, provisioning of quality STI and RTI services is essential not only for ensuring better clinical outcomes but also to promote overall sexual health and wellbeing. This approach helps in preventing significant morbidity and mortality associated with these infections.

1.5 Factors contributing to spread of STI and RTI

STI are infectious diseases, and their transmission mainly depends on sexual behavior and associated vulnerabilities. The taboo associated with sexual act, hesitation associated with discussion of sex and sexual health and associated stigma and discrimination poses a significant barrier in accessing sexual healthcare services and increases vulnerabilities across the society.

There are multiple factors contributing to the spread of STI and RTI:

- Biological, behavioral, and social factors increasing the risk of transmission (as described in the further sections)
- Lack of access to sexual healthcare services, lack of awareness of STI, and associated stigma.
- Iatrogenic RTI are common in settings where health care providers do not have the training or supplies to perform procedures safely.
- Postpartum and post abortion infections are more common where medical services and follow-up care are not provided safely.

7 Sexual health. Geneva: World Health Organization; 2023. Available from: https://www.who.int/health-topics/sexual-health

- Endogenous infections, such as Vulvo-vaginal candidiasis and bacterial vaginosis, are common worldwide and are influenced by environmental, hygienic, hormonal, and other factors like co existent diabetes and immune compromised states like advance HIV disease.

Factors increasing the risk of transmission: It is not necessary that every act of unprotected sex will result in STI/RTI transmission. The possibility of getting infected depends upon following factors:

1.5.1. Biological factors: Certain biological factors influence the transmission of STI and RTI which includes age, sex, immune status of the host and virulence of the organism:

- **Age:** The vaginal mucosa and cervical tissue of young women is immature and makes them vulnerable to STI than older women. Cervical ectopy describes the situation where cells that more readily allow infections to occur are found on the outer intra-vaginal surface of the cervix. Furthermore, oral contraceptive pills can further increase the risk of the ectopy.
- **Sex:** Infection enters more easily through a mucosal surface such as vaginal mucosa. As, the woman has much larger mucosal surface of exposure than the man and she is more vulnerable to get infected. In case of men, uncircumcised men are more likely to get an STI than circumcised men. It is more difficult for uncircumcised men to protect the inside surface of their foreskin from contact with body fluids.
- **Immune status:** The immune status of the host and the virulence of the infection affect transmission of STI. Certain STI increase the risk of HIV transmission. HIV, in turn facilitates the transmission of many STI and worsens the complications of STI by weakening the immune system.

1.5.2. Behavioral factors: Many behavioral factors affect the possibility of contracting STI and their exponential spread. Such behaviors, known as risky behaviors, are as follows:

- Sexual behaviors
- inconsistent or no condom use during penetrative vaginal, anal, or oral intercourse
- frequent change of sexual partner
- having more than one sexual partner
- having sex with casual partners, sex workers or their clients
- exchanging sex for money, goods, or favors (transactional sex)
- exchanging sex for drugs or drugs for sex
- Other personal behaviors (non-sexual) that are risky includes:

  1. use of alcohol or other drugs during or before sex
  2. blood transfusion

- Even if an individual has no risky behaviors, they may be at risk if their partner/s:

  - indulge in high-risk behavior
  - has STI
  - injects drugs

1.5.3. Social factors: A number of social factors link sex and behavioral issues and may affect a person's risk of contracting STI:

- In most cultures women have very little power over sexual practices and choices, such as use of condoms, which ultimately increases their risk.

- When women tend to economically dependent on their male partners, they are likely to tolerate men's risky behavior of multiple sexual partners, thus putting themselves at the risk of contracting STI
- Sexual violence tends to be directed more towards women by men, making it difficult for women to discuss sexual issues with their male partners
- Early marriage: The practice of early marriage where girl-child is married off to an adult male at a young age, exposes girls to infections
- Most STI transmission occurs within a small part of the population that has multiple sex partners. This does not mean that the rest of the community is not at risk for STI infection. A woman who has sex with only her husband can still get an STI if her husband has other partners.

In certain populations with high-risk practices, the vulnerability as well as burden of HIV and STI is higher than the general population. The high vulnerability is due to their sexual networks or behavioral or biologic factors, including number of concurrent/anonymous partners, tendencies to engage in condomless sex, transactional sex, or substance use etc. These practices may vary in different communities such as:

- Adolescent girls and boys who are sexually active and indulging in unsafe sex
- Person involved in transactional sex
- Sex workers and their clients
- Migration: men and women whose jobs force them to be away from their families or regular sexual partners
- Men having sex with men (MSM) and hijra/transgenders
- Drug users
- Population in Prison and other closed settings

1.6. Concepts of sex, gender and sexuality and its association with increased risk for STI

In order to understand the dynamics that increases the risk of STI among sexual and gender minorities, it is important to understand the concepts of sex, gender, and sexuality. The common terminologies are defined below:

- 'Sex' refers to biological make-up of a person, determined based on external and internal genital-reproductive parts, hormones, tissues, and chromosomes.
- While 'gender' is a societal construct with roles and behaviors assigned by society, 'gender roles' are derived from socio-cultural environment. Gender roles and behaviors are assigned by society and are learned rather than innate. This unequal value is the source of discrimination and oppression (especially among women and transgender persons)
- 'Gender identity' refers to how people perceive their own gender: whether they think of themselves as a man/woman/both/a different gender.
- 'Gender expression' is the way in which a person, through their appearance, manifests masculinity/femininity/both/ neither.
- **'**Sexual Behaviour' is defined as a persons' actual act of having sex and/or stimulation (with a person of the same gender or opposite gender or both or none).
- 'Sexuality' is defined as sexual feelings, thoughts, attractions and behaviors of a person towards others.

- 'Sexual orientation' of a person is defined as to whom the person is attracted to romantically, emotionally, and sexually. The common types of sexual orientation are as follows:
  1. **Heterosexual:** An individual who is sexually attracted to people of gender other than their own and/or who identifies as being heterosexual.
  2. **Homosexual:** An individual who is sexually attracted to people of the same gender as their own, and/or who identifies as being homosexual
  3. **Lesbian:** A woman who is sexually attracted to other women and/or identifies as a lesbian
  4. **Gay:** A man who is sexually attracted to other men and/or identifies as gay. This term can also be used to describe any person (man or woman) who experiences sexual attraction to people of the same gender.
  5. **Asexual:** An individual who is not sexually attracted to other individuals.
  6. **Bisexual:** identity corresponding to significant (not necessarily equal) attraction to two genders.
  7. **Pansexual:** used to denote identity corresponding to attraction to multiple genders (> 2).

Transgender persons have a gender identity or gender expression that differs from their assigned sex. They are sometimes called trans-sexual, if they desire medical assistance to transition from one sex to another. However, transgender persons may undergo gender affirmation surgical procedures or may choose to retain their biological gender due to various reasons. Infrequently, the term transgender is defined very broadly to include cross-dressers, regardless of their gender identity. Hijras are male-to-female transgenders who live as a part of 'social construct'.

The vulnerabilities associated with sex-gender-sexuality also dictates the risk for STI (including HIV). Some of these vulnerabilities are mentioned below:

- Risk of STI transmission during sexual intercourse:
  - Increases multiple times for a cis-gender woman and unoperated transgender man than cis-gender man
  - Significantly higher in anal sex for receptive partners (male/female/transgender)
  - Higher in partners involved in receptive oral sex
- Gender norms related to sexuality:
- Gender norms require women/girls to remain ignorant, passive, subordinate and faithful in sexual relations
- Women/transgender have less negotiation power in sexual relations
- Dominant masculine behavior and sexuality promotes men and boys as assertive, independent, and strong partner. The dynamics of dominant partner in homosexual relationship plays the same role putting the non-dominant partner at-risk
- These sexual and gender minorities face many barriers to access healthcare at the service facilities. These include fear of loss of identity, long queues, lack of basic amenities like drinking water, toilets etc, insensitive staff, fear of stigma and discrimination, inconvenient timings, and high travel costs. These issues pose a hindrance to the HRGs to access anti-retroviral treatment also.
- Gender-based violence is defined as intimate partner violence targets someone because of their gender or for non-compliance with gender norms. GBV can be physical/sexual/emotional/economic/structural where that violence increases the risk of STI:

- Forced sex of any kind with an infected partner increases the risk of transmission,
- Limiting the ability to negotiate safer sex/condom use.
- Victims of childhood sexual abuse are more likely to have high risk behaviours and vulnerable to get infected

- Effects of migration on increasing risk: The effects of migration for multiple groups are mentioned in the table 1.1. as below:

Table 1.1. Migration and Risk of STI and RTI

Migrant Workers	• live far from their families and regular sexual partners, experience loneliness • resort to paid sex, multiple partners and peer pressure to indulge in high-risk behaviours • reluctance to discuss sexual health and limited access to health services • young girls migrate to cities to work as maids/daily wage workers in households where the chances of sexual abuse and harassment remains significant
Transportation Workers	• engage with flying sex workers and companions • are untraceable due to constant travel • limited access to health services
Transgender/effeminate boys	• H/TG are commonly disowned by their families • Both H/TG and effeminate boys remains easy target for sexual harassment/violence/bully • may resort to earning money through sex work • limited access to health services
MSM	• societal pressure to marry leads them to migrate for work and continue their hidden life • exposes them to higher sexual risk in new locations

- Stigma and discrimination:
  - Stigma is the shame or disgrace attached to something regarded as socially unacceptable. 'Discrimination' means treating one person differently from another in a way that is unfair. Discrimination is enacted stigma.
  - HIV and STI-related stigma and discrimination refers to prejudice, negative attitudes and abuse directed at people infected or affected with HIV/AIDS and/or STI
  - Discrimination is the act of treating a person unfairly or unjustly because he /she is affected or infected with HIV/STIs
  - There is widespread stigma and discrimination associated with PLHIV, their families and populations at-risk.

1.7 Changing Paradigm – Use of Telemedicine in Sexual Health

There are person-centric barriers to access STI prevention and care services. The limited availability of accessible and acceptable health care providers in rural as well as urban settings, high costs associated with seeking care and fear of breach of confidentiality limits people from seeking care for STI and RTI in physical spaces. These barriers significantly affect a person's ability to seek health care services for STI and RTI.

Telemedicine offers a greater flexibility to both the patient and the provider by eliminating the need for travelling across geographies. It can increase patient satisfaction by providing services in settings that prevent public scrutiny, resulting in less anxiety by reducing anticipated and experienced stigma, and improve patient engagement and retention. Moreover, telemedicine services can also significantly reduce costs to access services. This can offer valuable solutions to the challenges and thereby can improve access to quality STI and RTI care. There is a need to explore these interventions and set ethical practices to practice telemedicine to reach out to greater population for providing holistic, cost effective and quality STI and RTI care.

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Chapter 2 Assessment of Clients for STI and RTI

The role of history taking, and clinical examination can never be overlooked to ensure appropriate diagnosis and provide quality STI and RTI services. It takes time and skill in taking a detailed sexual history and carrying out a comprehensive physical examination. The decision making should take into consideration the availability of resources for etiological diagnosis and proceed with the resources available in a particular setting. Those settings where even minimal laboratory setup and facilities for clinical examinations are not available, syndromic management should be provided on the basis of detailed history. This chapter details the basics of anatomy of genital-reproductive system and steps for history taking and clinical examination of clients seeking STI and RTI services.

Note: *The relevant glossary related to transgender persons and persons with intersex variations is mentioned in the end of this chapter for reference.*

2.1. Anatomy of Sexual & Reproductive System

2.1.1. Anatomy of Female Sexual & Reproductive System

The female reproductive system can be subdivided as internal and external genitalia. The internal genitalia comprise of organs and structures lying within the true pelvis. These include the vagina, cervix, uterus, fallopian tubes, and ovaries. The external genitalia comprise of organs lying outside the true pelvis. These include the perineum, mons pubis, clitoris, urethral meatus, labia majora and minora, vestibule (the area between the labia minora, and consists of the clitoris, urethral and vaginal opening), greater Vestibular/ Bartholin glands, Skene glands, and periurethral area. These structures are collectively called as vulva.

This anatomy corresponds to cisgender women, unoperated transmasculine persons (or transgender men) and other persons with ‘female’ sexual/reproductive anatomy.

2.1.2. Anatomy of Male Sexual & Reproductive System

The male genital reproductive system is a network of external and internal organs that function to produce, support, transport, and deliver viable sperm for reproduction. This system consists of a pair of testes and a network of excretory ducts [epididymis, ductus deferens (vas deferens), and ejaculatory ducts], seminal vesicles, the prostate, the bulbourethral glands, and the penis. Sperm is produced in the testes and is transported through the epididymis, ductus deferens, ejaculatory duct, and urethra. Concomitantly, the seminal vesicles, prostate gland, and bulbourethral gland produce seminal fluid that accompany and nourish the sperm as it is discharged from the penis during ejaculation and throughout the fertilization process.

This anatomy corresponds to cisgender men and unoperated transfeminine persons (or transgender women) and other persons with ‘male’ sexual/reproductive anatomy.

2.1.3. Special considerations for persons who have undergone gender-affirmative surgeries

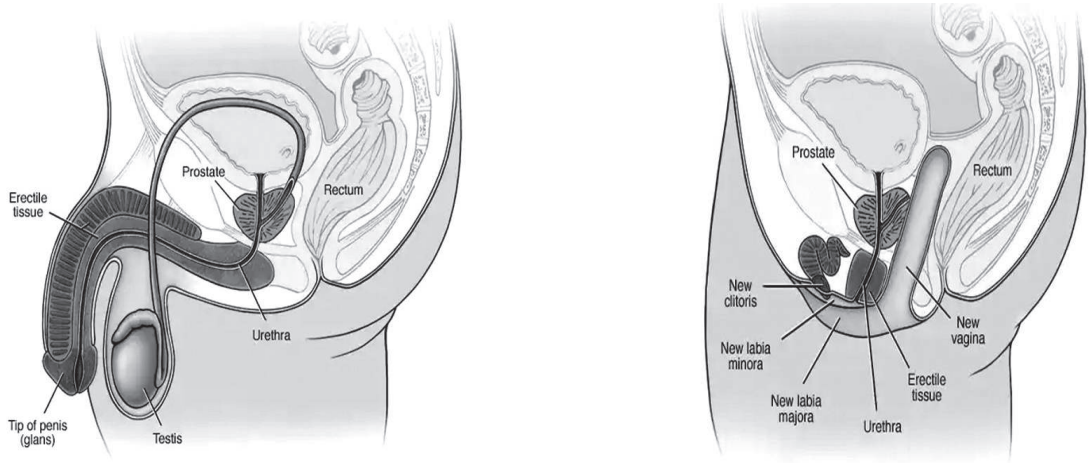
Gender-affirmative genital surgical procedures for the transfeminine persons (or transgender women) may include orchiectomy (surgical removal of testicles), penectomy (removal of parts/complete penis), vaginoplasty (construction of vagina), clitoroplasty (construction of clitoris), and labiaplasty (construction of labia minora).

Gender-affirmative genital surgical procedures for transmasculine persons (or transgender men) may include hysterectomy (removal of uterus and cervix), ovariectomy (salpingo-oophorectomy), vaginectomy, metoidioplasty, scrotoplasty, urethroplasty, placement of testicular prostheses, and phalloplasty.

It is key to note that individuals could identify as transgender (or gender non-binary and genderqueer) without undergoing any of these processes and may still present with their natal or birth anatomy. Further, transgender persons may also have undergone few gender-affirmation processes from those stated above and may either be in process of undergoing some more or may also have no intention to undergo additional processes.

2.1.3.1. Transgender women or transfeminine persons with neovagina

Vaginoplasty is a form of "bottom surgery" (surgery on the genitals) of transgender women, or those who identify as transfeminine which involves surgical creation of a vagina from existing genital tissue. It involves removing the penis, testicles and scrotum and rearranging tissue in the genital area to create a vaginal canal or opening (neovagina) and vulva (external genitalia), including the labia. This procedure can be performed either through penile inversion or using a non-genital flap such as rectosigmoid vaginoplasty or peritoneal flap vaginoplasty. Penile inversion vaginoplasty is a widely used approach for vaginoplasty for transgender persons.



A. Anatomy before procedure **B. Anatomy after penile inversion procedure**

Figure 2.1. Anatomy in transfeminine persons

The neovaginal canal is usually constructed using penile skin tube and skin grafts from the scrotum. Labiaplasty is usually performed using scrotal and penile skin. The glans penis and the inner layer of foreskin along with the neurovascular bundle are used to form the neoclitoris and its prepuce which are sutured under the pubic skin superior to the neovagina. The urethra is shortened, matured, and inset between the reconstructed clitoris and vaginal canal. (See Figure 2.1). The parts of natal male organs corresponding to neovagina is mentioned in Table 2.1.

Table 2.1. Corresponding parts of natal male organs with neovaginal anatomy

Natal Male Anatomy	Neovaginal Anatomy
Anterior Penile Flap	Anterior neovagina (vestibular lining and labia minora)
Posterior scrotal-perineal flap	Posterior neovagina
Scrotum	Vagina and labia majora
Glans Penis	Neoclitoris
Urethra	Neovaginal urethra, urethral meatus, and portions of anterior neovagina/vestibule

2.1.3.2. Transmasculine persons with phalloplasty

In transmasculine persons or persons with certain intersex conditions (e.g., aphalia or absence of phallus, ambiguous genitalia, micropenis etc.), phalloplasty involves construction of a new penis (neo-phallus/ neopenis). In FTM or female-to-male bottom surgery, hysterectomy, ovariectomy (salpingo-oophorectomy), vaginectomy is followed by metoidioplasty and phalloplasty. Metoidioplasty is a surgical procedure that uses the existing genital tissue to form a phallus or new penis.

2.1.4. Special Consideration for persons with intersex variations

The term 'Intersex' describes a group of congenital (or at-birth) conditions in which the reproductive organs, genitals, and/or other sexual anatomy do not develop according to traditional expectations for females or males. The preferred term to describe this group of persons is 'persons with intersex variations'

Intersex persons are born with these variations and may even develop/express them during childhood or after achieving puberty. There are many possible variations in genitalia, hormones, internal anatomy, or chromosomes, compared to the usual two ways that human bodies develop. Every person with intersex variations is different and there is no standard 'anatomy' of these individuals. There are over 40 medical terms for the different ways sex anatomy might develop. The common examples and traits are given in Table 2.2.

Table 2.2. Common Examples of Intersex Variations

Medical Term	Genetics	External	Internal	Puberty
Complete Androgen Insensitivity	XY	Vulva, clitoris	Testes, no uterus, sometimes partial vagina, or complete vagina	If testes are left alone, body goes through puberty via converting testosterone into estrogen
Partial Androgen Insensitivity	XY	Vulva and visibly large clitoris, or other differences	Testes, no uterus, varies	If testes are left alone, body has varying levels of response to testosterone

Medical Term	Genetics	External	Internal	Puberty
Congenital Adrenal Hyperplasia	XX	Vulva (labia may be fused), often visibly large clitoris	Ovaries, uterus, sometimes partial vagina, or complete vagina	May be early, higher testosterone can lead to features such as facial hair, changed fat distribution
Swyer's	XY	Vulva, clitoris	Streak gonads, uterus, sometimes partial vagina or complete vagina	No puberty because streak gonads do not produce any hormones
Klinefelter's	XXY	Penis, small testicles	May have low sperm count	Low levels of testosterone may cause breast development or other atypical features, may be very tall
Hypospadias	Varies by cause (often XY)	Penis (with urethral opening somewhere other than tip) and testicles; or small penis (with urethra near base or perineum) and open labioscrotal folds; or other differences		Varies by cause (often typical testosterone puberty)

2.1.5. Difference between transgenderism and intersex variations

People who identify as transgender or transsexual are usually people who are born with typical male or female anatomies but feel as though they've been born into the "wrong body." They may or may not use hormones or undergo surgery to have a body that is aligned with their self-affirmed gender identity. However, persons with intersex variations have anatomy that is not considered typically of male or female. The persons with intersex variations may identify themselves as male, female, or transgender. They may also decide to change their genders at some point in their life, so some people with intersex conditions might also identify themselves as transgender persons.

Note: It is essential to approach the gender affirming procedures and intersex variations with sensitivity and an awareness of the diverse anatomical and healthcare needs of transgender persons and those with intersex variations is essential to provide inclusive services these populations. Invasive questions on intersex genitalia should be avoided as there is no standard answer.

2.2. History Taking

History taking in medical practice is a fundamental aspect of patient assessment and diagnosis. The following are points of consideration while taking history of a client availing STI and RTI services:

Communication:

- Open and respectful communication is vital for taking a quality history assessment of sexual health. Healthcare providers (HCP) should use affirming language, ask for preferred names and pronouns, and create an environment where patients feel comfortable in discussing their bodies and sexual practices.
- History must be taken in a language understood well by the client.
- Clients are often reluctant to talk about their sexual conditions/behavior due to shyness and fear of stigma. Therefore, HCP should ensure a safe and stigma-free environment with adequate provisions for audio-visual privacy and confidentiality while taking history and conducting physical examination. The approach should be nonjudgmental, respectful as well as gender- and culturally sensitive.
- Ensure privacy by having a separate space for history taking and examination, which is not stigmatized with a nameplate for STI. There should be adequate auditory as well as visual privacy for history taking as well as conducting clinical examination.
- Start the conversation by welcoming your client, taking them into confidence and encouraging them to talk about their complaints. Asking their chosen name and pronouns would be a good way to ensure comfort, sensitivity, and respect. If a couple comes together, each of the person needs to be interviewed and examined separately.
- Usually, clients feel uncomfortable in directly talking about their sexual health, and individuals may come to the clinic with other nonspecific complaints or requesting a checkup, assuming that the HCP will notice anything abnormal that needs treatment. Therefore, HCP should maintain a high index of suspicion about STI and RTI among every client visiting the clinic.
- Patients with problems relating to the ano-genital area tend to be guarded and evasive while giving a history. The following points may be followed while taking history (may be reworded as per the context):
    - Ask an open-ended question, such as “What brought you to the hospital?” to initiate a dialogue.
    - Phrase your questions in a way such that the opportunity for the patient to mislead you is minimized. For example, “When did you last have sex with someone?” is preferred over “Did you have sex with someone?”
    - Once the subject is broached and patient is comfortable, closed-ended questions (calling for “yes” or “no” answers) can be helpful in eliciting brief answers, for example, “Do you have discharge from your genitals?”
    - Ask questions pertaining to gender reaffirmation processes if it is essential to the course of clinical examination.
    - In order to make an accurate diagnosis it is often necessary to ask more questions during the examination.
    - Do not show annoyance if the patient’s history has obvious discrepancies or keeps changing.

Informed Consent:

- Before conducting any physical examination or laboratory investigation, healthcare providers should explain the purpose, process, and potential discomfort involved. Informed (verbal) consent is crucial to ensure patient’s autonomy and comfort.

Cultural Competence:

- The HCP should understand the unique healthcare needs and concerns of different populations. Sensitivity to gender identity and cultural competence are essential for delivering effective care.
- The HCP should be aware of the common terminologies used for describing sexual health and STI and RTI as well as those used for high-risk behavior. These terms may vary in different geographical settings and population groups.

Individualized Approach:

- Clients seeking care for infectious diseases (like HIV, viral hepatitis etc.), gynecological care, antenatal care, family planning services, care for adolescent health issues and deaddiction services should be viewed as opportunities to provide general information and should be assessed for STI and RTI and provided with risk reduction counselling.
- The HCP should work with patients to develop individualized care plans that consider their medical history, personal preferences, and sexual behavior.
- Transgender/ intersex persons should be considered as special population and their risk assessment should be conducted on the basis of their current anatomy, sexual behaviors, and clinical presentation.
- The principles of trauma-informed care (as described in Chapter 7) should be incorporated into the history-taking process, recognizing that some clients may have experienced sexual trauma or sexual violence or abuse.

2.2.1. Current History

The common symptoms associated with STI and RTI can be investigated through effective history taking. These questions need to be clear and sensitive terminology should be used while taking details from a client.

Asymptomatic Patient: People with a history of HIV/STI-related risk behavior or exposure who show no symptoms/signs but still have an infection are the asymptomatic patients. Even when asymptomatic, such patients can continue harboring and transmitting the infection to their sexual partners or, in case of a pregnant woman, to her unborn child. Moreover, the infection can ascend in the sexual and reproductive tract leading to complications and negative sequelae. They need to be diagnosed and treated adequately.

Signs/Symptoms/Syndromes of STI and RTI

- A symptom is what a client/patient complaint or reports to an HCP.
- A sign is the observation of an HCP on clinical examination of a client/ patient.
- A syndrome refers to a set of medical signs and symptoms which are correlated with each other and often associated with a particular disease/ group of diseases

The common signs and symptoms of STI and RTI are enlisted in Table 2.3.

Table 2.3. Common signs and symptoms of STI AND RTI

Anatomical Part	Symptom
Oral/ Oropharynx (With history of oral sex)	• Ulcers in mouth, tongue, and lips • Sore throat • Voice changes, difficulty in speaking or shortness of breath
Male Genitalia	• Urethral discharge • Burning/ pain during micturition • Increased frequency of micturition • Genital itching • Swelling in groin area/ scrotal swelling • Vesicles or ulcers on penis, foreskin, urethral meatus, and in urethra • Genital Warts
Female Genitalia	• Unusual discharge from vagina* • Abnormal, heavy vaginal bleeding or other menstrual irregularities • Genital itching • Pain while having sex (dyspareunia) • Lower abdominal pain (below belly button/ pelvic pain) • Vesicles or ulcers on internal/external genitals • Genital warts
Anal/peri-anal area (history of receptive anal sex)	• Anorectal discharge • Vesicles or ulcers on anus or surrounding area • Pain while passing stools • Anal or peri-anal itching • Anal/peri-anal warts
Generalized Symptoms/ presentation	• Fever, body ache, muscle pain, dark-colored urine • Infertility • Skin rash, muco-cutaneous erosions

***Vaginal Discharge:** Vaginal discharge can be physiological. Normal vaginal discharge is usually clear, white, or off-white in colour, with minimal odor, pH ranging between 3.5-5.5, floccular in consistency, with a texture that changes throughout menstrual cycle. Factors like pregnancy, use of oral contraceptive pills, ovulation is associated with the change in texture and amount of vaginal discharge. The following characteristics may signify abnormal vaginal discharge:

- Abnormal increase in amount
- Change in the color of the discharge (against the normal pattern)
- Foul or unpleasant odor
- Change in texture or consistency of the discharge (against the normal pattern)
- Association with irritation, itching or pain in or around vagina

2.2.2. History of HIV/STI-related risk behaviors

The history of risk behaviors related to HIV/STI infection needs to be understood to provide tailor-made services to the clients. The following are some important questions (can be reworded as per the context) for assessment of risk behavior:

- Are you involved in any form of sexual activity? When was the last time you had anal/oral/vaginal sex?
- Have you had sex with a man, woman, or transgender person? (Probe for what kind of sex).
- Have you or your partner had sex with more than one partner?
- Do you practice correct and consistent condom use while having sex (oral/anal /vaginal)? If yes, whether every time or sometimes?
- Do you have sex under the influence of alcohol or any other intoxication?
- Is there any incidence of condom rupture or slippage during sex within 6 months?
- Do you pay or get paid for having sex? May also be rephrased as: Do you perform sex as a profession?
- Do you have sex in exchange of material support or other benefits?
- Do you indulge in group sex? May also be rephrased as: Do you involve in sex with multiple partners at the same time?
- Have your partner(s) had any sexually transmitted infection?
- Is there any incidence of violence during sex or for sex?

Some population-specific points that needs exploration are:

- Sex workers: Frequency of use of condoms and incidence of sexual violence with regular, paying, and casual partners
- Injecting drug use: Have you ever used or injected drugs for recreational purpose? (If yes, have you ever shared needles or injection equipment?) Have you ever had sex with anyone who had ever indulged in any form of substance use? There is a frequent practice of needle sharing among sexual partners and need to be discussed.
- Transgender persons: What kind of sexual practices are you involved in? The gender and body parts involved in sex/penetration should be elicited to understand the risk and provide tailor-made risk reduction services. This is also important for appropriate assessment of clients for STI and RTI and related syndromes. Moreover, the sexual act should not be assumed, and the services should be based on the information provided by the client.
- Adolescents: Tailored sexual history taking for adolescent clients, including age-appropriate language, confidentiality considerations, and addressing concerns related to sexual development and experimentation

2.2.3. Past History of STI and RTI

This information is important to understand the risky behavior of the client and completeness of treatment for any STI and RTI suffered in the past. The following can be some of the questions to elicit past history of the clients:

- In the past, have you ever had any sexually transmitted infection? If so, can you describe the symptoms and diagnosis, if known? It is not uncommon for clients to not understand the terms ‘sexually transmitted infections’ or ‘STI’. Therefore, local terms can be used better discussion.
- Have you been treated in the past for any sexually transmitted infection? By whom? (doctor/qualified or trained HCP or untrained person/alternative medicine person or healer)
- Did your partner receive treatment for the same infection at that time? Has your partner been treated in the past for any sexually transmitted infection? By whom? (doctor/qualified or unqualified person)

Note: Many people may not have information related to diagnosis of STI and RTI in past but may not be able to share symptoms. Therefore, the history taking should involve questions probing common symptoms of STI and RTI.

2.2.4. Medical, Obstetric and Menstrual History

The following information should also be noted:

- **Medical History:** Other illness as diabetes mellitus; HIV; current or past history of use of post-exposure prophylaxis (PEP) or pre-exposure prophylaxis (PrEP) for HIV; PEP for STI; presumptive treatment for STI
- **Menstrual History:** Last menstrual period, pain during menses, menstrual irregularities, excessive flow during menstruation, post-coital bleeding
- **Obstetric History:** Parity and gravida, pregnancy outcomes, contraception etc.
- Intake of gender-affirming hormone replacement therapy should be elicited among transgender persons.

Note: The transgender man/ transmasculine person should be asked about their menstrual and obstetric history if they have not undergone hysterectomy.

2.3. Clinical Examination

This is an important step to arrive at a probable diagnosis and avoiding an incorrect diagnosis based on the patient's history. The following points should be practiced while examining a client:

- Ensure audio-visual privacy during the clinical examination.
- Inform the patient that you will do a genital examination. Explain the exact process (e.g., "I will first feel your genitals for any swelling /tenderness etc") and obtain patient's permission.
- Any examination of the anogenital area should preferably be conducted in the presence of a chaperone/escort. A male HCP must have a female chaperone/escort in attendance at all times during clinical examination and vice versa.
- The examination must particularly focus on the anogenital area, but a general examination must also look for other manifestations of STI, such as lymphadenopathy, cutaneous and oral manifestations of STI and abdominal abnormalities, especially for women with pelvic inflammatory disease.
- Genital examination includes a speculum and bimanual examination of the genital tract for all clients with female genitalia, and rectal examination (including anoscopy, if indicated and available) for all clients (male/female/transgender) with a history of receptive anal sex.
- It is advisable to examine for regional lymph nodes before examining genitals, particularly in the presence of discharge, to avoid soiling of inguinal skin.

Note: The clinical examination of a woman during menstruation is not contraindicated and urine samples, vaginal swabs and blood tests can all be collected for STI testing during menstruation.

2.3.1. Clinical Examination of a Female Client

This section is relevant for clinical examination of cisgender-women, non-operated transmasculine and other persons with 'female' sexual/reproductive anatomy. The following steps may be followed:

- Wash hands before the examination and put on clean, fresh gloves for each patient.
- Ask the patient to undress from the chest down to enable examination.
- Ask the patient to lie down on an examination couch; the person should not be examined in standing position and should be covered with a draw sheet or a modesty blanket, exposing only the part of the body to be examined when ready.
- Ensure availability of good light while examination
- Genital examination must be performed with client in lithotomy position.
- If a male doctor is examining the female client, the presence of a female attendant or nurse is mandatory.

The signs to be observed during clinical examination of persons with female genitalia are mentioned in Box 2.1. The steps of per speculum examination and signs to be observed are mentioned in Box 2.2 & 2.3 respectively. The steps for bimanual examination of a woman are mentioned in Box 2.4. Further, the steps for anoscopic examination are mentioned in Box 2.5.

Box 2.1. Clinical Examination of a Female Client

Oral Examination

- Ulcers in mouth, tongue, throat, and lips (may be painful/ painless)
- Erythema, edema, and swelling of the pharynx including pharyngeal pillars & tonsils
- Enlargement of submandibular and periauricular lymph nodes
- Warts in throat (Laryngoscopy is advised when there are symptoms of shortness of breath, difficulty in speaking or change in voice)

Ano-genital Examination

Inspection

Presentation

- Staining of underclothes: discharge, exudative ulcers

Inguinal region

- Swelling, ulcer, lesions of fungal infections
- Lymph nodes: look for enlargement, number, location (horizontal or vertical group), single or multiple, scars and puckering, signs of inflammation on the surface and surrounding region
- Abrasions due to scratching and lesions on inner aspect of thighs

Pubic area

- Matting of hairs, pediculosis, folliculitis, or other skin lesions

Labia majora and minora

- Separate the labia majora with both hands and look for erythema, edema, esthiomene formation (lobulated fibrosed masses due to chronic lymphedema), fissuring, ulcers, warts, or other skin lesions

Ulcers

- Location, number (single, multiple), superficial (erosions) or deep, edge (undermined/ punched out), margins (regular/irregular) and floor (presence of exudates, slough/ granulation tissue)

Bartholin glands
- Enlargement, ductal opening, discharge (on each side of vaginal opening)

Introitus
Discharge – color, odor, profuse or scanty, curdy, or thin, back drop of redness and inflammation

Urethral meatus
- Discharge (pressing under the urethra with one finger may show drops of discharge), inflammation

Perianal examination
- Separate the buttocks with two hands for better visualization.
- Look for ulcer, macerated papules of Condyloma Lata, warts, discharge, patulous anus, hemorrhoids, fissures, fistula

Palpation

Inguinal region
- Lymph nodes: tenderness, increased warmth, superficial or deep, discrete, or matted, free mobility or fixed to deeper structures, consistency (firm or soft) and fluctuant.
- Rule out hernia

Palpation of ulcer at any site
- Tenderness, induration of the floor and edges, bleeding on maneuvering

Anoscopy Examination
- Indicated if history of receptive anal intercourse or ano-rectal discharge is reported.
- Should not be carried out if the client has painful perianal disease such as herpetic ulcers, fissures, or hemorrhoids.

Box 2.2. Steps for speculum examination

How to do speculum examination
- Ask the patient to pass urine.
- Ask the patient to loosen her clothing. Use a sheet or clothing to cover her.
- Have her lie on her back, with her heels close to her bottom and her knees up (lithotomy position).
- Wash your hands well with clean water and soap.
- Put clean gloves on both hands.
- Explain the women about the procedure and reassure that the procedure will be painless but may cause very minimal discomfort.
- Look at the outside genitals – using the gloved hand to gently look for lumps, swelling, unusual discharge, sores, tears, and scars around the genitals and in between the skin folds of the vulva.

Speculum examination
- Be sure the speculum has been properly disinfected before you use it. Wet the speculum with clean water before inserting it.

- Put the first finger of your gloved hand in the woman's vagina. As you put your finger in, push gently downward on the muscle surrounding the vagina (push slowly, waiting for the woman to relax her muscles).
- With the other hand, hold the speculum blades together between the pointing finger and the middle finger. Turn the blades sideways and slip them into the vagina. (Be careful not to press on the urethra or clitoris because this area is very sensitive). When the speculum is halfway in, turn it so the handle is down. Remove your gloved finger.
- Gently open the blades a little and look for the cervix. Move the speculum slowly and gently until you can see the cervix between the blades. Tighten the screw on the speculum so it will stay in place.
- Check the cervix which should look pink and round and smooth. Notice if the cervical os is open or closed, and whether there is any discharge or bleeding.
- Look for signs of cervical infection by checking for yellowish discharge, redness with swelling, or easy bleeding when the cervix is touched with a swab. If the woman has been leaking urine or stools gently turn the speculum to look at the walls of the vagina. Bring the blades closer together to do this.
- To remove the speculum, gently pull it toward you until the blades are clear of the cervix. Then bring the blades together and gently pull back. Be sure to disinfect your speculum again.

Cusco's bivalve self-retaining vaginal speculum is most commonly used for speculum examination. Either sterilized stainless steel or disposable speculums can be used for the examination.

Box 2.3. Signs for observation in speculum examination

- Vaginal discharge and redness of the vaginal walls are common signs of vaginitis. Note the color, smell, and characteristics of any vaginal discharge. When the discharge is white and curd like, there is high probability of candidiasis. Appropriate swabs can be taken from the fornix wherever indicated.
- Presence of any foreign body
- Ulcers, warts, sores, or blisters
- Redness of cervical and vaginal epithelium
- Look for cervical erosions. If the cervix bleeds easily when touched or the discharge appears mucopurulent with discoloration, there is high possibility of cervical infection. A strawberry appearance of the cervix may be due to trichomoniasis. A uniform bluish discoloration of the cervix may indicate pregnancy.
- When examining a woman after childbirth, induced abortion, or miscarriage, look for bleeding from the vagina or tissues fragments and check whether the cervix is normal.
- Tumors or other abnormal looking tissue on the cervix.
- Pap smear can be obtained during speculum examination.

Box 2.4. Steps for bimanual examination

- Put the pointing finger of your gloved hand in the vagina. As you put your finger in, push gently downward on the muscles surrounding the vagina. When the woman's body relaxes, put the middle finger inside too. Turn the palm of your hand up.
- Feel the opening of the cervix to see if it is firm (feels like tip of the nose and round). Then put one finger on either side of the cervix and move the cervix gently. It should move easily without causing pain. If it causes pain, she may have infection of the uterus, tubes, or ovaries. If her cervix feels soft, she may be pregnant.
- Feel the uterus by gently pushing on her lower abdomen with your outside hand. This moves the inside parts (uterus, tubes, and ovaries) closer to your inside hand. The uterus may be tipped forward or backward. If you do not feel it in front of the cervix, gently lift the cervix and feel around it for the body of the uterus. If you feel it under the cervix, it is pointed back.
- When you find the uterus, feel for its size and shape. Do this by moving your inside fingers to the sides of the cervix, and then 'walk' your outside fingers around the uterus. It should feel firm, smooth, and smaller than a lemon. If the uterus:
  - Feels soft and large, the client is probably pregnant.
  - Feels lumpy and hard, the client may have a fibroid or other growth.
  - Hurts when you touch it, the client may have an infection.
  - Does not move freely, she could have scars/adhesions from an old infection or surgery.
- Feel tubes and ovaries. If these are normal, they will not be felt. But if you feel any lumps that are bigger than an almond or that cause severe pain, she could have an infection or other emergency. If the client has a painful lump, and her monthly bleeding is late, or scanty, she could have ectopic pregnancy and needs immediate assessment.
- Move your finger and feel along with inside of the vagina. If the client has a problem with leaking urine or stool, check for a tear. Make sure there are no unusual lumps or sores.
- Have the patient to cough or push down as if she were passing stool. Watch to see if something bulges out of the vagina. If it does, she could have a uterine/bladder prolapse.
- Cervical movement tenderness and or adnexal tenderness is suggestive of PID
- When you are finished, clean and disinfect your glove. Wash your hands well with soap and water.

Box 2.5. Steps for Anoscopic Examination

- Lie the patient down in the left lateral position.
- Perform a direct ano-rectal examination.
- Separate the buttocks or ask the patient or an assistant to help and examine the perianal area for blisters, sores or discharge, warts, hemorrhoids, or polyp prolapse.
- Perform a digital rectal examination with a lubricated, gloved index finger, taking note of sphincter tone and any prostate abnormalities (in males and transgender women only).
- Remove the finger and change glove to a new one.
- Lubricate the anoscope and insert it into the anus gently and, pointing the anoscope towards the umbilicus, advance it completely into the anus or as far as the patient can tolerate.

- Remove the obturator of the anoscope to examine the anal mucosa, removing any fecal matter with a swab.
- Check for blood, mucus, pus or hemorrhoidal tissue.
- Gently remove the anoscope, when done, and observe the sides of the anal canal in the process.
- The health-care provider should remove the gloves before touching anything, and both the provider and the patient must wash their hands before the provider sits with the patient to give feedback on the examination findings.

2.3.2. Clinical Examination of Male Client

This anatomy corresponds to cisgender men and non-operated transfeminine and other persons with 'male' sexual/reproductive anatomy. The transgender women who have not undergone gender affirming genital surgery will also have this anatomy.

- Wash hands before the examination and put on clean gloves with each patient.
- Inform the patient what is going to take place at each step of the examination.
- Ask the patient to lie down on a couch and expose the genital area from umbilicus to knee level. Where a couch is not available, the patient may be examined in a standing position, but this should be avoided as much possible. Cover with a draw sheet or a modesty blanket, exposing only the part of the body to be examined when ready
- The patient may then be asked to bend the knees towards the chest (knee-chest position) to expose the perineum, buttocks, and anal region for examination. If the patient is examined in the standing position, he may be asked to turn his back to you and bend over, spreading his buttocks slightly, and the anus is then examined. The help of the patient might be sought for spreading the cheeks of the buttock.
- Both the examiner and the patient should wash their hands after completion of examination.

The signs to be observed during clinical examination of a man are mentioned in Box 2.6.

Box 2.6. Clinical Examination of a Male Client

Oral Examination
• Ulcers in mouth, tongue, throat, and lips (may be painful/ painless) • Erythema, edema, and swelling of the tonsils and pharyngeal pillars • Enlargement of submandibular and periauricular lymph nodes • Warts in throat (Laryngoscopy is advised when there are symptoms of shortness of breath, difficulty in speaking or change in voice)
Ano-genital Examination
Inspection
• **Staining of underclothes:** due to urethral discharge, sub-prepucial discharge or from exudative ulcers. • **Inguinal region:** swelling, ulcer, tinea, enlarged lymph nodes: look for number, location (horizontal or vertical group), single or multiple pointing, scars and puckering, signs of inflammation on the surface and surrounding region

- **Pubic area:** matting of hairs, pediculosis, folliculitis, or other skin lesions.
- **Scrotum:** erythema, skin lesions (Condyloma Lata), asymmetry, scrotal swelling.
- **Penis:** Size, oedema, deformity, phimosis, paraphimosis, autoamputation of genitals, foreign bodies, old scars, circumcision, retraction of prepuce.
- **Inspection of ulcers:** Number (single, multiple), superficial (erosions) or deep, edge (undermine/ punched out), margins (regular/irregular) and floor (presence of exudates, slough/granulation tissue)**.**
- **Meatal examination:** Erythema, discharge: thick, creamy, or mucopurulent, wart, ulcer.
- **Prepucial skin examination:** Erosions, ulcer, warts, posthitis or other skin lesions.
- **Coronal sulcus:** Ulcer, warts, pearly penile papules.
- **Glans penis examination:** Erosions, ulcers, warts, balanitis (candidial, trichomonial).
- **Shaft of penis:** papules, nodules, ulcers or other skin lesions, fibrosis.
- **Perianal examination:** Separate the buttocks with two hands for better visualization. Look for ulcer, macerated papules of condyloma lata, warts, discharge, patulous anus, hemorrhoids, fissures, fistula.

Palpation

- **Inguinal region:** Lymph nodes: tender or not, increased warmth, superficial or deep, discrete, or matted, free mobility or fixed to deeper structures, consistency: firm or soft and fluctuant. Rule out hernia.
- **Palpation of spermatic cords:** Tenderness, asymmetry, and thickening, varicoceles.
- **Palpation of scrotum:** Asymmetry, tenderness, consistency of testes and epididymis, transillumination for hydrocoele. Rule out hernia.
- **Palpation of ulcer at any site:** Tenderness, induration of the floor and edges, bleeding on maneuvering.
- **Meatal examination:** If no discharge, then milk the penis (urethra) gently from the base towards the urethral meatus to determine any discharge.

Anoscopy Examination

- Indicated if unprotected anal intercourse or ano-rectal discharge is reported.
- Should not be carried out if the client has painful perianal disease such as herpetic ulcers, fissures, or hemorrhoids.

2.3.3. Specific considerations for transgender persons

- The transgender persons are considered as special population and their risk assessment should be based on the current anatomy (regardless of gender presentation without assuming their anatomy or identity) and sexual behaviors based on history and sexual practices.
- The providers should use a gender-affirmative approach while conducting physical examination of a transgender person.
- Transgender persons who have undergone any/all gender affirming genital surgeries may have varying physical exam findings depending on the procedures performed.

- The current recommendations for management of confirmed STIs among transgender persons does not differ from those for cisgender persons. The screening intervals should be based on risk, with screening recommendations in every three months in individuals at high risk (multiple partners, condomless sex, transactional sex/sex work, sex under intoxication etc.).

2.3.3.1. Special Consideration for Vaginal Examination of a Transgender Women

- Not all transgender women have undergone gender affirmation genital surgeries. Moreover, those who have undergone surgery might have undergone different procedures in varying degrees. The genitals of those who have not undergone pelvic surgeries can be examined as per the procedure mentioned in box 2.6.
- Transgender women who have undergone vaginoplasty (creation of a vagina and vulva from existing genital tissue) do not have a cervix.
- The anatomy of a neovagina created in a transgender woman differs from a natal vagina. The neovagina is a blind cuff, lacks a cervix or surrounding fornices, and may have a more posterior orientation.
- Using an anoscope may be a more anatomically appropriate approach for a visual examination. The anoscope can be inserted, the trocar removed, and the vaginal walls visualized collapsing around the end of the anoscope as it is withdrawn.
- Anoscopic examination should be performed only if there is history of receptive anal sex.
- The following points need to be considered while examining a transgender woman who has undergone vaginoplasty:
    1. Screening for cervical HPV is not appropriate as cervix is absent.
    2. Anogenital warts (also known as condyloma acuminata) can be a presentation of HPV infection, with symptoms including neovaginal pain, post-coital bleeding, and visible warts.
    3. Some surgical approaches include the use of urethral tissue, which could result in mucosal infection such as chlamydia or gonorrhea. The risk of infection of intact, inverted penile skin with these organisms is unknown.
    4. The role of vaginal gonorrhea and chlamydia specimens, as opposed to urine testing only, is unknown in transgender women who have undergone penile inversion.
    5. The lesions for syphilitic chancre, herpes or chancroid may be present in the neovagina.
    6. Infectious prostatitis should be included in the differential diagnoses for sexually active transgender women with suggestive symptoms as prostate is not removed in vaginoplasty.

2.3.3.2. Special considerations for Pelvic Examination of a Transgender Men

- The use of testosterone in transgender men results in estrogen deficiency leading to vaginal atrophy similar to post-menopausal state in cisgender women.
- This atrophic vaginal tissue has poor tissue resilience and skin barrier function and increased susceptibility to altered microbial environment which increases the chances for bacterial vaginosis, cystitis as well as cervicitis.
- The use of lubricant and a small speculum may be appropriate for pelvic and speculum examination of transgender men with vaginas (sometimes referred to as “front holes” by transmasculine persons who do not want to use the term ‘vagina’).
- Pelvic inflammatory disease should be one of the differential diagnoses for transgender men with a uterus and fallopian tubes who are involved in vaginal intercourse and have lower abdominal pain or symptoms suggestive of pelvic inflammatory disease.

- Some transgender men retain vaginas after metoidioplasty (surgical creation of penis using existing genital tissue) and may require vaginal screening for STI based on sexual history.
- Anoscopic examination should be performed only if there is history of receptive anal sex.
- Anogenital warts can be a presentation of HPV infection, on the neo-phallus.
- Screening for cervical HPV should be performed in the presence of cervix.

2.3.3.3. Specific considerations for persons with intersex variations

- The persons with intersex variations are also considered as special population and their risk assessment should be based on the current anatomy (without assuming their anatomy or identity) and sexual behaviors based on the history and sexual practices.
- The providers should use a sensitive, non-judgmental approach while conducting physical examination of a person with intersex variations.
- Those individuals who have undergone any/all genital surgeries may have varying physical exam findings depending on the procedures performed.
- Anoscopic examination should be performed only if there is history of receptive anal sex or when presenting with ano-rectal discharge.

Note:

1. The sexual history should be elicited properly before examining a transgender person. The examination should be conducted as per the history of sexual act (vaginal/anal/oral) as provided by the client.
2. Transgender men and non-binary persons who still have a cervix should undergo cervical screening to help detect any cervical abnormalities. The screening should be conducted when the patient provides a history of vaginal sex (peno-vaginal, fingering, fisting etc.).
3. This opportunity should also be utilized to raise awareness and provide education on breast self-examination and breast cancer screening for transmen and women.

Glossary:

Terminology	Description
Sex	Sex refers to the biological make-up of a person, based on external and internal genital-reproductive parts, hormones, tissues, and chromosomes.
Gender	Gender is a social construct. Gender roles and behaviors are assigned by society and are learned rather than innate. These vary from society to society, and at different times in history.
Sexuality	Sexuality refers to someone's sexual feelings, thoughts, attractions, and behaviors towards other people.
Assigned sex at birth	The sex (male or female) assigned to a child at birth, most often based on the child's external genital anatomy. Also referred to as birth sex, natal sex, biological sex, or sex. AFAB means "assigned female at birth," while AMAB means "assigned male at birth.

Cisgender person	A term for people whose gender identity aligns to attributes generally associated with physical sex (associated by either the society or biological characteristics). That is, there is a match or congruence between gender identity and assigned sex at birth.
Transgender persons	An umbrella term for people whose gender identity does not necessarily align with attributes generally associated with the sex they were assigned at birth. This umbrella may include trans man, trans woman, *hijras, aravani, mangalmukhi, shivshakti and nupi manbi*. They may or may not use hormones or undergo surgery to have a body that is aligned with their self-affirmed gender identity. The transgender umbrella has also been expanded to include non-binary (NB or Enby) /agender/genderqueer individuals who identify with neither, multiple, or no gender identity.
Cross-dresser	A person who enjoys dressing in clothing typically associated with the other of the two socially sanctioned genders but may generally have no intent to live full-time as the other gender. Depending on the context, a person may also identify as transgender
Transgender man/ Transmasculine person	Refers to a person assigned female sex at birth but now identifies as a boy/man/male, regardless of whether they have had surgery. The term usually describes people assigned female at birth (AFAB) whose gender identity is partially or fully masculine or aligns with masculinity.
Transgender woman/ Transfeminine	Refers to a person who was assigned male sex at birth but now identifies as a girl/woman/female or feminine identity, regardless of whether they have had surgery.
Intersex	From a medical perspective, the term describes a group of congenital (or at-birth) conditions in which the reproductive organs, genitals, and/or other sexual anatomy do not develop according to traditional expectations for females or males. Intersex can also be used as an identity term for someone with one of these conditions, while the preferred term is “persons with intersex variations”
Gender-Affirmative Medical Interventions	
Gender-Affirmative (or Gender-Affirming)	An adjective used to refer to behaviors or interventions that affirm a transgender person’s desired gender identity (e.g., a physician using gender-affirmative hormone therapy for a transgender person).
Bottom surgery	A conversational phrase used by trans community members to describe gender-affirmative genital surgeries.
Metoidioplasty	A surgical procedure that works with existing genital tissue to form a phallus or new penis.

Penile construction/ phalloplasty	The construction of a penis generally includes several procedures that are often performed in tandem. They may include the following: a hysterectomy to remove the uterus, an oophorectomy to remove the ovaries, a vaginectomy to remove the vagina, a phalloplasty to turn a flap of donor skin into a phallus, a scrotoplasty to turn the labia majora into a scrotum, a urethroplasty to lengthen and hook up the urethra inside the new phallus, a glansplasty to sculpt the appearance of an uncircumcised penis tip, and a penile implant to allow for erection.
Vaginal construction/ vaginoplasty (or neovagina creation)	A procedure in which surgeons remove the penis and testes, if still present, and may use the penile and scrotal skin/tissue to construct vagina, clitoris, and labia.

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Chapter 3 Syndromic Case Management of STI and RTI

The purpose of comprehensive case management of STI and RTI is to provide appropriate treatment; achieve cure (wherever possible) and reduce infectiousness and risk of development of complications. This also involves risk reduction counsel to minimize risk-taking behavior and ensuring complete management of sexual partners. The following services are important for comprehensive case management of STI and RTI:

- Adequate assessment (history taking and clinical assessment)
- Appropriate diagnosis (whether syndromic, clinical, or etiological)
- Referral and screening for HIV, Syphilis, Hepatitis B & C (wherever possible)
- Appropriate advice and effective treatment
- Health Education and risk reduction counselling
- Adherence and follow-up counselling
- Promotion and provision for condom use
- Promotion and/or provision for other comprehensive interventions e.g., referral for vaccination against STI (wherever appropriate and feasible).
- Partner notification and their adequate management
- Adequate follow-up
- Need based referrals to STI laboratories

3.1. Approaches to STI and RTI Management

There are three common approaches used in the management of STI and RTI:

1. Traditional Clinical Approach (based on the use of clinical experience to identify signs and symptoms of a specific STI and its treatment)
2. Syndromic Approach (based on syndrome identification and treatment for the most-common organisms responsible for the syndrome)
3. Laboratory-assisted Approach (based on laboratory-based identification of organisms and their subsequent treatment)

The comparison of these approaches is mentioned in Table 3.1.

Table 3.1. Comparison of Approaches to STI and RTI Management

Traditional Clinical Approach	Syndromic Approach	Laboratory-assisted Approach
Interviews patient for symptoms	Interviews patient for symptoms – picks the relevant syndromic flowcharts	Interviews patient for symptoms
Clinical examination	Clinical examination using syndromic flowcharts as tools	Clinical examination
Use of clinical experience to identify signs and symptoms of a specific STI and RTI	Syndrome Identification	Collects samples for testing/ referrals to laboratories for testing
Treats patient for specific STI and RTI	Treats patient for the most-common organisms responsible for that syndrome	Treat organisms identified by the results of the laboratory tests
Education of patients for compliance and prevention, condom promotion, and notification and management of partners		

3.2. Syndromic Case Management (SCM)

A syndrome refers to a set of medical signs and symptoms which are correlated with each other and often associated with a particular disease/ group of diseases. An STI and RTI syndrome is a combination of symptoms and signs typically associated with sexually transmitted microorganisms or reproductive tract infection. Example: Genital ulcer disease syndrome could be due to *Treponema pallidum* (syphilis), Herpes simplex virus (genital herpes), *Haemophilus ducreyi* (chancroid) etc.

The aim of STI and RTI syndromic case management is to identify the syndrome correctly and manage them accordingly. Syndromic case management of STI and RTI is a public health approach where the health care provider uses the symptoms reported by the patient as well as the signs, he/ she observes during the clinical examination to identify the syndrome affecting the patient and provide treatment for all infections (if not, the most common ones) which could possibly cause that particular syndrome.

The syndromic approach has been considered as the backbone for STI and RTI services under National AIDS and STD Control Programme along with optimum utilization of available on-site diagnostics facilities (also known as Enhanced Syndromic Case Management or ESCM) without delaying the prompt treatment of patients. A health care provider who uses the syndromic case management approach will use terms such as vaginal discharge syndrome or lower abdominal pain syndrome.

Advantages of Syndromic Case Management (SCM)

- Fast – patient is diagnosed and put on treatment at first visit
- Highly effective for selective syndromes
- Relatively inexpensive since it minimizes the use of laboratory tests
- Scientifically tested
- Easy to learn and practice
- Easy integration in public health systems
- Standardized treatment regimens

- Useful for migratory and non-returning population

Limitations of Syndromic Case Management (SCM)

- Not useful in asymptomatic patients
- Over treatment, if patient have only one STI that causes a syndrome
- May be associated with decreased antibiotic susceptibility

The detailed list of STI and RTI syndromes and their possible causative organisms are presented in Table 3.2.

Table 3.2. STI and RTI Syndromes and their causative agents

Syndrome	Causative Agents	
	Male Genitalia & Reproductive System	**Female Genitalia & Reproductive System**
Urethral Discharge (UD) Syndrome	*Neisseria gonorrhoeae*, *Chlamydia trachomatis,* non-gonococcal and non-chlamydial pathogens, such as *Mycoplasma genitalium* and *Trichomonas vaginalis*	
Vaginal Discharge (VD) Syndrome		**Vaginal infection:** Bacterial vaginosis and infection with *Trichomonas vaginalis* and *Candida albicans* **Cervical infection:** *Neisseria gonorrhoeae, Chlamydia trachomatis, Trichomonas vaginalis*, genital herpes (especially primary HSV-2 infection) and *M. genitalium*
Lower Abdominal Pain (LAP)		*Neisseria gonorrhoeae*, *Chlamydia trachomatis* and Anaerobic bacteria
Genital Ulcer Disease (GUD) Syndrome	HSV 1 & 2, *Treponema pallidum* (syphilis) and *Chlamydia trachomatis* serovars L1–L3, causing lymphogranuloma venereum and *Haemophilus ducreyi* (chancroid), *Klebsiella granulomatis* (Donovanosis)	
Anorectal Discharge (ARD)	**Proctitis:** *Neisseria gonorrhoeae*, *Chlamydia trachomatis, M. genitalium* and HSV **Proctocolitis:** Shigella, Campylobacter, Salmonella, and cytomegalovirus and amoebiasis	
Painful Scrotal Swelling (PSS)	*Neisseria gonorrhoeae, Chlamydia trachomatis,* Enteric organisms (e.g., *E. coli*)	

The further sections describe the management of each STI/RTI syndrome. Each section details the clinical presentations and management of each syndrome along with limited details of laboratory diagnosis (wherever possible and feasible) preferred treatment options and syndromic management flowcharts. The detailed description of each infection and their laboratory testing is mentioned in Chapter 4 and 5.

3.2.1. Urethral Discharge Syndrome or UD Syndrome

The Urethral Discharge Syndrome is exclusively associated with discharge from penis. The signs of urethral discharge on examination can be present among persons without symptoms.

Causative Organisms	*Neisseria gonorrhoeae* (NG), *Chlamydia trachomatis* (CT), non-gonococcal and non-chlamydial pathogens, such as *Mycoplasma genitalium* (MG) and *Trichomonas vaginalis* (TV)
Clinical Presentations	• Discharge from urethra • Pain & discomfort during urination (dysuria) • Burning micturition • Increased frequency of micturition • Itching at the tip of urethra **Note:** At times, sub preputial discharges is mistaken as urethral discharge.
Examination Findings	• Redness and swelling of urethral meatus • Urethral discharge (scanty or copious; mucoid/mucopurulent/ purulent) • If urethral discharge is not seen, then gently massage the urethra from the ventral part of the penis towards the meatus and look for discharge (milking of urethra)
Laboratory Investigations (As per the availability)	**Microscopy** • Gram stain examination of the urethral smear can be conducted to demonstrate gram negative intracellular diplococci for gonorrhea. This will only confirm the presumptive diagnosis of gonorrhea. • Presence of more than 5 WBCs per oil immersion field (1000x) in the urethral smear or more than 10 WBCs per high power field in the sediment of the first void urine will be suggestive of non-gonococcal urethritis **Culture** • Culture of NG is still the gold standard method for performing antimicrobial susceptibility testing. **Molecular Diagnosis** • NAAT (Nucleic Acid Amplification Test) is the current gold standard for detecting NG and CT. • NAAT has the highest sensitivity for *T. vaginalis* and *M. genitalium.* However, these tests are not widely available. **Note:** HIV & Syphilis screening and counseling services should be offered to all clients visiting healthcare facilities for STI and RTI services.

Treatment	• Treat people with UD Syndrome (including persons with complaints of urethral discharge) for uncomplicated NG and CT to ensure same-day treatment (see Table 3.3). • Provide dual therapy for NG and CT to all cases of UD Syndrome. • After 7 days, if there is history of poor compliance or possibility of reinfection, retreat for NG & CT. If not, treat the recurrent or persistent cases using treatment failure regimens (see Table 3.3). • Refer the unresolved cases of urethral discharge to a centre with laboratory capacity for testing of NG, CT, TV and MG and appropriate antimicrobial susceptibility testing. • Refer the other unresolved cases for UD syndrome (when urethral discharge is absent) to Surgery/ Internal Medicine OPD for further assessment and management of other reasons for urethritis. • The syndromic management for urethral discharge is mentioned in Syndromic Management (SM) Flow Chart 1 and 2.
Partner Management	• All sexual partners of patients with UD syndrome whose last sexual contact with the patient was within 60 days before the onset of symptoms or diagnosis of infection should be evaluated and treated. • Treat all female partners on same lines after ruling out pregnancy and history of allergies (Table 3.3).
Follow-up	After seven days, • To document symptomatic cure • To record results of HIV and syphilis screening • In case of persistence, to assess whether it is due to treatment failure or re-infection and follow appropriate management. • Manage for treatment failure in persistent/ recurrent cases
Key Counselling Messages	• Educate and counsel clients and their sexual partner(s) regarding STI and RTI, safer sex practices and importance of taking complete treatment • Treat partner(s) as per syndromic recommendations • Advise sexual abstinence during the course of treatment • Provide condoms, educate about their correct and consistent use. • Schedule return visit after 7 days.

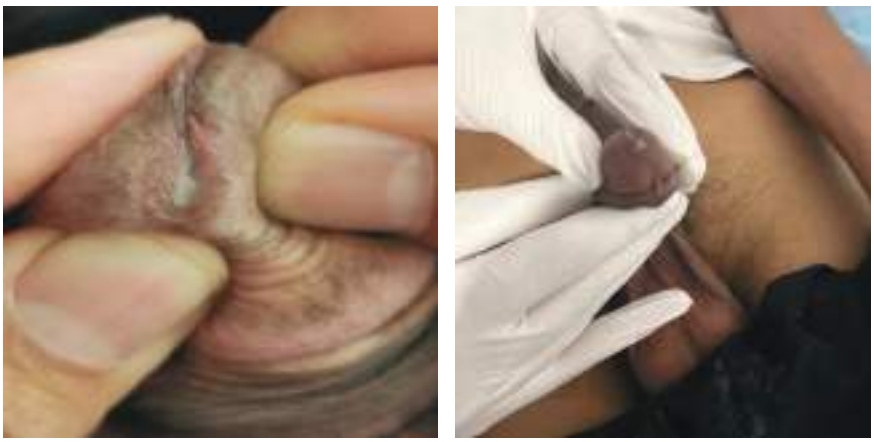


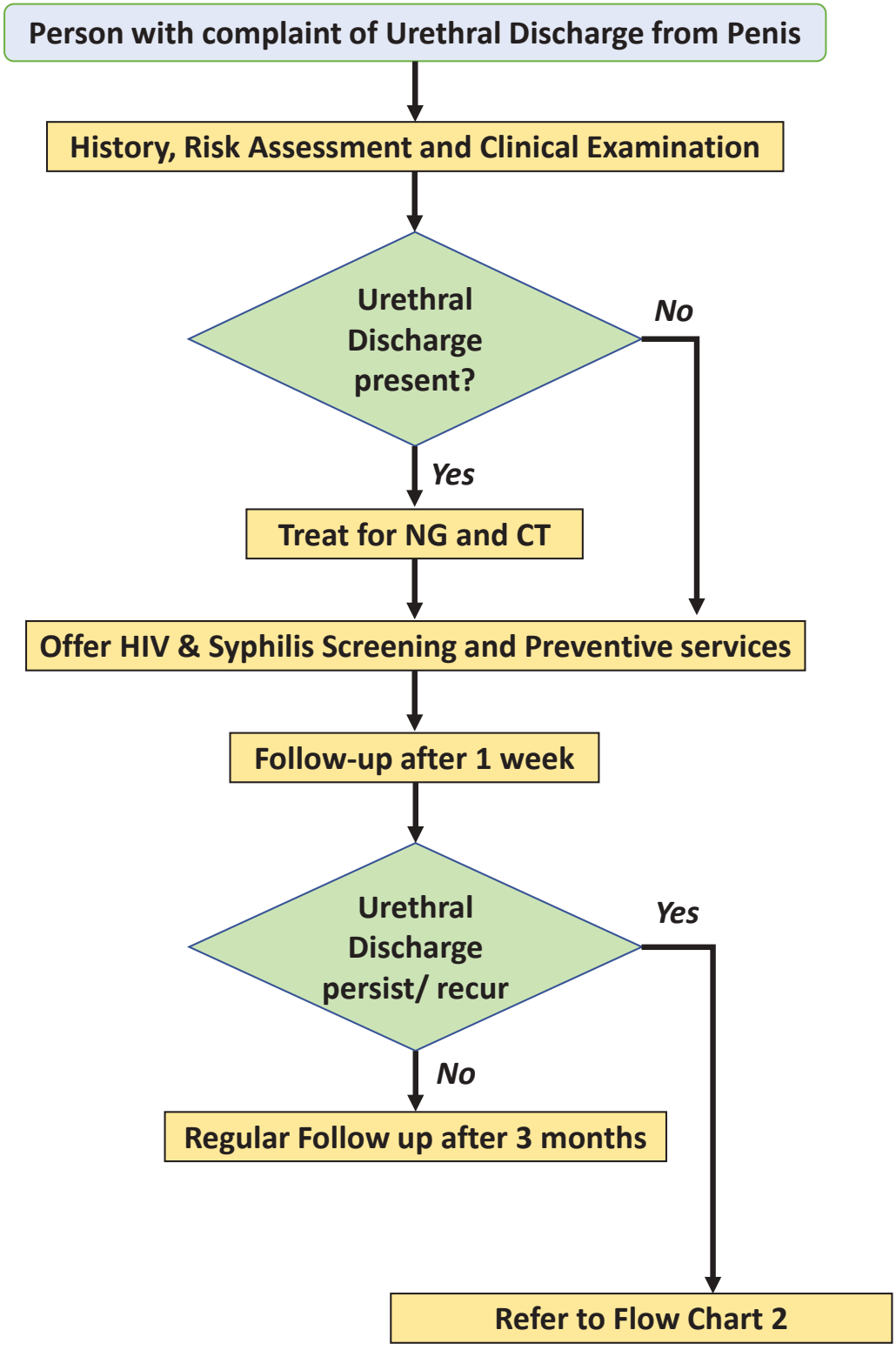
Image 3.1 & 3.2. Urethral Discharge (Purulent)

Table 3.3. Recommended Treatment Options for Urethral Discharge Syndrome

Infections Covered	First Line Options	Effective Substitutes
For Uncomplicated UD Syndrome		
Neisseria gonorrhoeae	**Ceftriaxone 500 mg**, intramuscularly, single dose	**Cefixime 800 mg**, orally, single dose
Chlamydia trachomatis	**Doxycycline 100 mg**, orally, twice daily for 7 days	**Azithromycin 1 gram**, orally, single dose, *or* **Erythromycin 500 mg**, orally, 4 times a day for 7 days, *or* **Ofloxacin 200–400 mg**, orally, twice a day for 7 days
Additional options for persistent/ recurrent cases (Treatment Failure Regimen)		
Trichomonas vaginalis	**Metronidazole 2 grams**, orally, single dose, *or* **Secnidazole 2 grams**, orally, single dose, *or* **Tinidazole 2 grams**, orally, single dose	**Metronidazole 400**, twice daily for 7 days
Mycoplasma genitalium	**Doxycycline 100 mg** orally 2 times/day for 7 days, followed by M**oxifloxacin 400 mg** orally once daily for 7 days	**Azithromycin 500 mg**, orally on day 1, then 250 mg daily on days 2–5

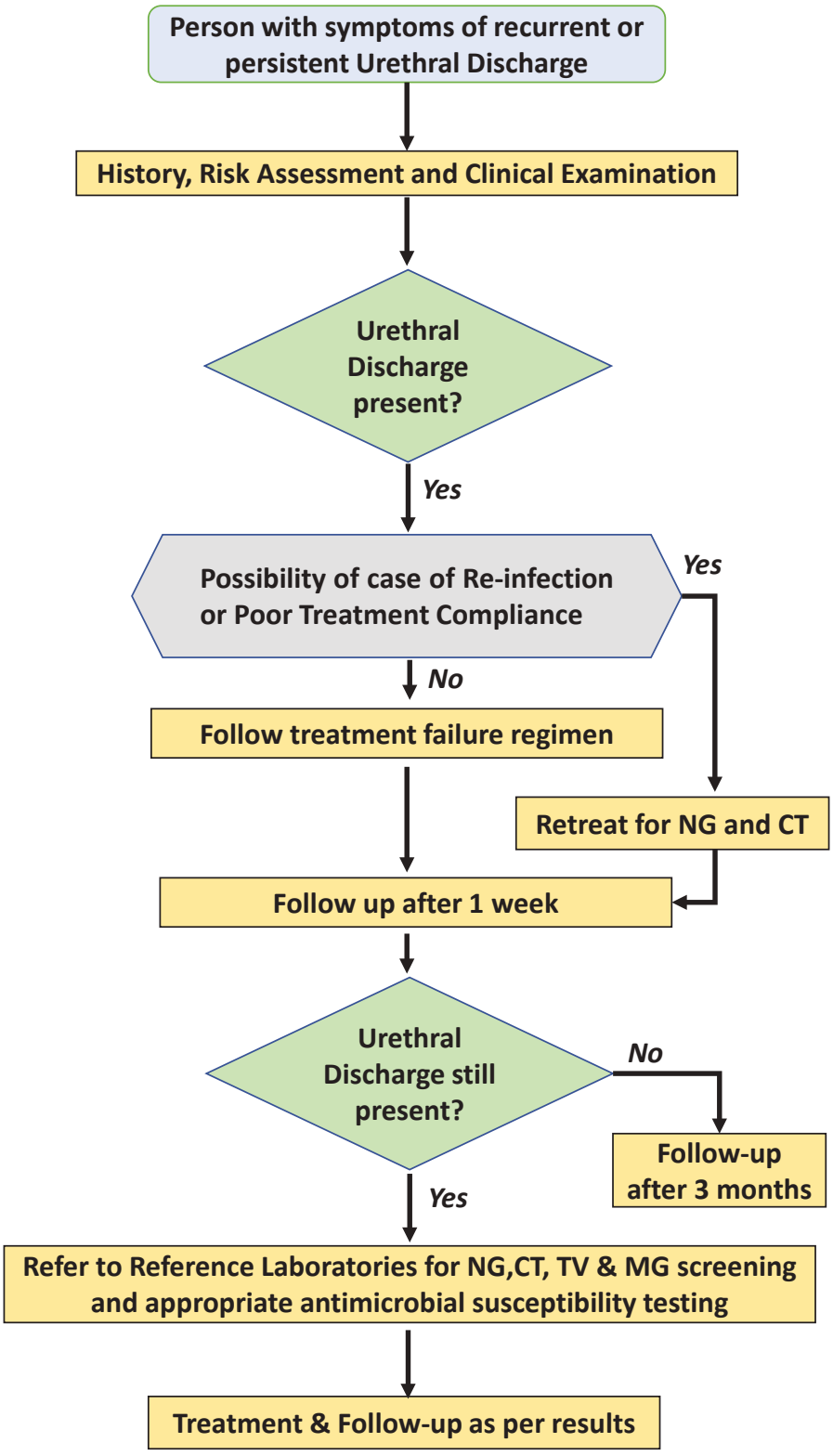
Note:

- The quinolones (like ofloxacin, ciprofloxacin), and doxycycline are contraindicated in pregnant women.
- People taking metronidazole should be cautioned to avoid alcohol.
- The efficacy of metronidazole regimen is equivalent to Secnidazole regimen in the management of *Trichomonas vaginalis*. However, the Secnidazole regimen is preferred in the National Programme due its better tolerability and minimum side-effects.



SM Flow Chart 1. Management of uncomplicated Urethral Discharge

Note: Partner notification and management services should be offered to patients at every visit



SM Flow Chart 2. Management of recurrent or persistent Urethral Discharge

3.2.2. Vaginal Discharge Syndrome or VD Syndrome

Vaginal discharge can be physiological. Normal vaginal discharge is usually clear, white, or off-white in colour, with minimal odor, pH ranging between 3.5-5.5, floccular in consistency, with a texture that changes throughout menstrual cycle. Factors like pregnancy, use of oral contraceptive pills, ovulation is associated with the change in texture and amount of vaginal discharge. The following characteristics may signify abnormal vaginal discharge:

- Abnormal increase in amount
- Change in the color of the discharge (against the normal pattern)
- Foul or unpleasant odor
- Change in texture or consistency of the discharge (against the normal pattern)
- Association with irritation, itching or pain in or around vagina

The most common causes of vaginal discharge syndrome are infection with *Candida albicans*, bacterial vaginosis and *Trichomonas vaginalis*. Among post-pubertal women, *Neisseria gonorrhoeae* and *Chlamydia trachomatis* infect the endocervix rather than the vagina, and can thus cause a cervical discharge, which may manifest as vaginal discharge. However, these two pathogens are less commonly associated with exclusive vaginal discharge. In the context of STI, it should be emphasized that vaginal discharge more reliably indicates vaginal infections but poorly predicts cervical infection caused by *Neisseria gonorrhoeae* and/or *Chlamydia trachomatis*. The symptoms of cervicitis have been clubbed under VD Syndrome from the perspective of presentation and management. There should be an attempt to conduct adequate risk assessment and clinical examination of all clients presenting with vaginal discharge syndrome for STI and RTI to minimize the over treatment.

Causative Organisms	**Vaginitis:** *Trichomonas vaginalis* (Trichomoniasis) and/or *Candida albicans* (Candidiasis) and/or infection with *Gardnerella vaginalis*, Mobiluncus spp., *Mycoplasma hominis*, *Ureaplasma*, other fastidious and uncultivated anaerobes e.g., Bacteroides spp. (Bacterial vaginosis) **Cervicitis:** *Neisseria gonorrhoeae, Chlamydia trachomatis, Trichomonas vaginalis*, genital herpes (especially primary HSV-2 infection) and *M. genitalium*
Clinical Presentations	• Abnormal vaginal discharge (may be foul smelling) • Genital itching • Burning micturition (dysuria) • Increased frequency of micturition • Pain during sexual intercourse (dyspareunia) • Any ulcer, swelling on the vulva or inguinal region • Lower backache • Abnormal vaginal bleeding

Examination Findings	Per speculum examination is essential to differentiate between vaginitis and cervicitis. **Vaginitis:** The classic clinical presentations of the various causes of vaginitis are mentioned below (may not be differentiated). **1. Trichomoniasis** • greenish-yellowish, frothy discharge • vulval erythema and oedema • vaginal walls may be erythematous. • cervix may have punctate hemorrhages- "strawberry cervix" **2. Candidiasis** • curdy white discharge (creamy and thick), may not always curd-like (sometimes described as cottage-cheese-like in character) but can vary from watery to homogeneously thick. • vulval erythema and excoriation • vulva/ labial swelling • pus-filled pimple like (pustulopapular) lesions peripheral to the erythematous area of the vulva • normal cervix **3. Bacterial Vaginosis** • Thin, white, homogenous discharge externally on the posterior fourchette of the vulva or the labia (may be adherent to the vaginal wall) • Cervix is usually normal in appearance **Cervicitis:** These infections may be present without any clinically evident abnormality of the cervical os. If an abnormality is present at the cervical os, it would be a mucus or purulent discharge or inflammation and friability of the cervical os. The cervix may bleed on contact. **Note:** • Mixed infections may present with atypical discharge • Conduct per speculum examination in all cases of VD syndrome followed by bimanual pelvic examination to rule out pelvic inflammatory disease
Laboratory Investigations (As per the availability)	**Rapid Tests** • 10% KOH preparation for *Candida albicans* (C alb) • Vaginal pH is normally between 4 and 4.5 among most women with candidiasis whereas pH of more than 4.5 is indicative of bacterial vaginosis. • An amine odor (dead fish odor) can be sensed spontaneously or after addition of a drop of 10% potassium hydroxide to vaginal fluid on a slide (Whiff test) which is suggestive of bacterial vaginosis. **Microscopy** • Wet mount microscopy of the discharge for *Trichomonas vaginalis* • A Gram stain of vaginal secretions from the walls of the vagina demonstrates gram-positive Candida species. • Gram stain of vaginal smear for clue cells (vaginal epithelial squamous cells coated with coccobacilli with absence of rods of lactobacilli) seen in bacterial vaginosis

	• Gram stain of endocervical smear to detect gonococci. Though this test has low sensitivity, it is highly specific. • A finding of leucorrhea (>10 WBCS per high-power field on microscopic examination of vaginal fluid) has been associated with chlamydial and gonococcal infection of the cervix. In the absence of inflammatory vaginitis, leucorrhea might be a sensitive indicator of cervical inflammation with a high negative predictive value. While this test is highly sensitive, it is not specific and can potentially lead to over treatment. **Molecular Diagnosis** • NAAT has become the recommended gold standard technology to diagnose and screen populations for NG & CT. **Note:** HIV & Syphilis screening and counseling services should be offered to all clients visiting healthcare facilities for STI and RTI services
Treatment	If per speculum examination is possible, • Treat all persons with evidence of cervicitis for NG & CT. • If vaginal discharge is present without the evidence of cervicitis, treat for BV, TV, and C alb. • If microscopy is possible, treat as per the results of microscopy (even in the absence of related symptoms). If speculum examination is not possible, • Treat all persons presenting with abnormal vaginal discharge for NG, CT, TV, BV, and C alb. • In absence of vaginal discharge, treat all persons at high-risk of STI for NG and CT, if not treated in past 6 months (presumptive treatment). Management of persistent/ recurrent cases: • All the persistent/recurrent cases should receive per speculum examination. • If there is history of poor compliance or possibility of reinfection, retreat for NG and CT. • *Mycoplasma genitalium* is a common reason for persistent cervicitis and all persistent cases should be treated through two-stage therapy. • The recurrent cases of vaginitis should be evaluated for recurrent trichomoniasis, recurrent bacterial vaginosis and complicated vulvovaginal candidiasis and should be managed as per the treatment protocols mentioned in Chapter 4. • All the persons with unresolved infections should be referred to the facilities with laboratory capacity for further diagnosis and management. The recommended treatment regimens are mentioned in Table 3.4. Refer to Syndromic Management Flow Chart 3 & 4.

Partner Management	In cases of vaginitis due to BV and Candidiasis: • Partner management is not required. • If partner is symptomatic, treat using syndromic management protocols In cases of *Trichomonas* infection and cervicitis: • Treat all sexual partners in the last 60 days
Follow-up	After 7 days, • To document symptomatic cure • To record results of tests done for HIV and syphilis. • If symptoms/signs persist assess whether it is due to lack of treatment compliance, treatment failure or re-infection and advise prompt management and further referrals.
Key Counselling Messages	• Educate and counsel clients and their sexual partner(s) regarding STI and RTI, safer sex practices and importance of taking complete treatment. • Provide condoms, educate about their correct and consistent use. • Schedule return visit after 7 days.

Table 3.4. Recommended Treatment Options for Vaginal Discharge Syndrome

Infections Covered	First Line Options	Effective Substitutes	Option for pregnant and breastfeeding women
For Cervicitis (Treat for NG & CT)			
Neisseria gonorrhoeae	**Ceftriaxone 500 mg**, intramuscularly, single dose	**Cefixime 800 mg**, orally, single dose	Both Regimens are recommended.
Chlamydia trachomatis	**Doxycycline 100 mg**, orally, twice daily for seven days	**Azithromycin 1 gram**, orally, single dose, *or* **Erythromycin 500 mg**, orally, 4 times a day for 7 days, *or* **Ofloxacin 200–400 mg**, orally, twice a day for 7 days	**Azithromycin 1 gram,** orally, single dose, *or* **Erythromycin 500 mg,** orally, 4 times a day for 7 days

For Vaginitis (Treat for TV & BV and C alb)			
Trichomonas vaginalis	**Metronidazole 2 grams**, orally, single dose, *or* **Secnidazole 2 grams**, orally, single dose, *or* **Tinidazole 2 grams**, orally, single dose	**Metronidazole** **400 mg,** orally, twice daily for 7 days, *or* **Tinidazole 500 mg orally,** twice daily for 5 days	**Metronidazole 200 mg,** orally, 3 times a day for 7 days, *or* **Metronidazole gel** 0.75%, one full applicator (5 grams) intravaginally, twice a day for 7 days
Bacterial vaginosis	**Secnidazole 2 grams**, orally, single dose, *or* **Metronidazole 2 grams,** orally, single dose	**Metronidazole** **400 mg,** orally, twice daily for 7 days, *or* **Clindamycin 300 mg,** orally, twice daily for 7 days	**Metronidazole 200 mg,** orally, 3 times a day for 7 days, *or* **Metronidazole gel** 0.75%, one full applicator (5 grams) intravaginally, twice a day for 7 days, *or* **Clindamycin 300 mg,** orally, twice daily for 7 days
Candida albicans	**Clotrimazole vaginal tablet, 100 mg,** inserted at night for 7 nights, *or* **Miconazole vaginal pessaries, 200 mg** inserted at night for 3 nights, *or* **Fluconazole 150 mg (or 200mg),** orally, single dose	**Nystatin, 200,000-unit vaginal tablet,** inserted at night for 7 nights	**Clotrimazole vaginal tablet 100 mg** inserted at night for 7 days, *or* **Miconazole 200 mg vaginal pessaries** inserted once daily for 3 days, *or* **Nystatin, 200,000-unit vaginal tablet,** inserted at night for 7 nights

Note:

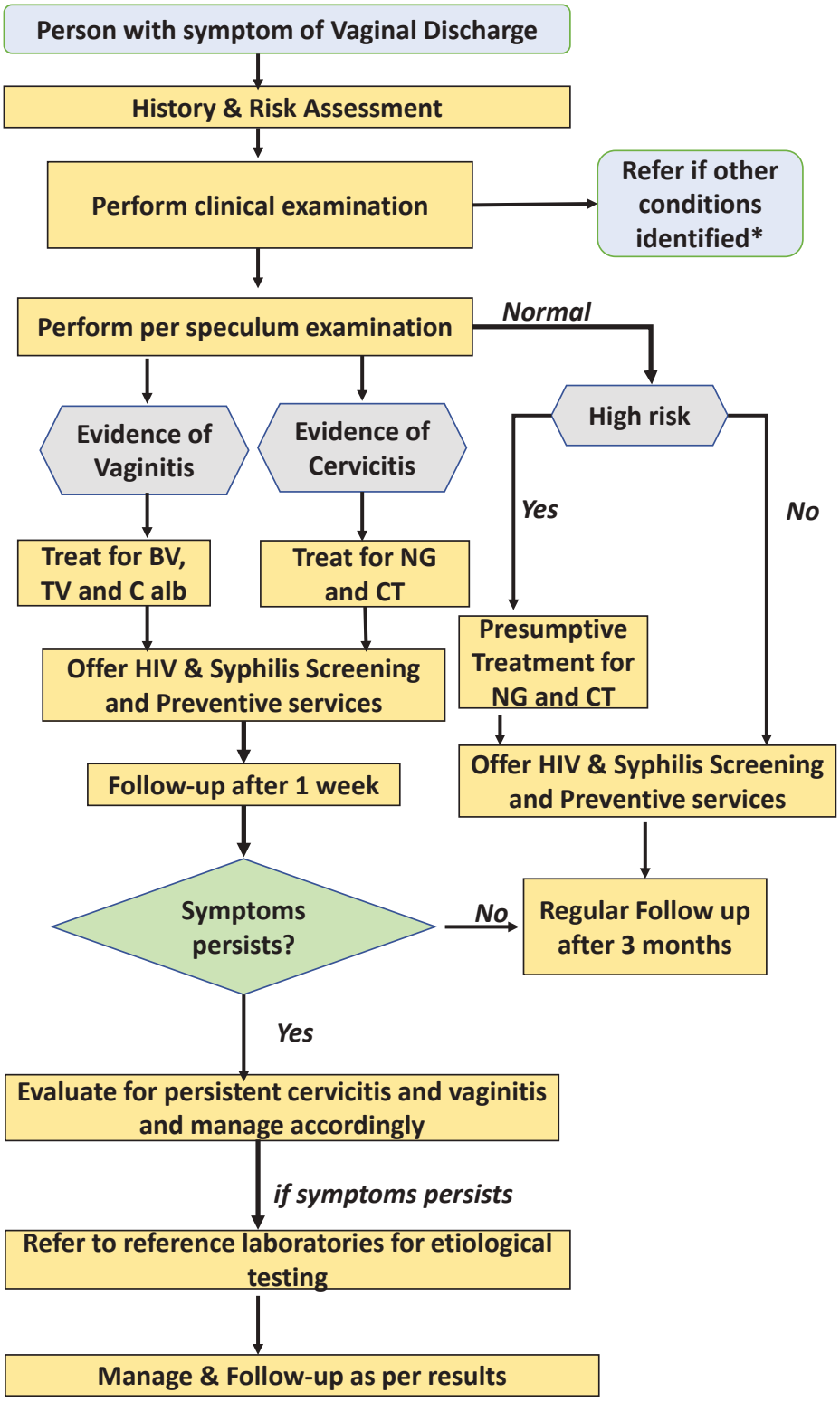
- The Dual Therapy for NG and CT should be provided to all cases of VD Syndrome (if physical and/or per speculum examination is not possible) and all cases of cervicitis (as evident on per speculum examination).
- The use of doxycycline, ofloxacin, secnidazole and tinidazole is contraindicated in pregnant and breastfeeding women
- Although metronidazole crosses the placenta, no evidence of teratogenicity or mutagenic effects among infants has been reported in multiple cross-sectional, case-control, and cohort studies of pregnant women[1],[2],[3]. The current evidence indicate that metronidazole therapy poses low risk during pregnancy and therefore, can be recommended even in first trimester of pregnancy.
- The efficacy of metronidazole and tinidazole regimens is equivalent to secnidazole regimen in management of *Trichomonas vaginalis* and Bacterial Vaginosis. However, the secnidazole regimen is preferred in the National Programme due its better tolerability and minimum side-effects.

Image 3.3. Vaginal Discharge

1 Burtin P, Taddio A, Ariburnu O, Einarson TR, Koren G. Safety of metronidazole in pregnancy: a meta-analysis. Am J Obstet Gynecol 1995; 172:525–9. PMID:7856680 https://doi. org/10.1016/0002-9378(95)90567-7

2 Piper JM, Mitchel EF, Ray WA. Prenatal use of metronidazole and birth defects: no association. Obstet Gynecol 1993; 82:348–52. PMID:8355932

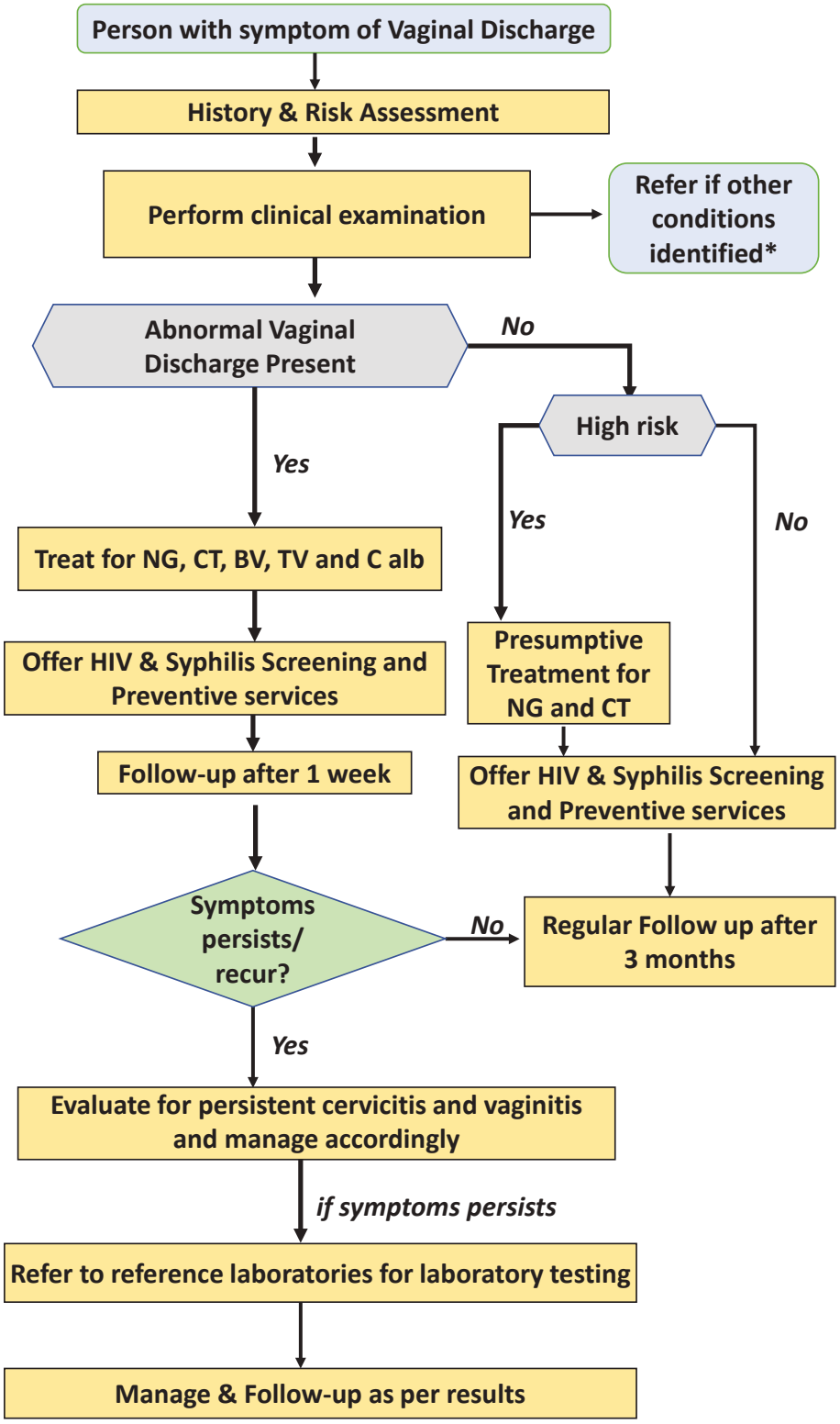
3 Sheehy O, Santos F, Ferreira E, Berard A. The use of metronidazole during pregnancy: a review of evidence. Curr Drug Saf 2015; 10:170–9. PMID:25986038 https://doi.org/10.2174/1574886310021505151 24548



SM Flow Chart 3: Management of Vaginal Discharge Syndrome (when speculum examination is available and acceptable)

**Warts, abnormal growth, or any other skin condition*

Note: Partner notification and management services should be offered to patients at every visit



SM Flow Chart 4: Management of Vaginal Discharge Syndrome (when speculum examination is neither available nor acceptable)

**Warts, abnormal growth, or any other skin condition*

Note: Partner notification and management services should be offered to patients at every visit

3.2.3. Lower Abdominal Pain (LAP)

Lower abdominal pain (LAP) syndrome comprises of a spectrum of inflammatory disorders of the upper female genital tract, including any combination of endometritis, salpingitis, tubo-ovarian abscess, and pelvic peritonitis (commonly known as Pelvic Inflammatory Disease or PID).

Causative Organisms	• *Neisseria gonorrhoeae* • *Chlamydia trachomatis* • Mobiluncus spp., *Mycoplasma hominis*, Gardnerella, anaerobic bacteria (Bacteroides sp. gram positive cocci) - bacteria associated with bacterial vaginosis
Clinical Presentations	• Lower abdominal pain • Fever • Vaginal discharge • Menstrual irregularities like heavy, irregular vaginal bleeding • Dysmenorrhea • Dyspareunia • Dysuria, tenesmus • Lower backache • History of use of Intrauterine Device (IUD) or illegal abortion
Examination Findings	• General examination: temperature, pulse, blood pressure • Per speculum examination: vaginal/cervical discharge, congestion, or ulcers • Per abdominal examination: lower abdominal tenderness or guarding • Pelvic examination: (uterine/adnexal tenderness & cervical movement tenderness) **Note:** A urine pregnancy test should be done in all women suspected of having PID to rule out ectopic pregnancy.
Diagnosis	• Diagnosis is usually based on clinical findings. • Empirical treatment should be initiated in sexually active young women and other women at risk for STI if they are experiencing pelvic or lower abdominal pain, if no cause for the illness other than LAP/PID can be identified, and if one or more of the following minimum criteria are present on pelvic examination: • Cervical motion tenderness • Uterine tenderness • Adnexal tenderness • One or more of the following additional criteria can be used to enhance the specificity of the diagnosis: Fever ➢ Abnormal cervical or vaginal muco-purulent discharge ➢ Presence of signs of lower genital tract inflammation (predominance of leucocytes in vaginal secretions, cervical exudates, or cervical friability) ➢ Presence of abundant numbers of WBC on saline microscopy of vaginal fluid.

	➢ Elevated erythrocyte sedimentation rate ➢ Elevated C-reactive protein ➢ Laboratory documentation of cervical infection with NG & CT.
Differential diagnosis	• Ectopic pregnancy • Twisted ovarian cyst • Ovarian tumor • Appendicitis • Abdominal tuberculosis
Treatment	• The treatment should involve therapy for NG, CT, and anaerobic bacteria (Refer to Table 3.5). • PID can be a serious condition. Refer the client to the hospital if the patient does not respond to treatment within 3 days and even earlier if her condition worsens. • Women with lower abdominal pain with any of the following conditions should be immediately referred for surgical or gynecological assessment: • missed or overdue period • recent delivery, abortion, or miscarriage • abdominal guarding and/or rebound tenderness • abnormal vaginal bleeding in excess of spotting • abdominal mass • detection of a suspected cervical lesion. • Pregnant woman suspected to have PID should be referred (because of the high risk for maternal morbidity and preterm delivery) to a higher centre for hospitalization and treatment with a parenteral regimen which would be safe in pregnancy. • Consumption of alcohol should be avoided by patients during metronidazole therapy and for at least 48 hours after completion of treatment. (The treatment recommendations are mentioned in Table 3.5. Refer to SM Flow chart 5)
Partner Management	• Male sexual partners of women with LAP/PID should be examined and treated if they had sexual contact with the patient during the 60 days preceding the patient's onset of symptoms. • Patients should be instructed to abstain from sexual intercourse until the completion of treatment and resolution of symptoms. • Treat all male partners for UD as per syndromic recommendations. • Provide condoms, educate on correct and consistent use • Inform about the complications and sequelae, if left untreated

Follow-up	• Schedule return visit after 3, 7 and 14 days: • To ensure compliance • To document symptomatic cure • To record results of tests done for HIV and syphilis. • Patients should demonstrate substantial clinical improvement (e.g., defervescence, reduction in direct or rebound abdominal tenderness, reduction in uterine, adnexal, and cervical motion tenderness) within 3 days after initiation of therapy with subsequent follow-ups on day 7 and 14. • Patients who do not improve within this period usually require hospitalization, additional diagnostic tests, and surgical intervention. • If symptoms/signs persist, assess whether it is due to lack of treatment compliance or treatment failure or re-infection and advise prompt referral.
Key Counselling Messages	➢ Educate and counsel client and sex partner(s) regarding STI and RTI, safer sex practices and importance of taking complete treatment. ➢ Provide condoms, educate about their correct and consistent use. ➢ Schedule return visit after 3 days.

Table 3.5. Recommended Treatment Options for Lower Abdominal Pain

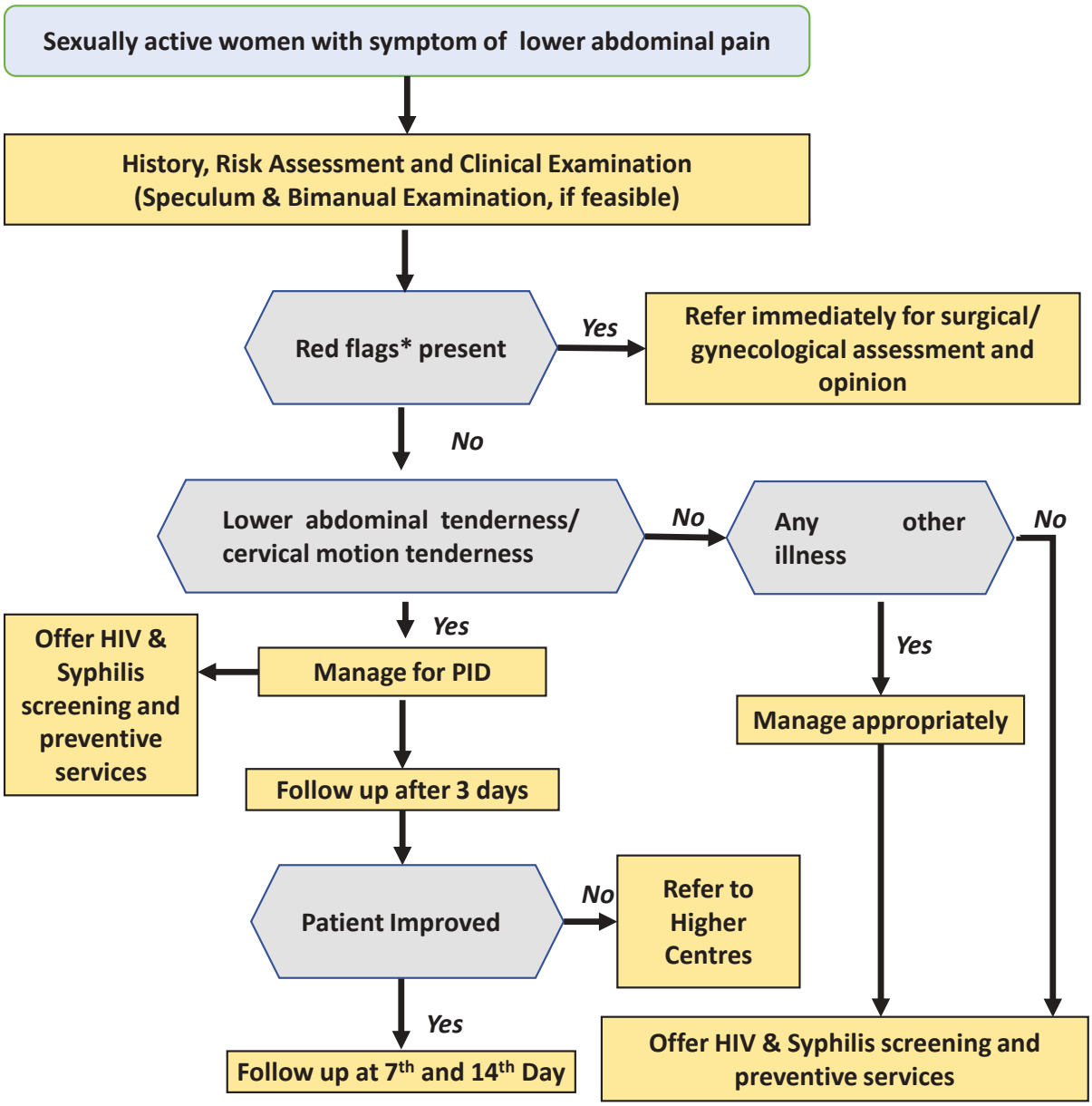
Infections Covered	First Line Options	Effective Substitutes
Neisseria gonorrhoeae (NG)	**Ceftriaxone 500 mg**, intramuscularly, single dose	**Cefixime 800 mg**, orally, single dose
Chlamydia trachomatis (CT)	**Doxycycline 100 mg**, orally, twice daily for 14 days	**Azithromycin 1 gram,** orally, single dose, *or* **Erythromycin 500 mg,** four times daily for 14 days (to be given only if gonorrhea therapy did not include azithromycin)
Anaerobes	**Metronidazole 400 mg**, orally, twice daily for 14 days	

Note:

- ➢ Doxycycline 100 mg oral dose twice a day for 14 days should be preferred over Azithromycin 1 gm single oral dose for management of LAP syndrome /PID.
- ➢ The following regimen is recommended as the choice of treatment under the National Programme:

Cefixime 800 mg single dose + Doxycycline 100 mg BD for 14 days + Metronidazole 400 mg BD for 14 days

1 National Guidelines on Elimination of Vertical Transm ission of HIV and Syphilis.2024. Ministry of Health and Family Welfare, Government of India.



***Red Flags**

- Missed/overdue period
- Recent delivery/abortion/miscarriage
- Abdominal guarding and/or rebound tenderness
- Abnormal vaginal bleeding
- Abdominal mass

SM Flow Chart 5. Management of Lower Abdominal Pain

3.2.4. Genital Ulcer Disease Syndrome or GUD Syndrome

Ulcer refers to breaks in the skin or mucosa and may even present as sores or vesicles. Anogenital ulcers refer to those located on the genital or anal areas and may be painful or painless. Genital Ulcer Disease or GUD syndrome encompasses all anogenital ulcers.

Causative Organisms	• Herpes Simplex Virus (HSV 1 & 2) • *Treponema pallidum* (Syphilis) • *Chlamydia trachomatis* serovars L1–L3 (Lymphogranuloma venereum) • Haemophilus ducreyi (Chancroid) • *Klebsiella granulomatis* (Granuloma inguinale or Donovanosis)
Clinical Presentations	• Solitary painless (primary syphilis) & painful (chancroid) ulcer • Cluster of vesicular lesions on the genital or perianal area (indicative of genital herpes) • Localized itching and mild/ burning pain • Swelling of lymph nodes • Recurrent lesions or history of similar lesions in the past (indicative of genital herpes)
Examination Findings	• Presence of genital ulcer- single or multiple • Possible characteristics of respective ulcers: • Painless ulcer (usually single) with firm lymph nodes – Syphilis • Painless ulcer (usually multiple) without involvement of inguinal lymph nodes - Granuloma inguinale • Transient painless penile ulcer with painful, enlarged inguinal lymph nodes/ bubo – LGV • Painful ulcers (usually multiple) and associated with painful inguinal bubo – Chancroid • Presence of vesicles/genital erosions/multiple ulcers – HSV Clinical manifestations of genital ulcer disease may be altered or mixed in the presence of HIV infection.
Laboratory Investigations (As per the availability)	• Serological investigation (type-specific) for HSV 1 & 2. • Tzanck smear for multinucleated giant cells and NAAT for HSV infection • Non treponemal (e.g., RPR, VDRL) & Treponemal (e.g., TPHA, TPPA, TP-ELISA) tests for syphilis • Bacteriological culture for chancroid • Leishman stain/ Giemsa stain for donovanosis **Note:** • Refer all clients for HIV and Syphilis counselling and screening services. • A negative serological test for syphilis when anogenital ulcers have been present for less than three weeks does not definitively exclude syphilis, since antibodies may not yet be present to be detected by a serological test for syphilis.

Treatment	• Initiation of syndromic management of GUD is recommended on the same day as per the characteristics of ulcer. • Treat for herpes if the ulcer is recurrent or vesicular. The management varies as per the history of recurrence of the infection. ➢ Primary Infection: First episode of vesicular ulcers ➢ Recurrent Outbreaks: The following could be the line of management in recurrent outbreaks: ➢ **Episodic Therapy:** It is recommended at the onset of every outbreak. ➢ **Suppressive Therapy:** It is recommended for individuals with 4–6 or more recurrent episodes per year or in episodes with severe symptoms or that cause distress.
	• Suppressive therapy may be discontinued after a maximum of one year and the frequency of recurrence should be reassessed. Patients who continue to have unacceptably high rates of recurrence may be restarted on treatment. • Dose adjustments are recommended for valaciclovir and famciclovir but not for acyclovir in PLHIV and immunosuppressed individuals (as detailed in Chapter 4). • Treat all patients with GUD (when the ulcer is not vesicular or no history of recurrence) for syphilis and chancroid. The treatment recommendations are mentioned in Table 3.6. Refer to SM Flow chart 5. **Syphilis in Pregnancy:** The pregnant women will be managed and followed-up as per the updated National Guidelines on Elimination of Vertical Transmission of HIV & Syphilis (2024), India[1]. **Herpes in Pregnancy:** The pregnant women should be asked history of genital herpes and examined carefully for herpetic lesions. • Women without symptoms or signs of genital herpes or its prodrome can deliver vaginally. • Women with genital herpetic lesions at the onset of labour should be delivered by caesarean section to prevent neonatal herpes. • Acyclovir may be administered orally to pregnant women with first episode genital herpes or recurrent herpes. **Inguinal Bubo:** If inguinal buboes are present, manage as per the guidelines mentioned in section 3.2.4.1. Also, Table 3.6 & SM Flowchart 6 can be referred to treat LGV when there is no-response or emergence of enlarged and/or painful inguinal lymph nodes after 1 week of treatment of GUD.
Partner Management	• Partners should be treated for syphilis and chancroid with same regimen. No partner treatment for herpes is recommended in the absence of active episode/ lesions. • Assess and treat all partners who are in contact with client in last 3 months prior to the onset of ulcer.

[1] National Guidelines on Elimination of Vertical Transmission of HIV and Syphilis.2024. Ministry of Health and Family Welfare, Government of India.

Follow-up	• Follow-up after seven days, • To document symptomatic cure • To record results of HIV and syphilis screening • If symptoms/signs persist assess whether it is due to lack of treatment compliance or treatment failure/non-response. • If there is no-response to treatment or enlargement of inguinal lymph nodes within 7 days, additionally treat for LGV. Refer all cases of enlarged and/or painful inguinal lymph nodes to a General Surgeon for further assessment. • Follow up of individuals treated for syphilis and found non-reactive for syphilis while screening: • Individuals should be re-tested after 4 weeks. If the test turns out to be positive, ensure complete treatment. • Follow up of individuals treated (under syndromic management) for syphilis and found reactive for syphilis: • Ensure complete treatment as per the stage of syphilis. • Individuals should be followed up after 3 months for treatment monitoring. • During each follow up visit, conduct clinical examination, qualitative, and semi-quantitative non-treponemal tests (RPR/VDRL) with tires. • Retreatment should be undertaken if there is serological evidence of re-infection. • To ensure that results are comparable, follow up test should be performed by using the same non-treponemal kit that was used initially from the same laboratory. • Suppressive therapy for herpes should be provided under closed supervision and regular follow-ups (once in every 3 months).
Key Counselling Messages	• Educate and counsel clients and their sexual partner(s) regarding STI and RTI, safer sex practices and importance of taking complete treatment • Treat partner(s) as per syndromic recommendations • Advise sexual abstinence during the course of treatment/ lesions heal (whichever is later). • Provide condoms, educate about their correct and consistent use • Schedule return visit after 7 days

Table 3.6. Recommended Treatment Options for Genital Ulcer Disease Syndrome

Infections Covered	First Line Options	Effective Substitutes	Option for pregnant and breastfeeding women and people younger than 16 years
Genital Herpes- **Primary infection**	**Acyclovir 400 mg,** orally, 3 times a day for 7 days, *or* **Acyclovir 200 mg,** orally, 5 times a day for 7 days	**Valaciclovir 500 mg,** twice a day for 7 days, *or* **Famciclovir 250 mg,** orally, 3 times a day for 7 days	The dosage is the same as for primary infection in non-pregnancy.
Genital Herpes- **Recurrent episodes of herpes (episodic therapy)**	**Acyclovir 800 mg,** orally, twice daily for 5 days, *or* **Acyclovir 400 mg,** orally, 3 times a day for 5 days, *or* **Acyclovir 800 mg,** 3 times a day for 2 days	**Valaciclovir 500 mg,** twice daily for 5 days, *or* **Famciclovir 250 mg,** orally, twice daily for 5 days	**Acyclovir 400 mg,** orally, 3 times a day for 5 days, *or* **Acyclovir 800 mg,** orally, twice daily for 5 days, *or* **Acyclovir 800 mg,** 3 times a day, for 2 days
Genital Herpes- **Recurrent episodes of herpes (Suppressive therapy)**	**Acyclovir 400 mg,** orally, twice daily, *or* **Valaciclovir 500 mg,** once daily	**Famciclovir 250 mg,** orally, twice daily (Famciclovir 500 mg, twice daily for people living with HIV or immunocompromised)	**Acyclovir 400 mg,** orally, twice daily*
Early Syphilis (treatment for primary, secondary, and early latent** syphilis)	**Benzathine penicillin 2.4 million units,** intramuscularly in a single dose (divided into 1.2 million units in each buttock following a test dose)	**Doxycycline 100 mg,** orally, twice a day for 14 days, *or* **Erythromycin 500 mg,** 4 times a day for 14 days, *or* **Ceftriaxone 1-2 gm** per day, intravenously or intramuscularly for 10-14 days (titrated as per the discretion of the doctor)	Follow National Guidelines on Elimination of Vertical Transmission of HIV & Syphilis (2024)

Late Syphilis (treatment for late latent*** and tertiary syphilis) (This option is also recommended for treatment of syphilis of unknown duration)	**Benzathine penicillin 2.4 million units** by intramuscular injection, once weekly for 3 consecutive weeks (divided into 1.2 million units in each buttock)	**Doxycycline 100 mg,** orally, twice daily for 28 days, *or* **Procaine penicillin 1.2 million units** by intramuscular injection, once daily for 20 consecutive days	
Chancroid	**Tab. Azithromycin** 1 gm orally single dose	**Ceftriaxone 250 mg** single dose intra-muscularly	**Tab. Azithromycin** 1 gm orally single dose
Lymphogranuloma Venereum (LGV)	**Doxycycline 100 mg**, orally, twice daily for 21 days# *or* **Azithromycin 500 mg**, 2 tablets once a week for 3 weeks	**Erythromycin 500 mg,** four times daily for 14 days (may be extended as per the assessment)	**Azithromycin 500 mg**, 2 tablets once a week for 3 weeks

*It is recommended to initiate suppressive therapy in all cases with recurrent episodes of genital herpes at 36th week of pregnancy
** Syphilis < 1 year of duration
*** > 1 year of duration
#Preferred in cases of Inguinal Bubo or painful/enlarged inguinal lymph nodes.

Note:
Injection Benzathine Penicillin G (BPG) is the preferred choice of treatment for syphilis. The skin test should be performed before administration of BPG. The details on desensitization of penicillin for cases with history of allergic reaction is mentioned in Chapter 4.

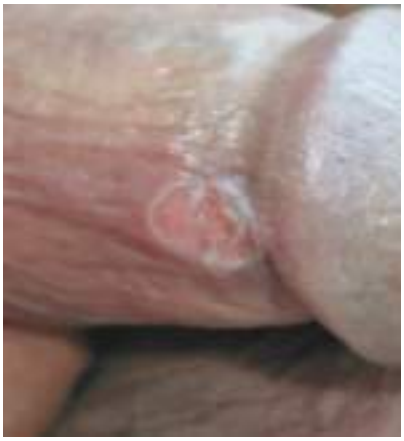


Image 3.4. Primary Syphilitic Ulcer (Chancre) at Penis

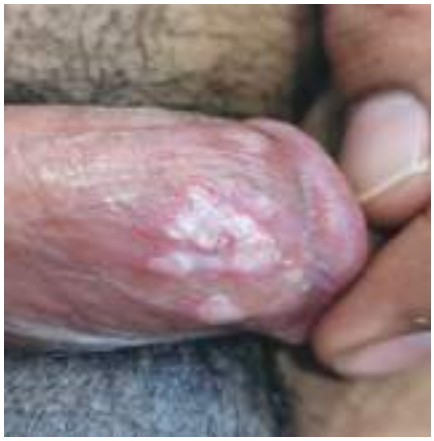
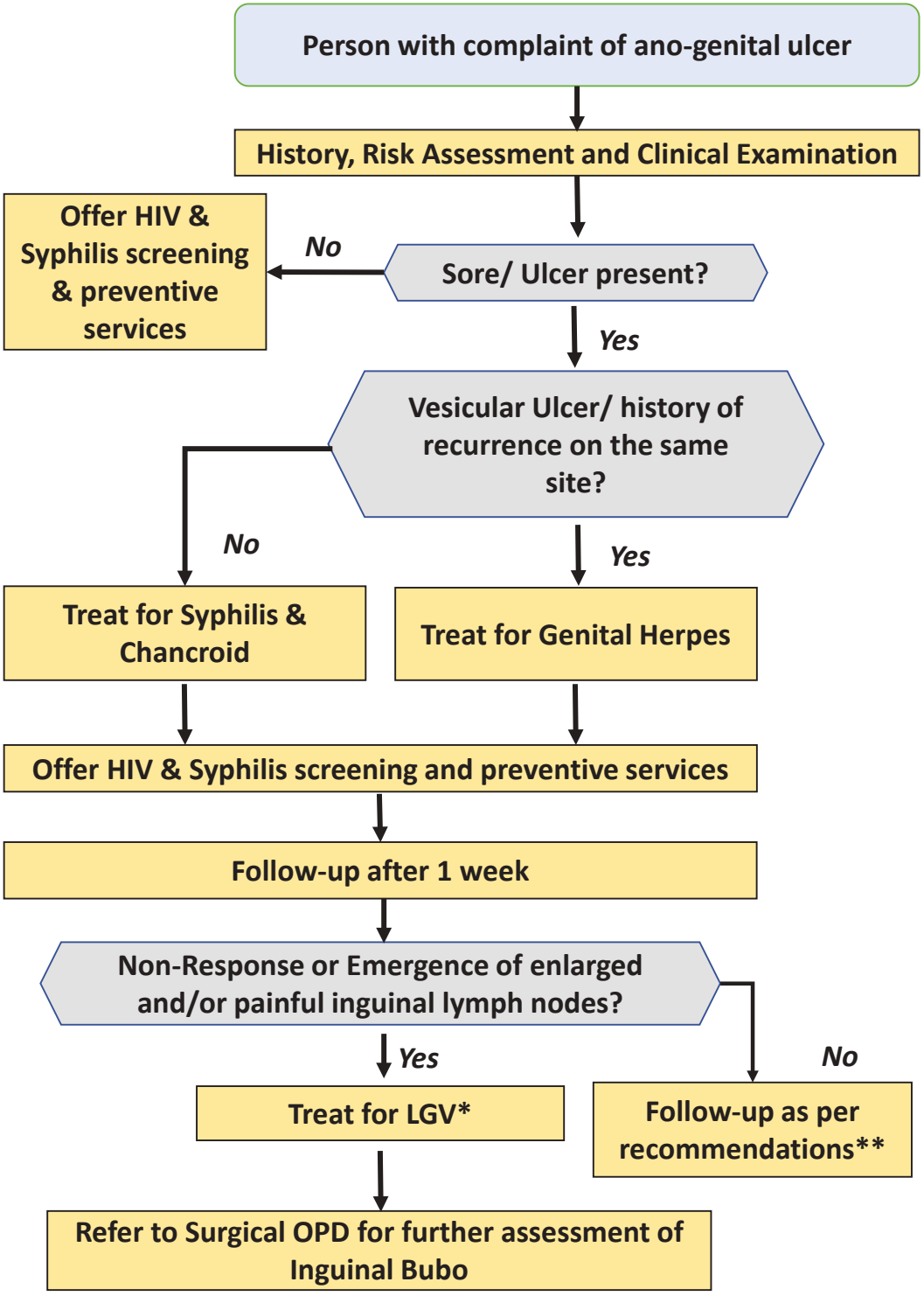


Image 3.5. Herpetic Ulcers-Penis

Image 3.6. Herpetic Ulcers - Female External Genitalia



SM Flowchart 6. Management of Genital Ulcer Disease Syndrome

**If Doxycycline regimen (Doxycycline 100 mg twice a day orally for 14 days) is used for treatment of syphilitic ulcer (for primary syphilis), then extend the treatment till 21 days to complete treatment for LGV. If Doxycycline regimen is not used, then provide a complete treatment for 21 days (Doxycycline 100 mg twice a day orally for 21 days)*

***Follow-up and treatment as per the stage of syphilis (if treatment is provided for syphilitic ulcer)*

3.2.4.1. Inguinal Bubo

Inguinal bubo, an enlargement of the lymph nodes in the groin area, is rarely the sole manifestation of an STI and is usually found together with other genital ulcer diseases (mostly with LGV infection). Local and systemic infections other than STI (e.g., infections of the lower limb) can also cause swelling of inguinal lymph nodes.

Clinical Presentations	• Swelling in inguinal region (which may be painful) • Preceding history of genital ulcer • Systemic symptoms like malaise, fever
Examination Findings	• Localized enlargement of lymph nodes in the groin (tender and/or fluctuant) • Inflammation of skin over the swelling • Presence of sinus (may be single/multiple) • Oedema of genitals and lower limbs • Associated UD and/or GUD syndrome
Differential Diagnosis	• Tuberculosis lymphadenitis/ Scrofuloderma • Filariasis • Any acute infection of skin of pubic area, genitals, buttocks, anus, and lower limbs can also cause inguinal swelling • Malignancy
Treatment	• Treat all isolated cases of Inguinal Bubo (with history of high-risk behavior) for LGV (as mentioned in Table 3.6). • Do not incise and drain bubo at the primary health centre, even if it is fluctuant, as there is a high risk of a fistula formation and chronicity. If a bubo becomes fluctuant always aspirate. • In severe cases with vulval oedema in females, surgical intervention in the form of vulvectomy may be required for which they should be referred to a higher centre. • Treat as per the syndromic guidelines for GUD and UD as per the findings of the assessment. • Offer HIV and syphilis screening and counselling services • Refer all cases of Inguinal Bubo to surgical OPD for ruling out other causes and further management. • If malignancy or tuberculosis is suspected refer to higher centre for biopsy.
Follow-up	After 7, 14 and 21 days: • To document symptomatic relief and confirm if the patient underwent referral assessment. • To record results of HIV and syphilis screening.

3.2.5. Anorectal Discharge or ARD Syndrome

Anorectal symptoms and anorectal STI are prevalent among individuals who engage in receptive anal sexual intercourse. Few examples of high-risk sexual behavior associated with anorectal infections are:

- Receptive anal sex
- Oro-anal sex (anilingus or rimming)
- Fisting (inserting a hand into the rectum)
- Fingering (touching another's genitals or anus using fingers or digital-anal penetration)
- Nudging (unprotected penile-anal external contact without penetration)
- Dipping (partly inserting or briefly inserting the penis into the anus without a condom, followed by immediate withdrawal)
- Sharing sex toys

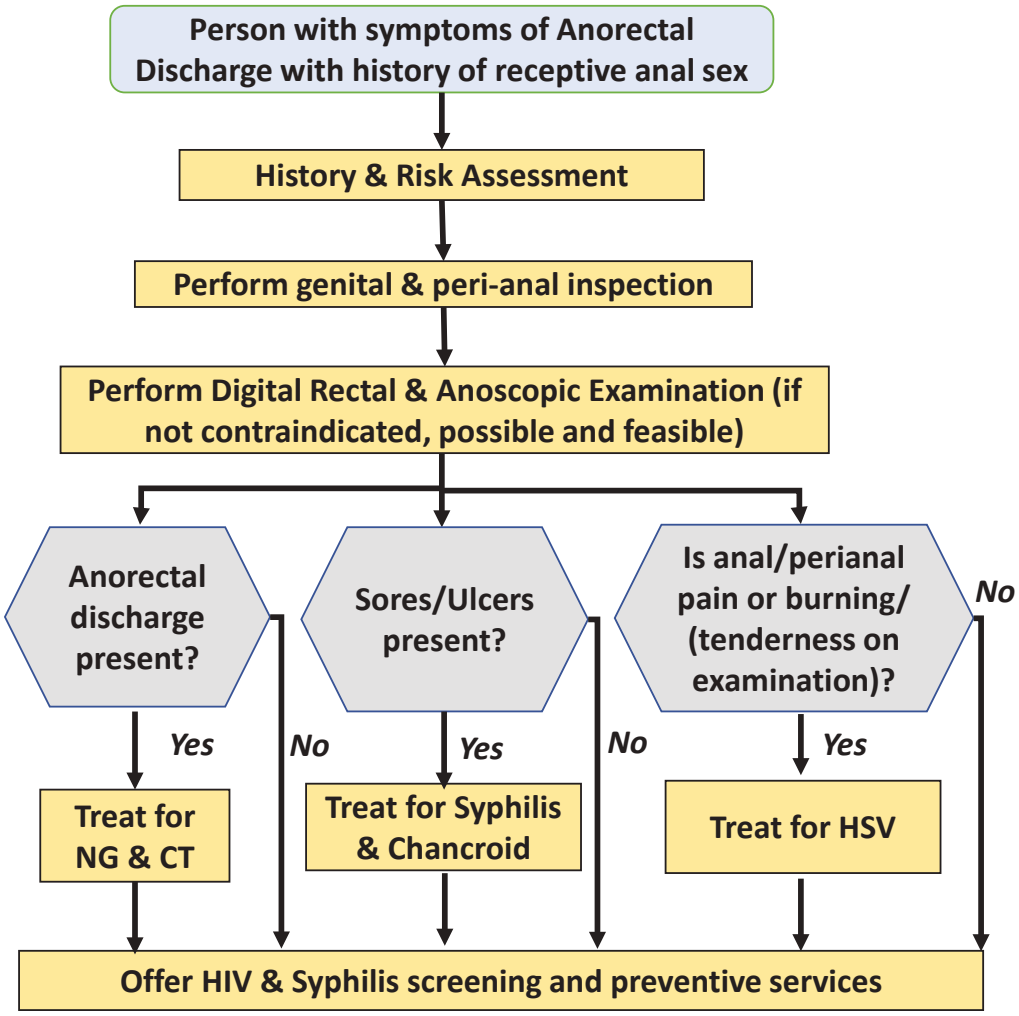
Causative Organisms	• Proctitis: *Neisseria gonorrhoeae*, *Chlamydia trachomatis, M. genitalium* and HSV • Proctocolitis: Shigella, Campylobacter, Salmonella, and cytomegalovirus and amoebiasis
Clinical Presentations	• Anorectal pain, itching, discharge, and bleeding • Sensation of rectal fullness • Tenesmus (difficulty in passing stools) • Mucus streaking of stools.
Examination Findings	• Before examining the patient, establish that the person engages in receptive anal sex. • Visual examination may reveal ulcers, excoriations, vesicles, and discharge. • Digital rectal and anoscopic examination should not be carried out if the client has painful perianal/anal disease such as herpetic ulcers, fissures, or hemorrhoids. • May demonstrate bloody, mucoid and/or purulent discharge
Laboratory Investigations (As per the availability)	• Gram-staining for NG • NAAT also performs well for anorectal samples for NG, CT and HSV. • For anorectal samples among MSM, chlamydia genovar testing for lymphogranuloma venereum could be done. • Offer HIV & Syphilis screening and counselling services to all patients
Treatment	The following are the recommendations for persons with history of receptive anal sex: • Treat for NG and CT if discharge is present. • Treat for genital herpes if anorectal pain/burning or tenderness on examination is present. • Further follow syndromic management guidelines for GUD if anorectal ulcer is present. • Refer the unresolved cases of anorectal discharge to a centre with laboratory capacity to test for NG and CT and antimicrobial testing for NG. • *M. genitalium* can be a possible reason for unresolved anorectal discharge and therefore, may be covered in unresolved cases. • Additionally refer all unresolved cases to a surgeon for further assessment. The treatment recommendations are mentioned in Table 3.7. Refer to SM Flowchart 7.

Partner Management	• All sexual partners of the patients should be evaluated and treated accordingly for UD and GUD syndrome.
Follow-up	After seven days, • To document symptomatic cure • To record results for HIV and syphilis screening • If symptoms/signs persist assess whether it is due to lack of treatment compliance or treatment failure or re-infection and advise prompt referral.
Key Counselling Messages	• Treat partner(s) as per syndromic recommendations • Advise sexual abstinence during the course of treatment/ lesions heal (whichever is later). • Provide condoms, educate about their correct and consistent use • Schedule return visit after 7 days

Table 3.7. Recommended Treatment Options for Anorectal Discharge Syndrome

Infections covered	First-line options	Effective substitutes
N. gonorrhoeae	**Ceftriaxone 500 mg,** intramuscularly, single dose	**Cefixime 800 mg,** orally, single dose
C. trachomatis	**Doxycycline 100 mg** orally, twice daily, for 7 days, *or* **Doxycycline 100 mg** orally, twice daily for 21 days **(if LGV is suspected or confirmed).**	**Erythromycin 500 mg,** orally, 4 times a day for 14 days
Chancroid (if ulcer present)	**Tab. Azithromycin** 1 gm orally single dose	**Ceftriaxone 250 mg** single dose intra-muscularly
Syphilis (if ulcer present)	**Benzathine penicillin 2.4 million units** intramuscularly, single dose People with Late Syphilis/unknown duration: administer the same dose at weekly intervals for a total of three doses	**Doxycycline 100 mg** orally, twice daily for 14 days *or* **Erythromycin 500 mg** 4 times a day, orally, for 14 days Extend treatment to 28 days in cases of Late Syphilis/ unknown duration
Genital Herpes	**Primary genital herpes:** **Acyclovir 400 mg,** orally, 3 times a day for 7 days, *or* **Acyclovir 200 mg,** 5 times a day for 7 days	**Primary genital herpes:** **Valaciclovir 500 mg,** orally, twice daily for 7 days

	Recurrent infection: **Acyclovir 400 mg,** orally, 3 times a day for 5 days, *or* **Acyclovir 800 mg,** orally, 3 times a day for 2 days, *or* **Acyclovir 800 mg,** orally, 2 times a day for 5 days	**Recurrent infection:** **Valaciclovir 500 mg,** twice daily for 3 days
	Suppressive therapy for recurrent herpes: **Acyclovir 400 mg,** orally, twice daily, *or* **Valaciclovir 500 mg,** once daily	**Suppressive therapy for recurrences:** Famciclovir 250 mg, orally, twice daily (Famciclovir 500 mg, twice daily for people living with HIV or immunocompromised)



SM Flowchart 7. Management of Anorectal Discharge Syndrome

3.2.5.1. LGV Proctitis

Proctitis is the main manifestation of rectal LGV infection which can be characterized by severe symptoms of anorectal pain, haemopurulent discharge and bleeding per rectum. Pain is the most important symptom in combination with constipation and perianal ulcerations to suspect LGV in ARD Syndrome. Please note that the same symptomatology might also be seen with Monkey pox cases.

The most ideal consideration to suspect LGV proctitis would be to perform light microscopic examination objectifying inflammation (>10 PMNL per HPF) on rectal swabs from symptomatic patients in combination with the above-mentioned symptoms. The diagnosis of LGV can be confirmed by the detection of genovar-specific *C. trachomatis* DNA. For sensitive and specific detection of LGV genovar (L1, L2 and L3, including subvariant)-specific *C. trachomatis* DNA, a two-step procedure is recommended:

- Detection of *C. trachomatis* DNA/RNA in suspected clinical samples using NAAT
- If *C. trachomatis* DNA/RNA is detected, LGV genovar specific *C. trachomatis* DNA should be detected from the same specimen

Recommendations: If patients with history of receptive anal sex presents with pain, constipation, and peri-anal ulceration or other symptoms of LGV proctitis, complete treatment of LGV should be preferred. The recommended regimen is as follows:

Doxycycline 100 mg orally, twice daily for 21 days

3.2.6. Painful Scrotal Swelling or PSS Syndrome

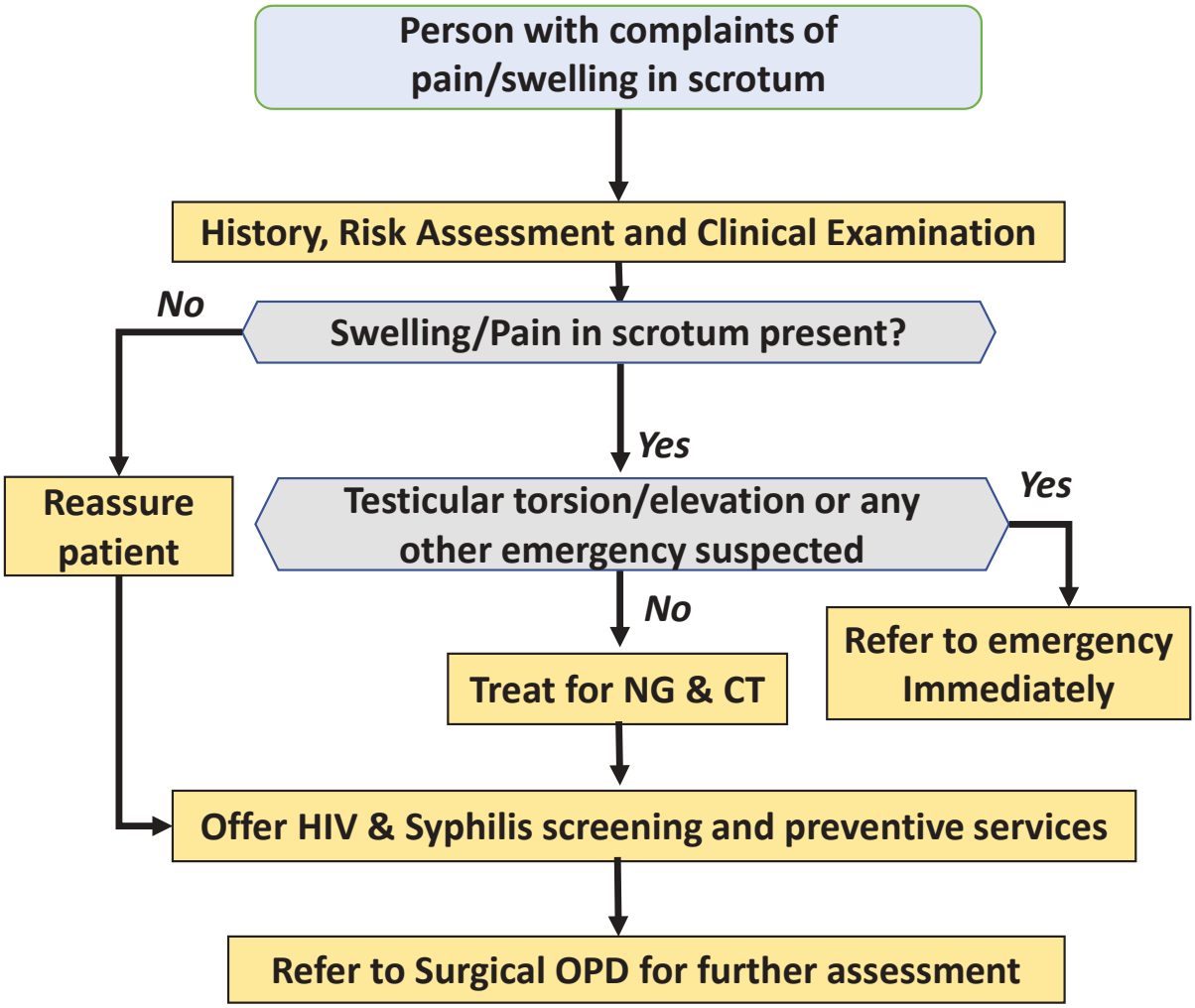
Scrotal swelling can be caused by trauma, a tumor, torsion of the testis or epididymitis. Inflammation of the epididymis is usually accompanied by pain, oedema, and erythema and sometimes by urethral discharge, dysuria and/or increased frequency. Epididymitis could be acute or chronic (≥ 6-weeks history of symptoms). The adjacent testis is often also inflamed (orchitis), producing epididymo-orchitis. The sudden onset of unilateral swollen scrotum may be caused due to trauma or testicular torsion and requires immediate referral. Non STI-related causes of PSS include tuberculosis, filariasis, coliforms, pseudomonas, mumps virus infection. If not treated, STI-related epididymitis may lead to infertility.

Causative Organisms (STI)	• *Neisseria gonorrhoeae* • *Chlamydia trachomatis* • Enteric organisms (e.g., *E. coli*) **Note:** Sexually transmitted enteric organisms can also be the causative agents in MSM who are insertive partners or heterosexual men who are involved in unprotected penetrative anal sex
Clinical Presentations	• Swelling and pain in scrotum • Pain or burning while passing urine • Urethral discharge • Systemic symptoms like malaise, fever
Examination Findings	• Swelling in scrotum • Redness and edema of overlying skin and local raised temperature • Tenderness of epididymis and vas deferens • May be associated with UD/GUD/IB

Laboratory Investigations (As per the availability)	• Associated tests for UD/GUD • Offer HIV and Syphilis screening and counselling services to all patients
Treatment	• Treat for NG and CT • Additionally treat for enteric organisms when there is history of anal sex (as insertive partner) • Supportive therapy to reduce pain (bed rest, scrotal elevation with T-bandage and analgesics) • Refer to surgical OPD for further assessment and management. The treatment recommendations are mentioned in Table 3.8. Refer to SM Flowchart 8.
Partner Management	• All sexual partners of patients with PSS syndrome, whose last sexual contact with the patient was within 60 days before onset of symptoms or diagnosis of infection in the patient, should be evaluated and treated.
Follow-up	After seven days, • To document symptomatic relief and confirm if the patient underwent referral assessment. • To record results of HIV & syphilis screening
Key Counselling Messages	• Educate and counsel clients and their sexual partner(s) regarding STI an RTI, safer sex practices and importance of taking complete treatment. • Treat partner(s) as per syndrome recommendations • Advise sexual abstinence during the course of treatment/ lesions heal (whichever is later). • Provide condoms, educate about their correct and consistent use • Schedule return visit after 7 days

Table 3.8. Recommended Treatment Options for Painful Scrotal Swelling

Infections Covered	First Line Options	Effective Substitutes
Neisseria gonorrhoeae	**Ceftriaxone 500 mg**, intramuscularly, single dose	**Cefixime 800 mg**, orally, single dose
Chlamydia trachomatis	**Doxycycline 100 mg**, orally, twice daily for seven days	**Azithromycin 1 gram**, orally, single dose, *or* **Erythromycin 500 mg**, orally, 4 times a day for 7 days, *or* **Ofloxacin 200–400 mg**, orally, twice a day for 7 days
Enteric Organisms	**Levofloxacin 500 mg** orally once daily for 10 days	



SM Flowchart 8. Management of Painful Scrotal Swelling

3.3. STI color-coded kits under NACP

Under NACP, STI color-coded kits are distributed as a part of syndromic case management approach to streamline and simplify the diagnosis and management of common STI/RTI. Each kit consists of pre-packaged medications tailored for specific STI/RTI syndromes. The contents are determined based on the most common causative organisms and the recommended treatment protocols. Each kit is color-coded to correspond with specific STI/RTI syndrome, ensuring quick identification and appropriate use by healthcare providers. The STI color-coded kits have proven to be an effective strategy for controlling the spread of these infections and improving public health outcomes in India. The details of STI-color coded kits for syndromic case management of STI and RTI under NACP is mentioned in Table 3.9.

Table 3.9. STI-color coded kits under NACP

Kit	Composition	Targetted Syndrome
Kit – 1 (Grey)	Tab. Azithromycin 1000 mg and Tab. Cefixime 800 mg single dose	➢ Urethral Discharge Syndrome ➢ Vaginal Discharge Syndrome (for cervicitis) ➢ Painful Scrotal Swelling ➢ Presumptive treatment (PT)
Kit 2 (Green)	Tab. Secnidazole 2000 mg and Tab. Fluconazole 150 mg single dose	• Vaginal Discharge Syndrome (for vaginitis)
Kit 3 (White)	Inj. Benzathine penicillin G 2.4 MU and Tab. Azithromycin 1000 mg single dose Disposable syringe 10 ml with 21-gauge needle and Sterile water 10 ml	• Genital Ulcer Disease Syndrome (for Syphilis and Chancroid)
Kit 4 (Blue)	Tab. Doxycycline 100 mg (28 capsules as twice/day dose for 14 days) and Tab. Azithromycin 1 g single dose	• Genital Ulcer Disease Syndrome (for Syphilis and Chancroid when unavailability or history of allergy to BPG)
Kit 5 (Red)	Tab. Acyclovir 400 mg (21 tablets as three times/ per day dose for 7 days)	• Genital Ulcer Disease Syndrome (for Herpetic Ulcers)
Kit 6 (Yellow)	Tab. Cefixime 800 mg single dose and Tab. Metronidazole 400 mg (28 tablets as twice/day dose for 14 days) and Cap. Doxycycline 100 mg (28 capsules as twice/ day dose for 14 days)	• Lower Abdomen Pain • PID
Kit 7 (Black)	Tab. Doxycycline 100 mg (42 capsules as twice/day dose for 21 days)	• Inguinal Bubo under Genital Ulcer Disease Syndrome • LGV Proctitis under Anorectal Discharge Syndrome
Kit 8 (Brown)	Tab. Cefixime 800 mg STAT dose and Tab. Doxycycline 100 mg (14 capsules as twice/ day dose for 7 days)	• Anorectal Discharge Syndrome

3.4. Presumptive Treatment for STI

Presumptive treatment (PT) can be defined as one-time treatment for an assumed infection in a person, or a group of people, at high risk of infection. While syndromic case management depends on signs and symptoms, presumptive treatment addresses the more problematic asymptomatic infections as well as symptomatic infections in persons presumed to be at high risk and with high probability of the infection. The recommendations on presumptive treatment of STI are as follows:

- Under National Programme, all HRGs undergo risk assessment and medical examination for STI and RTI during their Regular Medical Checkups (RMCs) once in every three months. Moreover, the bridge population (BP) are assessed using standard NACO's risk assessment tool and those BPs who are screened to be at-risk for HIV/STI should receive medical checkups through

appropriate modality. BPs can be mobile populations. However, those BPs who can be followed up periodically; should be assessed bi-annually/annually. The population under P&OCS should receive a routine medical checkup annually.

- Presumptive Treatment for STI should be included within the package of STI and RTI services, including syndromic case management, regular screening for HIV and syphilis, and the promotion of condom use.
- All HRGs attending clinic for the first time should be provided with presumptive treatment for gonorrhoea and chlamydia using STI color-coded kit 1.
- Presumptive treatment should also be provided to asymptomatic HRGs who are missing their routine medical check-ups for a consecutive period of six or more months.
- The services for presumptive treatment are not provisioned for BPs and population under P&OCS in the National Programme.
- The dual therapy using single dose regimens (for example - azithromycin plus cefixime) is recommended for NG and CT to minimize the development of resistance.
- Under National Programme, all HRGs should be screened for HIV and Syphilis bi-annually. While all at-risk BPs are minimally screened for HIV and Syphilis at the time of assessment, the population under POCS are screened for HIV and Syphilis annually.

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Chapter 4 Brief Introduction, Diagnosis & Management of Common STI and RTI

This chapter provides details of common sexually transmitted infections and reproductive tract infections prevalent in India. Please note that the chapter only briefly describes the diagnostic considerations of the diseases. For details on diagnostic considerations, please refer to Chapter 5.

Group 1. Diseases characterized by Urethritis, Cervicitis & Vulvovaginal Itching, Burning, Irritation, Odor, or Discharge

1.1. Urethritis

Urethritis is inflammation of urethra and can be a manifestation of either infectious or non-infectious conditions. It may be asymptomatic and when symptomatic, it may present with dysuria, urethral pruritis and mucoid/purulent/muco-purulent discharge among men. The most common sexually transmitted, infectious causes of urethritis are *N. gonorrhoeae* and *C. trachomatis.* Moreover, *M. genitalium* and *T. vaginalis* are also strongly associated with urethritis. There are other etiological agents responsible for urethritis including bacteria, such as *Haemophilus* species, *N. meningitidis*, HSV, and adenovirus.

Diagnostic Considerations:

1. Demonstration of mucoid/purulent/muco-purulent discharge from urethra.
2. Presence of gram-negative intracellular diplococci (GNID) in WBCs in Gram stain or intracellular purple diplococci in Methylene Blue or Gentian Violet smears of urethral secretions.
3. Demonstration of WBCs in Gram stain of urethral secretions. The cut-offs may vary as per the background prevalence (≥2 WBCs/high power field [HPF] in high-prevalence settings [e.g., STI clinics] or ≥5 WBCs/HPF in lower-prevalence settings)
4. Positive leucocyte esterase test on first-void urine sample.
5. Demonstration of ≥10 WBCs/HPF on microscopic examination of sediment from a spun first-void urine sample.
6. Non-gonococcal urethritis (NGU) is confirmed for symptomatic men when diagnostic evaluation of urethral secretions indicates inflammation, without evidence of diplococci by Gram, Methylene Blue, or Gentian Violet smear on microscopy.
7. Demonstration of NG and CT using NAAT (Nucleic Acid Amplification Test).
8. Testing for MG and TV should be performed among men with complaints of persistent or recurrent symptoms after initial empirical therapy.
9. Additionally, testing for TV should be considered among men with history of sex with woman in areas of high prevalence or when the partner is infected.

Management Considerations:

- Persons with NG/CT should receive recommended treatment (as prescribed in further sections).
- If all of these clinical/diagnostic criteria are absent, empirical treatment for NG and CT (dual therapy) in symptomatic urethritis is recommended for high-risk individuals who are unlikely to return for a follow-up evaluation.
- All sex partners (in last 60 days) should be referred for evaluation and provided presumptive treatment.
- All patients should be instructed to abstain from sexual intercourse until completion of treatment and resolution of symptoms in them and their sexual partners or 7-days following a single-day therapy.
- Persons with recurrent or persistent symptoms should be evaluated for MG, TV and antimicrobial susceptibility for NG and should be treated accordingly.
- All the patients should be screened for HIV and Syphilis.
- There is no difference in the management of urethritis among PLHIV and HIV-negative persons.

1.2. Cervicitis

Cervicitis is commonly asymptomatic but might present with an abnormal vaginal discharge and inter-menstrual bleeding (especially after sexual intercourse). The two major diagnostic signs of cervicitis are:

- Presence of purulent/mucopurulent endocervical exudate in the endocervical canal or on an endocervical swab specimen
- Endocervical bleeding induced by gentle passage of a cotton swab through cervical os

The most common infectious causes of cervicitis are *N. gonorrhoeae* and *C. trachomatis.* Moreover, trichomoniasis, genital herpes (especially primary HSV-2 infection) and *M. genitalium* infection are also strongly associated with cervicitis.

Diagnostic Considerations:

- All the persons with cervicitis should be tested for NG and CT and should be evaluated for PID and for concomitant trichomoniasis and BV. NAAT on vaginal, cervical or urine samples should be preferred over other diagnostics tests.
- The sensitivity of criterion of using increased number of WBCs on endocervical Gram stain in the diagnosis of cervicitis is low.
- Leukorrhea is defined as >10 WBCs/HPF on microscopic examination of vaginal fluid. It might be a sensitive indicator of cervical inflammation with a high negative predictive value as cervicitis is unlikely in the absence of leukorrhea.

Management Considerations:

- All the women presenting with cervicitis should be treated for NG and CT. The appropriate treatment should be provided for trichomoniasis, C alb and BV as per the findings of examination.
- Presumptive treatment for NG and CT should be provided to all high-risk women.
- All sex partners (in last 60 days) should be referred for evaluation and provided presumptive treatment for TV, NG, and CT.
- All patients should be instructed to abstain from sexual intercourse until completion of treatment and resolution of symptoms in them and their sexual partners or 7-days following a single-day therapy.

- Women with persistent or recurrent cervicitis should be re-evaluated for possible re-exposure or treatment failure.
- All the patients should be screened for HIV and Syphilis.
- Women with cervicitis and HIV infection should receive the same treatment regimen as HIV negative persons.
- Diagnosis and management of cervicitis doesn't differ in pregnancy.

1.3. Chlamydial infections

C. trachomatis is the etiological agent of chlamydiasis and is responsible for a spectrum of diseases in a variety of sites (i.e., genital, ocular, lymph nodes, and bronchial sites). *C. trachomatis* has been classified into three biovars, each containing several serovars or genotypes: those causing trachoma (serovar A-C), genital sexually transmitted infection (serovar D-K), and a genital ulcer disease: lymphogranuloma venereum or LGV (serovar L1, L2 & L3).

The predominant biovar consists of serovars D–K, which are responsible for urethritis in men and cervicitis (and urethritis) in women. The urogenital infections are asymptomatic in up to 50% of men and 90% of women. The infection can ascend up to the upper genital tract and cause epididymitis in men and pelvic inflammatory disease (PID) and related sequelae (ectopic pregnancy and tubal factor infertility) in women, if left untreated. These serovars can also get transmitted to the neonate during vaginal delivery of an infected women and result in complications including ophthalmia neonatorum and pneumonia. The clinical manifestations of genitourinary infection of *C. trachomatis* are mentioned in table 4.1.

Table 4.1. Clinical Manifestations of *C. trachomatis* genital sexually transmitted infection (serovar D-K)

Site	Primary Manifestations	Sequelae
Male genitourinary tract	Urethritis, urethral discharge, dysuria	Epididymitis, prostatitis
Female genitourinary tract	Cervicitis, dysuria, friable cervix, pain in lower abdomen, cervical motion tenderness, vaginal discharge	Ectopic pregnancy, salpingitis, tubal-factor infertility, PID
Ano-rectal	Anal discharge, rectal pain, blood in stool	Proctitis
Oropharyngeal	Sore throat, pharyngitis	

Diagnostic Considerations:

- The infection can be diagnosed using NAAT on vaginal/cervical swabs among women and first-void urine sample among men.
- Persons engaging in receptive anal/ oral sex can be tested for rectal and oropharyngeal chlamydial infections using NAAT.

Management:

- The current evidence supports adequate efficacy for doxycycline in treatment of urogenital, rectal, and oropharyngeal infections. Although azithromycin has high efficacy in treatment of urogenital infections, its efficacy in concomitant rectal and pharyngeal infections is limited.
- All patients should be instructed to abstain from sexual intercourse until completion of treatment or 7-days following a single-day therapy and resolution of symptoms in them and their sexual partners.
- All the patients diagnosed with *C. trachomatis* should be screened for HIV, gonorrhea & syphilis.
- The test of cure (based on NAAT/PCR) to ensure success of treatment is not advised for non-pregnant persons and can be undertaken at least after 4 weeks of completion of treatment.
- PLHIV co-infected with chlamydia should receive the same treatment regimen as those who do not have HIV.

Recommended Regimen:

- Doxycycline 100 mg orally twice/day for 7 days; or
- Azithromycin 1 g orally in a single dose; or
- Erythromycin 500 mg, orally, four times a day for 7 days; or
- Ofloxacin 200–400 mg, orally, twice a day for 7 days

Note: The doxycycline regimen is preferred over azithromycin for management of anorectal and pharyngeal infections.

For Pregnant Women:

The doxycycline and ofloxacin regimens are not recommended in pregnancy.

- Azithromycin 1 g orally in a single dose; or
- Amoxicillin 500 mg orally three times/day for 7 days; or
- Erythromycin 500 mg, orally, four times a day for 7 days

1.4. Gonococcal Infections

Gonorrhea is caused by *N. gonorrhoeae.* This bacterium infects humans only and colonizes mucosal surfaces and is responsible for urethritis in men and cervicitis in women. Though the infection is asymptomatic in minority of men, it is asymptomatic in around 50% women.

The urethral infections can produce symptoms among men that cause them to seek curative treatment soon enough to prevent sequelae, but often not soon enough to prevent transmission to others. Among women, gonococcal infections are commonly asymptomatic or might not produce recognizable symptoms until the development of complications. PID can result in tubal scarring that can lead to infertility or ectopic pregnancy. Infections of pharynx and rectum are commonly asymptomatic and can occur in persons involved in receptive oral and anal sex respectively. The clinical manifestation of gonorrhea is mentioned in Table 4.2.

Table 4.2. Clinical Manifestations of Uncomplicated Gonococcal Infections

Anatomical Site	Clinical Manifestations
Urethra	Discharge (copious/scanty, purulent/clear), dysuria
Cervix	Dysuria, red & friable cervical os, purulent discharge from cervical os, salpingitis, lower abdominal tenderness
Rectum	Copious purulent discharge, burning/stinging pain, tenesmus, blood in stools
Pharynx	Mild pharyngitis, erythema

Diagnostic Considerations:

- Culture, NAAT, and PoC NAAT are available for detecting genitourinary infection with *N. gonorrhoeae*. Culture is also available for detecting rectal and oropharyngeal gonococcal infection.
- Culture along with anti-microbial susceptibility testing should be conducted in all cases of treatment failure.

Management Considerations:

- There has been widespread drug resistance reported with fluoroquinolones. There has been reports on reduced susceptibility of azithromycin in treatment of gonorrhea. Therefore, third generation cephalosporins are the backbone for treatment of gonorrhea.
- All patients should be instructed to abstain from sexual intercourse until completion of treatment or 7-days following a single-day therapy and resolution of symptoms in them and their sexual partners.
- All the patients diagnosed with gonorrhea should be screened for HIV, chlamydia, and syphilis. If chlamydia cannot be excluded, all patients should receive a dual therapy for both NG and CT.
- Treatment failure should be suspected in following scenarios when no sexual contact is reported during the posttreatment follow-up period:
  - Symptoms do not resolve within 3–5 days after recommended treatment
  - Positive test of cure (i.e., positive culture >7 days or positive NAAT > 3 weeks after receiving recommended treatment)
- All the suspected case for treatment failure should be assessed for antimicrobial resistance.
- PLHIV co-infected with NG should receive the same treatment regimen as those who do not have HIV.

Recommended Regimen:

For uncomplicated urogenital gonococcal infections:

- Ceftriaxone 500 mg IM in a single dose (for persons weighing > 150 kg, one 1gm dose is recommended), or
- Cefixime 800 mg orally in a single dose, or
- Gentamicin 240 mg IM in a single dose plus Azithromycin 2 g orally in a single dose
  (This is not recommended for pregnant women)

For oropharyngeal gonococcal infections:

1. Ceftriaxone 500 mg IM stat dose

Note:

- The ceftriaxone and doxycycline regimen are recommended as the first line of treatment for NG and CT respectively. The cefixime and azithromycin are the preferred alternative regimen.
- The dual therapy for NG and CT can be continued in settings with limited access to laboratory diagnosis of NG and CT. The same is recommended for management of Urethral Discharge Syndrome and Vaginal Discharge Syndrome. The recommended doses are:
  - Ceftriaxone 500 mg IM in a single dose plus Doxycycline 100 mg orally twice/day for 7 days
  - Cefixime 800 mg in a single dose plus Doxycycline 100 mg orally twice/day for 7 days
  - Cefixime 800 mg in a single dose plus Azithromycin 1000 mg orally in a single dose
- The doxycycline is recommended over azithromycin for management of rectal and pharyngeal chlamydial infections.
- The operational feasibility for implementation of the above-mentioned regimens under the National Programme should be considered as a part of public health approach. The updated evidence on antimicrobial susceptibility should be utilized to choose/update regimens under the National Programme.

1.5. *Mycoplasma genitalium* infection

M. genitalium causes symptomatic and asymptomatic urethritis in both men and women. It is the etiology of non-gonococcal urethritis (NGU), non-chlamydial NGU, and persistent or recurrent urethritis. There is insufficient evidence on implications of *M. genitalium* infection on chronic complications among men (e.g., epididymitis, prostatitis, or infertility). The infection is associated with cervicitis, PID, preterm delivery, spontaneous abortion, and infertility among women. There is approximately 2-fold increase in the risk for these outcomes among women with *M. genitalium* infection. There is also evidence of rectal infections with *M. genitalium*.

Diagnostic Considerations:

- Men with recurrent NGU, women with recurrent cervicitis and PID should be tested for *M. genitalium* using NAAT.

Management Considerations:

- *M. genitalium* infection should be suspected in cases of persistent or recurrent urethritis or cervicitis and PID and should be treated (even if testing facility is not available).
- Widespread resistance to macrolides including emerging resistance to azithromycin has been reported globally.
- Two-stage resistance guided therapy can be considered for treatment. However, it requires for macrolide-resistance testing.
- As a part of this approach, doxycycline is provided as initial empirical therapy, which reduces the organism load and facilitates organism clearance, followed by macrolide-sensitive *M. genitalium* infections treated with high-dose azithromycin and macrolide-resistant infections are treated with moxifloxacin. The scenario where there is no access to macrolide-resistance testing, moxifloxacin should be preferred over azithromycin.

- PLHIV co-infected with MG should receive the same treatment regimen as those who do not have HIV.

Recommended Regimen:

Scenario 1: Access to macrolide-resistance testing

- **Macrolide sensitive:**
  Doxycycline 100 mg orally 2 times/day for 7 days, followed by azithromycin 1 g orally initial dose, followed by 500 mg orally once daily for 3 additional days
- **Macrolide resistant:**
  Doxycycline 100 mg orally 2 times/day for 7 days followed by moxifloxacin 400 mg orally once daily for 7 days

Scenario 2: No access to macrolide-resistance testing

- Doxycycline 100 mg orally 2 times/day for 7 days, followed by moxifloxacin 400 mg orally once daily for 7 days

Scenario 3: PID

- Doxycycline 100 mg orally 2 times/day for 14 days, followed by moxifloxacin 400 mg orally once daily for 14 days

1.6. Epididymitis

Epididymitis is a clinical syndrome which involves inflammation of epididymis and may involve testicle or scrotum (referred as epididymo-orchitis). It could be acute or chronic. It may present as pain or discomfort in scrotum, testicles or epididymis and also manifest as painful scrotal swelling.

Acute Epididymitis

- Lasts < 6 weeks and usually accompanied by symptomatic/ asymptomatic urethritis
- Could be caused by sexually transmitted (e.g., *N. gonorrhoeae, C*. *trachomatis* or *M. genitalium*) or enteric organisms (e.g., *E. coli*)
- Sexually transmitted enteric organisms may be the causative agents in MSM who are insertive partners or heterosexual men who are involved in unprotected anal sex
- May also occur due to bacteriuria due to obstruction in urogenital tract in non-sexual cases
- Typically presents with unilateral testicular pain and tenderness, hydrocele, or palpable swelling of the epididymis
- Differential Diagnosis: testicular torsion (may present as sudden onset of pain and is a surgical emergency)

Chronic Epididymitis

- Characterized by ≥ 6-week history of symptoms
- Usually observed in conditions associated with granulomatous reaction and most commonly associated with tuberculosis.
- Differential diagnosis: trauma, cancer, autoimmune conditions

Diagnostic Considerations:

- All suspected cases of acute epididymitis should be tested for *C. trachomatis* and *N. gonorrhoeae* by NAAT. Urine is the preferred specimen for NAAT for men.
- Urine bacterial cultures can also be performed for all men to evaluate for the presence of genitourinary organisms and to determine antibiotic susceptibility.

Management Considerations:

- All cases should be referred to a specialist for evaluation and hospitalization should be considered when symptomatic relief is not achieved within 72 hours, or alternative diagnosis is considered.
- Levofloxacin monotherapy should be considered in cases when the infection is most likely caused by enteric organisms only, and gonorrhea has been ruled out by Gram, MB, or GV stain.
- The treatment should be guided by results of bacterial culture and antimicrobial susceptibility and all the patients should be advised bed rest, scrotal elevation and NSAIDS.
- All the patients should also be screened for HIV and syphilis.
- The patients should be advised to abstain from sexual intercourse until they and their sexual partners are treated completely, and symptoms are resolved.
- Sexual partners of persons within last 60 days preceding symptom should be evaluated, tested, and presumptively treated for chlamydia and gonorrhea.
- Men with HIV infection should receive similar therapy as HIV negative person.

Recommended Regimens for acute epididymitis:

Scenario 1: When likelihood of NG/CT

Ceftriaxone 500 mg IM in a single dose plus Doxycycline 100 mg orally twice/day for 10 days

Scenario 2: For MSM who are insertive partners or heterosexual men who are involve in unprotected anal sex

Ceftriaxone 500 mg IM in a single dose plus Levofloxacin 500 mg orally once daily for 10 days

Scenario 3: When likelihood of enteric organisms only

Levofloxacin 500 mg orally once daily for 10 days

1.7. Trichomoniasis

Trichomoniasis is estimated to be the most prevalent non-viral STI across the world. The majority of infected persons either have minimal/no genital symptoms, and untreated infections might last from months to years. Women might present with diffuse, malodorous, or yellow-vaginal discharge with or without vulvar irritation and might have a strawberry-appearing cervix during colposcopy. The infection can be transmitted between sexual partners during peno-vaginal sex, exchange of vaginal fluids or fomites even in women who have sex with women. The infection may also present as urethritis, epididymitis, or prostatitis among men.

It results in reproductive morbidity and increases the likelihood of preterm birth, premature rupture of membranes and low birth weight. It is also associated with increased risk for PID and enhance risk for HIV transmission and acquisition.

Diagnostic Considerations:

- The diagnostic testing for trichomoniasis is recommended for women seeking care for vaginal discharge. Annual screening can be considered for women at high risk for infection. E.g., multiple sexual partners, transactional sex, drug misuse, or a history of STI or incarceration, use and sharing of sex toys etc.
- NAATs are highly sensitive over wet-mount microscopy and culture among women in detecting more *T. vaginalis* infections.

Management Considerations:

- All patients diagnosed with trichomoniasis should be screened for HIV, gonorrhea, chlamydia, and syphilis
- The patients should be instructed to abstain from sexual intercourse until completion of treatment and resolution of symptoms in them and their sexual partners.
- Retesting is suggested in all sexually active women within 3 months of treatment completion.
- Recurrent manifestations can result from treatment failure, lack of adherence, or reinfection from an untreated sex partner. The same course of treatment should be repeated in case of recurrent infections or treatment failure cases. When the infection persists, drug sensitivity testing should be considered, and the treatment should be guided accordingly. Treatment with high-dose oral metronidazole or tinidazole can also be considered in such cases.
- All partners should be provided with presumptive treatment to prevent re-infection.

Recommended Regimen:

- Metronidazole 2 g orally in a single dose, or
- Metronidazole 400 mg orally twice/day for 7 days, or
- Tinidazole 2g orally in a single dose, or
- Secnidazole 2g orally in a single dose, or
- Tinidazole 500 mg orally, twice daily for 5 days

For pregnant women,

- Metronidazole 400 mg orally twice/day for 7 days, or
- Metronidazole 200 mg, orally, 3 times a day for 7 days, or
- Metronidazole 2 g orally in a single dose, or
- Metronidazole gel 0.75%, one full applicator (5 grams) intravaginally, twice a day for 7 days

Note: Although metronidazole crosses the placenta, there is no evidence of teratogenicity or mutagenic effects among infants reported in various research studies. The current evidence indicate that metronidazole therapy poses low risk during pregnancy and therefore, can be recommended even in the first trimester of pregnancy.

High-dose Oral Regimen (for persistent cases)

- Tinidazole 2g orally single dose daily for 7 days or,
- Metronidazole 2g orally single dose daily for 7 days
- Tinidazole 2 g oral dose daily plus intravaginal tinidazole 500 mg twice/day for 14 days. If this regimen fails, high-dose oral tinidazole (1g thrice/day) plus intravaginal paromomycin (4 g of 6.25% intravaginal paromomycin cream nightly) 14 days

1.8. Bacterial Vaginosis or BV

BV is a vaginal dysbiosis resulting from the replacement of *Lactobacillus* species in the vagina with high concentrations of anaerobic bacteria, (including *Gardnerella vaginalis*, *Prevotella* species, *Mobiluncus* species, *A. vaginae*, and other BV-associated bacteria). It is associated with the practice of having multiple male sex partner, new sex partner, inconsistent condom use, vaginal douching, and HSV-2 seropositivity. It is reported to increase among women using copper-containing IUDs. Male circumcision is associated with decline in the risk of BV in female partners.

BV increases the risk for acquisition and transmission of HIV and acquisition of *N. gonorrhoeae*, *C. trachomatis*, *T. vaginalis*, *M. genitalium*, HPV, and HSV-2. It is also associated with increased complications after gynecologic surgery and complications in pregnancy.

Diagnostic Considerations:

- BV can be diagnosed by determining Nugent score from a vaginal Gram stain or using clinical criteria (i.e., Amsel's diagnostic criteria). These criteria are well defined in Chapter 5.

Management Considerations:

- Treatment for BV is recommended for women with symptoms.
- Women should be advised to abstain or to ensure consistent and correct use of condoms while having sex during the BV treatment regimen. Douching might increase the risk for relapse and should be avoided.
- The routine treatment of sex partners is not recommended.
- The chances of recurrence of BV are higher among WLHIV. WLHIV with BV should receive the same treatment regimen as those who do not have HIV.

Recommended Regimens:

For non-pregnant women,

- Metronidazole 400 mg orally 2 twice/day for 7 days
- Metronidazole 2 g orally, single dose
- Secnidazole 2 g orally in a single dose
- Tinidazole 2 g orally once daily for 2 days
- Tinidazole 1 g orally once daily for 5 days
- Clindamycin 300 mg, orally, twice daily for 7 days

For pregnant women,

- Metronidazole 400 mg orally 2 times/day for 7 days
- Metronidazole 200 mg, orally, 3 times a day for 7 days
- Metronidazole gel 0.75%, one full applicator (5 grams) intravaginally, twice a day for 7 days
- Clindamycin 300 mg, orally, twice daily for 7 days

Note: Although metronidazole crosses the placenta, there is no evidence of teratogenicity or mutagenic effects among infants reported in various research studies. The current evidence indicate that metronidazole therapy poses low risk during pregnancy and therefore, can be recommended even in the first trimester of pregnancy.

Recommendations for recurrent/persistent cases

There is limited evidence on optimal management strategies for persistent or recurrent BV. The following is recommended in persistent or recurrent cases of BV:

- Retreat with the same recommended regimen at first recurrence.
- Use different recommended regimen in the following recurrences.
- The following regimens can be explored to reduce incidence of recurrence in cases with multiple recurrences (suppressive therapy):
  - Metronidazole gel 0.75% or 750 mg metronidazole vaginal suppository twice weekly for >3 months
  - Metronidazole or tinidazole 500 mg 2 times/day for 7 days, followed by intravaginal boric acid 600 mg daily for 21 days and suppressive 0.75% metronidazole gel twice weekly for 4–6 months
  - Metronidazole 2 g plus fluconazole 150 mg monthly

1.9. Vulvovaginal Candidiasis

Vulvovaginal Candidiasis (VVC) is usually caused by *Candida albicans* (approximately 90% cases) but can occasionally be caused by other *Candida* species (e.g., *C. glabrata, C. tropicalis, C. krusei and C. parapsilosis*). The common symptoms of VVC include pruritus, vaginal soreness, dyspareunia, dysuria, and abnormal vaginal discharge. The signs include vulvar edema, fissures, excoriations, and thick curdy vaginal discharge.

Recurrent VVC is defined as the occurrence of ≥ 3 episodes of symptomatic VVC within a year. It can be either idiopathic or related to frequent antibiotic use, diabetes, or other underlying host factors. The complicated VVC cases includes recurrent VVC, severe VVC, non-albicans candidiasis, women with uncontrolled diabetes and immunocompromising conditions (e.g., Advanced HIV Disease)

Diagnostic Considerations:

- The diagnosis can be made in a symptomatic woman through a wet preparation (saline, 10% KOH) or Gram stain of vaginal discharge demonstrating budding yeasts, hyphae, or pseudo-hyphae, culture, and speciation of *Candida*.

Management Considerations:

- VVC is not usually acquired through sexual contact. Therefore, treatment of sexual partners is not recommended. However, in case of acquired balanitis or balanoposthitis characterized by erythematous lesions on glans penis/foreskin, the treatment can be provided in the form of topical anti-fungal agents.
- The rates of VVC are higher in WLHIV and is proportionate with severity of immunosuppression. However, the treatment considerations are same for both WLHIV and HIV uninfected women.
- The women with recurrent VVC should be managed with longer duration of initial therapy (for mycological remission) followed by a maintenance regimen in consultation with a specialist.
- Use of oral fluconazole is not recommended in pregnancy.

Recommended Regimens:

Uncomplicated VVC

For non-pregnant women,

- Fluconazole 150 mg (or 200mg), orally, single dose, or

- Clotrimazole vaginal tablet, 100 mg, inserted at night for 7 nights, or
- Miconazole vaginal pessaries, 200 mg inserted at night for 3 nights, or
- Clotrimazole 1% 5gm cream intravaginally for 7 days, or
- Clotrimazole 2% 5gm cream intravaginally for 3 days, or
- Miconazole 2% 5gm cream intravaginally for 7 days, or
- Miconazole 4% 5gm cream intravaginally for 3 days

For pregnant women,

- Miconazole 200 mg vaginal pessaries inserted once daily for 3 days, *or*
- Clotrimazole vaginal tablet 100 mg inserted at night for 7 days
- Clotrimazole 1% 5gm cream intravaginally for 7 days, or
- Clotrimazole 2% 5gm cream intravaginally for 3 days, or
- Miconazole 2% 5gm cream intravaginally for 7 days, or
- Miconazole 4% 5gm cream intravaginally for 3 days

Complicated VVC

Mycological remission,

- Topical Azole therapy for 7 – 14 days (e.g., clotrimazole 1% 5gm cream, Miconazole 2% 5gm cream intravaginally), or
- Oral fluconazole (150 mg) on days 0, 3 and 6

Maintenance regimen,

- Oral fluconazole (150 mg) weekly for 6 months

Note: Boric Acid is considered as the choice of treatment in cases with azole-resistant non-*C. albicans* infection. The recommended regimen for boric acid is 600 mg in gelatin capsules inserted per vagina at night for 14 days. Nystatin, 200,000-unit vaginal tablet, inserted at night for 7 nights is also recommended as a potential option in these cases.

If susceptibility tests confirm *C. glabrata* sensitivity to amphotericin B or flucytosine, topical regimens of either agent can be used. The treatment regimens recommended are Amphotericin B (3–4%) or 100 mg vaginal suppositories daily for 14 days.

1.10. Pelvic Inflammatory Disease

Pelvic Inflammatory Disease (PID) covers a range of inflammatory disorders of the upper female genital tract, including any combination of endometritis, salpingitis, tubo-ovarian abscess, and pelvic peritonitis. The most common sexually transmitted microorganisms implicated for PID are *N. gonorrhoeae* and *C. trachomatis.* The microorganisms responsible for Bacterial Vaginosis have also been associated with PID. In addition, *T. vaginalis*, *M. hominis, M. genitalium,* cytomegalovirus (CMV), and *U. urealyticum* might also have some role in pathogenesis of PID.

Women with PID often have subtle or nonspecific symptoms or are asymptomatic. However, mild, or asymptomatic PID might also lead to infertility, ectopic pregnancy, or other long term reproductive sequalae among women. PID is difficult to diagnose, and the healthcare providers should maintain a low

threshold for clinical diagnosis of PID. Moreover, diagnosis and management of other causes of lower abdominal pain (e.g., acute appendicitis, ectopic pregnancy, ovarian cyst, ovarian torsion, etc.) are not impaired by initiating antimicrobial therapy for PID. Therefore, initiating empirical therapy for PID and simultaneously evaluating for causes for lower abdominal pain can be practiced safely.

Management Considerations:

The presumptive treatment for PID should be initiated in following scenarios:

- sexually active young women and other women at risk for STI if they are experiencing pelvic or lower abdominal pain,
- no cause for the illness other than PID can be identified in women,
- one or more of these clinical criteria are present on pelvic examination: cervical motion tenderness, uterine tenderness, or adnexal tenderness. In addition, one or more of the following criteria can also be used to enhance the specificity of the diagnosis:
  - Fever
  - Abnormal cervical or vaginal muco-purulent discharge
  - Presence of signs of lower genital tract inflammation (e.g., cervical friability) and predominance of leucocytes in vaginal secretions, cervical exudates
  - Presence of abundant numbers of WBC on saline microscopy of vaginal fluid.
  - Elevated erythrocyte sedimentation rate
  - Elevated C-reactive protein
  - Laboratory documentation of cervical infection with NG & CT.
- The patient should be assessed for other causes of lower abdominal pain and managed accordingly.
- All patients should be instructed to abstain from sexual intercourse until completion of treatment and resolution of symptoms in them and their sexual partners.
- All the patients diagnosed with PID should be screened for HIV, gonorrhea, chlamydia, and syphilis.
- If no clinical improvement has occurred within 72 hours (e.g., defervescence; reduction in direct or rebound abdominal tenderness; and reduction in uterine, adnexal, and cervical motion tenderness) after treatment, then hospitalization, assessment of the antimicrobial regimen, and additional diagnostics are recommended.
- Sexual partners of persons with PID in last 60 days preceding symptoms should be evaluated, tested, and presumptively treated for chlamydia and gonorrhea, regardless of the etiology of PID.
- All the pregnant women should be hospitalized and provided with parenteral therapy.
- Women living with HIV responds well to recommended parenteral, IM or oral antibiotic regimens as women without HIV.
- The risk for developing PID with use of intrauterine devices (IUD) is primarily confined to the first 3 weeks after insertion. If an IUD user receives a diagnosis of PID, the IUD does not need to be removed. However, the woman should receive treatment according to these recommendations and should have close clinical follow-up. If no clinical improvement occurs within 48–72 hours of initiating treatment, providers should consider removing the IUD.

Recommended Regimens:

- Ceftriaxone 500 mg IM single dose plus Doxycycline 100 mg orally twice/day for 14 days with metronidazole 400 mg orally twice/day for 14 days
- Cefixime 800 mg IM single dose plus Doxycycline 100 mg orally twice/day for 14 days with metronidazole 400 mg orally twice/day for 14 days
- Cefoxitin 2 g IM in a single dose and probenecid 1 g orally administered concurrently in a single dose plus Doxycycline 100 mg orally twice/day for 14 days with metronidazole 400 mg orally twice/day for 14 days.

Group 2. Diseases characterized by ano-genital ulcers

2.1. Syphilis

Syphilis is a sexually transmitted infection caused by a bacterial spirochete *Treponema pallidum*. This infection may progress to chronic infection with various adverse systemic outcomes, if not treated in early stages. The stages of Syphilis are classified as:

- **Primary Syphilis:** The primary stage starts after 21 days (range of 10 – 90 days) following syphilis infection. The infected person may present with a painless ulcer which may last up to 2 to 6 weeks.
- **Secondary Syphilis:** The secondary stage is characterized by the development of skin rashes over the body [palm (See Image 4.1) and soles], often associated with fever and muscle pain. The stage lasts for 2 to 6 weeks. This stage may be followed by a latent stage for a few years. The stage is characterized with no signs and symptoms. The spirochetes may circulate in blood during this phase leading to infection of all the organs in the body.
- **Tertiary Syphilis:** The stage occurs after several years of infection and can be manifested as neurosyphilis (when brain/spinal cord is affected), cardiovascular syphilis (when heart and aorta is affected) or late benign syphilis (when the skin is primarily involved). The complications can be developed in 40% of people with latent infection in the absence of treatment.

Image 4.1. Primary Chancre

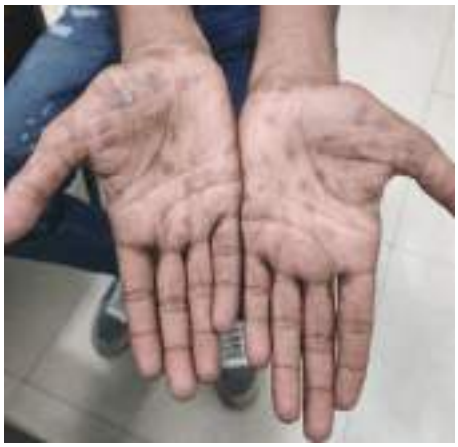

Image 4.2. Rash on palms in Secondary Syphilis

Neurosyphilis: *T. pallidum* can infect the Central Nervous System (CNS), which can occur at any stage of syphilis and result in neurosyphilis.

- Early neurologic clinical manifestations or syphilitic meningitis (e.g., cranial nerve dysfunction, meningitis, meningovascular syphilis, stroke, and acute altered mental status) are usually present within the first few months or years of infection.
- Late neurologic manifestations (e.g., tabes dorsalis and general paresis) occur 10 to >30 years after infection.

Ocular Syphilis: Ocular syphilis often presents as pan-uveitis but can involve structures in both the anterior and posterior segment of the eye, including conjunctivitis, anterior uveitis, posterior interstitial keratitis, optic neuropathy, and retinal vasculitis.

Oto-Syphilis: It presents with cochleo-vestibular symptoms, including tinnitus, vertigo, and sensorineural hearing loss. Hearing loss can be unilateral or bilateral, have a sudden onset, and progress rapidly. Oto-syphilis can result in permanent hearing loss.

Both ocular syphilis & oto-syphilis can also occur at any stage of syphilis but is commonly identified during the early stages and can present with or without additional CNS involvement.

Serological Testing of Syphilis: There are two types of serological tests for syphilis: 1) treponemal tests; 2) non-treponemal tests. Treponemal tests detect antibodies to *Treponema pallidum* proteins while non-treponemal tests detect antibodies directed against lipoidal antigens, damaged host cells, and possibly from treponemes. Both tests are used to screen or confirm the infection and determine whether the disease is active. Moreover, the treponemal tests may remain positive when the disease is inactive or even throughout life. The examples of treponemal tests are *Treponema pallidum* hemagglutination assay (TPHA), *Treponema pallidum* passive particle agglutination assay (TPPA), TP-ELISA, fluorescent treponemal antibody absorption (FTA-Abs) test and chemiluminescence. The majority of PoC or rapid tests including Dual RDT kits for syphilis are treponemal tests. The examples of non-treponemal tests are Wasserman reaction (WR), rapid plasma reagin (RPR) and Venereal Disease Research Laboratory (VDRL).

The CSF evaluation is warranted in individuals with clinical signs of neurosyphilis. All patients with ocular symptoms and reactive syphilis serology should receive complete ocular examination, including cranial nerve evaluation. If cranial nerve dysfunction is present, a CSF evaluation is needed. In individuals with auditory abnormalities and reactive syphilis serology, CSF evaluation is likely to be normal and is unnecessary before treatment.

The diagnostic and treatment algorithms for syphilis are mentioned in Figure 4.1. and 4.2.

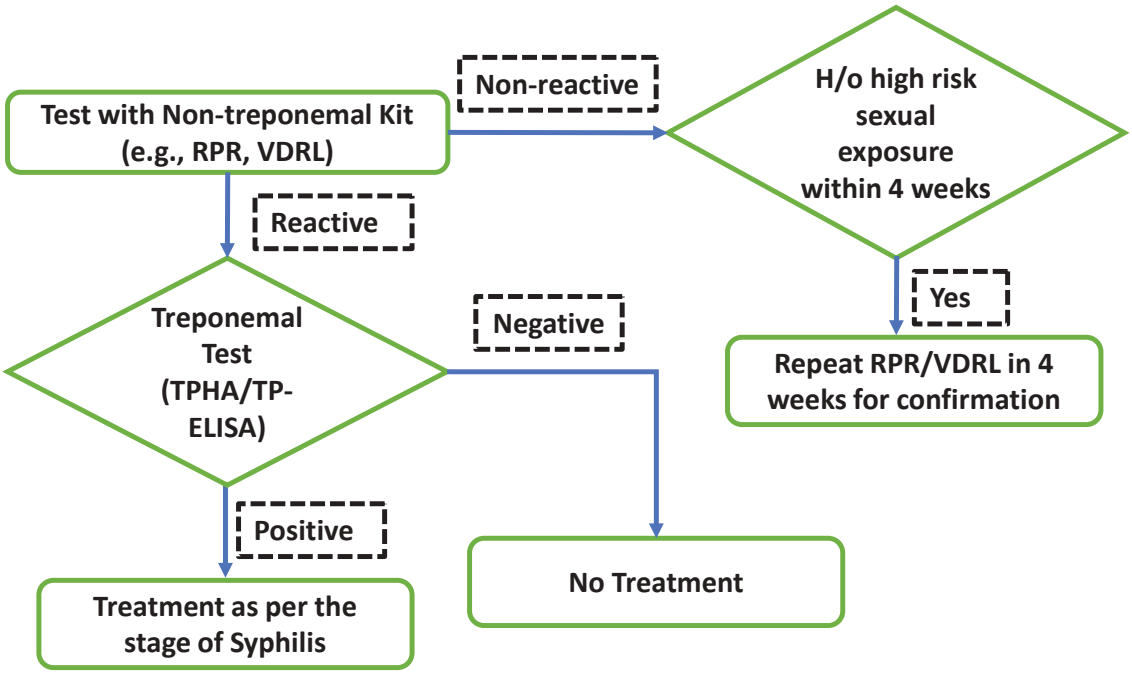

Figure 4.1. Traditional Algorithm for diagnosis and management of Syphilis**

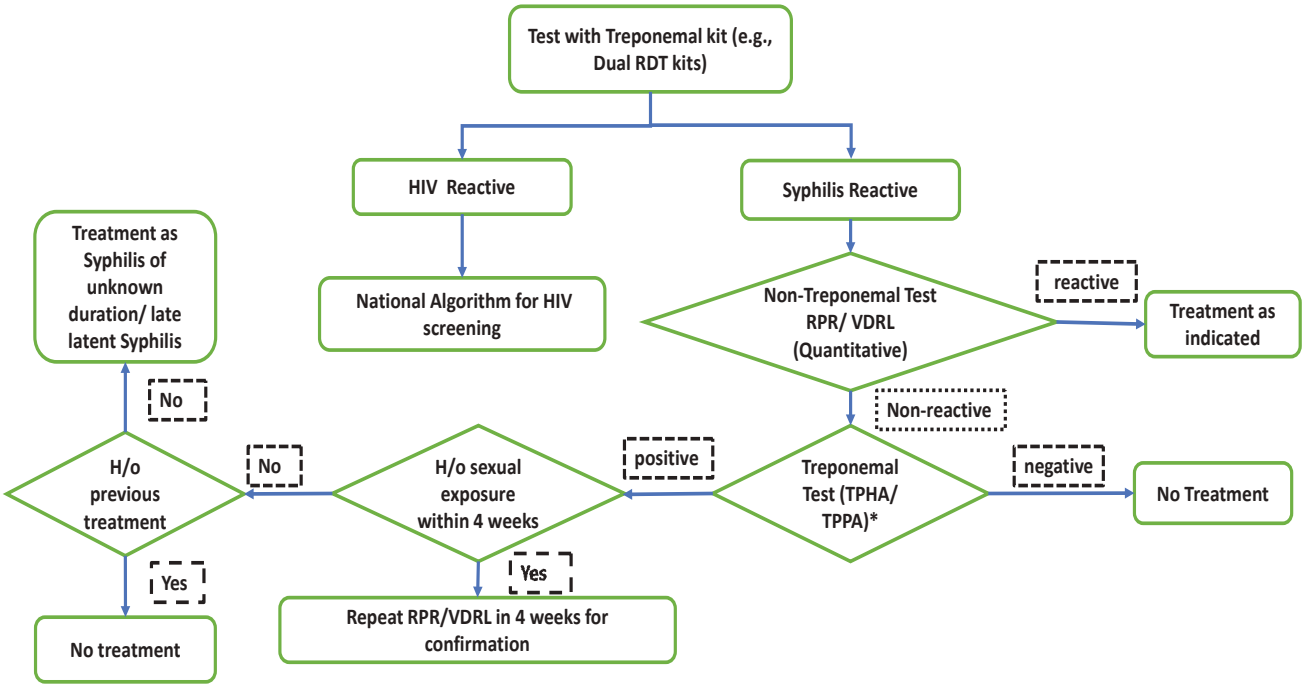

Figure 4.2. Reverse Algorithm for diagnosis and management of Syphilis**

**Treponemal test with different antigen than the test used for screening*
***The detailed operations for screening and management of syphilis is mentioned in Annexure 3.*

Management Considerations:

- Injection Benzathine Penicillin G is the most effective and preferred treatment for syphilis.
- All patients should be treated as per the stage of syphilis (see table 4.3.)
- The RPR/VDRL titers should not be used for staging of syphilis. However, titers are important to monitor treatment response.
- All the suspected cases of neurosyphilis, oto-syphilis and ocular syphilis should be referred to an infectious disease specialist for adequate investigations and management.
- The sex partners of persons diagnosed with syphilis should be considered at risk for infection and should be evaluated:
  - Sex partners within 3 months plus duration of symptoms when person is diagnosed with primary syphilis,
  - Sex partners within 6 months plus duration of symptoms when person is diagnosed with secondary syphilis,
  - Sex partners within 1 year for persons diagnosed with early latent syphilis (syphilis < 1 year).
- Sexual partners of a person who receives a diagnosis of primary, secondary, or early latent syphilis within 180 days should be treated presumptively for early syphilis, even if serologic test results are negative.
- All the patients should be screened for HIV and other STI.

Table 4.3. Recommended Treatment for Syphilis

Stage of Syphilis	Preferred Regimen	Alternative Regimen
Primary/ Secondary/ Early Latent/ Syphilis < 1 year	Injection Benzathine Penicillin G (BPG) 2.4 million IU one intramuscular dose (Deep intramuscular, half in each buttock, after sensitivity testing)	Cap Doxycycline 100 mg orally twice daily for 14 days, or Erythromycin 500 mg, 4 times a day for 14 days, or Ceftriaxone 1–2 g per day, intravenously for 10-14 days, to be titrated as per the discretion of the treating physician
Late Latent/ Tertiary/ Syphilis of unknown duration	Injection Benzathine Penicillin G 2.4 million IU intramuscular dose once a week for three weeks	Cap Doxycycline 100 mg orally twice daily for 30 days, or Procaine penicillin 1.2 million units by intramuscular injection, once daily for 20 consecutive days
Neurosyphilis, Oto-syphilis and Ocular Syphilis	Aqueous crystalline penicillin G 18–24 million units per day, administered as 3–4 million units IV every 4 hours or continuous infusion for 10–14 days, to be titrated as per the discretion of the treating physician	Procaine penicillin G 2.4 million units IM once daily *plus* Probenecid 500 mg orally 4 times/day, both for 10–14 days or Ceftriaxone 1–2 g per day, intravenously for 10-14 days, to be titrated as per the discretion of the treating physician

Note:

- The BPG regimen should be given after skin test to rule out any allergic reaction and in a facility with availability of emergency tray and facility for referral/linkages to emergency IPD services. The details on administration of BPG and management of anaphylaxis reaction is mentioned in Annexure 1.
- Syphilis during pregnancy can result in vertical transmission to the baby. Benzathine Penicillin G is the only effective antimicrobial for the treatment of pregnant women with syphilis to prevent vertical transmission. Once a presumptive diagnosis of penicillin allergy had been established, the desensitization of penicillin allergy can be performed in cases where there are no other suitable options to treat syphilis (including pregnant women). The oral desensitization can be performed in accordance with the protocol described by Wendel et al (1985)[1].

Monitoring of Treatment Response

The treatment response should be monitored through comparing titre values of RPR/VDRL with the baseline value at the time of confirmation of infection. The same non-treponemal test (either RPR or VDRL) used at the time of confirmation of syphilis from the same manufacturer should be conducted from the same laboratory for comparing the titre values.

- The fourfold reduction in titers, equivalent to a change of two dilutions [e.g., from 1:16 to 1:4] indicates successful treatment. This fourfold reduction is usually achieved after 6 months in most of the cases.
- Serologic titers should not be repeated before 8 weeks after completion of treatment. It should be preferably repeated at least after 12 weeks of treatment. The four-fold reduction in titre value may not be achieved within this duration. However, if the titre values (after 12 weeks) are decreasing in comparison to the titre values at the time of confirmation and there is no clinical evidence of syphilis, no further treatment is suggested.
- If the titer values persist at the same level or increases after 12 weeks or there are clinical manifestations of syphilis, treatment failure or re-infection can be suspected, and complete treatment should be given according to the treatment protocol.
- The clinical and serological evaluation should further be conducted at 6, 9 and 12 months after complete treatment.

The National Guidelines on Elimination of Vertical Transmission of HIV & Syphilis (2024) can be referred for details on screening and management of syphilis in pregnant women and exposed infants.

Interpretations of results of syphilis testing and monitoring

The results of serological tests for syphilis only aids in a presumptive diagnosis and the treatment decision should be taken together with sexual history, findings of physical examination, stage of the disease while considering the possibility of false-positive or false-negative reactions due to other underlying diseases or previous history of treatment.

- The results of non-treponemal tests may become negative when the treatment is administered in primary or secondary stage of syphilis. However, when the treatment is administered in late syphilis, the non-treponemal tests may remain positive for life.
- The treponemal tests may become positive earlier than the non-treponemal tests. Once positive, most (85%) remain positive on successive treponemal tests even with successful treatment of the infection.

1 Wendel GD Jr, Stark BJ, Jamison RB, Molina RD, Sullivan TJ. Penicillin allergy and desensitization in serious infections during pregnancy. N Eng l J Med. 1985 May 9;312(19):1229-32. PMID: 3921835https://www.nejm.org/doi/10.1056/NEJM198505093121905

(See figure 4.3 & 4.4).

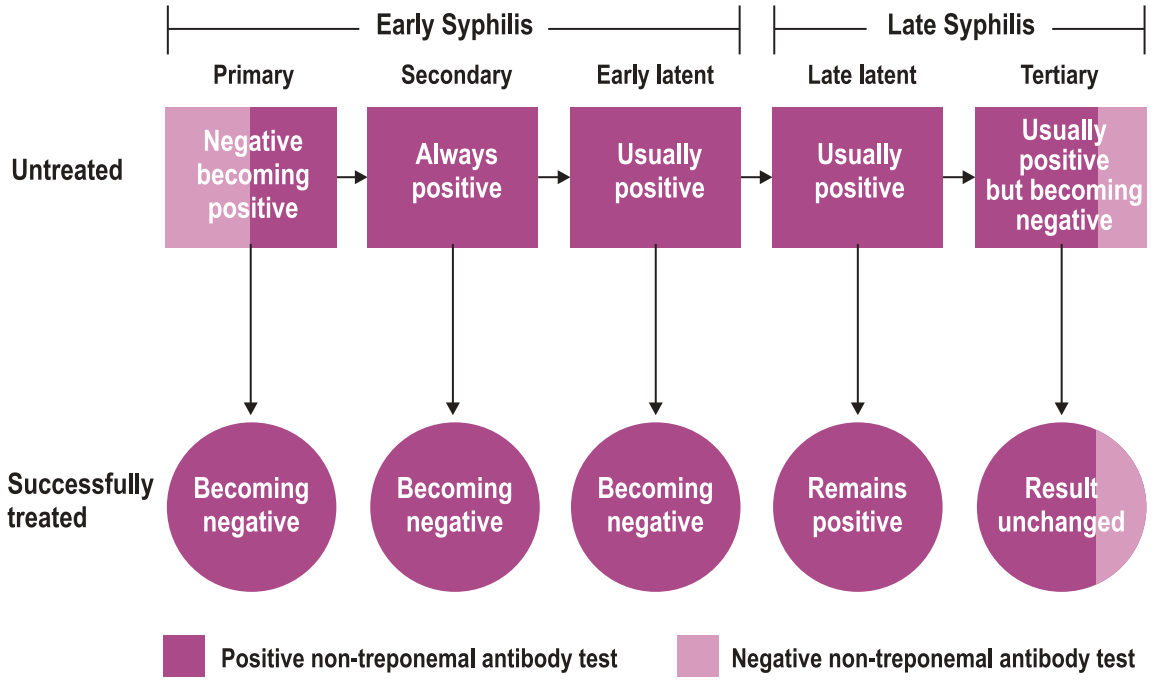

Figure 4.3. Interpretation of non-treponemal tests by stage of syphilis and effect of treatment

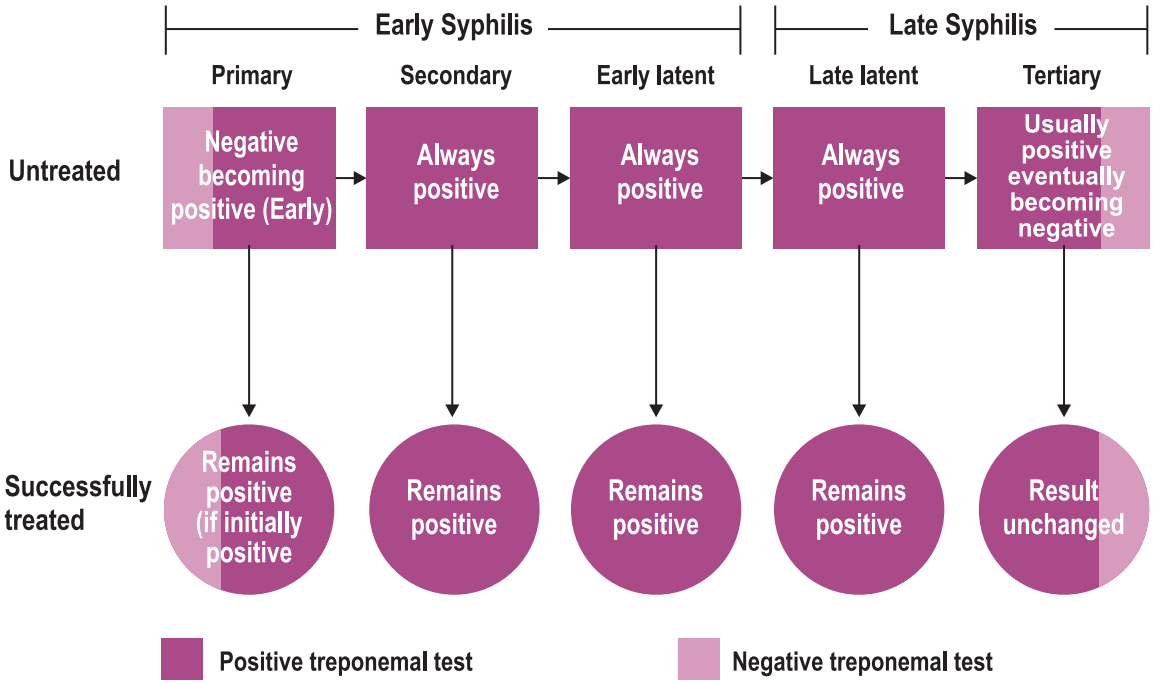

Figure 4.4. Interpretation of treponemal tests by stage of syphilis and effect of treatment

(**Figure 4.3 and 4.4 Credits:** Unemo M, Ballard R, Ison C, Lewis D, Ndowa F, Peeling R, editors. Laboratory diagnosis of sexually transmitted infections, including human immunodeficiency virus. Geneva: World Health Organization; 2013 (http://apps.who.int/iris/bitstream/10665/85343/1/9789241505840_eng.pdf)

Syphilis infection in PLHIV

- Though rare, unusual responses for treponemal & non-treponemal tests might be observed among people living with HIV with syphilis co-infection which may involve:
  - Higher (than expected)/ fluctuated post-treatment serological titers
  - False negative serological test results and delayed appearance of sero-reactivity
- 'Prozone phenomenon' refers to a false negative response of a serological test resulting from overwhelming antibody titers. It is most often associated with secondary syphilis, HIV co-infection, and pregnancy.
- Neurosyphilis, ocular syphilis, and oto-syphilis should be considered as the differential diagnosis of neurologic, ocular, and other signs and symptoms among persons with HIV infection.
- CSF examination should be conducted for those with an abnormal neurologic examination (e.g., cranial nerve dysfunction, meningitis, stroke, acute or chronic altered mental status, or loss of vibration sense).
- Treatment must be considered in all PLHIV when the clinical findings are suggestive of syphilis, but serological titers are non-reactive, or their interpretation is unclear.
- No treatment regimens for syphilis have been demonstrated to be more effective in treating syphilis among persons with HIV infection than the syphilis regimens recommended for persons without HIV.
- The patients should be evaluated clinically and serologically for treatment failure at 3, 6, 9, 12, and 24 months after therapy.
- Using ART as per latest National Guidelines for HIV Care and Treatment, NACO might improve clinical outcomes among persons coinfected with HIV and syphilis.
- Concerns related to adequate treatment of syphilis among persons with HIV infection might not apply to those who have sustained HIV virologic suppression.

2.2. Genital Herpes

Genital herpes is a chronic, lifelong viral infection. It is associated with recurrent symptoms and occurs as painful lesions in the genital organs. There are two types of HSV that can cause genital herpes: HSV-1 and HSV-2. Majority of cases of recurrent genital herpes are caused by HSV-2. However, an increasing fraction of anogenital herpetic infections have been ascribed to HSV-1 (prominent among young women and MSM).

The virus enters the body through breaks in the skin or mucosa and enters in the epithelial cells where it is taken up by sensory nerve endings and transported to the respective sensory ganglion. The skin manifestations involve vesicular lesions leading to shallow ulcerations that heals within 2-3 weeks without scarring. The virus remains latent in the sensory ganglion for the lifetime. It may periodically re-activate and travel back to the skin/mucosa through the involved nerves. This may be responsible for intermittent viral shedding with or without clinical manifestations. This is responsible for recurrence of lesions in the same area of the skin. There are chances of vertical transmission of genital herpes from infected mother to her baby.

The clinical manifestations include papular/vesicular lesions on ano-genital or extra-genital areas, perineal pain, dysuria, dyspareunia, inguinal discomfort or pain, pharyngitis, vaginal/cervical/urethral discharge, urethritis, and cervicitis.

Diagnostic Considerations:

- Genital herpetic infection is often diagnosed on clinical grounds, but laboratory confirmation of the diagnosis may be necessary. Laboratory methods used in the diagnosis of HSV infection include direct detection of HSV (virological tests) and indirect serological methods.

Management Considerations:

- The management varies as per the history of recurrence of the episodes:
  - **Primary Infection:** First episode of vesicular ulcers
  - **Recurrent Outbreaks:** The following could be the line of management in recurrent outbreaks:
    - Episodic Therapy: It is recommended at the onset of every outbreak.
    - Suppressive Therapy: It is recommended for individuals with 4–6 or more recurrent episodes per year or in episodes with severe symptoms or that cause distress.
- Suppressive therapy may be discontinued after a maximum of one year and the frequency of recurrence should be reassessed. Patients who continue to have unacceptably high rates of recurrence may be restarted on treatment. It should be provided under closed supervision and regular follow-ups (once in every 3 months).
- The pregnant women should be asked history of genital herpes and examined carefully for herpetic lesions.
  - Women without symptoms or signs of genital herpes or its prodrome can deliver vaginally.
  - Women with genital herpetic lesions at the onset of labour should be delivered by caesarean section to prevent neonatal herpes.
  - Acyclovir may be administered orally to pregnant women with first episode genital herpes or recurrent herpes.
- No treatment is recommended for herpes in partners in the absence of active episode/ lesions. However, the infected person should abstain from sex when active lesions or prodromal symptoms are present.
- Immunocompromised patients (including HIV infected persons) can have long or severe episodes of ano-genital or oral herpes with painful and atypical lesions. There is greater shedding of HSV in PLHIV. Though ART decreases the severity and frequency of symptomatic HSV infection, there might be frequent subclinical shedding of virus. Moreover, there are chances of clinical worsening of genital herpes during immune reconstitution when ART is initiated (maximum in first 6 months). Suppressive therapy for first 6 months can be considered in PLHIV infected with HSV while initiating ART. Dose adjustments are recommended for valaciclovir and famciclovir but not for acyclovir in PLHIV and immunosuppressed individuals.

Recommended Regimens:

The recommended regimens are mentioned in Table 4.4.

Table 4.4. Treatment for Ano-genital herpes

Infections Covered	First Line Options	Effective Substitutes	Option for pregnant and breastfeeding women and people younger than 16 years
Primary infection	**Acyclovir 400 mg,** orally, 3 times a day for 7 days, *or* **Acyclovir 200 mg,** orally, 5 times a day for 7 days	**Valaciclovir 500 mg,** twice a day for 7 days, *or* **Famciclovir 250 mg,** orally, 3 times a day for 7 days	The dosage is the same as for primary infection in non-pregnancy.
Recurrent Episodes of Herpes (episodic therapy)	**Acyclovir 400 mg,** orally, 3 times a day for 5 days, *or* **Acyclovir 800 mg,** orally, twice daily for 5 days, *or* **Acyclovir 800 mg,** 3 times a day for 2 days	**Valaciclovir 500 mg,** twice daily for 5 days, *or* **Famciclovir 250 mg,** orally, twice daily for 5 days	**Acyclovir 400 mg,** orally, 3 times a day for 5 days, *or* **Acyclovir 800 mg,** orally, twice daily for 5 days, *or* **Acyclovir 800 mg,** 3 times a day, for 2 days
Recurrent episodes of Herpes (Suppressive therapy)	**Acyclovir 400 mg,** orally, twice daily, *or* **Valaciclovir 500 mg,** once daily	**Famciclovir 250 mg,** orally, twice daily (Famciclovir 500 mg, twice daily for people living with HIV or immunocompromised)	**Acyclovir 400 mg,** orally, twice daily*

*It is recommended to initiate suppressive therapy in all cases of recurrent episodes of genital herpes at 36th week of pregnancy

2.3. Chancroid

Chancroid is caused by *Haemophilus ducreyi*. The disease presents as multiple painful ano-genital ulcers. It may be associated with unilateral painful inguinal lymphadenitis which if not treated promptly and adequately may lead to spontaneous rupture of suppurating lymph nodes (buboes). The ulcer is typically present on coronal sulcus in men and vulva in women. The perianal ulcers are common in receptive MSM and women who engage in anal/peri-anal intercourse.

The ulcer is painful, irregular with undermined edges, and usually not indurated. The base of the ulcer is frequently covered with purulent and necrotic exudates. Multiple lesions are common and may coalesce to form large ulcers.

Diagnostic Considerations:

There is no antigen detection, serological or NAAT available for commercial use for diagnosis of *H. ducreyi*. The diagnosis can be made through microscopy (Gram Stain) and culture.

Management Considerations:

- Patients should be followed-up within 7 days of initiation of therapy. In case of successful treatment, ulcers usually improve symptomatically within 3-7 days. The complete healing occurs in > 2 weeks. However, it may be delayed in uncircumcised men and PLHIV.
- All patients should be screened for HIV and syphilis.
- There are chances of slow healing of ulcers or treatment failure in PLHIV. Therefore, they should be monitored closely.
- All the sexual partners in previous 10 days of onset of symptoms should be examined and treated for chancroid.

Recommended Regimens:

- Tab. Azithromycin 1 gm orally single dose, or
- Injection Ceftriaxone 250 mg single dose intra-muscularly

2.4. Lymphogranuloma Venereum (LGV)

Lymphogranuloma Venereum or LGV is caused by *C. trachomatis* serovars L1, L2, or L3. LGV can cause severe inflammation and tissue invasion, in contrast with *C. trachomatis* serovars D–K that cause mild or asymptomatic urogenital infection. The clinical manifestations of LGV can include genital ulcers, lymphadenopathy, or proctocolitis (in case of anal exposure). The cases of proctocolitis may present with mucoid/hemorrhagic anal discharge, anal pain, constipation, fever, or tenesmus. The lymphadenopathy is unilateral and may results in the formation of inguinal bubo.

Diagnostic Considerations:

Genital or oral lesions, rectal specimens, and lymph node specimens can be tested for *C. trachomatis* by NAAT or culture.

Management Considerations:

- All the patients should be screened for HIV, syphilis, gonorrhea, and chlamydia.
- All the sexual partners within last 60 days should be screened and evaluated. Asymptomatic persons can be presumptively treated for chlamydia.
- The treatment recommendations remain similar for PLHIV. However, the resolution may be delayed in immunocompromised state.

Recommended Regimens:

- Doxycycline 100 mg, orally, twice daily for 21 days (preferred in cases of Inguinal Bubo or painful/ enlarged inguinal lymph nodes), or
- Azithromycin 500 mg, 2 tablets once a week for 3 weeks, or
- Erythromycin 500 mg, four times daily for 14 days (may be extended as per the assessment)

2.6. Granuloma inguinale (Donovanosis)

Granuloma inguinale or donovanosis is a genital ulcerative disease caused by the intracellular bacterium *Klebsiella granulomatis.* This infection causes chronic destructive lesion in the form of a well-defined ulcer in the skin, mucus membranes and lymphatic tissue of genital region. The ulcer can be painless

with slow progression without regional lymphadenopathy. However, it may be associated with formation of subcutaneous granulomas or pseudo-buboes. The ulcers are highly vascular (beefy red appearance) and may bleed.

Diagnostic Considerations: The causative organism is difficult to culture, and diagnosis involve visualization of Donovan bodies on tissue crush preparation or biopsy.

Management Considerations:

- All the patients should be screened for HIV, syphilis, gonorrhea, and chlamydia.
- All the sexual partners within last 60 days should be screened and treated as per the evaluation.
- The treatment recommendations remain similar for PLHIV.

Recommended Regimens:

- Azithromycin 1 g orally once weekly or 500 mg daily for >3 weeks, or
- Doxycycline 100 mg orally 2 times/day for at least 3 weeks, or
- Erythromycin base 500 mg orally 4 times/day for >3 weeks, or
- Trimethoprim-sulfamethoxazole one double-strength (160 mg/800 mg) tablet orally twice/day for >3 weeks

The treatment should be continued until all lesions are completely healed.

Group 3. Human Papilloma Virus (HPV) infections

Sexually active persons are usually exposed to HPV during their lifetime. The majority of HPV infections are self-limiting and are asymptomatic/unrecognized. Oncogenic, high-risk HPV infection (e.g., HPV types 16 and 18) are responsible for the majority of cervical, penile, vulvar, vaginal, anal, and oropharyngeal cancers and precancers, whereas other HPV infection (e.g., HPV types 6 and 11) causes genital warts and recurrent respiratory papillomatosis. Persistent oncogenic HPV infection is an important risk factor for development of HPV-attributable precancers and cancers.

Image 4.2. Penile Wart

HPV infection can be easily transmitted between sexual partners through skin-to-skin contact, sexual intercourse or sharing of sex toys. Condoms and dental dams can reduce the chances of HPV transmission but do not prevent it completely.

HPV infection may present as following disease manifestations:

3.1. Anogenital warts (condylomata acuminata): These are benign exophytic, papular or flat growths in the anogenital area and rarely cause problems when it results in obstruction. They are common in sexually active populations and are largely diagnosed clinically. There is a common tendency for recurrence after treatment. HPV types 6 and 11 are responsible for the majority of anogenital warts. Biopsy is indicated in the circumstances when the patient is immunocompromised (including those with HIV infection) and the diagnosis is uncertain, the lesions do not respond to standard therapy, or the disease deteriorates during therapy.

Management considerations:

- The entire external anogenital area and urethral meatus should be examined with good illumination.
- When the warts are located at the introitus, where the upper limit cannot be visualized, or when the external warts are presented with other vulvovaginal symptoms such as irritation, bleeding, or discharge, per speculum examination is recommended to understand the extent of the wart.
- Proctoscopy and digital anorectal examination are advised when the warts are located at the anal margin where the upper limit cannot be visualized, or when the external warts are associated with other anal symptoms such as irritation, bleeding, or discharge.
- Prompt biopsy is advised in lesions with atypical clinical features and/or when there is clinical suspicion of malignancy.
- A combination therapy (provider-administered cryotherapy with patient-applied topical therapy between visits to the provider) is preferred by most of the health providers. Anogenital warts typically respond within 3 months of therapy.
- HPV testing of sex partners is not recommended. Partners should be physically examined to detect genital warts and screened for other STI.
- Consistent and correct condom use is advised to reduce the risk of transmission of HPV to the partners.
- Smoking is associated with increased incidence and reduced clearance of HPV infection and recurrence of ano-genital warts. Therefore, it is recommended to avoid smoking in patients with ano-genital warts.

Recommended Regimens:

Provider-administered Therapy

- Cryotherapy with liquid nitrogen or cryoprobe, or
- Surgical removal by tangential scissor excision, tangential shave excision, curettage, laser, or electrosurgery, or
- Trichloroacetic acid (TCA) or bichloroacetic acid (BCA) 80%–90% solution
- Podophyllum resin 20%

Patient-applied Therapy

- Imiquimod 3.75% or 5% cream applied overnight thrice a week for up to 16 weeks (not recommended in pregnancy), or

- Podophyllotoxin 0.5% solution or 0.5 -1.5% cream twice daily for 3 days, followed by 4 days of no treatment (this cycle can be repeated up to four times), or
- Sinecatechins 15% ointment

Considerations in pregnancy:

- Ano-genital warts can proliferate and become friable during pregnancy
- Podofilox, podophyllin, trichloroacetic acid and sinecatechins should not be used during pregnancy. Though imiquimod pose low risk, it should be avoided during pregnancy.
- Although removal of warts can be considered during pregnancy, resolution might be incomplete or poor.
- Rarely, HPV types 6 and 11 can cause respiratory papillomatosis among infants and children. However, the route of transmission (i.e., transplacental, perinatal, or postnatal) is not completely understood.
- Cesarean delivery is indicated for women with anogenital warts in case of obstruction or if vaginal delivery would result in excessive bleeding.
- Pregnant women with anogenital warts should be counseled about the potential low risk for warts on the larynx of their infants or children (recurrent respiratory papillomatosis).

Note:

1. Podophyllin should not be applied to the cervix, vagina, or anal canal where the squamocolumnar junction is vulnerable to dysplastic changes. The solution should be allowed to dry completely after application to prevent irritation.
2. Patients should apply a thin layer of Imiquimod to external, visible warts, then rub in the cream until it vanishes. The area is washed with soap and water 6-10 hours after treatment. Imiquimod may weaken condoms and diaphragms, and sexual contact is not recommended while the cream is on the skin.
3. There are cases reported for dyspareunia following surgical excision/cautery of genital warts (especially in females)

3.2. Recurrent respiratory papillomatosis (RRP): This is a rare condition characterized by recurrent wart-like growths or papilloma in the upper respiratory tract (may occur in lower respiratory tract) resulting in morbidity and mortality. Infection with HPV types 6 and 11 is responsible for RRP. When larynx is affected, it may lead to changes in voice. This can be diagnosed clinically through laryngoscopy/ bronchoscopy and treated surgically. The recurrence is not uncommon.

3.3. Anogenital precancers and cancers: Persistent infection with oncogenic HPV genotypes is strongly associated with an increased risk of anogenital cancer.

Anal Cancer

An annual digital ano-rectal examination (DARE) can be performed to detect early anal cancer in persons with HIV infection and all MSM with a history of receptive anal intercourse. The anal cytology and HPV testing is not recommended for screening of anal cancer.

Cervical Cancer

There are two approaches defined to screen and manage cervical cancers among women:

Approach 1: Screen-and-Treat Approach

The decision to treat under this approach is dependent on the positive results of the primary screening test only.

Approach 2: Screen-Triage-and-Treat Approach

The decision to treat under this approach is based on the positive result of the sequential second test (also known as 'triage' test) when the primary test is positive; with or without the histological confirmation of the diagnosis.

The latest guidelines on Ministry of Health and Family Welfare, Government of India can be referred for screening recommendations of cervical cancer.

HPV Vaccination

There are three types of HPV vaccines: bivalent (targets HPV types 16 and 18, currently not available in India); quadrivalent (targets HPV types 6, 11, 16, and 18); and nonavalent (targets HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58). HPV vaccination only prevents HPV infection and does not treat the existing infection. Therefore, it is advised to ideally vaccinate before the 'sexual debut'.

In India, HPV vaccination is recommended as a one-time catch-up for 9 to 14-year-old adolescent girls followed with routine introduction at 9 years. The latest guidelines on Ministry of Health and Family Welfare, Government of India can be referred for recommendations on HPV vaccination.

Group 4. Viral Hepatitis

Viral hepatitis is caused by Hepatitis A, B, C, D and E viruses and can lead to acute, chronic or sequel of chronic infection. While hepatitis A and E are often the cause for sporadic or outbreaks of hepatitis, hepatitis B and C can either clear spontaneously or can lead to chronic infection and there after sequelae like cirrhosis and hepatocellular carcinoma (HCC). The viral hepatitis A, B and C can be transmitted through sexual route.

4.1. Hepatitis A Virus (HAV) Infection

HAV infection produces a self-limiting disease that does not result in chronic infection or chronic liver disease. However, approximately 10% of patients experience a relapse of symptoms during the 6 months after acute illness. Acute liver failure from hepatitis A is rare. HAV infection is primarily transmitted through fecal-oral route, by either person-to-person contact or through consumption of contaminated food or water. Transmission of HAV during sexual activity probably results from fecal-oral contact.

Presence of IgM antibody to HAV is diagnostic of acute HAV infection. A positive test for total anti-HAV indicates immunity to HAV infection but does not differentiate current from previous HAV infection. There is no role of antiviral drugs in the treatment of HAV infection. Most of the patients with hepatitis A infection recover completely with no clinical sequelae.

4.2. Hepatitis B Virus (HBV) Infection

HBV infection can be either self-limiting or chronic. Sexual contact and percutaneous transmission contribute to the transmission of HBV. It can transmit vertically and occasionally horizontally in childhood. Around half of newly acquired HBV infections are symptomatic in adults, and approximately 1% of reported cases result in acute liver failure and death. The risk for chronic infection is inversely related to the age of acquisition of infection. The risk for premature death from cirrhosis or hepatocellular carcinoma in chronic HBV infection is 15%–25%.

The primary risk factors for infection among adolescents and adults are unprotected sex with an infected person, multiple sexual partners, MSM with history of other STI, and injecting drug use.

Hepatitis B vaccine provides protection from HBV infection when used for both pre-exposure vaccination and post-exposure prophylaxis. Three different 3-dose schedules are available for adolescents and adults for monovalent hepatitis B vaccines and can be administered at 0, 1, and 6 months; 0, 1, and 4 months; or 0, 2, and 4 months. Under National Viral Hepatitis Control Program (NVHCP), hepatitis B vaccine is provisioned for HRGs those who screened negative for HBsAg.

4.3. Hepatitis C Virus (HCV) Infection

Hepatitis C infection is usually acquired through infected syringes and needles, and transfusion of infected blood. Sexual transmission of HCV occurs infrequently and is reported to be more common in HIV-positive persons, particularly in MSM[2]. The risk of transmission of HCV from a mother to her child occurs in 4–8% of births to women with HCV infection. HCV causes both acute and chronic hepatitis. Acute hepatitis is often clinically mild and marked by fluctuating elevations of serum aminotransferase levels; >50% likelihood of chronicity, leading to cirrhosis in >20%. HCV infection is curable, and persons with diagnosed HCV infection should be linked to care and treatment.

Note: Refer to the National Guidelines for Diagnosis & Management of Viral Hepatitis for further details on diagnosis and management of viral hepatitis in India.

Group 5. Sexually transmitted infestations

Infestations refers to parasitic diseases caused by animals such as arthropods (i.e., mites, ticks, and lice) and worms. There are ectoparasitic infestations that can spread to sexual and close contact.

5.1. Pediculosis Pubis

Pediculosis pubis or pubic lice infestation is caused by an ectoparasite, *Phthirus pubis* and is usually transmitted through sexual contact. It may also spread through close personal contact or contact with articles used by an affected person (e.g., bed linens, clothes, or towels). A pubic lice have three forms: the egg (also called a nit), the nymph, and the adult. They are usually found on pubic hairs and may occasionally found on coarse body hairs on legs, torso, armpits, mustache, and eyebrows/eyelashes. Pubic lice on eyebrows/eyelashes of children may be an indication of sexual exposure/abuse. These persons should be considered at-risk for HIV and other STI and should be screened and properly examined.

2 Nijmeijer, B. (2019). Sexually transmitted hepatitis C virus infections: current trends, and recent advances in understanding the spread in men who have sex with men. *Journal of the International AIDS Society*, *22 Suppl 6*(Suppl Suppl 6), e25348. https://doi.org/10.1002/jia2.25348

Pubic lice do not transmit any infection and are associated with intense itching in pubic and groin area. The scratching may lead to sores and local bacterial infection of the skin.

Diagnostic Considerations:

Pediculosis pubis is diagnosed by finding a “crab” louse or eggs on hair in the pubic region or, other parts of the body as mentioned above. Though pubic lice and nits can be seen with the naked eye, a magnifying lens may be used to find lice or eggs.

Management Considerations:

- The bed linens, towels and clothing should be machine washed and dried by using the heat cycle or dry cleaned
- The affected persons should be screened for STI (including HIV and Syphilis).
- All the sex partners within a month should be screened and treated accordingly.
- Persons should abstain until they and their partners have been successfully treated and reevaluated to rule out persistent infestation.
- Pregnant and breastfeeding women can be treated with permethrin.
- The treatment recommendations are similar for PLHIV infested with pubic lice.

Recommended Regimens:

- Permethrin 1% cream rinse applied to affected areas and washed off after 10 minutes, or
- Pyrethrin with piperonyl butoxide applied to the affected area and washed off after 10 minutes, or
- Malathion 0.5% lotion applied to affected areas and washed off after 8–12 hours, or
- Ivermectin 250 *μ*g/kg body weight orally (should be taken with meal)

The treatment should be repeated after 7-14 days.

5.2. Scabies

Scabies is caused by the mite *Sarcoptes scabiei*. It is associated with severe pruritus (itching) which becomes worse at night. The mites are transmitted through sexual and close contact and sharing of clothes, towels, or linens. The scabies in children is usually not sexually acquired. The complications involve eczematization (with or without secondary infections), urticaria, glomerulonephritis and contact dermatitis against anti-scabies drugs.

Crusted Scabies (Norwegian Scabies): It is an aggressive form of scabies that usually occurs in immunocompromised, elderly, debilitated or malnourished persons, persons on systemic corticosteroid therapy, organ transplant recipients or persons infected with HIV or HTLV-1 and with hematologic malignancies. It is highly contagious, presents as thick crusts of skin that contain large numbers of scabies mites and eggs and may result in outbreaks.

Diagnostic Considerations:

- Diagnosis can be made by identifying burrows, eggs, mites, or their feces on the skin or from the skin scrapings collected from affected areas of the body.
- Tiny burrows can be observed on the skin which may appear as tiny raised and crooked (serpiginous) grayish-white or skin-colored lines on the skin surface. They are found most often in the finger webs, skin folds on the wrist, elbow, or knee, and on the penis, breast, or shoulder blades.

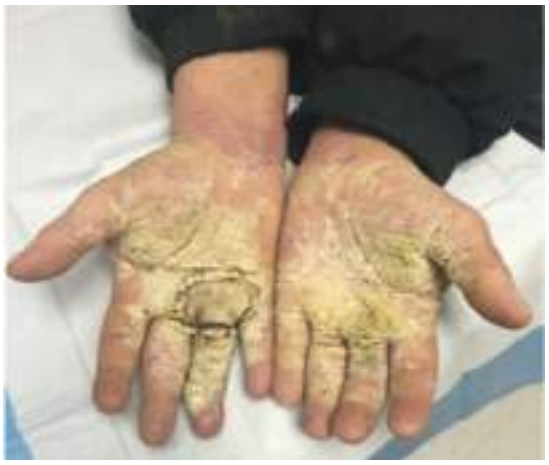

Image 4.3 Norwegian Scabies[1]

Management Considerations:

- The bed linens, towels and clothing should be machine washed and dried by using the heat cycle or dry cleaned
- The affected persons should be screened for HIV and other STI.
- All the sex partners within a month should be screened and treated accordingly.
- Persons should abstain until they and their sexual partners have been successfully treated and re-evaluated to rule out persistent infestation.
- Pregnant and breastfeeding women can be treated using the same regimens. However, infants and young children should be treated with permethrin only.
- The PLHIV infested with uncomplicated scabies can be treated with the same regimen as HIV negative persons. The patients with crusted scabies should be referred to specialist for adequate management.
- Mass drug administration with oral ivermectin is suggested in outbreaks and endemic areas.
- Retreatment after 2 weeks is recommended for those persons who are still symptomatic or when live mites are observed.
- Combination treatment with a scabicide and ivermectin is recommended in the cases of crusted scabies.

Recommended Regimens:

- Permethrin 5% cream applied to all areas of the body from the neck down and washed off after 8–14 hours, or
- Ivermectin 200 *µg*/kg body weight orally (should be taken with meal) *, or
- Ivermectin 1% lotion applied to all areas of the body from the neck down and washed off after 8–14 hours*

*Should be repeated in 14 days.

For crusted scabies,

- Permethrin 5% cream (applied to all areas of the body from the neck down and washed off after 8–14 hours) daily for 7 days, followed by twice/ week application until cure, plus

[1] Image Credit: Aukerman W, Curfman K, Urias D, Shayesteh K. Norwegian Scabies management after prolonged disease course: A case report. Int J Surg Case Rep. 2019;61:180-183. doi: 10.1016/j.ijscr.2019.07.025. Epub 2019 Jul 23. PMID: 31376739; PMCID: PMC6677688.

- Oral ivermectin 200 *u*g/kg body weight on days 1, 2, 8, 9, and 15. (Additional treatment may be needed in severe cases on days 22 and 29)

Group 6. Molluscum Contangiosum

It is caused by Pox virus. The virus spreads from direct person-to-person physical contact (including sexual contact) and through contaminated fomites. The infection is characterized by multiple, smooth, glistening, globular umblicated papules of varying size from a pinhead to a split pea can appear anywhere on the body. Sexually transmitted lesions can be seen in genital and surrounding areas of the body. The lesions are not painful except in cases of secondary infection. When the lesions are squeezed, a cheesy material comes out. Low CD4 cell count is associated with widespread facial molluscum and therefore it is considered as a marker for severe HIV disease.

Diagnostic Considerations:

Diagnosis is based on the above-mentioned clinical features.

Management:

- Individual lesions usually regress without treatment in 9-12 months.
- The recommended topical treatments are podophyllotoxin (contraindicated in pregnant women), 10% potassium hydroxide, 17% salicylic acid (associated or not with povidone-iodine), 5-10% benzoyl peroxide and tretinoin 0.05%.
- Each lesion should be thoroughly opened with a fine needle or scalpel. The contents should be exposed, and the inner wall touched with 25% phenol solution or 30% trichloroacetic acid.
- Physical removal can be done using cryotherapy with liquid nitrogen, curettage, or laser treatment.
- Gentle squeezing or pricking with a sterile needle are alternatively recommended methods for management of lesions.

Group 7. Emerging and Re-emerging STI

There are infections which were previously not known to be sexually transmitted are emerging as STI. Though changing sexual dynamics and behavioral patterns may be a contributing factor in this emergence, increased globalization and physical connectivity has resulted in spread of these emerging STI. This list includes dengue, Ebola, *Entamoeba histolytica,* hepatitis C, methicillin-resistant *Staphylococcus aureus* (MRSA), *Mycoplasma genitalium, Neisseria meningitidis*, *Shigella flexneri*, Zika etc[3].

7.1. Mpox

Mpox (formerly known as Monkeypox) is a viral illness caused by the monkeypox virus, a species of the genus *Orthopoxvirus* and family *Poxviridae*. There are two clades of the virus: Clade I and Clade II. The Clade I and II, are further divided into two sub clades- Clade Ia & Ib and Clade IIa & II b.

3 Balaji, S., Bhargava, A., & Aggarwal, S. (2022). Emerging and re-emerging sexually transmitted diseases: A review of epidemiological evidences. *Indian journal of sexually transmitted diseases and AIDS*, *43*(1), 20–26. https://doi.org/10.4103/ijstd.ijstd_58_21

Mode of Transmission

Mpox can spread through close contact with infected individuals or contact with contaminated materials or infected animals. Human-to-human transmission is known to occur through large respiratory droplets generally requiring a prolonged close contact with infected person. Being face-to-face (talking or breathing close enough for droplets to carry) with an infected person is a risk factor. It can also be transmitted through direct contact with body fluids or lesion material, and indirect contact with lesion material, such as through contaminated clothing or linens of an infected person. Transmission between sexual partners, having skin-to-skin contact, including sex and mouth-to-mouth or mouth-to-skin contact are among the risk factors. Pregnant women with Mpox can pass the virus to the fetus during pregnancy or to the new-born during and after birth. The understanding about mode of transmission is still evolving.

Animal-to-human transmission of Mpox may occur by bite or scratch of infected animals like small mammals including rodents (rats, squirrels) and non-human primates (monkeys, apes) or through bush meat preparation. Skinning such animals or eating their meat if it's not cooked thoroughly also exposes one to the disease. Close contact with a pet that is infected, including petting, cuddling, hugging, kissing, licking, and sharing sleeping spaces or food, can spread Mpox to a person. People with low or compromised immunity are at a higher risk. Moreover, it is currently unclear why more children are contracting Mpox.

Incubation period: The incubation period (interval from infection to onset of symptoms) of Mpox is usually from 6 to 13 days but can range from 5 to 21 days.

Clinical Presentation

Mpox is usually a self-limiting disease with symptoms lasting from 2-4 weeks. Severe cases occur more commonly among children and are related to extent of virus exposure, patient health status and nature of complications. The extent to which asymptomatic infection occurs is unknown. Mpox is characterized by an incubation period, prodrome, and rash.

Prodrome (0-5 days): A person may be contagious during this period. Isolation is advised when patient develop symptoms like fever, headache, muscle aches, exhaustion, chills and/or sweats, sore throat and cough and lymphadenopathy (peri-auricular, axillary, cervical or inguinal, could be unilateral or bilateral).

Skin involvement (rash): Lesions typically develop simultaneously and evolve together on any given part of the body. The evolution of lesions progresses through four stages —macular, papular, vesicular, to pustular —before scabbing over and desquamation. A person is contagious until after all scabs on the skin have fallen off and a fresh layer of intact skin has formed underneath. The lesions could be deep-seated, well-circumscribed and often develop umbilication. Lesions are often painful until healing phase when they become itchy (in crust stage). The area involved is face (98%), palms and soles (95%), oral mucous membranes (70%), genitalia (28%), conjunctiva (20%). Generally, skin rashes are more apparent on the limbs and face than on the trunk. The lesion heals with hyper-pigmented atrophic scars, hypo-pigmented atrophic scars, patchy alopecia, hypertrophic skin scarring and contracture/deformity of facial muscles following healing of ulcerated facial lesions. A notable predilection for palm and soles is characteristic of Mpox.

The differential diagnosis includes Varicella (Chicken pox), disseminated herpes zoster, disseminated herpes simplex, measles, chancroid, secondary syphilis, hand foot & mouth disease, infectious mononucleosis, molluscum contagiosum and Buffalopox.

Mpox in children

The Clade I of the monkeypox virus has been more commonly reported in children than clade II, but a new variant, clade Ib, is disproportionately affecting children. It is currently unclear why more children are contracting Mpox. However, it is postulated that in endemic areas, long-term exposure to the virus may have allowed adults to develop immunity over time, making them less vulnerable to the disease. In contrast, children are immunologically naïve and, therefore, more likely to contract the disease compared to adults

The complications of Mpox in children can be severe and may include secondary bacterial infections, severe skin infections, dehydration, pneumonia, encephalitis, ocular complications, and even longer sequelae such as scarring of skin lesions.

Case Definition

Case Definition include the following:

a. **Suspected case:** A person of any age having history of travel to affected countries within the last 21 days presenting with an unexplained acute rash AND one or more of the following signs or symptoms:
   • Swollen lymph nodes
   • Fever
   • Headache
   • Body aches
   • profound weakness
b. **Probable case**: A person meeting the case definition for a suspected case, clinically compatible illness and has an epidemiological link to a confirmed case.
c. **Confirmed case:** Any case which is laboratory confirmed for Mpox virus (by detection of unique sequences of viral DNA either by polymerase chain reaction (PCR) and/or sequencing).

Laboratory Diagnosis of Mpox

The recommended specimen type for laboratory confirmation of Mpox is skin lesion material from multiple sites, including swabs of lesion surface and/or exudate, roofs from more than one lesion, or lesion crusts. Oropharyngeal swab is recommended for diagnosis, if feasible, in addition to skin lesion material. The detailed procedure for sample collection and transportation of the clinical specimen are included in MoHFW Guidelines for Management of Mpox Disease (Available at: https://mohfw.gov.in/?q=diseasealerts-0).

All the clinical specimens should be transported to NCDC/NIV Pune/VRDLs routed through the IDSP network of the respective district/state. A network of testing laboratories is being enhanced for early diagnosis, with laboratories quipped for testing. The current list of laboratories equipped with Mpox testing is attached in **Annexure 2**. The updated list of laboratories can also be referred from Mpox CD Alert from NCDC, MoHFW. (Available at: https://ncdc.mohfw.gov.in/wp-content/uploads/2024/08/CD-Alert-Mpox-August-2024.pdf)

The flowchart for laboratory diagnosis of Mpox is mentioned in figure 1.

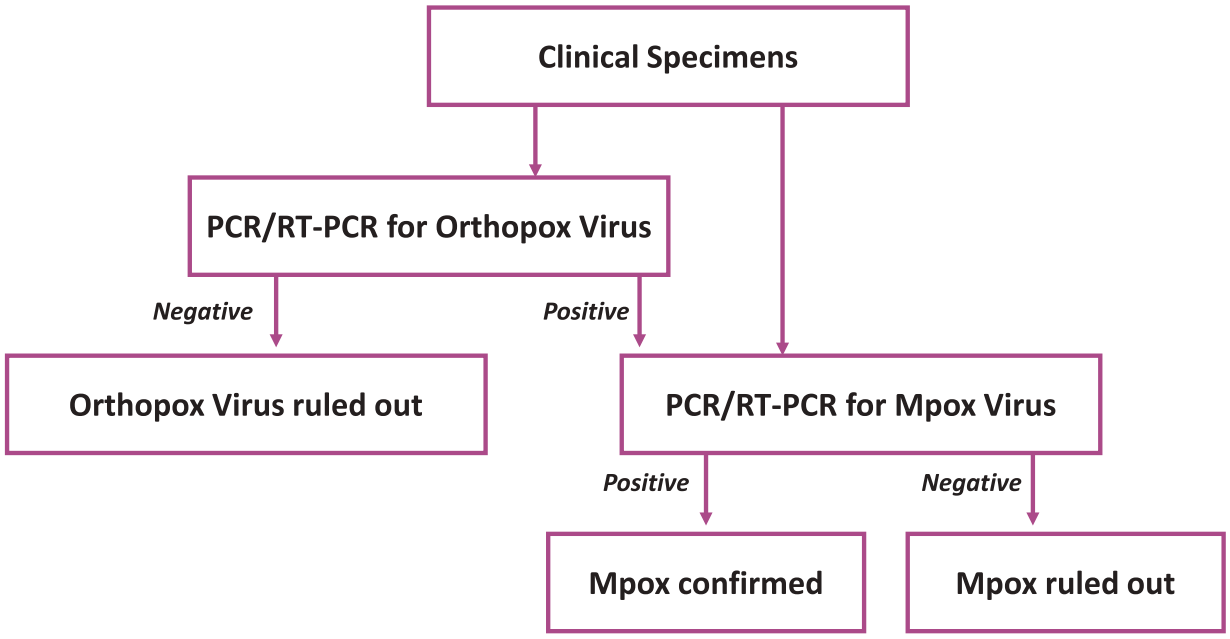

Figure 4.5. Flowchart for Laboratory Diagnosis of Mpox

Management

The treatment of Mpox is primarily supportive. The principles of management include:

- Patient isolation
- Protection of compromised skin and mucous membranes
- Rehydration therapy and nutritional support
- Symptom alleviation
- Antibiotics to treat secondary bacterial infections if they develop
- Monitoring and treatment of complications
- Isolation of patient is advised until all lesions have resolved, and scabs have completely fallen off and a fresh layer of intact skin transformed.

The drugs may be considered in special severe cases, strictly as per treating physician and are NOT to be self-administered. These include Tecovirimat, Vaccinia Immune Globulin Intravenous, Cidofovir & Brincidofovir (effective against Orthopoxviruses in invitro & animal studies).

As Mpox is an emerging disease, the updated guidance of MoHFW can be referred for further information.

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Chapter 5 Laboratory Diagnosis of STI and RTI

Sexually transmitted and reproductive tract infections are caused by more than 30 viral, bacterial, protozoal, and parasitic organisms. Although most of these organisms are transmitted sexually from one person to another, these may be acquired through other routes of transmission including blood, body fluids and close physical contact. There are a large number of laboratory-based as well as point-of-care (PoC) tests that aid in the screening and diagnosis of these infections. Each test has its own merits and potential limitations that can be decisive in their implementation in respective settings and level of intervention. In healthcare facilities with limited availability of resources**,** it is of paramount importance to prioritize test selection on the basis of prevalence and impact of the infection; performance characteristics, costs involved and the implementation settings. The purpose of laboratory investigations of STI and RTI is mentioned in Table 5.1.

Table 5.1. Purpose of Laboratory Testing for STI AND RTI

No.	Purpose	Details
1.	Screening	Testing of at-risk persons without documented signs/symptoms (screening) helps in identifying infected persons and therefore, reducing risks of further transmission and development of complications. The approach of screening for STI and RTI among high-risk or at-risk populations can be an effective approach to control the spread of these infections.
2.	Confirmatory Diagnosis	Conducted for patients presenting with specific signs/symptoms and/or reactive screening tests to ascertain accurate diagnosis for guiding management of patients and their partners.
3.	Validation of Syndromic Management	Periodic laboratory testing of patients diagnosed and treated using syndromic management algorithms for STI and RTI should be conducted, to confirm that the algorithms are successful in targeting the infections treated under particular syndromes.
4.	Determination of Antimicrobial susceptibility	The emergence of antimicrobial resistance has impacted the management of STI and RTI. Therefore, periodic determination of antimicrobial susceptibility is essential for updating the antimicrobial profile and ensuring appropriate treatment. This is of special importance in gonorrhea.
5.	Surveillance	Surveillance is the systematic collection, and analysis of data to determine how common an infection is within a community or population. It is an essential element for planning of public health interventions.

Quality Assurance: The domain of quality assurance involves quality control and assessment. Quality control assures that tests are performing as intended and quality assessment ensures that tests are being used appropriately and all steps needed to use tests are being carried out appropriately. The periodic testing of standardized specimens is essential to assess laboratory proficiency and to assure expected accuracy of the test. This ensures proper functioning of laboratory.

This chapter briefly describes screening and diagnosis of important STI and RTI. As the development and upgradation of diagnostics is a real-time process, this chapter attempts to provide most recent updates on the laboratory diagnosis of STI and RTI.

5.1. Gonorrhoea

Neisseria gonorrhoeae is the causative organism for a spectrum of diseases in urogenital, pharyngeal, rectal, and conjunctival sites. The disease is frequently asymptomatic, especially among women, and in the pharyngeal, and rectal sites. The symptoms, if present, can be non-specific. In males, the disease may present as a profuse and purulent urethral discharge while in females, the infection may present as cervicitis. Laboratory confirmation of clinical diagnosis of urethral discharge in men and cervicitis in women should be undertaken, wherever available and possible.

N. gonorrhoeae (or gonococcus) is a fastidious, non-flagellated, non-sporing, gram negative diplococcus (arranged in pairs), that appears as a characteristic kidney or coffee bean morphology in microscopy. It requires complex, nutritionally rich, culture media for in-vitro growth. It is aerobic, capnophilic (prefer enhanced concentration [3–7%] of carbon dioxide), intra/extra cellular, and oxidase- and catalase producing cocci.

Microscopy:

- Identification of gram-negative, intracellular diplococci in polymorphonuclear leukocytes (PMNL) in a gram-stained smear of specimen is suggestive of gonorrhoea. (See Figure 5.1).
- The sensitivity and specificity for the diagnosis of gonorrhoea through microscopy in symptomatic men with urethral discharge is more than 95% and 97%, respectively.
- The detection of the organism in smears of cervical secretions in females, is only 40–60% of culture-positive specimens.
- Direct microscopic examination is not recommended for the diagnosis of rectal and pharyngeal infections due to low sensitivity as large number of other organisms are present in the specimen.
- Screening of asymptomatic persons using microscopy is not recommended, except in high-risk groups.

Culture:

- Culture of *N. gonorrhoeae* is the “gold standard” for the diagnosis of genital as well as extra-genital (rectal, oropharyngeal, and conjunctival) gonococcal infections.
- If conducted in optimized circumstances, it is sensitive and highly specific.
- This method also allows for antimicrobial susceptibility testing (AST) for *N. gonorrhoeae* and to detect plasmid mediated resistance of *N. gonorrhoeae* to penicillin by performing Beta-Lactamase test

(See Image 5.1 & 5.2)

Nucleic Acid Amplification Test (NAAT)

- The sensitivity of NAAT (specific types) in detecting *N. gonorrhoeae* from urogenital and non-genital anatomical sites is superior to culture.
- The optimal specimen for screening of urogenital infections using NAAT include urethral swabs in males and urethral and/or cervical swabs in females or first-void urine specimen in either sex.

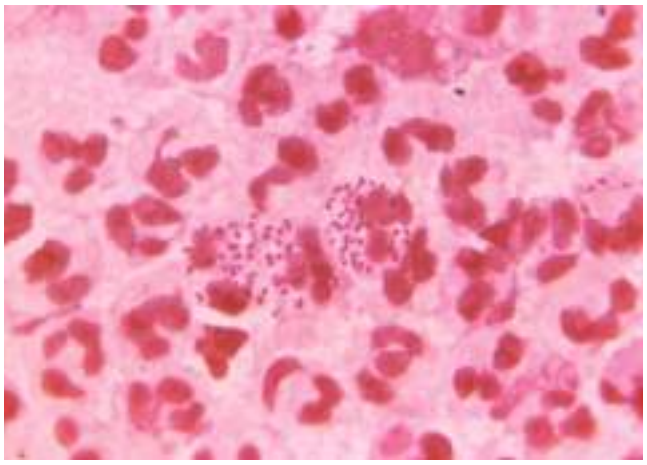

Image 5.1. Presence of intracellular Gram-negative, diplococci, amongst numerous polymorphonuclear leukocytes (PMNs)

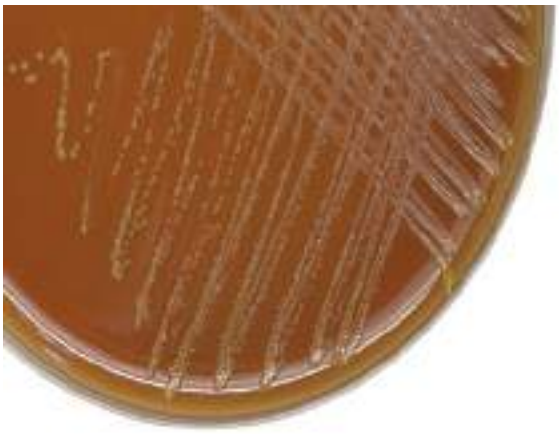

Image 5.2. Typical colonies of *N. gonorrheae* on chocolate agar

There are no enzyme immunoassays, immunofluorescence assays and rapid PoC tests for antigen/antibody detection available for diagnosis of gonorrhoea with appropriate performance characteristics.

5.2. Chlamydial Infections

C. trachomatis is the etiological agent of chlamydiasis and is responsible for a spectrum of diseases in a variety of sites (i.e., genital, ocular, lymph nodes, and bronchial sites). *C. trachomatis* has been classified into three biovars, each containing several serovars or genotypes: those causing trachoma (eye infection), genital infection (STI), and lymphogranuloma venereum (LGV; a genital ulcer disease).

The predominant serotypes which can transmit sexually and infect the genital epithelium, consist of serovars D to K. These serovars are responsible for causing urethritis in men and cervicitis (and urethritis) in women. The LGV serovar, consisting of serovars L1–L3 is also sexually transmitted, with preference for lymphoid cells and more aggressive disease progression. The urogenital infections are asymptomatic in up to 50% cases in men and up to 90% in women.

Microscopy:

- Smear examination is not helpful in the diagnosis of genital chlamydia infection as it has less sensitivity (<30%).
- Gram stain of urethral specimen from men with urethral discharge demonstrating polymorphonuclear leukocytes (PMNL) without the presence of Gram-negative diplococci is strongly indicative of chlamydial infection.

Antigen/Antibody Detection:

- Direct Fluorescent Antibody (DFA) technique is sensitive in symptomatic patients.
- Enzyme Immunoassays are less reliable than tissue culture. The rapid immunoassays (PoC) have further lower sensitivity than classic immunoassays.
- The use of antibody detection has limited use in diagnosis of urogenital infections. The serological tests (e.g., Micro immunofluorescence test and ELISA) can be of possible aid in the diagnosis and/or screening for complicated *C. trachomatis* infections, neonatal pneumonia, and LGV infections, as well as in epidemiological studies.

Tissue Culture:

- Tissue culture using Mc Coy cell line or any other cell lines, although highly specific, is an expensive, slow, labour intensive and technically difficult procedure for most of the laboratories.
- Though the specificity of culture is 100%, its sensitivity is estimated to be around 70-85%.
- Culture has a suboptimal sensitivity in comparison to commercially available and internationally approved NAATs and cannot be recommended for diagnostics if appropriate NAAT is available and affordable.

Nucleic Acid Amplification Test (NAAT)

- NAATs are the most sensitive tests for detecting *C. trachomatis* infection through urethral swab (in men), cervical swab (in women) and first void urine (in both men and women). Therefore, NAATs are strongly recommended for diagnosis and screening of chlamydial infections.
- Newer NAATs have demonstrated improved sensitivity and specificity in diagnosing *C. trachomatis* in rectal and oropharyngeal sites.

Note: Gonorrhoea and chlamydiasis often co-exist and should be investigated and treated, when present together.

5.3. Syphilis

Syphilis is caused by the bacterium *Treponema pallidum* subspecies *pallidum* which is a spirochete. It is a delicate, spiral organism closely related to the causative organisms for other non-venereal treponematoses [those causing Yaws (subspecies *pertenue*), Endemic Syphilis (subspecies *endemicum*) and Pinta (*Treponema carateum*)]. These pathogens are morphologically and antigenically identical and can only be differentiated by local epidemiology, mode of transmission, clinical manifestations and through genetic sequencing.

The transmission of venereal syphilis occurs due to the contact of infectious lesion with the mucous membrane or injured skin. The pathogen cannot be cultivated on artificial media. Therefore, the diagnosis of syphilis is conducted by:

- Direct detection methods from specimens obtained from skin lesions or tissues in early syphilis. E.g., Dark field microscopy, direct immunofluorescence and tests detecting specific DNA sequences.
- Serological tests by detecting antibodies to the pathogen in serum or spinal fluid.

5.3.1. Serological Tests

The serological tests for syphilis can be further sub-divided into non-treponemal and treponemal tests. A presumptive diagnosis of syphilis requires a positive result from at least one of these types of tests. A confirmed diagnosis requires positive results from both types of serologic tests. Serum is the specimen of choice for serological testing, although plasma/ whole blood can be used in some of the serological tests. Cerebrospinal fluid can be used to diagnose congenital and tertiary syphilis and when neuro-syphilis is suspected.

Non-Treponemal Tests: The most widely available non-treponemal tests are the microscopic Venereal Diseases Research Laboratory (VDRL) and Rapid Plasma Reagin (RPR) tests (see Image 5.3). These tests detect anti-cardiolipin IgM or IgG antibodies. As these antibodies can also be formed in other

diseases, non-treponemal tests are not highly specific for syphilis. These tests can give false-positive results in conditions such as acute febrile viral infections and some chronic autoimmune diseases. These tests may be negative for up to four weeks after the appearance of lesion of primary syphilis and can be negative in the stage of late latent syphilis. Moreover, these tests may be false negative due to 'prozone phenomenon' in primary and secondary syphilis. Repeat testing after 2-4 weeks may be required to exclude syphilis (in case primary syphilis is suspected). A negative non-treponemal test after three months of onset of the primary chancre excludes the diagnosis of syphilis. The non-treponemal tests may be qualitative or semi-quantitative. The titres of a semi-quantitative test can be used to monitor response to treatment.

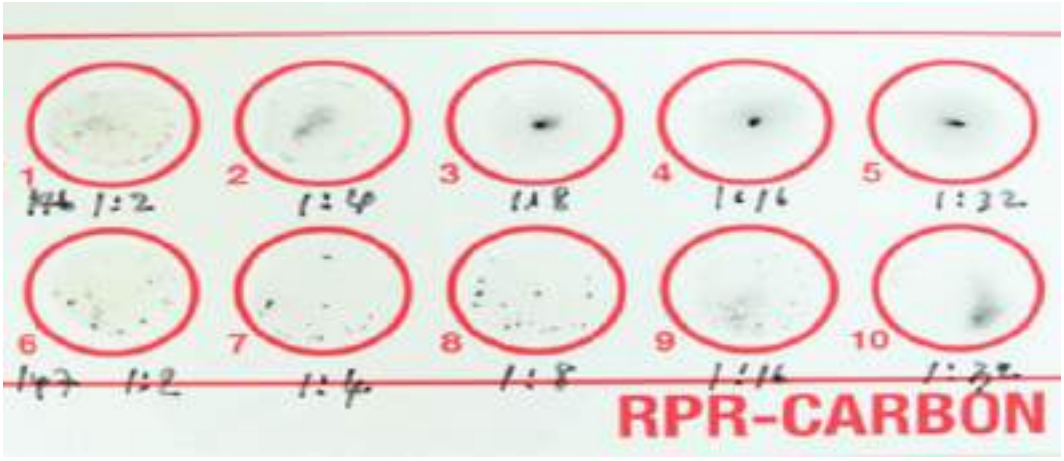

Image 5.3. Rapid Plasma Reagin Test

Treponemal Tests: These tests include the *Treponema pallidum* hemagglutination assay (TPHA), the *Treponema pallidum* particle agglutination assay (TPPA), TP-ELISA and the fluorescent treponemal antibody absorption (FTA-Abs) tests. As these tests detect antibodies against specific treponemal antigen, they are considered to be highly specific. However, these tests do not differentiate venereal syphilis from endemic syphilis, unless antigens specific to the organism are used in the test. The treponemal tests usually remain positive (85%) for the patient's lifetime, regardless of treatment (immunological scar). Thus, a positive treponemal test does not distinguish between active infection and infection that has been previously treated.

5.3.2. Diagnostic Algorithm of Syphilis

5.3.2.1. Algorithm A (Reverse Algorithm): The majority of patients who have been screened reactive for treponemal tests will have reactive results for the remaining of their lives, regardless of adequate treatment or disease activity. However, 15%–25% of patients treated during the primary stage revert to being serologically nonreactive after 2–3 years. As HIV and syphilis testing using Dual Rapid Diagnostic Testing (RDT) kits (referred as Dual RDT kits) uses a treponemal test for screening of syphilis, a non-treponemal test (RPR/VDRL) can be employed for confirmation of diagnosis. This is known as Reverse Algorithm (See figure 5.1). The following points should be taken into consideration for confirmation of diagnosis:

- Persons with a positive treponemal screening (e.g., Dual RDT) test should have a standard semi-quantitative non-treponemal test (RPR/VDRL) with titers performed, to guide decisions for patient management.

- This reverse algorithm for syphilis diagnosis can identify persons previously treated for syphilis, those who are untreated or incompletely treated, and those with false-positive results that can occur with a low likelihood of infection.
- If the non-treponemal test (RPR/VDRL) is negative, the laboratory should perform a treponemal test (TPHA/TPPA/TP-ELISA etc.), based on different antigens than the original test), to decide the results of the initial test.
- If a second treponemal test is positive (e.g., Dual RDT reactive → RPR nonreactive → second treponemal test reactive), persons with a history of previous treatment will require no further management unless sexual history (sexual exposure within 4 weeks) indicates a re-exposure. In this instance, a repeat nontreponemal (RPR/VDRL) test after 2–4 weeks with assessment is recommended to evaluate for early infection. Those without a history of treatment for syphilis should be offered treatment. Unless a medical history or results of a physical examination indicate a recent infection, previously untreated persons should be treated for syphilis of unknown duration or late latent syphilis.
- If the second treponemal test is negative (Dual RDT reactive → RPR nonreactive → second treponemal test nonreactive) and the epidemiologic risk and clinical probability for syphilis are low, further evaluation or treatment is not indicated.

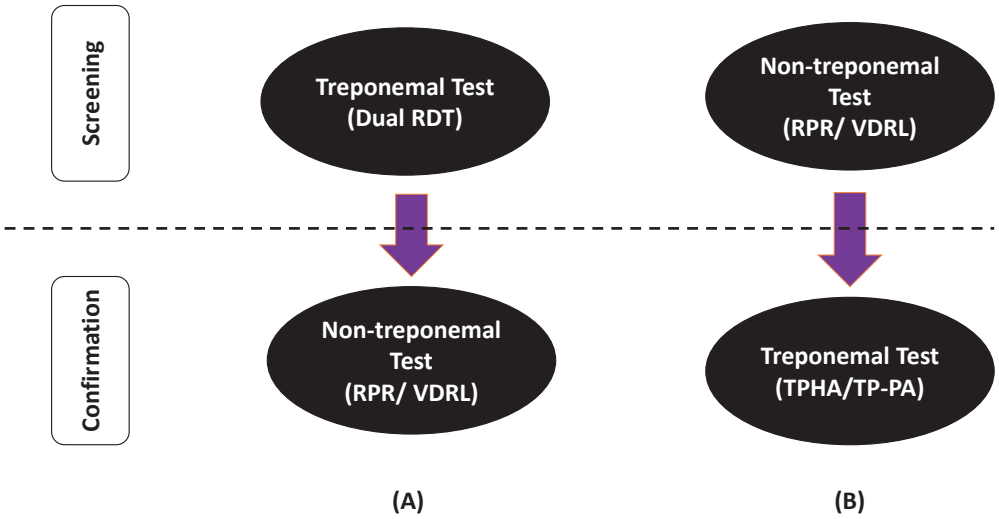

Figure 5.1. Syphilis Testing Algorithms. A: Reverse Algorithm, B: Traditional Algorithm

5.3.2.2. Algorithm B (Traditional Algorithm): The non-treponemal tests can be false-positive in presence of multiple conditions and factors unrelated to syphilis e.g., HIV, autoimmune conditions, vaccinations, injecting drug use etc. Therefore, a treponemal test is used to confirm syphilis diagnosis following a sero-reactive result of a non-treponemal test. This is the traditional algorithm for syphilis diagnosis. (See figure 5.1).

5.3.3. Diagnosis of Congenital Syphilis

The diagnosis of congenital syphilis through laboratory investigations is intensive with limited outcomes. Some considerations related to evaluation of syphilis exposed are :

- The maternal nontreponemal and treponemal IgG can be transferred through the placenta to the fetus. Therefore, the diagnosis of congenital syphilis can be difficult due to complicated interpretation of reactive serologic tests among neonates (infants aged <30 days).

- The umbilical cord blood can become contaminated with maternal blood and yield a false-positive result, and Wharton's jelly within the umbilical cord can yield a false-negative result.
- The treponemal tests on neonatal serum are not recommended as they are difficult to interpret, as passively transferred maternal antibodies can persist for >15 months.
- Neonates born to mothers who are sero-reactive for syphilis should be evaluated with a semi-quantitative RPR or VDRL (non-treponemal test) performed on their serum only. The RPR/VDRL test performed on the neonate should be of the same type of nontreponemal test performed on the mother at the time of delivery. The presence of RPR/VDRL titers four-fold or higher in comparison to the mother is suggestive of congenital syphilis in neonates.
- The commercially available IgM tests are not recommended under the National Program.

Therefore, the management decisions for congenital syphilis are taken on the basis of following factors:

- Identification of syphilis in the mother during pregnancy
- Adequacy of maternal treatment
- Presence of clinical or laboratory evidence of syphilis in the neonate
- Comparison of maternal and neonatal non-treponemal serologic RPR/VDRL titers (at the time of delivery) by using the same test, preferably conducted by the same laboratory.

All syphilis exposed infants should be managed as per the '**Scenario-based Case Management'** protocol for syphilis exposed babies as mentioned in Chapter 6. Refer to National Guidelines on Elimination of Vertical Transmission of HIV and Syphilis (2024) for operational aspects of screening and management of syphilis in pregnancy and congenital syphilis in India.

5.4. Herpes Simplex Virus (HSV) Infection

Genital herpes is a chronic, lifelong viral infection. It is associated with recurrent symptoms and occurs as painful lesions in the genital organs. There are two types of HSV that can cause genital herpes: HSV-1 and HSV-2. Majority of cases of recurrent genital herpes are caused by HSV-2. However, an increasing fraction of anogenital herpetic infections have been ascribed to HSV-1 (prominent among young women and MSM).

Genital herpetic infection is often diagnosed on clinical grounds, but laboratory confirmation of the diagnosis may be necessary. Laboratory methods used in the diagnosis of HSV infection include direct detection of HSV (virological tests) and indirect serological methods. The tests available for diagnosis of HSV include antigen detection, viral culture, and nucleic acid amplification tests (NAAT) for viral DNA, as well as serological assays by detecting HSV-type specific antibodies.

Cytological Examination:

- Direct and indirect cytological examination using conventional staining procedures (Tzanck smears, Papanicolaou, or Romanowsky stains) have low sensitivity and specificity and are not reliable tests for the diagnosis of HSV.

Virologic Tests:

- HSV NAAT assays are sensitive tests as they detect HSV from genital ulcers or other mucocutaneous lesions. These tests vary in sensitivity (> 90%) and are considered to be highly specific.
- The sensitivity of viral culture is low, especially for recurrent lesions. This further decrease rapidly as the healing starts in ulcer.

- The failure to detect HSV by NAAT or culture, especially in older lesions or the absence of active lesions, does not specify an absence of HSV infection.
- The random testing of swabs in the absence of lesions should not be used to diagnose genital HSV infection because sensitivity is low, and a negative result does not exclude the presence of HSV infection.

Serologic Tests:

- The antibodies to HSV 1 & 2 develop in the first weeks after infection and persist indeterminately.
- The available type-specific HSV serologic assays are based on the HSV-specific glycoprotein G2 (gG2) for HSV-2 and glycoprotein G1 (gG1) for HSV-1. The type-common antibody tests do not distinguish between HSV-1 and HSV-2 infection.
- IgM testing for HSV-1 or HSV-2 is not recommended as IgM tests are not type-specific and might be positive during recurrent genital or oral episodes of herpes.
- Type-specific HSV-2 serologic assays for diagnosing HSV-2 are useful in the following scenarios:
  - Recurrent or atypical genital symptoms or lesions with a negative HSV PCR or culture
  - Clinical diagnosis of genital herpes without laboratory confirmation
  - Partner is infected with genital herpes.

5.5. Chancroid

Chancroid is caused by *Haemophilus ducreyi*. The disease presents with multiple painful ano-genital ulcers. It may be associated with unilateral painful inguinal lymphadenitis which if not treated promptly and adequately may lead to spontaneous rupture of suppurating lymph nodes (buboes). The causative agent *H. ducreyi* is a short, non-motile, gram-negative coccobacillus. It is a fastidious organism and has complex nutritional requirements. There is no antigen detection, serological or NAAT available for commercial use for diagnosis of *H. ducreyi*.

Microscopy:

- Direct examination of specimen on gram-stained smears can be useful for the diagnosis if typical small Gram-negative coccobacilli grouped in chains of “schools of fish”, “railroad track”, are seen. However, these classical morphological appearances are not common.
- Gram staining has poor sensitivity and specificity but is still preferred due to its ease of performance and lack of culture and NAAT facilities in most routine laboratories. The findings should be corelated with clinical observations.

Culture:

- Bacteriological culture remains the main tool for diagnosis of chancroid.
- The Mueller Hinton agar having 1% hemoglobin, 5% fetal calf serum and 1% HD supplement can be used for culture. GC agar base can also be used.
- *H. ducreyi* has few distinguishing biochemical characteristics: all strains reduce nitrate to nitrite, are positive for both oxidase and alkaline phosphatase, and require haemin (X factor) for growth.

5.6. Lymphogranuloma Venereum (LGV)

Lymphogranuloma Venereum or LGV is caused by *C. trachomatis* serovars L1, L2, or L3. LGV can cause severe inflammation and tissue invasion, in contrast with *C. trachomatis* serovars D–K that cause

mild or asymptomatic urogenital infection. The clinical manifestations of LGV can include genital ulcers, lymphadenopathy, or proctocolitis.

Diagnostic Considerations:

- A definitive diagnosis can be made only with LGV-specific molecular testing (e.g., PCR-based genotyping). However, these tests are not widely available. Therefore, diagnosis is based on clinical suspicion, epidemiologic information, and a *C. trachomatis* NAAT at the symptomatic anatomic site, along with exclusion of other etiologies for proctocolitis, inguinal lymphadenopathy, or genital, oral, or rectal ulcers.
- Genital or oral lesions, rectal specimens, and lymph node specimens can be tested for *C. trachomatis* by NAAT or tissue culture. NAAT is the preferred approach for testing because it can detect both LGV strains and non–LGV *C. trachomatis* strains.
- For sensitive and specific detection of LGV genovar (L1, L2 and L3, including subvariant)-specific *C. trachomatis* DNA, a two-step procedure is recommended:
  - Detection of *C. trachomatis* DNA/RNA in suspected clinical samples using NAAT
  - If *C. trachomatis* DNA/RNA is detected, LGV genovar specific *C. trachomatis* DNA should be detected from the same specimen
- Chlamydia serology (complement fixation or micro-immunofluorescence) is not very conclusive and hence, not used routinely as a diagnostic tool for LGV.

5.7. Granuloma Inguinale (Donovanosis)

Granuloma inguinale or donovanosis is a genital ulcerative disease caused by the intracellular bacterium *Klebsiella granulomatis.* This infection causes chronic destructive lesion in the form of a well-defined ulcer in the skin, mucus membranes and lymphatic tissue of genital region. Its spread to inguinal region can give rise to the formation of pseudo bubo.

Diagnostic Considerations:

- The organism is difficult to culture, and diagnosis requires visualization of dark-staining Donovan bodies on tissue crush preparation or biopsy, stained by Giemsa stain, which is diagnostic of this infection. They appear as coccobacilli inside large vacuoles (giving appearance of being surrounded by a halo) in the cytoplasm of the large histiocytes, plasma cells and PMNL.

5.8. Trichomoniasis

The causative agent of Trichomoniasis is *Trichomonas vaginalis*, an anaerobic protozoan parasite. *T. vaginalis* may cause an abnormal vaginal discharge in women and may be responsible for non-gonococcal urethritis cases in men. The infection may be asymptomatic in at least 50% of women and 70–80% of men.

Wet Mount Microscopy:

- Wet-mount microscopy has been used as the preferred diagnostic test for *T. vaginalis* among women.
- The slide should be read at 100× magnification to look for motile trichomonads. The confirmation of pear-shaped morphology, including visualization of flagella, should be performed using 400× magnification. (See Figure 5.4).
- It must be performed and interpreted within 10 minutes for optimal results and has highest sensitivity in symptomatic women.

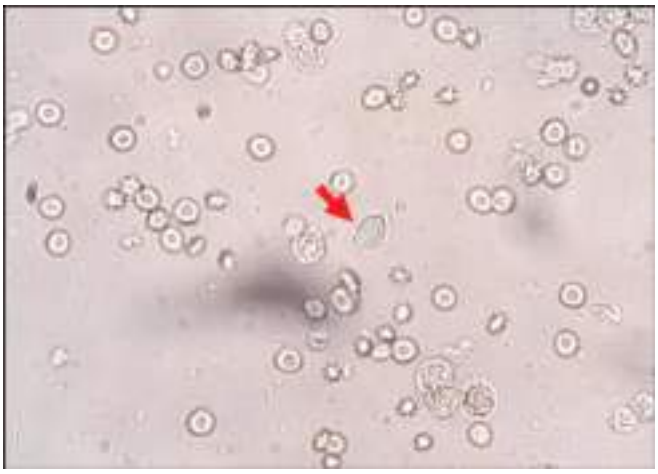

Image 5.4. *T. vaginalis* on wet mount preparation

Point of Care (PoC) Antigen Detection Test

- Several antigen detection assays have been developed for detection of *T. vaginalis*. Many of these assays are intended for use only in symptomatic women, making them less useful than other options.

Culture

- Culture (usually performed using modified Diamond's medium or Whittington's or Kupferberg medium, or the commercial In-Pouch TV culture system) was considered to be the most sensitive method before the availability of NAAT for diagnosing *T. vaginalis* infection.
- It has sensitivity of 44%–75% and specificity of <100%.
- The preferred specimen type for culture is vaginal discharge in women, as urine culture is less sensitive. The culture specimens in men can be a urethral swab, urine sediment, or semen.

Nucleic Acid Amplification Test (NAAT)

- NAAT has the highest sensitivity and specificity of all available diagnostic methods for *T. vaginalis* and offers the greatest flexibility in sample collection methods.
- Residual samples used for diagnosis of chlamydiasis, and gonorrhoea are appropriate for detection of *T. vaginalis* nucleic acids and laboratories that routinely run chlamydiasis and gonorrhea tests should consider testing for trichomonas as per the local prevalence.

5.9. Bacterial Vaginosis

Bacterial vaginosis (BV) is the most common cause of vaginal discharge among women in reproductive age. Although not contemplated as a sexually transmitted infection, sexual activity is considered as a risk factor and the incidence of BV has been shown to be associated with multiple sexual partners, presence of new sexual partner, inconsistent use of condom and practice of douching.

The condition is associated with alterations in the vaginal ecology causing an increase in the local pH, that results from a reduction in the lactobacilli. Lactobacilli help in maintaining the acidic pH of the healthy vagina and inhibiting the growth of other anaerobic microorganisms. The lactobacilli population is reduced significantly in BV, resulting in the increase of various anaerobes and *Gardnerella vaginalis*. The anaerobes implicated in BV include *Mobiluncus spp., Prevotella spp., Peptostreptococcus, Bacteroides spp., Fusobacterium*, and *Eubacterium spp.*

The culture, isolation and identification of individual organisms is not appropriate and of no clinical use in the diagnosis of BV and could also lead to over-treatment. The diagnosis of BV is best achieved either by use of Amsel's clinical criteria or by assessment or scoring of bacteria in a Gram-stained vaginal smear by the Nugent's criteria.

5.9.1. Amsel Criteria: The clinical diagnosis of BV using Amsel's criteria involves presence of at least three of the following four symptoms/ signs:

- Homogeneous, thin, adherent discharge (milk like consistency) that smoothly coats the vaginal walls.
- Clue cells (squamous epithelial cells covered with many small coccobacillary organisms, giving a stippled, granular aspect; the edges of these epithelial cells are not clearly defined, owing to the large number of bacteria present and the apparent disintegration of the cells) on microscopic examination (see Image 5.5)
- pH of vaginal fluid >4.5
- A fishy odor of vaginal discharge before or after addition of 10% KOH (i.e., the whiff test)

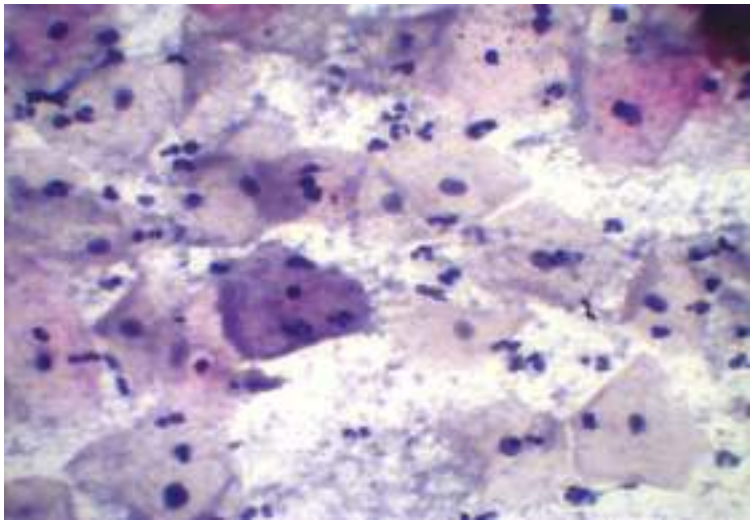

Image 5.5. Clue Cells in Bacterial Vaginosis

5.9.2. Scoring of Bacteria in a Gram-stained vaginal smear: The Gram-stained vaginal smear can be graded using any of the following methods:

- **Nugent's Score**
- **Ison-Hay Criteria**

Nugent's Scoring: The Nugent's scoring system is a weighted combination of lactobacilli, *G. vaginalis* or Bacteroides (small Gram-variable or Gram-negative rods) and curved Gram-variable rods (Mobiluncus). Each of these three groups is quantitatively weighted on a score of 0–4 on a smear, as mentioned in table 5.2.

Table 5.2. Nugent's Scoring

Score	Number of morphotype per oil field
0	Nil
1+	<1
2+	1-4
3+	5-30
4+	>30

Moreover, the presence of many lactobacilli morphotypes on a smear is considered normal; thus, lactobacilli scores are inversely related to their number. 4+ lactobacillus scores 0, 3+ scores 1, etc.

The scores for Gardnerella and Mobiluncus morphotypes correlate to the number of organisms. 4+ Gardnerella scores 4, etc. Mobiluncus are weighted lower; thus, 1+ and 2+ scored organisms score 1, and 3+ and 2+ score 2.

Interpretations:

- A diagnosis of "severe BV" scores 10 (4 for absence of lactobacilli morphotypes, 4 for 4+ Gardnerella morphotypes, and 2 for 4+ Mobiluncus morphotypes).
- A "normal" vaginal Gram smear scores 0 (0 for 4+ lactobacilli morphotypes, 0 for 0 Gardnerella morphotypes and 0 for 0 Mobiluncus morphotypes).
- In Nugent's score, a total score of 7 to 10 (the sum of the rating scores of the 3 groups described above) is indicative of BV, a score of 4 to 6 intermediate flora, and 0 to 3 normal flora.

5.10. Vulvovaginal Candidiasis

Vulvovaginal candidiasis (VVC) is most commonly caused by *Candida albicans* (in approximately 85% cases) and other candida species including *C. glabrata, C. krusei, C. parapsilosis and C. tropicalis*. The causative agent is usually of endogenous origin and can be isolated in 25% asymptomatic healthy women in childbearing age group. To colonize the vagina, *Candida spp.* must adhere to vaginal epithelium, then germinate and proliferate before causing symptomatic inflammation. Therefore, changes in the vaginal environment are essential before the induction of pathological effects. The significance of *Candida spp.* in men is unclear. However, it may be transmitted between sexual partners and may cause balanitis, balanoposthitis and rarely urethritis.

Direct Microscopy:

- The diagnosis of VVC is confirmed with a combination of clinical features and microscopy of a sample of an appropriate specimen.
- The KOH Wet Mount (addition of 10% KOH to the Wet Mount preparation) increases the sensitivity for detection of mycelia or pseudo hyphae. (See Image 5.6).
- The yeast cells are gram-positive cells and can be identified in gram-stained slides as gram-positive budding yeast cells, looking like a figure of '8' and yeast hyphae.
- When microscopy is not available, the detection of pH < 4.5 is a good indicator of VVC in symptomatic women. This can also help in differentiating the VVC from trichomoniasis and bacterial vaginosis as the latter typically presents with a pH > 4.5.

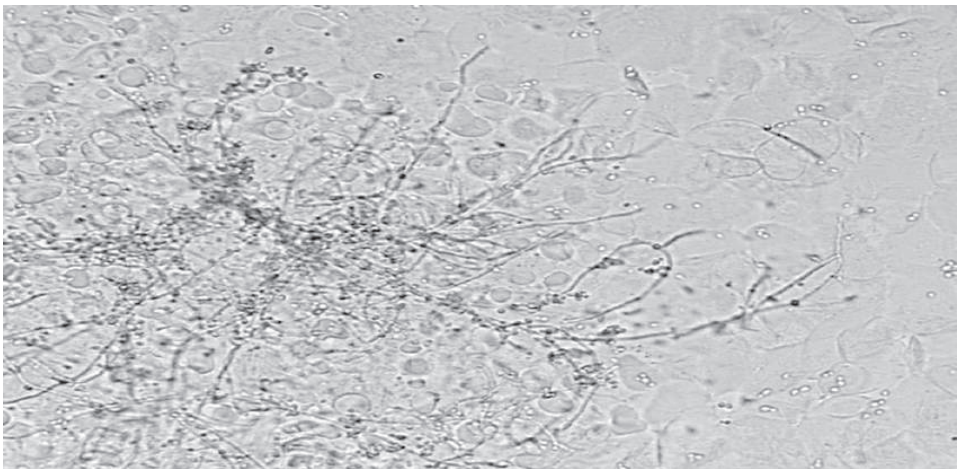

Image 5.6. KOH Mount for Vulvovaginal Candidiasis

Culture:

- When the results of direct microscopy are negative in presence of clinical symptoms, the culture of genital discharge should be considered.
- Sabouraud dextrose agar with chloramphenicol is an excellent growth medium for the isolation of *Candida spp*. The colonies of yeast cells are opaque and white to creamy in color and microscopy can be used to confirm the presence of yeast cells. Further identification of yeasts into various *Candida* species is necessary because some of the non-*Candida albicans* species are known to be inherently resistant to the routinely used drugs to treat VVC (e.g., Fluconazole). The germ tube test can be conducted for the presumptive identification of *C. albicans*.
- A complete identification of yeasts to species level can be performed by means of auxanographic methods for carbohydrate and nitrate assimilation, or through carbohydrate fermentation tests.
- The antimicrobial testing of *Candida spp.* is needed in the view of emergence of resistance/ treatment failure.

Molecular Diagnosis:

- The PCR tests for detection of *Candida spp.* offers no advantage over currently available tests and is associated with over-diagnosis and unnecessary treatment.
- Antifungal Susceptibility testing (AFST) - In view of the emerging resistance to routinely used drugs in treatment of VVC, it is important to perform AFST. For e.g., *C. auris* isolates have been found to be resistant to all three (Triazole, Polyene, Echinocandin) classes of antifungal drugs. All *Candida auris* isolates should undergo antifungal susceptibility testing. Although *C. auris* is commonly multidrug resistant, levels of antifungal resistance can vary widely across isolates.

5.11. Genital Mycoplasmas

Mycoplasmas are tiny free-living bacteria, lacking rigid cell wall which makes them resistant to penicillin and related antimicrobials. *M. genitalium* and *M. hominis* and the two Ureaplasma species: *U. urealyticum* (previously known as *U. urealyticum*, biovar 2) and *U. parvum* (previously known as *U. urealyticum*, biovar 1) are commonly found in the human urogenital tract. Ureaplasma spp. and *M. hominis* can be considered primarily as commensals when detected in the lower genital tract.

M. genitalium causes symptomatic and asymptomatic urethritis among men and is a common etiology of non-gonococcal Urethritis (NGU), non-chlamydial NGU, and persistent or recurrent urethritis. It has been associated with cervicitis, PID, preterm delivery, spontaneous abortion, and infertility among women.

Diagnostic Considerations:

- *M. genitalium* is an extremely slow-growing organism and its culture can take up to 6 months.
- NAAT is the only practical method for diagnosis of *M. genitalium* as there are no serological/ antigen detection assays, or point-of-care tests available for the diagnosis of these urogenital infections.
- Men with recurrent NGU should be tested for *M. genitalium* using NAAT. Women with recurrent cervicitis should be tested for *M. genitalium*, and testing should be considered among women with PID.
- Screening of asymptomatic *M. genitalium* infection is not recommended.
- Macrolide resistance in *M. genitalium* is very common in patients failing treatment with azithromycin. Therefore, testing should be accompanied with resistance testing, if available.
- Macrolide resistance in *M. genitalium*, mediated by specific mutations in the 23S rRNA gene, can be detected by PCR-amplifying and sequencing this gene directly from clinical specimens.

5.12. Human Papilloma Virus (HPV) Infection

Sexually active persons are usually exposed to HPV during their lifetime. The majority of HPV infections are self-limiting and are asymptomatic/unrecognized. Oncogenic, high-risk HPV infection (e.g., HPV types 16 and 18) are responsible for the majority of cervical, penile, vulvar, vaginal, anal, and oropharyngeal cancers and precancers, whereas other HPV infections (e.g., HPV types 6 and 11) cause genital warts and recurrent respiratory papillomatosis. Persistent oncogenic HPV infection is an important risk factor for development of HPV-attributable precancers and cancers.

Diagnostic Considerations:

- HPV is not readily cultivatable using traditional viral diagnostic methods. The serology is also not sensitive. Therefore, the detection relies on molecular technology.
- The diagnosis of anogenital warts is usually done on visual inspection and can be confirmed upon biopsy.
- HPV testing is not recommended for diagnosis of anogenital warts as the test results are not confirmatory and has limited role in guiding the treatment.
- Smear examination of exfoliated cells by Papanicolaou smears (Pap smear) to detect the cytological changes in cervix is a simple and an indirect method for detection of HPV.
- Primary HPV screening (detecting viral DNA or mRNA) can be incorporated into cervical cancer screening in various combinations with traditional cervical cytology (Pap smear test)/VIA.
- There is insufficient evidence to recommend routine anal cancer screening with anal cytology among populations at risk for anal cancer.

5.13. Viral Hepatitis

5.13.1. Hepatitis A Virus (HAV) Infection

HAV infection leads to a self-limiting liver disease that does not result in chronic infection/ liver disease. The virus replicates in the liver and is shed in high concentrations in feces. The infection is primarily transmitted through faeco-oral route, either through consumption of contaminated food or water or by person-to-person contact. The transmission of HAV during sexual activity results from fecal-oral contact especially during oral penetrative sex. The antibody produced in response to HAV infection stays for life and confers protection against reinfection.

Diagnostic Considerations:

- Presence of IgM antibody to HAV is diagnostic of acute HAV infection.
- A positive test for total anti-HAV indicates immunity to HAV infection but does not differentiate current from previous HAV infection.
- Anti-HAV tests also might be positive after hepatitis A vaccination.

5.13.2. Hepatitis B Virus (HBV) Infection

HBV infection can be either self-limited or chronic. Among adults, approximately half of newly acquired HBV infections are symptomatic, and approximately 1% of reported cases result in acute liver failure and death. HBV is efficiently transmitted by percutaneous or mucous membrane exposure to HBV-infected blood or body fluids that contain HBV. The primary risk factors associated with infection among adolescents and adults are unprotected sex with an infected partner, having multiple partners, men having sex with men, having history of other STI, and injecting drug use. In addition, studies have demonstrated other modes of HBV transmission, including lapses in infection control procedures, as fewer common sources of transmission.

Diagnostic Considerations:

- The serologic testing is required for diagnosis of acute or chronic HBV infection.
- As HBsAg is present in both acute and chronic infection, presence of IgM antibody to hepatitis B core antigen (IgM anti-HBc) is diagnostic of acute or recently acquired HBV infection.
- The antibody to HBsAg (anti-HBs) is produced after a resolved infection and is the only HBV antibody marker present after vaccination.
- The presence of HBsAg and anti-HBc, with a negative test for IgM anti-HBc, indicates chronic HBV infection.
- The presence of total anti-HBc alone might indicate acute, resolved, or chronic infection or a false-positive result.

The detailed interpretations are present in table 5.3.

Table 5.3. Interpretations of HBV tests

HBsAg	Total anti-HBc	IgM anti-HBc	Anti-HBs	Interpretations
–	–	–	–	Never infected
+	–	–	–	Early acute infection; transient (≤18 days) after vaccination
+	+	+	–	Acute infection
–	+	+	–	Acute resolving infection
–	+	–	+	Recovered from past infection and immune
+	+	–	–	Chronic infection
–	+	–	–	Past infection; low-level chronic infection; passive transfer to infant born to HBsAg-positive mother; false positive (no infection)
–	–	–	+	Immune if concentration is >10 mIU/mL after vaccination, passive transfer after HBIG administration

anti-HBc = antibody to hepatitis B core antigen; anti-HBs = antibody to hepatitis B surface antigen; HBIG = hepatitis B immune globulin; HBsAg = hepatitis B surface antigen; IgM = immunoglobulin M.

5.13.3. Hepatitis C Virus (HCV) Infection

HCV is not efficiently transmitted through sexual route. However, recent evidence shows that sexual transmission can occur, especially among PLHIV. An association exists between HCV infection with high-risk and traumatic sexual practices (e.g., condomless receptive anal intercourse or receptive fisting) and concurrent genital ulcerative disease or STI-related proctitis. HCV transmission among MSM (living with HIV) has also been associated with group sex and chemsex.

Diagnostic Considerations:

- An antibody test to HCV is used for screening of HCV infection. The confirmation can be done using NAAT for detection of HCV RNA.
- The antibody to HCV remains positive after spontaneous resolution or successful treatment. Hence, subsequent testing for reinfection among vulnerable population should be limited to HCV RNA.

5.13.4. Hepatitis D Virus (HDV) Infection

Hepatitis D virus (HDV or delta virus) is a satellite virus, which is dependent on HBV for the generation of envelope proteins. The virus is incapable of independent multiplication but is activated by the presence of HBV. The natural HDV infections occur as either a co-infection with HBV or a super-infection of HBV

carriers. HDV can cause severe acute and chronic liver diseases in HBV-infected individuals; most of the HBV carriers super-infected with HDV become carriers of both HBV and HDV.

The HBV-HDV co-infection is clinically indistinguishable from an acute icteric HBV infection. However, super-infection may result in an acute flare-up of previously inactive chronic HBV infection.

Diagnostic Considerations:

- The diagnosis is confirmed by finding serum IgM anti-HDV in the presence of IgM anti-HBc. The HDV RNA is an early marker of infection.

5.14. Point of Care Testing for STI and RTI

A significant proportion of cases of STI and RTI are asymptomatic. Most of these cases are often identified during partner notification or as a result of incidental/regular screening. Regular screening of key and other at-risk populations and early and correct diagnosis of infection are crucial to provide effective treatment. This is essential to reduce the infectiousness and prevent the spread of STI along with preventing sequelae.

The laboratory diagnosis of STI and RTI is intensive and requires adequate technical expertise, resources, and functional laboratory set-up. This restricts the implementation of these services to limited settings. Hence, availability of point-of-care testing (PoCT) is important to provide evidence-based STI and RTI services. However, the availability of PoCT is limited and there is a need to advance research activities for the development of quality POCT for STI. Moreover, it is also important to evaluate currently available PoCTs for implementation in public health programmes as it supports etiological management of STI and RTI. This also avoids overuse and misuse of antimicrobials and could thus prevent development of antimicrobial resistance (AMR), reduce costs, reduce waiting times, speed up and increase accurate treatment, and improve patient follow-up. Accurate, rapid, and affordable PoCT could increase access to testing and identification of STI and RTI in resource limited settings and could be used at all levels of the healthcare system while also contributing to the improvement of STI surveillance.

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Chapter 6 STI and RTI among special populations

This chapter provide details on specific considerations on STI and RTI for following populations:

- Pregnant and Breastfeeding Women
- Infants
- Children and adolescents
- Key and other vulnerable populations
- Bridge population & population in prisons and other closed settings (P&OCS)
- People living with HIV

6.1. Pregnant and Breastfeeding Women

STI and RTI are among the most important causes of maternal and perinatal morbidity and mortality. The consequences of STI and RTI can be severe and life-threatening, such as pelvic inflammatory disease (PID), ectopic pregnancy and adverse pregnancy outcomes including abortion, stillbirth, preterm birth, and congenital infections (due to syphilis, HSV, hepatitis B virus and HIV).

6.1.1. STI and RTI in pregnancy

The interactions between STI/RTI and pregnancy include the effects of STI/RTI on pregnancy and of the pregnancy on STI/RTI. The former is more important because STI may affect pregnancy outcomes (see Table 6.1).

Table 6.1. Effect of STI/RTI on Pregnancy and Pregnancy on STI

Infection	Effect of STI/RTI on pregnancy and neonate	Effect of pregnancy on STI/RTI
Gonorrhea	• Ectopic pregnancy (in case of tubal scaring) • Premature rupture of membranes • Prematurity • Ophthalmia Neonatorum & sepsis in infants • Disseminated gonococcal infection in infants	• Disseminated gonococcal infection in pregnant women

Chlamydia	• Ectopic pregnancy (in case of tubal scaring) • Chorioamnionitis • Postpartum sepsis • Ophthalmia Neonatorum • Infant pneumonia	• No effect
Syphilis	• Abortion • Prematurity • Intrauterine growth retardation (IUGR) • Stillbirth • Congenital syphilis	• No effect
Chancroid	• No adverse effects	• Ulcers may increase in size and become more vascular
Genital Herpes	• Abortion • IUGR • Premature delivery • Congenital HSV • Neonatal herpes	• Longer duration of symptoms • Primary infections are more severe • Systemic dissemination
Human papilloma virus (genital warts)	• Laryngeal papillomatosis (rare)	• Increase in size and number of warts
Trichomoniasis	• Premature rupture of membranes • Pre-term labour • Low birth weight	• No effect
Candidiasis	• No effect	• Increased frequency and severity of infection
Bacterial vaginosis	• Chorioamnionitis • Premature rupture of membranes • Low birth weight • Puerperal sepsis • Postpartum endometritis	• No effect

The antenatal care (ANC) visits provide opportunities for preventing and detecting STI and RTI among pregnant women. Therefore, women should be encouraged to attend antenatal clinics early in pregnancy. Since most STI and RTI are asymptomatic in women, screening facilitates the identification of these infections in pregnant women. The HCPs should facilitate the screening of pregnant women considered to be at high risk for STI, since early detection and appropriate treatment of STI prevents vertical transmission of infections during pregnancy and delivery.

The management of STI and RTI in pregnant women is the same as for non-pregnant women (unless stated otherwise). The following points may be noted when providing STI and RTI services to pregnant women:

- The recommended therapy should be provided to the patient as certain drugs are contraindicated in pregnancy.

- The partner notification, assessment and management should be ensured to prevent re-infection to the pregnant women.
- The couple should be educated/counselled on prevention of STI and RTI during the course of pregnancy, as the infections acquired during pregnancy may lead to adverse pregnancy outcomes.
- The patient should be followed up adequately for completion of treatment, resolution of infection and prevention of further infections.
- The baby should be assessed, preferably by a pediatrician as soon as possible after delivery for any impact from maternal infection.

The details of treatment for each infection in pregnancy are given in previous chapters.

6.1.2. Vaginal Infections

The details on screening and management of vaginal infections in pregnancy is provided in table 6.2.

Table 6.2. Screening for Vaginal Infections

When to screen	Minimal Test recommended	Recommended approach
• Asymptomatic pregnant women with a history of spontaneous abortion or preterm delivery should be screened for Syphilis, bacterial vaginosis (BV) and trichomoniasis • Pregnant women at risk (with history of multiple sexual partners, new partner, inconsistent condom use, vaginal douching, sharing of toys etc.)	• Syphilis screening using Dual RDT kits, PoC Syphilis or RPR/VDRL • Gram-stained microscopic examination of a vaginal smear. • Wet mount of vaginal fluid in a drop of normal saline	The pregnant women should be managed as per the recommendations in previous chapters.

The pregnant women with abnormal vaginal discharge should receive syndromic management for NG, CT, TV, BV, and CA (if per speculum examination is not possible).

Note: Oral Fluconazole is not recommended for use in pregnancy. However, intravaginal application and vaginal pessaries (azole therapy) can be used for treatment during pregnancy.

6.1.3. Genital Herpes

- All pregnant women should be asked history of genital herpes and examined carefully for herpetic lesions:
  - ➢ Women without symptoms or signs of genital herpes or its prodrome can deliver vaginally.
  - ➢ Women with genital herpetic lesions at the onset of labour should be delivered by caesarean section to prevent neonatal herpes.

- ➢ Acyclovir may be administered orally to pregnant women with first episode genital herpes or recurrent herpes. Only Acyclovir Regimen are recommended in pregnancy.

- Suppressive therapy is recommended in all case of recurrent episodes of genital herpes from 36th week of pregnancy. This may reduce the chances of recurrence and necessity for caesarean section. However, it may not protect against transmission to neonates in all cases.

6.1.4. Syphilis

The 'Universal Screening' of syphilis should be ensured for all pregnant women. The pregnant women should be screened for HIV and syphilis at their first ANC visit (preferably in the first trimester. The pregnant women screened reactive for syphilis (either through Dual RDT or RPR/VDRL) should be provided with first on-spot dose of injection benzathine penicillin G (BPG) at the nearest treatment facility without waiting for the confirmation. The second test for confirmation will be RPR/VDRL (when the screening test was a PoC treponemal test or dual RDT kit – Reverse Algorithm) or TPHA/TP-ELISA, if available (when the screening test was RPR/ VDRL – Traditional Algorithm). The availability of confirmatory testing should not be a criterion to provide on-spot dose of BPG.

Syphilis is not transmitted from mother-to-child (vertical transmission) through breastfeeding. If a mother (during her lactation period) is infected with syphilis, she should be managed as per the existing guidelines for non-pregnant women.

Criteria for Re-testing among At-risk Pregnant Women

If pregnant women are 'at-risk' of HIV/Syphilis, the screening should be repeated in third trimester and at time of labour. The additional criteria for repeat syphilis testing are mentioned below:

- Pregnant women with a history of repeated abortions, stillbirths, or past history of delivery of premature babies or neonatal deaths.
- Testing at the time of delivery in cases where the partner of previously syphilis reactive pregnant women was not tested/managed.
- The screening should also be repeated among pregnant women who live in areas with high prevalence of Syphilis (>1% sero-positivity among pregnant women).

Management of Syphilis in Pregnant Women

Treatment Considerations:

- Benzathine Penicillin G is the only known effective antimicrobial for treating syphilis infection in pregnancy and preventing congenital syphilis. This is a safe drug and evidence suggests that anaphylaxis is extremely rare.
- A single dose of BPG is sufficient to prevent infection to the foetus, regardless of the stage of syphilis. However, complete treatment as per the stage of infection is necessary for the complete management of sero-reactive pregnant women.
- The use of tetracycline and doxycycline for management of syphilis should be avoided in pregnancy.
- Erythromycin and azithromycin should not be used because these drugs neither reliably cures maternal infection nor treats an infected fetus.
- Data are insufficient to recommend ceftriaxone or other cephalosporins for the treatment of maternal infection and prevention of congenital syphilis.

Treatment Protocols:

- The “Test & Treat” policy for syphilis should be followed under the National Programme, and at least one dose (on-spot dose) of injection BPG should be given to all pregnant women screened positive/reactive for syphilis (when screening was conducted using Dual RDT, PoCT Syphilis or RPR/VDRL kits).
- All pregnant women screened reactive for syphilis should be provided with an on-spot dose of 2.4 million IU of Injection Benzathine Penicillin G. This may result in over-treatment due to false positive results in the screening. However, the benefit of preventing congenital syphilis outweighs the risk of over-treatment.
- All pregnant women screened positive for RPR/VDRL should receive complete treatment with injection BPG administered as three doses of 2.4 million units IM each at one-week interval. This may result in overtreatment of false positive cases and cases with primary/secondary/early latent syphilis. However, this is justified in the context of pregnant women to achieve the programmatic goal of eliminating vertical transmission of syphilis in India.
- If the last dose of injection benzathine penicillin G is administered less than 30 days before delivery, the treatment is considered to be ‘inadequate’ to prevent the vertical transmission of syphilis.
- The HCPs should rule out the history of a severe allergy to Benzathine Penicillin through oral history taking. A skin test should be conducted to rule out the possibility of anaphylaxis. An emergency tray should be available at all facilities providing treatment.
- Pregnant women presenting with manifestations of neurosyphilis, ocular syphilis, and oto-syphilis should be referred to a tertiary care centre for further management.

Monitoring of Treatment Response

To monitor the treatment response for maternal syphilis, it is important to compare the titres values of RPR/VDRL tests with the baseline value. It is crucial to use the same non-treponemal test (either RPR or VDRL) from the same manufacturer and perform the test at the same laboratory to ensure consistency in the results for comparing the titres values.

A fourfold reduction in titres, equivalent to a change of two dilutions (e.g., from 1:16 to 1:4), indicates successful treatment. Titres should not be repeated 8 weeks after completion of treatment but preferably after 12 weeks of treatment, at the 32nd week of pregnancy, or at the time of labour (whichever is earlier).

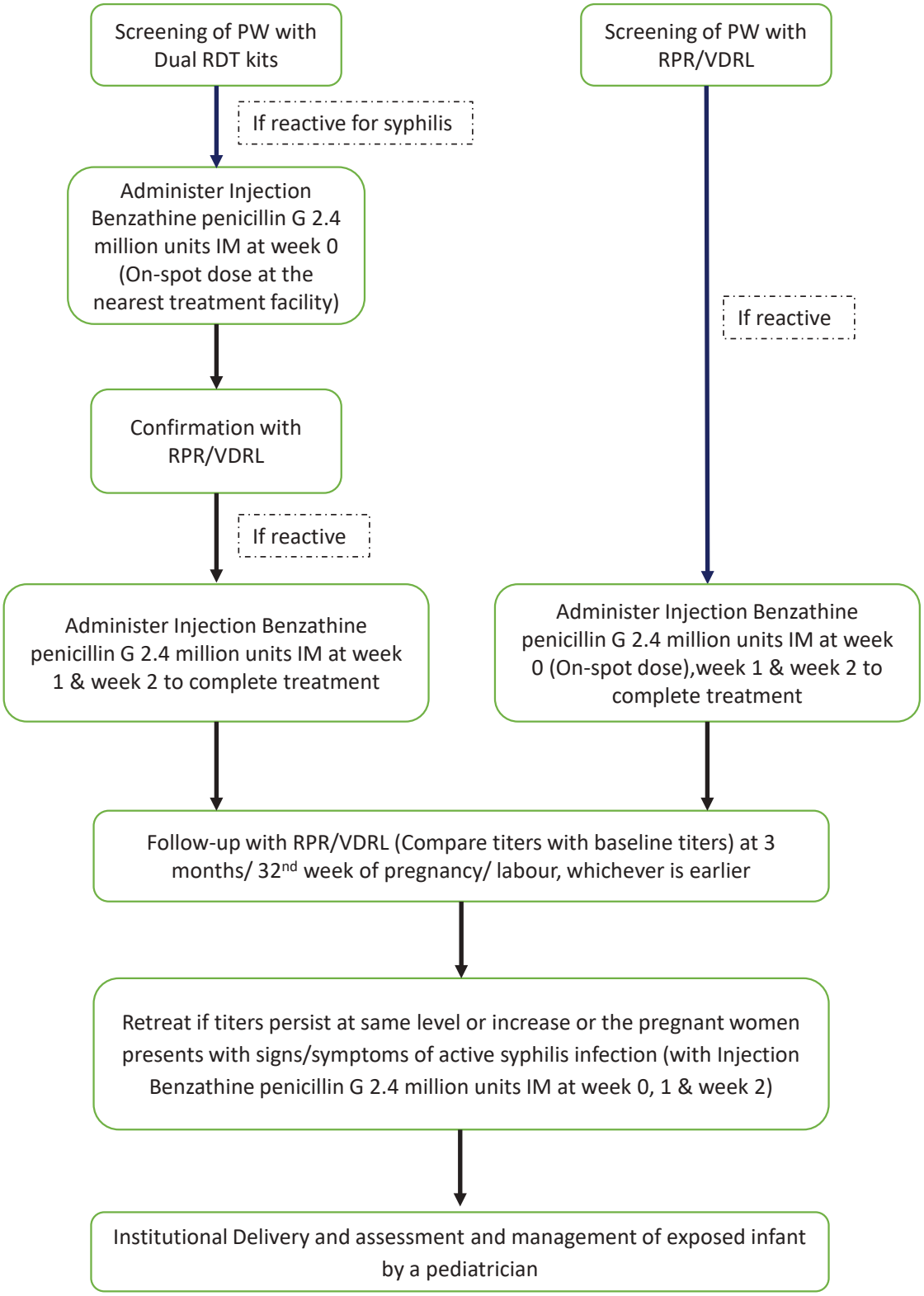

Figure 6.1. Screening and Management of Syphilis in Pregnancy

If the titre value at 12 weeks is decreasing compared to the baseline titre values, and there is no clinical evidence of syphilis, no further treatment is needed. However, if the titre values persist at the same level or increase after 12 weeks, treatment failure or re-infection can be suspected, and complete treatment should be given according to the treatment protocol.

It is important to note that for syphilis diagnosed and treated after 24 weeks of gestation, achieving a fourfold decrease in titres may not be possible, although this does not necessarily indicate treatment failure. Regular monitoring of the treatment response is essential to ensure the best possible outcome for both the mother and baby.

Follow-up of pregnant women treated for syphilis

- The treated women should receive a follow-up testing for RPR/VDRL titers at 3 months/ 32nd week of pregnancy/ labour, whichever is earlier. Re-treatment should be undertaken if there is serological evidence of active disease or re-infection. This may be attributed to re-infection from an untreated partner. Therefore, screening and management of partners should be actively taken up.
- The syphilis reactive pregnant women should be referred for delivery to a facility where a pediatrician is available for assessment of baby for further management.

The details are provided in Figure 6.1.

Direct-in Labour Cases

- The following pregnant women coming directly in-labour (DIL) should be screened syphilis:
  - No history of ANC visits
  - No documentation of syphilis screening during pregnancy
  - Pregnant women at high risk for HIV/STI
- These direct-in-labour cases can be screened for syphilis as per the availability of screening kits – RPR/VDRL or Dual RDT kits.
- If screened reactive, the women will receive complete treatment as per the stage of syphilis after delivery. The first dose of injection BPG can be administered during the hospital stay. This will not be beneficial to the infant; however, it will ensure initiation of treatment of the mother.
- The syphilis exposed infant should be referred to a pediatrician for further assessment and adequate management. The exposed infants should be managed as per the protocols detailed in National Guidelines on Elimination of Vertical Transmission of HIV and Syphilis (2024).

6.1.5. Ano-genital Warts

- Ano-genital warts can proliferate and become friable during pregnancy
- Podofilox, podophyllin, trichloroacetic acid and sinecatechins should not be used during pregnancy. Though imiquimod pose low risk, it should be avoided during pregnancy.
- Although removal of warts can be considered during pregnancy, resolution might be incomplete or poor.
- Rarely, HPV types 6 and 11 can cause respiratory papillomatosis among infants and children. However, the route of transmission (i.e., transplacental, perinatal, or postnatal) is not completely understood.
- Cesarean delivery is indicated for women with anogenital warts in case of obstruction or if vaginal delivery would result in excessive bleeding.

- Pregnant women with anogenital warts should be counseled about the potential low risk for warts on the larynx of their infants or children (recurrent respiratory papillomatosis).

Some more STI-related drug interactions for pregnant and breastfeeding women

- Although metronidazole crosses the placenta, no evidence of teratogenicity or mutagenic effects among infants has been reported. The current evidence indicate that metronidazole therapy poses low risk during pregnancy and therefore, can be recommended even in first trimester of pregnancy.
- There is no evidence of adverse effects of metronidazole among breastfed infants. However, certain clinicians recommend delaying breastfeeding for 12-24 hours after treatment with 2 gm dose of metronidazole. On the contrary, lesser dose produce low concentration in breast milk and is considered compatible for breastfeeding.
- The use of secnidazole and tinidazole is not recommended in pregnant and breastfeeding women. Tinidazole should be deferred for 72 hours after a single 2-g oral dose of tinidazole.
- Use of Acyclovir is considered safe during pregnancy and breastfeeding and is recommended for management of genital herpes.
- The use of quinolones (like ofloxacin, ciprofloxacin), tetracycline and doxycycline are contraindicated in pregnant and breastfeeding women.
- Use of Lindane is not recommended for the treatment of pediculosis in pregnant and breastfeeding women.
- There is limited data on safety of Ivermectin in pregnancy and breastfeeding. Therefore, permethrin is recommended for management of pediculosis and scabies in pregnant and lactating women.
- Ciprofloxacin and Levofloxacin have potential toxicity during breastfeeding and should be avoided.
- The use of oral fluconazole is not recommended in pregnancy.
- Podofilox, podophyllin, trichloroacetic acid and sinecatechins should not be used during pregnancy. Though imiquimod pose low risk, it should be avoided during pregnancy.

6.2 Infants

The selective STI and RTI can be transmitted vertically from mother to child during pregnancy and childbirth. Moreover, STI and RTI can also be transmitted in cases of sexual abuse of infants and children. This section provides summary on common STI in infants due to vertical transmission.

6.2.1. Congenital Syphilis

Syphilis is associated with various adverse birth outcomes including early fetal loss, still births, neonatal deaths, low birth weight, prematurity, and transmission of infection to infant (also known as congenital syphilis). Congenital syphilis is a serious but preventable disease that can be eliminated through effective screening of pregnant women and adequate and appropriate treatment of infected women. Congenital syphilis is asymptomatic in almost 50% of infants, especially in the first week after birth. The clinical symptoms may appear in the first month but may be delayed up to 2nd year after birth. The term ***'Syphilis exposed babies'*** in this document is used to refer to infants born to mothers infected with syphilis, until congenital syphilis can be reliably excluded or confirmed

The clinical manifestations of early congenital syphilis might include rhinitis ("snuffles"), non-immune hydrops, hepatosplenomegaly, skin rash with desquamation, chorioretinitis and pigmentary

chorioretinopathy (salt and pepper type), interstitial keratitis, glaucoma, cataract, optic neuritis, periostitis and cortical demineralization of metaphysis and diaphysis areas of long bones, anemia, and thrombocytopenia. Some of the clinical signs consistent with congenital syphilis – such as hydrops and hepatosplenomegaly – might also be detected by ultrasound during pregnancy.

Infants who remain undiagnosed and untreated can progress to late congenital syphilis, resulting in numerous additional clinical manifestations, including, but not limited to saddle nose due to destruction of cartilage, frontal bossing due to periostitis, tibial thickening (saber shins), joint swelling (Cluttons joints), perforation of hard palate, abnormal tooth development (Hutchinson's teeth, mulberry molars), interstitial keratitis, neurologic deafness, and optic atrophy.

Infants might be born without clinical signs of syphilis but go on to develop late-stage manifestations of untreated congenital syphilis that include developmental delay, neurologic manifestations, and physical signs of late congenital syphilis.

6.2.1.1. Clinical Case Definition

The infants born to a syphilis sero-reactive mother who was either not treated or inadequately treated for syphilis during pregnancy are suspected to be cases of congenital syphilis. The clinical case definitions for congenital syphilis are described in Table-6.3.

Table 6.3. Case Definitions for Congenital Syphilis

Case	Definition
Suspected Case of Congenital Syphilis	A fetal death beyond 20 weeks of gestation or > 500 g weight (including stillbirth*) or a live baby born to a syphilis sero- reactive mother who was inadequately** treated for the stage of infection.
Confirmed Case	A live baby born to syphilis sero-reactive mother with an RPR/VDRL quantitative titre four-fold higher than the mother's titre. Or A child within first two years of life with clinical evidence*** of syphilis and syphilis-reactive serology irrespective of mother's serology.

*A baby who dies after 28 weeks of pregnancy, but before or during birth.
**Treatment completed less than 30 days before delivery with penicillin regimen or treatment with a non-penicillin regimen is considered as 'inadequate'.
***Clinical Evidence of Syphilis: At least two of the following: Swelling of Joints, Snuffles, Bullous Skin Lesions, Hepatosplenomegaly, Jaundice, Anemia, Radiological Changes in long bones

6.2.1.2. Clinical Assessment/ Evaluation of Syphilis exposed babies at birth

All syphilis exposed infants at birth should be referred to the nearest pediatric treatment facility. The pediatrician at the facility should undertake following assessment and management:

- Clinical assessment of the infant for signs/symptoms of congenital syphilis
- Serological investigation with RPR/VDRL titers and comparison with maternal titers at birth
- Determine and provide further management to the syphilis exposed babies as per the treatment protocols

- Assessment for signs of complications related to prematurity and low birth weight in the infant and ensuring further management

All syphilis exposed babies should be managed as per the '**Scenario-based Case Management'** protocol as discussed in Table- 6.4.

Table 6.4. Scenario-based Case Management of Syphilis-exposed Babies[1]

Scenario	Whether clinical examination of infant suggestive of Congenital Syphilis? (Yes/No)	Whether serum quantitative RPR/ VDRL titers of infant is fourfold (or greater) higher than the mother's titers* at delivery? (Yes/No)	Additional Evaluation/ Remarks	Recommended Treatment
Scenario 1	Yes	Yes	Any of the two is 'Yes'	Curative Treatment
Scenario 2	No	No	Mother was not treated/ inadequately treated/ no documentation of treatment.	Curative Treatment
Scenario 3	No	No	Mother received appropriate treatment, at least: ≥ 4 weeks prior to delivery **AND** No evidence of reinfection or relapse in mother	Prophylactic Treatment**
Scenario 4	No	No	Adequate treatment before pregnancy **AND** Mother's RPR/VDRL titers remained low and stable before and during pregnancy and at delivery	Prophylactic Treatment**

* A serum quantitative non-treponemal (RPR/VDRL) serologic titer that is fourfold (or greater) higher than the mother's titer at delivery (e.g., maternal titer = 1:2, neonatal titer ≥1:8 or maternal titer = 1:8, neonatal titer ≥1:32).

**No treatment can be considered if infant follow-up at 14th week and 6 month is certain with monitoring of RPR/VDRL titers.

1 Adapted from CDC; Sexually Transmitted Infections Treatment Guidelines, 2021; available at link: https://www.cdc.gov/std/treatment-guidelines/STI-Guidelines-2021.pdf

The curative and prophylactic treatment protocols for CS are described in Table- 6.5.

Table-6.5: Curative and Prophylactic treatment protocols for syphilis exposed infants/children

Treatment modality	Medication
Curative Treatment	Aqueous crystalline penicillin G 100,000–150,000 units/kg body weight/day, administered as 50,000 units/kg body weight/dose IV every 12 hours during the first 7 days of life and thereafter every 8 hours for 3 days to complete a total of 10 days treatment. Or Procaine penicillin G 50,000 units/kg body weight/dose IM in a single daily dose for 10 days
Prophylactic Treatment	Benzathine penicillin G 50,000 units/kg body weight/dose IM in a single dose

Management considerations for infants:

- Infants are not allergic to penicillin.
- Hospitalization should be considered in order to provide full course of treatment.
- If >1 day of therapy is missed, the entire course should be restarted.
- If an experienced venipuncturist is available, aqueous benzyl penicillin may be preferred over intramuscular procaine penicillin.
- For premature or low-birth babies with inadequate muscle mass, curative treatment with intramuscular procaine penicillin is not recommended.
- With appropriate treatment of symptomatic syphilis exposed babies, the clinical features of congenital syphilis (hepatomegaly, jaundice, bone changes etc.) subside by 3 months and RPR/VDRL titers decline by 3 months.

6.2.1.1. Follow up

A. Clinical evaluation:

All syphilis exposed babies should be evaluated during follow-up by a pediatrician at 14th week (in alignment with the immunization visit) and 6 months. The infant should be evaluated for following:

- Resolution of clinical signs of congenital syphilis (if symptomatic at birth).
- Comparison of current RPR/VDRL titers with titers at-birth.
- Appearance of symptoms and signs of congenital syphilis (in incubating cases).
- Growth, development, and signs of malnutrition in exposed infants

All the syphilis exposed babies should receive routine Immunization and Vitamin A supplementation as recommended in Universal Immunization Programme (UIP). The mother/caretaker should receive infant feeding and nutritional counselling

B. Serological evaluation

- All syphilis-exposed babies should be tested for RPR/VDRL titers at 14th weeks & 6 months.
- All infants with reactive RPR/VDRL tests at birth should be serologically tested every 3 months until the test become non-reactive.
- In scenario 3 & 4 (where exposed infants either received prophylactic treatment or no treatment), the RPR/ VDRL titers should decrease by the age of 3 months and be non-reactive by age of 6 months. The following scenarios should be considered in such cases at the age of 6 months:
  - If the RPR/VDRL test is nonreactive, no further evaluation or treatment is needed
  - If the RPR/VDRL test is still reactive after 6 months, the infant is likely to be infected and should receive curative treatment.
  - Treated infants who exhibit persistent RPR/VDRL titers by age 6–12 months should be referred to experts/ pediatric centre of excellence for further evaluation and management.

The exposed infants should be followed up by a pediatrician at the FRU at 14th week and 6th month for RPR/VDRL screening and other clinical assessment. The screening test should be same at every evaluation and should be done from the same laboratory. The further follow-ups can be decided only for monitoring of infants receiving re-treatment.

C. Radiological evaluation

The exposed infants receiving re-treatment may be assessed with radiological evaluation of the long bones to rule out bone changes associated with CS (for example, osteochondritis, diaphyseal osteomyelitis, periostitis). The infant may be examined for x-ray for long bones at the follow-up visits.

The operational guidelines on screening and management of syphilis-exposed infants under NACP-V can be referred from National Guidelines on Elimination of Vertical Transmission of HIV and Syphilis (2024). The detailed flow-diagram for screening and management of syphilis-exposed babies is presented in Figure 6.2.

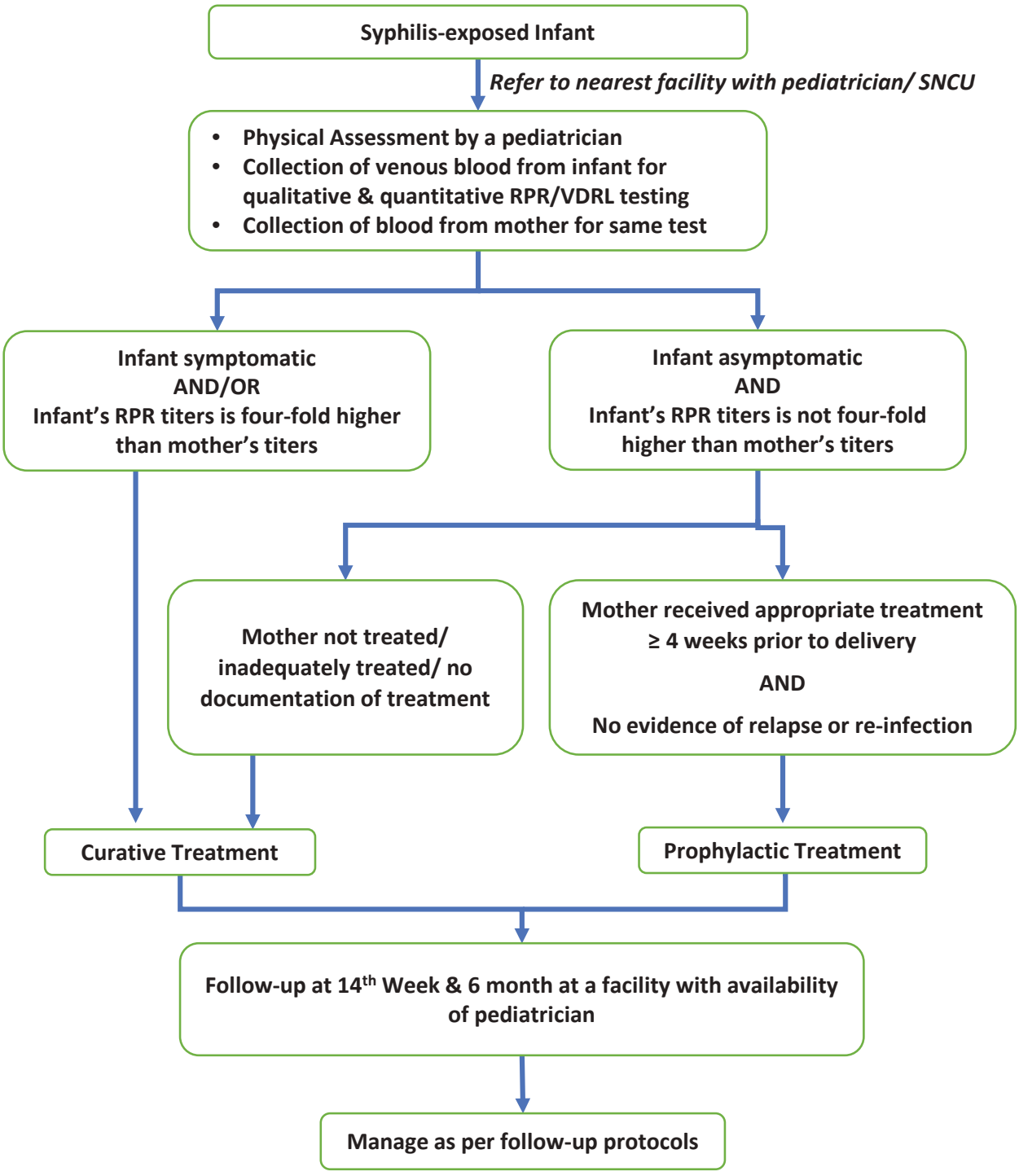

Figure 6.2. Screening and management of syphilis-exposed babies

6.2.2. Neonatal Herpes

The risk of transmission of HSV to a neonate born to a mother who acquired primary genital infection near the time of delivery is estimated to be 25% to 60%. In contrast, the risk to a neonate born to a mother shedding HSV as a result of reactivation of infection acquired during the first half of pregnancy

or earlier is less than 2%. Newborns are exposed to HSV during childbirth which can be documented by virologic testing of maternal lesions or presumed by the presence of maternal lesions at the time of delivery. These exposed infants should be followed clinically in consultation with a pediatrician.

The clinical diagnosis of Neonatal Herpes is challenging as the early manifestation can be subtle and nonspecific. The infection can mimic other diseases, including bacterial illnesses (sepsis or meningitis) and other viral illnesses, particularly enterovirus. The prompt treatment requires early consideration of neonatal herpes as a possibility in neonates with mucocutaneous lesions, CNS abnormalities, or a sepsis-like picture. The HSV infection in neonates and infants can manifest as: mucocutaneous vesicles, sepsis-like illness (fever or hypothermia, irritability, lethargy, respiratory distress, apnea, abdominal distension, hepatomegaly, ascites), CSF pleocytosis, seizures, focal neurologic signs, and abnormal neuroimaging, respiratory distress, apnea, or progressive pneumonitis, thrombocytopenia, elevated liver transaminases, viral hepatitis, or acute liver failure and conjunctivitis, excessive tearing, or painful eye symptoms.

The administration of acyclovir might be considered for neonates born to women who acquired HSV near term because the risk for neonatal herpes is high for these newborn infants. All newborn infants who have neonatal herpes should be promptly evaluated and treated with systemic acyclovir. The recommended regimen for infants treated for known or suspected neonatal herpes is acyclovir 20 mg/kg body weight IV every 8 hours for 14 days if disease is limited to the skin and mucous membranes, or for 21 days for disseminated disease and disease involving the CNS.

6.2.3. Chlamydial Infections

C. trachomatis infection of neonates result from perinatal exposure to the mother's infected cervix. The neonatal infection initially involves mucous membranes of the eye, oropharynx, urogenital tract, and rectum. However, the infection might remain asymptomatic in these locations. The infection among neonates is commonly recognized by conjunctivitis (ophthalmia neonatorum) that develops 5–12 days after birth. *C. trachomatis* can also cause a subacute, afebrile pneumonia with onset at ages 1–3 months.

Neonates born to mothers at high risk for chlamydial infection, with untreated chlamydia, or with no or unconfirmed prenatal care, are at high risk for infection. However, presumptive treatment of the neonate is not indicated. Infants should be monitored to ensure prompt and age-appropriate treatment if symptoms develop.

6.2.4. Gonococcal Infection

Gonococcal infection among neonates results from perinatal exposure to the mother's infected cervix. It is usually an acute illness that manifests 2–5 days after birth. The most severe manifestations of *N. gonorrhoeae* infection among neonates are ophthalmia neonatorum and sepsis, which can include arthritis and meningitis. Less severe manifestations include rhinitis, vaginitis, urethritis, and scalp infection at sites of previous fetal monitoring. Ocular prophylaxis of the exposed infant and preventive gonorrhea screening and treatment of infected pregnant women are especially important because ophthalmia neonatorum can result in perforation of the globe of the eye and blindness. Ocular prophylaxis for gonococcal ophthalmia neonatorum has been an important intervention in preventing sight-threatening gonococcal ocular infections.

6.3. Children, Adolescents and Youth Populations

STI and RTI in children, adolescent and youth populations can be acquired through three different ways:

- transplacental (occurring in utero) or intrapartum transmission (during labour and delivery) e.g., syphilis, HIV, cytomegalovirus (CMV) and human papilloma virus infection (HPV) – mainly in children
- post-natal transmission (during breast feeding, accidental and through sexual abuse) - – mainly in children
- sexual abuse or unsafe sexual practices among sexually active young children & adolescents. The common sexual abuse encountered by girls is genital contact, masturbation, vaginal, oral, or anal intercourse, while boys are subjected to oral or anal intercourse.

The physiological risk of increased susceptibility to infections among adolescent girls is due to the presence of greater cervical ectopy which makes the cervix more susceptible to gonorrhea, chlamydia, and HPV. Adolescents and youth persons face enhanced vulnerability to unwanted pregnancy and STI including HIV. Many interrelated and complex factors that put adolescents/youth populations at risk of STI include poor education, unemployment, and poverty. Urbanization tends to disrupt family relationships and social networks while generating more opportunity for sexual encounters.

Emergence of affordable and accessible internet services and online dating platforms expose young children, adolescents and youth populations to pornographic content and ease the opportunity for early sexual encounters. Lack of information on sexual health, as well as prevention, symptoms and treatment also put them at risk of STI and their negative consequences.

Even when adolescents/youths have accurate knowledge about STI, some incorrectly perceive their risk as low due to familiarity with the sexual partner. Furthermore, talking about sexual health and wellbeing, condoms and safer sexual practices is still considered as a taboo which limits young and adolescent persons to seek services. Therefore, there is an urgent need for improving the accessibility of preventive, diagnostic and treatment STI and RTI services for adolescents including information and counselling on sexual health and wellbeing.

Clinical presentation of STI and RTI in children, adolescents, and youth populations

The presenting symptoms of STI and RTI among adolescents/ youth populations are very peculiar as very often they present with symptoms other than those of the infection. Therefore, risk assessment plays a crucial role. The increasing tendency for exploration for gender and sexual identities results in experiments and risk behavior. Therefore, the assessment should be comprehensive and non-judgmental. The sexual exposures should not be assumed, and the person should be dealt with utmost sensitivity.

Adolescent Girls and Young Females

- In general, endogenous vaginitis rather than an STI/RTI is the main cause of vaginal discharge among adolescent females.
- Approximately 85% of gonococcal infection in females remains asymptomatic. However, there may be vulval itching, minor discharge, urethritis or proctitis. In prepubescent girls, a purulent vulvo-vaginitis may occur.
- Similarly, *Chlamydia trachomatis* infection is asymptomatic in the majority of cases.

- Symptoms that may occur in the adolescents are inter menstrual bleeding, post-coital bleeding, and an increase in vaginal secretions. Presence of ano-genital warts and Molluscum Contangiosum should be looked for during examination.
- *Candida albicans* is uncommon in adolescents prior to puberty. If present, the adolescent may have a discharge, vulval itching, dyspareunia, perianal soreness, or a fissuring at the introitus. Attacks of candida vulvitis may be cyclical in nature and correspond to menstruation.
- Bacterial vaginosis does not produce vulvitis and the adolescent will not complain of itching or soreness.
- The signs of acquired syphilis in children present with small chancres or mucocutaneous moist lesions either on the vulva or anus. Presentation of syphilis is the same in adolescents and adults.

Adolescent Boys and Young Men

- Gonorrhea among boys presents as proctitis, urethral discharge, asymptomatic pyuria, penile oedema, epididymitis, and testicular swelling. Disseminated gonorrhea presents with multiple systemic manifestations.
- Chlamydia can present as non-specific urethritis.
- Presence of ano-genital warts and Molluscum Contangiosum should be looked for during examination.

Transgender persons

- The sexual activity in transgender adolescents starts early than cis-gender boys and girls. This may be attributed to repetitive sexual abuse at a younger age due to their vulnerabilities. The abandonment from home, repetitive violence and bullying puts them at higher risk for sexual assault and further makes them sexually active.
- The signs and symptoms should be assessed as per the behavior and clinical assessment.

Recommendations for Primary Prevention

Primary prevention and anticipatory guidance for recognizing symptoms and behaviors associated with STI should be incorporated into all types of health care visits for adolescents and young adults. The following recommendations for primary prevention of STI (i.e., vaccination and counseling):

- Information regarding transmission, prevention, and testing for STI (including HIV) and implications of these infection should be regarded as an essential component of the preventive guidance and should be provided to all adolescents and young adults as part of routine health care.
- The IEC campaigns should be adapted as per the needs, cultural setting, and technological advancement for adolescent and young populations.
- All adolescents and young adults who have not previously received HBV vaccination during childhood should be vaccinated for HBV.
- Integrated sexuality education should be incorporated into clinical practice wherever healthcare services are provided to young and adolescent persons. Health care providers should counsel adolescents about the sexual behaviors that are associated with risk for acquiring STI and should educate patients regarding evidence-based prevention strategies, which includes a discussion about abstinence and other risk-reduction behaviors (e.g., consistent, and correct condom use and reduction in the number of sex partners including concurrent partners).

- Interactive counseling approaches (e.g., patient-centered counseling and motivational interviewing) are effective STI and HIV prevention strategies and are recommended. Educational materials (e.g., handouts, pamphlets, and videos) can reinforce safer practices. There should be adequate discussion on substance use with the young and adolescents. The population should be informed about the risks involved with sexual exposures under the influence of substance use or intoxication and provided with adequate referrals and linkages for harm reduction services.

6.4. Key and other vulnerable Populations

In certain populations which involve in high-risk behaviors such as sex workers (male/female/transgender), men who have sex with men, hijra/transgender persons, and people who inject drugs, the vulnerability as well as burden of HIV and STI is higher than the general population. The high vulnerability is due to their sexual networks or behavioral or biologic factors, including number of concurrent/anonymous partners, tendencies to engage in condomless sex, practice of anal sex, transactional sex, or substance use etc.

Clinical Management of STI and RTI

Effective prevention, screening, and management of STI and RTI among key populations requires attention to both symptomatic and asymptomatic infections and have the following two components:

- **Management of symptomatic infections:** The symptomatic persons should be screened and managed as per the recommended syndromic case management protocols mentioned in earlier chapters.
- **Screening and management of asymptomatic infections**: Regular medical check-ups should be conducted at least once in every three months (Routine Medical Checkups) where the HCP takes history and carries out a clinical examination to rule out the possibility of an STI. The following is recommended for key populations:
- Under National Programme, all HRGs undergo risk assessment and medical examination for STI and RTI during their Regular Medical Checkups (RMCs) once in every three months.
- Biannual serologic screening for HIV and syphilis and annual screening for Hepatitis b & c.
- Presumptive treatment for asymptomatic gonococcal and chlamydial infections. This should be administered to sex workers, MSM, transgender persons and PWID during their first clinic visit and should be repeated only if there is no regular check-up for six consecutive months.

All the key populations should be encouraged to attend the STI clinic for periodic routine health checkups. During the visit, the clinic staff should take a detailed history and perform an examination. Regular medical check-up should include oral, ano-rectal and genital examination including proctoscopy (when there is a history of receptive anal intercourse).

Key populations should be counselled at every opportunity (in the clinic and in the community) on the importance of using condoms and safer sexual practices. Peer educators/outreach workers/counsellors and clinic staff should reinforce the following messages:

- The only reliable way to protect oneself from HIV and STI is consistent and correct use of condoms.
- Presumptive treatment is not a vaccine and will not cure all STI and RTI. Hence, it is essential to educate them on the importance of regular medical check-ups and STI screening.

Peer educators/outreach workers/counsellors/clinic staff should also remind clients about their clinic appointments and help them keep-up with their appointments. The programmatic recommendations for regular screening and management of STI and RTI among key populations are mentioned in Chapter 3.

Specific points of considerations

- A detailed sexual history should be taken for all clients to identify anatomic locations exposed to infection for adequate screening. The specific details on adequate assessment can be referred from Chapter 2.
- The individuals with a history of anal/oral sex should be assessed and managed as per the recommendations mentioned in Chapter 2 and 3. The presence of rectal gonorrhea and chlamydia is associated with HIV infection, and persons with repeated rectal infections are at substantial risk for HIV infection. The pharyngeal infections with gonorrhea or chlamydia in the receptive partner might be a principal source of urethral infections in the insertive partner. The rectal and pharyngeal testing for gonorrhea and chlamydia (as per the recommendations described in earlier chapters) is recognized as an important sexual health consideration for persons (including MSM, TGs & sex workers) involved in receptive anal/oral sex.
- The following are recommended (wherever available and feasible) for gonorrhea and chlamydia:
  - Test for urethral infection should be conducted in persons who acted as the insertive partner in previous one year.
  - Test for rectal infection should be conducted in persons who acted as the receptive partner during anal sex in previous one year.
  - Test for oropharyngeal infection (only gonococcal infections) when there is history of receptive oral sex in previous one year.
- The routine assessment of persons with female reproductive systems (including cis-gendered women and transgender men) should involve per-speculum and bimanual examinations for adequate assessment of STI and RTI.
- As there is a lot of variations among transgender persons related to gender-affirming procedures, hormone use, and their patterns of sexual behavior, the screening for STI should be conducted on the basis of the patient's sexual practices and anatomy.
- The screening recommendations for females should be extended to transgender men and nonbinary persons with a cervix. Similarly, the screening recommendations for males should be extended to transgender women with penis (unoperated persons).
- Transgender women who have had vaginoplasty should undergo routine STI screening for all exposed sites (e.g., oral, anal, or neo-vaginal). The techniques for creating a neovagina do not result in the creation of a cervix; therefore, no rationale exists for cervical cancer screening.
- If transgender men have undergone metoidioplasty with urethral lengthening and have not had a vaginectomy, assessment of genital bacterial STI 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.
- Vaccination against HBV is recommended in all key populations when there is no documentation of previous infection or vaccination. There should also be consideration for HPV vaccination as per the recommendations.

Special Considerations for Women who have sex with women (WSW) and Women who have sex with other women and men (WSWM)

This group comprise of lesbian, bisexual and non-binary/gender queer women which includes diverse groups with variations in sexual identity, practices, and risk behaviors. The risk for STI and RTI (including

HIV) is higher in WSWM in comparison to WSW. The practices of fingering, fisting, sharing of toys, vaginal douching, cunnilingus and anilingus etc. puts these groups at significant risk of STI and RTI. Moreover, WSWM may acquire infections from their male partners and may transmit it to their female partners. Practices involving digital-vaginal or digital-anal contact, particularly with shared penetrative sex items/toys, present a possible means for transmission of infected cervicovaginal or anal secretions.

- HPV can be transmitted through skin-to-skin contact, and sexual transmission of HPV is likely to occur between WSW through sharing of toys and fomites. Moreover, WSWM are also at greater risk of acquiring HPV from their male as well female partners. Therefore, these populations should receive HPV vaccination and regularly screened for cervical cancer according to latest recommendations.
- There are chances of transmission of HSV 1 and 2 and trichomoniasis in WSW and WSWM. Moreover, the limited evidence supports transmission of microbiota for Bacterial Vaginosis among WSW.
- Increasing awareness of signs and symptoms of STI and RTI among women and encouraging healthy sexual practices (e.g., avoiding shared sex toys, proper cleaning of shared sex toys, and using barriers) might benefit women and their partners.

6.5. Bridge Population & Population in Prisons and other closed settings (P&OCS)

Individuals who have sexual partners in the high-risk groups along with other partners of lower risk (general population) are called as “bridge population”, because they form a transmission bridge from the high-risk groups to the general population. They are the clients or partners of sex workers and other key populations. Transportation and migrant workers are named as bridge population through close proximity to high-risk groups and are at the risk of contracting HIV and other STI.

They are a critical group because of their ‘mobility with HIV’. Their living and working conditions, sexually active age, and separation from regular partners for extended periods of time predispose them to paid sex or sex with non-regular partners. Further, inadequate access to services for screening and management of STI aggravates their risk of contracting and transmitting HIV.

The population in prison and other closed settings are also at high-risk of acquiring HIV and STI. Most of these persons have had limited access to medical care before incarceration or have faced various social determinants of health including insufficient social and economic support, living in communities with high local STI prevalence or indulging in drug use.

Effective prevention and treatment of STI and RTI among bridge populations and populations in P&OCS setting requires attention to regular screening and prompt treatment:

- The BPs are assessed using standard NACO’s risk assessment tool and those BPs who are screened to be at-risk for HIV/STI should receive medical checkups through appropriate modality. BPs can be mobile populations. However, those BPs who can be followed up periodically; should be assessed bi-annually/annually. The population under P&OCS should receive a routine medical checkup annually.
- The population should be screened and managed as per the protocols of syndromic case management and treated promptly using STI color coded kits.
- While all at-risk BPs are minimally screened for HIV and Syphilis at the time of assessment, the population under P&OCS are screened for HIV and Syphilis annually. Annual screening for Hepatitis b & c is recommended in this population.

- The mobile populations should be counselled on importance of safer sexual practices, safer injection practices, consistent and correct condom use, and partner screening and management. Moreover, they should be informed about the public health facilities providing HIV and STI services across the country to make them avail these services during their entire course of migration.
- The P&OCS population should be routinely screened for STI and RTI and counselled on importance of safer sexual practices, safer injection practices and consistent and correct condom use. There should be identification of referral and linkages in case of treatment failure or persistent cases.

Note: The detailed operations for screening and management of syphilis under TI and LWS is mentioned in Annexure 3. Further, Standard Operating Procedures for Preventive and Clinical Services for High-Risk Groups and Bridge Population under National AIDS & STD Control Program can be referred for approved operations of STI and RTI services in these facilities.

6.6. People living with HIV

The presentation of STI and RTI among people living with HIV may be unusual, atypical, or severe. The STI and RTI co-infections in PLHIV are associated with significant risk of complications and increased sexual-reproductive morbidity and sequalae for the person and their sexual partners.

Relationship between STI, RTI and HIV

- Presence of STI and RTI facilitates the risk of HIV acquisition and transmission as a result of breach of protective mucosal barriers and increased recruitment and activation of susceptible immune cells at the site of infection.
- Immune dysregulation among PLHIV results in reduced protective response against STI and RTI.
- Presence of STI and RTI may result in increase in HIV viral load in blood, plasma and genital fluids and decrease in CD4 cells.
- STI and HIV appear to exist in a bi-directional pathogenic relationship where presence of one infection can accelerate disease progression of the other infection.
- Local inflammation of genital-reproductive tract due to STI and RTI increases HIV infectiousness as a result of increased viral shedding.

Screening recommendations for STI and RTI among PLHIV

- All PLHIV should be screened and managed accordingly for STI and RTI at the time of initiation of ART. Thereafter, all sexually active PHIV should be screened for STI and RTI annually or as per the recommendations. All the PLHIV from key populations should be screened as per the existing guidelines of screening for key populations (once in 6 months).
- A detailed sexual history should be taken to decide the investigations. The samples for investigation of N. *gonorrhoeae and C. trachomatis* should be taken as per the anatomic site of exposure (as per the sexual preferences and behavior).
- All women living with HIV (WLHIV) should be screened for cervicitis and vaginitis (including trichomoniasis, vulvovaginal candidiasis and bacterial vaginosis) at the initial visit and thereafter annually. All WLHIV should be screened for cervical cancer as per the latest recommendations.
- All the sexual partners should be screened and managed accordingly to prevent re-infection and reduce the risk of HIV transmission. PrEP can be offered to prevent transmission of HIV to

the sero-negative sexual partner(s) as per the existing National Technical Guidelines for Pre-Exposure Prophylaxis, NACO.

- In scenarios when PLHIV or their sexual partners (both HIV sero-positive and sero-negative partners) are diagnosed with STI and RTI, the persons should be counselled to abstain till the completion of treatment and resolution of infection. PrEP could be considered for the sero-negative partners when either of the partner is infected with STI and RTI.
- PLHIV (especially immunocompromised patients) are more likely to experience slow resolution of symptoms and poorer treatment outcomes and therefore should be monitored closely.

Disease Specific Considerations for PLHIV:

The guidelines for screening and case management of STI and RTI (can be referred from Chapter 2,3,4 & 5) can be referred while assessing and managing PLHIV for STI and RTI. The disease specific considerations for PLHIV are presented in the further section.

Syphilis

- There is an increased risk of neurologic complications and higher rates of inadequate serologic response with the recommended regimens in HIV-syphilis coinfection.
- Though rare, unusual responses for treponemal & non-treponemal tests might be observed among people living with HIV with syphilis co-infection which may involve:
  - Higher/ fluctuated post-treatment serological titers than expected
  - False negative serological test results and delayed appearance of sero-reactivity
- 'Prozone phenomenon' refers to a false negative response of a serological test resulting from overwhelming antibody titers. This phenomenon is most often associated with secondary syphilis, HIV co-infection, and pregnancy.
- All persons with HIV and latent syphilis infection should undergo a thorough neurologic, ocular, and optic examination.
- Neurosyphilis, ocular syphilis, and oto-syphilis should be considered as the differential diagnosis when there are neurological, ocular, and other signs and symptoms among persons with HIV infection.
- CSF examination should be reserved for those with an abnormal neurologic examination (e.g., cranial nerve dysfunction, meningitis, stroke, acute or chronic altered mental status, or loss of vibration sense).
- Treatment must be considered in all PLHIV when the clinical findings are suggestive of syphilis, but serological titers are non-reactive, or their interpretation is unclear.
- No treatment regimens for syphilis have been demonstrated to be more effective in treating syphilis among persons with HIV infection than the syphilis regimens recommended for persons without HIV. Injection Benzathine Penicillin should be considered as the preferred choice of treatment for syphilis among PLHIV.
- The patients should be evaluated clinically and serologically for possible treatment failure at 3, 6, 9, 12, and 24 months after therapy.
- Using ART as per current guidelines[2] might improve clinical outcomes among persons coinfected with HIV and syphilis.

2 National AIDS Control Organization (2021). National Guidelines for HIV Care and Treatment, 2021. New Delhi: NACO, Ministry of Health and Family Welfare, Government of India.

Ano-genital Herpes

- Immunocompromised PLHIV can have severe and/or prolonged episodes of genital or oral herpes. The lesions can be painful, and atypical.
- There is increased shedding of HSV among PLHIV. Though ART reduces the severity and frequency of symptoms, there is frequent subclinical shedding of virus.
- The recommended therapy for first episode of genital herpes remains same for HIV-infected person. However, treatment might need to be extended for complete resolution of lesions.
- Suppressive therapy is recommended for individuals with 4–6 or more recurrent episodes per year or in episodes with severe symptoms or that cause distress and should be preferred over episodic therapy among PLHIV.
- The risk for genital ulcer disease in persons with genital herpes increases in the first 6 months after the initiation of ART especially in the cases of Advanced HIV Disease. The disease severity might also worsen during immune reconstitution phase following ART initiation. Therefore, suppressive antiviral therapy can be provided to all PLHIV with a history of ano-genital herpes for at least for first 6 months after initiation of ART.
- The history of recurrent/ vesicular ulcers of genital herpes should be elicited in all PLHIV at every clinical visit.
- Dose adjustments are recommended for treatment of herpes with valaciclovir and famciclovir but not for acyclovir as mentioned in Table 6.6.

Table 6.6. Dose Adjustments of Antiviral Drugs in Ano-genital Herpes among PLHIV

Drug Regimen for Herpes	Episodic Therapy	Suppressive Therapy
Valaciclovir	500 mg one dose for 5 days (instead of 3 days)	500 mg twice daily (instead of one dose per day)
Famciclovir	500 mg twice a day for 5 days (instead of 250 mg)	500 mg twice daily (instead of 250 mg)

Chancroid, Granuloma Inguinale (or Donovanosis) and Lymphogranuloma Venereum (LGV)

- PLHIV with chancroid may experience rapidly aggressive and erosive ulcers to a level of destroying the genital organs. The ulcers may resemble chancre of syphilis and may be less purulent.
- PLHIV with chancroid/LGV/Donovanosis are more likely to experience slow healing of ulcers and are prone to treatment failure. Therefore, these patients should be monitored closely.
- The patients might require repeated or longer course of therapy.

Urethritis & Cervicitis

- The screening and management protocols for urethritis/cervicitis among PLHIV is similar to HIV-negative persons.
- Cervicitis is associated with increased cervical HIV shedding.
- The treatment recommendations for gonorrhea, chlamydia and mycoplasma are same for PLHIV.

Bacterial Vaginosis (BV)

- Bacterial Vaginosis increases the risk of acquisition of HIV as specific BV-associated bacteria can increase susceptibility to HIV and the risk for HIV transmission to male sexual partners.
- BV appears to recur with higher frequency among WLHIV.
- The treatment recommendations are same for WLHIV.

Trichomoniasis

- *Trichomonas vaginalis* (TV) infection is associated with an increase vaginal shedding of HIV and increased risk of PID among WLHIV.
- As the infection is common and is associated with increased risk of PID, adverse birth outcomes and increased risk of HIV transmission, routine screening is recommended for WLHIV.
- The infection is also associated with increased risk of vertical transmission of HIV. Therefore, all HIV positive pregnant women should be screened for TV infection in first trimester and managed accordingly.
- The single oral dose of Metronidazole 2 gm has been demonstrated to be less effective in the treatment of TV among WLHIV. Therefore, only 7-days regimen is recommended as mentioned below:

  Metronidazole 400 mg orally 2 times a day for 7 days

Vulvovaginal Candidiasis (VVC)

- The rates of colonization of *Candida* species in vagina are higher in WLHIV.
- Symptomatic VVC is more frequent among WLHIV and correlates with the severity of immunodeficiency. There are higher chances of complicated VVC among immunocompromised WLHIV.
- The treatment for uncomplicated and complicated VVC is same for WLHIV. However, long-term prophylactic therapy with fluconazole 200 mg (weekly dose) has been reported to be effective in reducing colonization of *Candida albicans* and symptomatic VVC.

PID

- There in not much evidence on differences in clinical manifestations of PID among WLHIV and women who are HIV-negative.
- The limited evidence reports that there is no difference in the manifestations of PID among WLHIV except increased chances of development of tubo-ovarian abscess in WLHIV.
- The treatment recommendations are same for WLHIV as there is not much evidence on superiority of intensive management of PID among WLHIV

Epididymitis

- The treatment recommendations are same for PLHIV.

Pediculosis Pubis

- The treatment recommendations are same for PLHIV.

Scabies

- Immunocompromised PLHIV are at increased risk for development of crusted/ Norwegian scabies.
- The PLHIV infested with uncomplicated scabies can be treated with the same regimen as HIV negative persons. The patients with crusted scabies should be referred to specialist for adequate management as described in chapter 4.

HPV

Anogenital Warts

- There are greater chances of development of anogenital warts among PLHIV than non-infected persons in case of infection with HPV types 6 and 11. HPV types 16, 18, 31, 33, and 35 can be associated with anogenital warts with foci of high-grade squamous intraepithelial lesion (HSIL) among persons who have HIV infection.
- The lesions can be multiple and larger in size and may not respond to the therapy among PLHIV. There are greater chances of episodes of recurrences after treatment among PLHIV.
- There are greater chances of squamous cell carcinomas arising or resembling anogenital warts among immunocompromised PLHIV. Therefore, biopsy is recommended for confirmation of diagnosis in suspicious cases.

Cervical cancer

- WLHIV have a six-fold increased risk of cervical cancer in comparison to women without HIV.
- There are chances of rapid progression of high-risk HPV infection into pre-cancerous lesions and subsequently into cervical cancer. Moreover, there is less likelihood of regression of pre-cancerous lesions and higher rates of recurrence following treatment.
- Cervical cancer screening is recommended among all the women diagnosed with HIV at the time of initiation of ART and thereafter undergo regular screening as per the latest guidelines.
- Trans-men and non-binary people infected with HIV who retain cervix should undergo cervical screening and the screening should be conducted when the patient provides a history of vaginal sex (peno-vaginal, fingering, fisting etc.).

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Chapter 7 Education and Counselling for STI and RTI

Education on sexual health and well-being and risk reduction counselling is an essential component of comprehensive STI and RTI services. All clients accessing HIV and STI services should be provided with tailormade risk reduction and sexual health counselling. These interventions are most effective when provided in a nonjudgmental and empathetic manner appropriate to the client's culture, language, sex and gender identity, sexual orientation, age, and developmental level. This should be directed at a person's risk, the situations in which risk occurs, and the use of personalized goal-setting strategies.

The behavior change counselling is a challenging, long-driven process and should incorporate the use of technology and tailor-made virtual interventions to ensure sustained risk reduction. In addition to one-on-one HIV and STI risk reduction counselling, short messages, videos, other social media strategies and large group presentations can provide explicit information concerning HIV and STI, reducing disease transmission and promoting sound sexual health and wellbeing.

This chapter mentions details on importance of partner notification, approaches and process for notification and key points necessary for counselling of STI and RTI clients. This chapter further mentions about strategies to prevent STI.

7.1. Partner Notification and Management

The concept of "partner services" encompasses a range of clinical assessments, counseling sessions, diagnostic tests, and treatment strategies aimed at enhancing the identification and treatment of infected individuals while curbing transmission within sexual networks.

Partner management plays a crucial role in patient care and the control of STI. It involves notifying partners and providing them with appropriate screening and management. Partner notification involves informing the sexual contacts of a patient infected with STI about their potential risk, offering them screening, and providing treatment if necessary. The objective is to identify and treat undiagnosed infections, often asymptomatic, thereby reducing reinfection in the primary case and preventing further spread of STI in the community. Partner notification serves as a targeted method for early diagnosis and treatment, reducing transmission, preventing complications, and creating an opportunity to discuss safer sexual practices.

The possible approaches for Partner Notification are mentioned in Table 7.1

Table 7.1. Possible Approaches for Partner Notification

Approach	Description
Patient referral	The patient takes on the responsibility of informing their sexual partner(s) and directing them to a clinic for treatment. Simple patient referral: A healthcare professional advises the patient that their sexual partners require treatment and explains the process. Enhanced patient referral (EPR): In addition to simple patient referral, the patient is provided with written information about the infection and digital resources to emphasize the importance of screening and management for their partners.
Provider referral	A healthcare professional notifies the partner of potential exposure without disclosing the identity of the patient. The provider referral is commonly requested for casual or former partners whom the patient prefers not to approach directly.
Contract/ Conditional referral	The patient agrees to inform partners within a specified timeframe, and if they fail to do so, the healthcare professional will proceed with provider referral.

The discussion regarding the importance of notifying partners should ideally take place promptly, preferably at the time of disclosing the diagnosis. Patients should be offered support and guidance from a healthcare provider trained/experienced in partner notification. In cases where this isn't feasible, healthcare professionals need to address partner notification while explaining the diagnosis. The process for partner notification is mentioned in figure 7.1

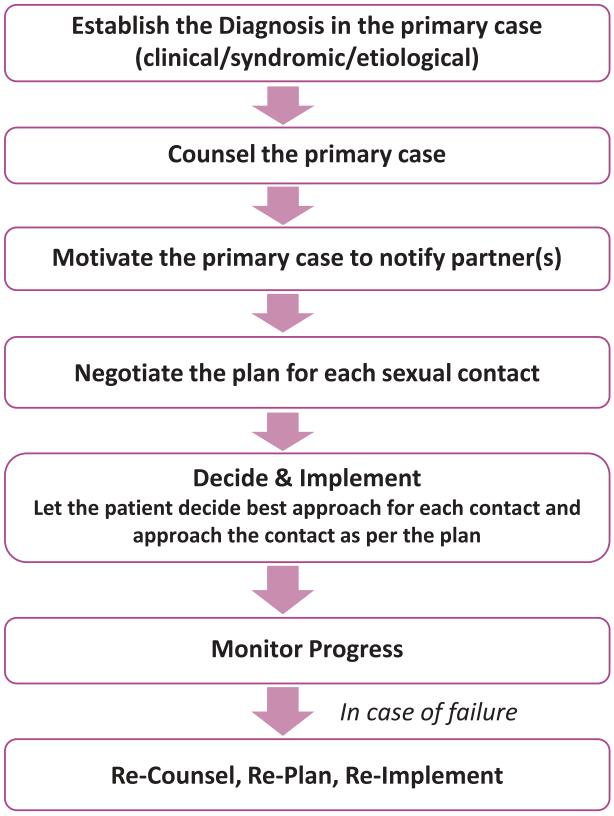

Figure 7.1 Process for Partner Notification

Although theoretically straightforward, this process requires a high level of sensitivity and empathy. Patients often express concerns about confidentiality, potential impacts on their relationships, and how to approach the subject with their partners. It is essential to consider the potential negative consequences of disclosing an STI to a partner, such as the risk of stigma, discrimination, abuse, or violence following the disclosure.

Clinicians must navigate a delicate balance between their responsibility to the individual patient and the protection of others. In most instances, this balance tilts towards prioritizing the patient's needs, ensuring they receive treatment, follow-up care, and are not dissuaded from seeking sexual health services in the future due to overly aggressive partner notification approaches. Utilizing innovative communication technologies, such as web-based notification systems, holds promise for reaching partners, particularly those increasingly encountered through online platforms.

7.2 Sexual Health Education and Risk Reduction Counselling:

It is important to provide sexual health education and risk reduction counselling to all clients seeking sexual health services. This could include discussing safer sex practices, the importance of regular STI and HIV screening, and the benefits of vaccination for certain STI. The table 7.2 mentions information (not an exhaustive list) that a client/patient and their partner(s) need to know while accessing STI and RTI services.

Even the mere fear of having an STI seriously compromise the mental health and wellbeing of a person. Therefore, the psychosocial impact of STI and RTI on clients, such as their emotional well-being, relationship dynamics, and any stigma or discrimination should be discussed with the client and necessary interventions should be done. Appropriate support and referrals to mental health services can be done, when needed.

Table 7.2 Information for STI and RTI clients/patient, and their partners*

Information about STI and RTI	Information Screening and Management of STI and RTI	Information on strategies for prevention of STI AND RTI
• Basics of STI and RTI • Modes and risks of transmission • Range of symptoms; details about asymptomatic infections • Consequences and complications • Link with HIV infection	• Methods for screening and diagnosis • Appropriate treatment and treatment adherence • Importance of follow-up and detailed information on follow-up plan • Details on re-infection/ persistent infection/ treatment failure • Importance of partner notification and management	• Tailor-made risk reduction strategies • Correct and consistent use of condoms • Condom negotiating skills • Safer sex practices • PrEP & PEP for HIV • PEP for STI • Vaccination

**Acknowledge gender inequalities which may impact clients/their partners to seek services*

The further section provides some details on primary prevention methods for STI and RTI.

7.2. Primary Prevention Methods

7.2.1. Vaccination

Pre-exposure vaccination stands out as one of the most efficacious approaches to thwarting the sexual transmission of HPV, HAV, and HBV. For those who are sexually active with multiple partners or undergoing assessment or treatment for an STI and have not been vaccinated or infected, hepatitis B vaccination is strongly advised. Furthermore, MSM, transgender persons, PWID, sex workers, and individuals with HIV or hepatitis C infections who have not previously received hepatitis A or hepatitis B vaccines are recommended to undergo vaccination for both hepatitis A and B. The latest guidelines can be referred for information on HPV vaccination.

7.2.2. Condoms

When used consistently and correctly, external condoms, or male condoms, effectively prevent the sexual transmission of HIV infection. Regular condom use also lowers the risk of contracting other STI, such as chlamydia, gonorrhea, hepatitis B, and trichomoniasis. By reducing infections in the lower genital tract, condoms may also decrease the likelihood of pelvic inflammatory disease (PID) in women. Furthermore, the consistent and proper use of external condoms reduces the risk of HPV infection and associated diseases, genital herpes, syphilis, and chancroid when covering the infected area or potential exposure sites.

Internal condoms, also known as female condoms, offer protection against the acquisition and transmission of STI, although data supporting their effectiveness are limited. These condoms provide the advantage of being controlled by the receptive partner as a method of preventing STIs and HIV. However, their use for receptive anal sex is not recommended due to a higher risk of condom failure. It is important to note that contraceptive methods lacking mechanical barriers do not provide protection against HIV or other STI.

For a more detailed description of condom use for HIV and STI prevention, please refer to NACO's National Guidelines on HIV Counselling and Testing Services - 2024.

7.2.3. Pre-Exposure Prophylaxis for HIV

Pre-Exposure Prophylaxis (or PrEP) for HIV refers to the use of anti-retroviral medication by people at substantial risk of acquiring HIV infection to reduce the chances of getting infected. PrEP is the method of prevention for HIV negative persons while those already infected should be linked immediately to HIV care and treatment services. Though PrEP for HIV is not associated with risk reduction of STI; but PrEP can be recommended to HIV-negative persons who are diagnosed with STI and are at continuous risk for HIV/STI. For further details please refer to National Guidelines for Pre-Exposure Prophylaxis 2021.

7.2.4. Post-Exposure Prophylaxis for HIV

Post Exposure Prophylaxis (or PEP) for HIV refers to comprehensive management instituted to prevent the transmission of HIV following a potential exposure. Non-occupational exposure of HIV refers to the exposures outside the healthcare service delivery settings and may include unsafe and risky sexual exposures/ injection exposure. This includes high risk exposures (condom less sexual encounters/ condom failure/injection exposure) with virally unsuppressed PLHIV or persons with unknown HIV status. This also involves consensual high-risk sexual exposures or exposures during sexual assault. Though PEP for HIV is not associated with risk reduction of STI; it can be clubbed with PEP for STI in cases of non-occupational exposures.

7.2.5. Post-Exposure Prophylaxis for STI

Studies have investigated the use of STI-PEP or Doxy-PEP, involving doxycycline 200 mg taken after unprotected anal sex among MSM and transgender women. The results have shown a 70% reduction in the incident of chlamydia and a 73% reduction in syphilis, but no effect on gonorrhea. Additional research is in progress regarding the prophylactic use of doxycycline for bacterial STI. Evidence from three randomized trials has demonstrated that the use of doxy-PEP within 24 to 72 hours after unprotected sex significantly lowers the risk of chlamydia, syphilis in MSM and transgender women with a history of STI in the prior year. Therefore, the doxy PEP for STI can be recommended in the cases of high-risk sexual exposures among MSM and transgender women.

Further studies are necessary to ascertain the effectiveness and benefits of STI doxy-PEP as a strategy for STI prevention among other populations including cis-gender women and transgender men.

7.3. Trauma-Informed Sexual Health Care

Trauma-informed care is a strengths-based approach that acknowledges and responds to the impact of trauma. This framework prioritizes physical, psychological, and emotional safety for all individuals, fostering environments where survivors can regain a sense of control and empowerment. The principles of trauma-informed sexual health care are as follows:

- Safety: The client should feel physically, culturally, religiously, socially, and psychologically safe. It is important to inform clients that the health services are provided in a safe space and promote them to open up and talk about themselves.
- Trustworthiness and transparency: Service providers should be transparent and seek to build and maintain trust with their clients. Along with transparency, honesty is also crucial (which involves following through on actions and never “promising” anything that cannot be achieved).
- Peer support: Using peers can help to develop trust, safety, and a sense of mutual self-help. Involving peers and support groups can have significant impact on the continuation in care and achieving positive outcomes.
- Collaboration and mutuality: This aim to balance the power of those making decisions and recognizes that healing occurs in relationships where there is shared power in the decision-making process.
- Empowerment, voice, and choice: The strengths and agency of the clients need to be recognized, built upon, and validated in service provision. Educating clients about sexual health leads to empowerment, and empowerment leads to awareness, higher self-value, and choice. Choice and control over one’s own behaviors are crucial when it comes to sexual health.
- Culture, gender, history, and identity: Services must be responsive to a young person’s culture, gender, religious background, sexual orientation, and ability, and recognize and address historical trauma, genocide, and institutional racism. Services should also leverage the healing value of traditional cultural connections.

Positive experiences of sexual health and sexuality informs access to comprehensive sexual health education. It is crucial to engage people who have experienced trauma in a manner that promotes positive outcomes. Everyone has a role in ensuring people receive effective and positive sexual health education, both within service delivery points and the broader community.

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Chapter 8 Management of Sexual Violence

Sexual violence inflicts considerable physical and psychological damage and anguish upon the victims. While women and girls are predominantly affected, young boys also fall victim to sexual abuse. Additionally, adult men may be subjected to sexual violence, as can sexual minorities, particularly transgender persons. The perpetrators of sexual violence come from various backgrounds, ranging from strangers to intimate partners (intimate partner violence). The evidence suggests that in majority of the cases, the perpetrators are individuals who are known to the victims. The management of sexual violence is a cross-cutting domain and requires a lot of interdisciplinary coordination. This chapter briefly describes the medical aspects of sexual violence.

Sexual Violence is defined as "any sexual act, attempt to obtain a sexual act, unwanted sexual comments/ advances, and acts to traffic, or otherwise directed against a person's sexuality, using coercion, threats of harm, or physical force, by any person regardless of relationship to the victim in any setting, including but not limited to home and work." Sexual assault, a form of sexual violence, is a term often used synonymously with rape. However, sexual assault could include anything from touching another person's body in a sexual way without the person's consent to forced sexual intercourse, including oral and anal sexual acts, child molestation, fondling and attempted rape.

The forms of Sexual Violence may include:

- Rape by strangers
- Coerced/forced sex in marriage or live-in or dating relationships
- Systematic rape during armed conflict or sexual slavery
- Unwanted sexual advances or sexual harassment
- Sexual abuse of children
- Sexual abuse of people with mental and physical disabilities
- Forced prostitution, sex slavery and trafficking for the purpose of sexual exploitation
- Child and forced marriage
- Denial of the right to use contraception or to adopt other measures to protect against HIV/STI
- Female genital mutilation
- Inspections for virginity
- Forced exposure to pornography
- Forcibly disrobing and parading naked any person

In 2013, the Indian Penal Code was amended to expand the definition of rape to include all forms of sexual violence-penetrative (oral, anal, vaginal) including by objects/weapons/fingers and non-penetrative (touching, fondling, stalking, etc.) and recognized right to treatment for all survivors/victims/ victims of sexual violence by the public and private health care facilities. The Bharat Nyaya Sanhita, 2023, which came into force on 1 July 2024, incorporates the same provision in section 63. The failure/

rejection to treat is considered as an offence under the law. The law further disallows any reference to past sexual practices of the survivor. Health professionals need to respond comprehensively to the needs of survivors. The components of a comprehensive response include:

- Providing necessary medical support to the survivor of sexual violence.
- Establishing a uniform method of examination and evidence collection by following the recommended protocols.
- Taking separate written informed consents for history taking, medical examination, and evidence collection.
- Medicolegal certificate (MLC) should be made in every case but Police intimation and registering FIR should be done only when the victim/survivor wants with informed consent, with the exception of cases of child sexual abuses, where reporting is mandatory.
- First contact for psychological support and validation**.**
- Maintaining a clear and fool-proof chain of custody of medical evidence collected.
- Referring to appropriate agencies for further assistance (e.g., legal support services, shelter services, etc.)

The Section 164A of the Criminal Procedure Code, which has been incorporated as section 184 in the Bhartiya Nagrik Suraksha Sanhita, 2023 (w.e.f. 1st July 2024) lays down the following legal obligations of the health workers in cases of sexual violence:

- Examination of a case of rape shall be conducted by a registered medical practitioner (RMP) employed in a hospital run by the government or a local authority and in the absence of such a practitioner, by any other RMP. Both private and public healthcare professionals are obligated to provide treatment.
- Take specific consent of the woman for the purpose of examination. In case of a child, i.e., person < 18 years, take the consent of the parents or guardian.
- Record consent obtained specifically for this examination and the report shall specifically record that the consent of the woman or of the person competent, to give such consent on her behalf to such examination had been obtained.
- Examination to be conducted without delay and a reasoned report to be prepared by the RMP.
- The report shall include the name, age, and address of the woman and of the person by whom she was brought; description of the material taken for DNA profiling; marks of injury, if any; general mental condition of the woman and any other material particulars.
- Exact time of arrival to the hospital, starting of the examination (including history taking) and finishing of the examination to be recorded.
- RMP to forward report within a period of seven days to Investigating Officer (IO). In the case of child sexual abuse, the report must be submitted within 24 hours.

Health professionals play a dual role in responding to the survivors of sexual assault. The first is to provide the required medical treatment and psychological support. The second is to assist

survivors in their medico-legal proceedings by collecting evidence and ensuring good quality documentation. As a doctor it is crucial to remember that the site of treatment are also the sites for evidence collection. Often, because the victims feel uncomfortable talking about sexual violence, they may come to the clinic with nonspecific complaints or request a check-up, assuming that the healthcare provider will notice anything abnormal that needs treatment. Therefore, healthcare workers should maintain a high index of suspicion and ask about any experience of sexual violence or abuse.

A model format of management of sexual violence is mentioned in Figure 9.1 for reference and includes the various components of a comprehensive health care response to sexual violence and must be carried out in all cases. Examinations should be conducted by an experienced clinician in a way that minimizes further trauma to the survivor.

Trichomoniasis, BV, gonorrhoea, and chlamydial infection are the most frequently diagnosed infections among women who have been sexually assaulted. Post assault examination presents an important opportunity to identify or prevent STI. Chlamydial and gonococcal infections in women are of particular concern because of the possibility of ascending infection. In addition, HBV infection can be prevented by post exposure administration of hepatitis B vaccine and immunoglobulin. The female survivors of reproductive age should be evaluated for pregnancy, if necessary.

A comprehensive response to the survivor of sexual violence should include the following services:

- **Initial resuscitation/ first aid**
- **Informed consent**: Consent should be taken for the following purposes: examination, sample collection for clinical and forensic examination, and treatment. Doctors shall inform the person being examined about the nature and purpose of examination and in case of child (<18 years of age) to the child's parent/guardian/ or a person in whom the child reposes trust. The survivor or the guardian (in case where the survivor is <18 years of age) should be informed regarding their right to refuse either a medico-legal examination or collection of evidence or both, and that refusal will not be used to deny treatment to survivor after sexual violence. However, informed refusal should be mentioned in the report with the survivor/guardian's signature.
- Police personnel should not be present during any part of the examination.
- In any case, the doctor is bound to inform the police as per law regarding the sexual offence or possible sexual offence. In case the survivor does not want to pursue a police case, an MLC must be made, and she must be informed that she has the right to refuse to file FIR. In short, health professionals are bound to make MLC in all such cases and to inform police. But filing an FIR is done only with the consent of the survivor.
- **Detailed history taking** including:
  - Menstrual history. If the survivor is menstruating at the time of examination, then a second examination is required on a later date in order to record the injuries clearly.
  - Details of prior vaccination especially with regard to tetanus and hepatitis B, in order to ascertain if prophylaxis is required.
  - Sexual violence history- present and previous episode(s)
  - Relevant medical history in relation to STI (gonorrhoea, HIV, HBV etc.). If there is vaginal discharge, record its type, i.e., texture, colour, odour, etc.
  - Relevant surgical history in relation to treatment of fissures/injuries/scars of ano-genital area should be noted
- **Medical examination**: Should include a general physical examination, examination of injuries, and local examination of genital parts/other orifices as per the recommended protocol. It is important to remember the presence of injuries is only observable in one third cases of forced sexual intercourse. Absence of injuries does not mean the survivor had consented to sexual activity. As per the law, if resistance was not offered that does not mean the person has consented.
- **Age estimation** (physical/dental/radiological) – if requested by the investigating agency.

- **Evidence collection as per the protocol**: If a survivor reports within 96 hours (4 days) of the assault, all evidence including swabs must be collected, based on the nature of assault that has occurred. The likelihood of finding evidence after 72 hours (3 days) is greatly reduced; however, it is better to collect evidence up to 96 hours in case the survivor may be unsure of the number of hours lapsed since the assault. Evidence on the outside of the body and on materials such as clothing can be collected even after 96 hours.

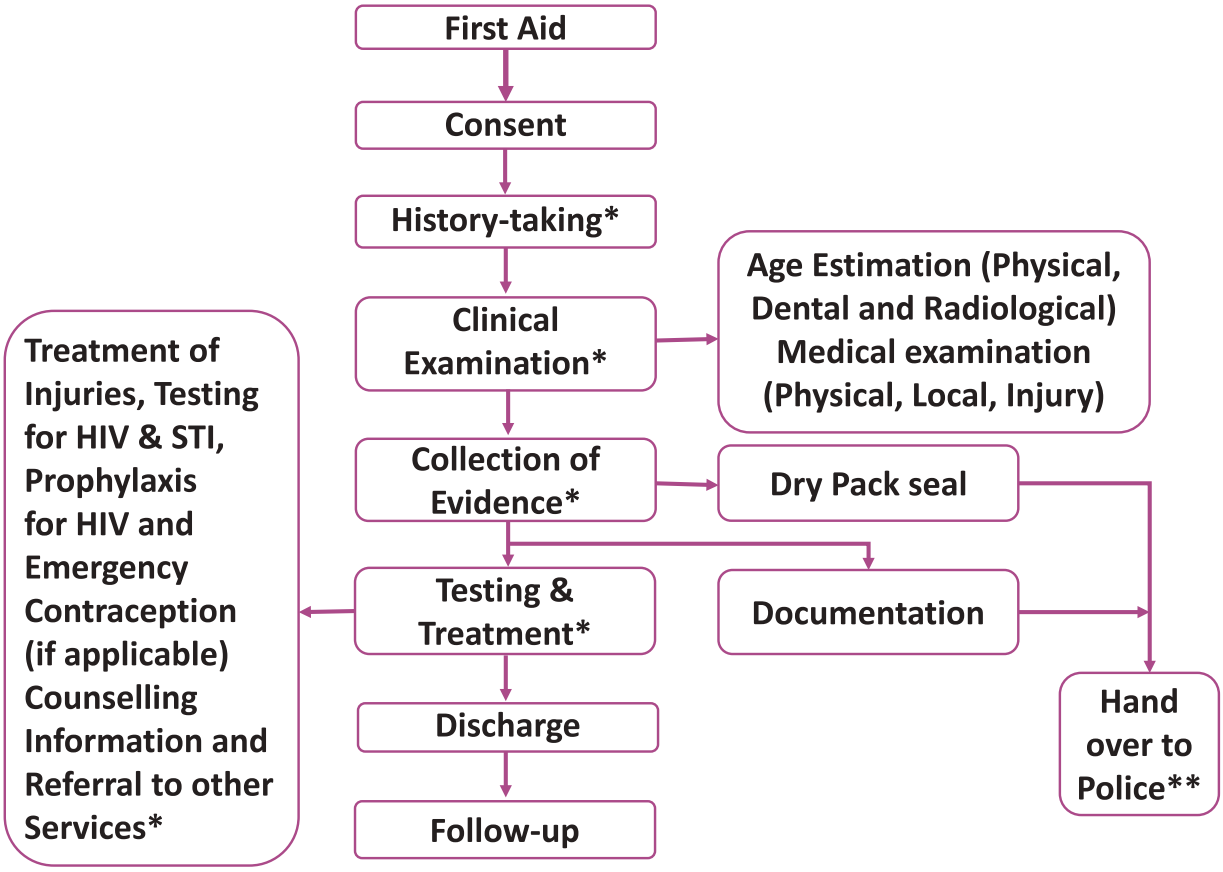

Figure 9.1 Management of Sexual Violence

*Consent should be taken before clinical examination, collection of evidence, testing and treatment and while providing referrals for other services
**collect proof of receiving

- **Documentation, packing, sealing, and handing over the collected evidence:** After the examination the medical practitioner should document the report, formulate opinion, sign the report and handover the report and sealed samples to police under due acknowledgment. The report should be made in triple copies (one for the hospital record where, receiving of report and samples from police has been taken, one for the police, and one for the survivor as they have the right to have a copy of the report).
- **Treatment of injuries**: clean lacerations with antiseptic or soap and water. If the survivor is already immunized with Tetanus Toxoid or if no injuries, TT not required. If there are injuries and survivor is not immunized, administer 0.5 ml TT IM. If lacerations require repair and suturing, which is often the case in minor girls, refer to the nearest centre offering surgical treatment.

- **Testing/prophylaxis for STI, HIV, Hepatitis B and Pregnancy**: If facilities permit, swabs must be collected from various sites for investigations of a number of causative organisms. Blood samples should be collected for VDRL/RPR, HIV and HbsAg tests. Urine may be tested to rule out pregnancy.

Note: It is important to obtain informed consent for any examination, treatment, or referral in a case of a victim of sexual assault.

The compliance with follow-up visits among survivors of sexual assault is poor. As a result, the following routine preventive therapy after a sexual assault should be encouraged:

- **Prevention of unwanted pregnancy:** Emergency Contraception (EC) to prevent unwanted pregnancy should be given within 72 hours of unprotected sexual intercourse. The preferred choice of treatment is 2 tablets of Levonorgestrel 750 mg, within 72 hours. If vomiting occurs, repeat within 3 hours (or 2 tablets Combined Oral Contraceptives Mala D - 2 tablets stat repeated 12 hours within 72 hours). Although emergency contraception is most efficacious if given within the first 72 hours, it can be given for up to 5 days after the assault. Pregnancy assessment must be done on follow up and the survivor must be advised to get tested for pregnancy in case she misses her next period. In the case of child sexual abuse, the possibility of pregnancy and emergency contraception should be discussed with the pubertal child and her parent or any other person on whom such child has trust and confidence. If the child is found to be pregnant, the RMP shall counsel such child and her parent, guardian, or support person about the various lawful options available under the Medical Termination of Pregnancy Act, 1971 and the Juvenile Justice (Care and Protection of Children) Act, 2015.
- **Post-exposure prophylaxis of STI:** STI prophylaxis should be started as early as possible, although the doses should be spread out (and taken with food) to reduce side-effects (See Table 9.1).

Table 9.1: Post-exposure prophylaxis for STI

Weight of the victim	Infection	PEP drugs and schedule
More than 45 kg	Chancroid, gonorrhoea and chlamydia	Injection Ceftriaxone 500 mg IM plus Doxycycline* 100 mg, orally, twice daily for seven days or Tab. Azithromycin 1gm plus Tab. Cefixime 800mg orally
	T. vaginalis and Bacterial vaginosis	Tab Secnidazole 2gm orally single dose or Tab Metronidazole 2gm orally single dose or Tab Tinidazole 2gm orally single dose
Children and Adults Less than 45 kg	Chancroid and chlamydia	Tab Azithromycin single oral dose-20 mg/kg on empty stomach
	Gonorrhoea	Tab Cefixime 8 mg/kg of body weight as a single dose, OR Inj. Ceftriaxone 125 mg, single dose, IM
	T. Vaginalis	Oral Metronidazole-15 mg/kg/dose, 3 times a day for 7 days

*Should be preferred in cases of receptive anal sex

Post-exposure prophylaxis of STI in children: The identification of sexually transmissible agents in children beyond the neonatal period suggests sexual abuse. The significance of the identification of a sexually transmitted agent in such children as evidence of possible child sexual abuse varies by pathogen. Post-natally acquired gonorrhoea, syphilis, and non-transfusion, non-perinatally acquired HIV is usually diagnostic of sexual abuse. Sexual abuse should be suspected when genital herpes is diagnosed.

The general rule that sexually transmissible infections beyond the neonatal period are evidence of sexual abuse has exceptions. For example, rectal or genital infection with C. trachomatis among young children might be the result of perinatally acquired infection and has, in some cases, persisted for as long as 2–3 years. Genital warts have been diagnosed in children who have been sexually abused, but also in children who have no other evidence of sexual abuse. BV has been diagnosed in children who have been abused, but its presence alone does not prove sexual abuse. In addition, most HBV infections in children result from household exposure to persons who have chronic HBV infection. Moreover, congenital syphilis may also have late manifestations.

The examination of children for sexual assault or abuse should be conducted in the presence of the parent of the child or any other person in whom the child reposes trust or confidence. In case the parent or a person in whom the child reposes trust is not available, such examination shall be conducted in the presence of a woman nominated by the head of the medical institution. The examination of children should be done in a manner designed to minimize pain and trauma to the child. The scheduling of an examination should depend on the history of assault or abuse. During the initial examination and 2-week follow-up examination (if indicated), the following should be performed:

- Visual inspection of the genital, peri-anal, and oral areas for genital discharge, odour, bleeding, irritation, warts, and ulcerative lesions. The clinical manifestations of some STI are different in children than in adults.
- Specimen collection for *N. gonorrhoeae* culture from the pharynx and anus in boys and girls, the vagina in girls.
- Cultures for *C. trachomatis* from specimens collected from the anus in both boys and girls and from the vagina in girls. Culture and wet mount of a vaginal swab specimen for *T. vaginalis* infection and BV.
- Collection of serum samples to be evaluated immediately, preserved for subsequent analysis, and used as a baseline for comparison with follow-up serologic tests. Sera should be tested immediately for antibodies to sexually transmitted agents like *T. pallidum*, HIV, and HBV.

Follow-up examination:

- In circumstances in which transmission of syphilis, HIV, or hepatitis B is a concern but baseline tests are negative, it is recommended to conduct follow-up examinations at approximately 6 weeks, 3 months, and 6 months after the last suspected sexual exposure to allow time for antibodies to infectious agents to develop. In addition, results of HBsAg testing must be interpreted carefully, because HBV can also be transmitted non-sexually.
- **Post-exposure prophylaxis of HIV:** Refer to district hospital and follow latest NACO guidelines. The details of PEP regimens are mentioned in table 9.2.

Table 9.2. PEP Regimens for HIV

Sexual Assault victim	PEP Drugs and Dosages
Adolescents and Adults (>10 years of age and >30 kg weight)	TLD one tablet once a day
Children (20-29.9 kg weight) or >10 years and <30 kg	Abacavir + Lamivudine (Dosage as per weight band) + Dolutegravir (50 mg), or Zidovudine + Lamivudine + Dolutegravir 50 mg (Dosage as per weight band), If Hb > 9 g/dl
Children <20 kg weight	Abacavir + Lamivudine + Dolutegravir 10mg (Dosage as per weight band), or Zidovudine + Lamivudine + Dolutegravir 10 mg (Dose as per weight band) If Hb > 9 g/dl

Refer to latest PEP guidelines from NACO for further details.

- **Post-exposure prophylaxis against Hepatitis B**: This is recommended if the sexual assault survivor has not been vaccinated earlier. Administer 0.06 ml/kg HB immune globulin immediately (anytime up to 72 hours after the sexual act). In addition, the first dose of the hepatitis B vaccine is to be provided at the time of the initial examination. Follow-up doses of vaccine should be administered as per the latest recommendations for HBV vaccination. The provisions for HBV vaccine in general health system will be as per the supplies made under NVHCP.
- **Follow-up services:** It is essential to explain the importance of follow-up appointments and services during the first visit itself. Sexual assault survivors should be clearly told whom to contact if they have other questions or subsequent physical or emotional problems related to the incident. The follow-up examinations provide an opportunity to:
  - detect new infections acquired during or after the assault,
  - complete hepatitis B vaccination, if indicated,
  - complete counselling and treatment for other STI, and
  - monitor side effects and adherence to post exposure prophylactic medication, if prescribed.
- **Psychological support (both at time of crisis and long-term)**: Psychosocial management includes counselling and supportive services, which should be available onsite or by referral. Women or children who have been sexually abused may need shelter and legal protection. Adolescents in particular may need crisis support, as they may not be able or willing to disclose the assault to parents or caretakers. An evaluation of the sexual assault survivor's personal safety should be made by a protective services agency or shelter, if available, and arrangements made for protection if needed.

Transgender persons, who are victims of sexual violence, should be treated in a manner that respects their dignity and privacy. There should be no discrimination in handling a survivor of sexual assault on the basis of their gender identity and expression. Self-identity of transgender persons must be respected at all times in regard to examination, treatment and follow up services.

POCSO Act (Protection of Children from Sexual Harassment Act, 2012)

POCSO Act can be defined "an Act to protect children from offences of sexual assault, sexual harassment, and pornography and provide for the establishment of Special Courts for the trial of such offences and matters connected therewith or incidental thereto." The POCSO Act was enacted to protect children aged less than 18years from sexual assault, abuse and harassment, and pornography.

- The act mandates that investigation in the cases is to be completed in two months (from the date of registration of FIR) and trial in six months.
- The Act defines a child as any person below eighteen years of age.
- POCSO states a sexual assault is to be considered aggravated if –
  - The abused child is mentally ill or,
  - When the abuse is committed by a member of the armed forces or Security forces, public servant, or a person in a position of trust or authority of the child, like a family member, police officer, teacher, or doctor or a person-management or staff of a hospital, whether Government or private.
- It prescribes rigorous imprisonment for a term which shall not be less than ten years, but which may extend to imprisonment for life and also fine as punishment for aggravated penetrative sexual assault.
- It also makes provisions for avoiding the re-victimization of the child at the hands of the judicial system.
- The Act also makes it mandatory to report such cases. It makes it the legal duty of a person aware of the offence to report the sexual abuse. In case he fails to do so, the person can be punished with six months of imprisonment or a fine.
- It also prescribes punishment to the people who traffic children for sexual purposes.
- The Act also provides for punishment against false complaints or untrue information.
- The act was amended in 2019 to increase the minimum punishment from seven years to ten years. It further adds that if a person commits penetrative sexual assault on a child below the age of 16 years, he will be punishable with imprisonment between 20 years to life, with a fine.
- Aggravated penetrative sexual assault under POCSO Act, 2012 is the equivalent provision for aggravated rape.
- A person can be charged with this offence in certain aggravating circumstances, such as if the rape occurs within a relationship of trust or authority, or if it leads to pregnancy, among others.
- Under POCSO, the consent of a person under the age of 18 is irrelevant, regardless of the nature and circumstance of the sexual interaction, or the particulars of the person with whom it takes place. This means that any sex with a minor is rape.

Reference:

- Guidelines and Protocols for Medico-legal care for survivors/victims of sexual violence, 2014, MOHFW, Govt of India. Available at: https://main.mohfw.gov.in/sites/default/files/953522324.pdf
- The Bharatiya Nyaya Sanhita, 2023. Ministry of Law and Justice (Legislative Department). Available at: https://www.mha.gov.in/sites/default/files/250883_english_01042024.pdf
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- Guidelines for Forensic Medical examination in sexual assault cases, 2018, CSFL, Dte. Forensic Sciences, Chandigarh. Available at: https://www.mha.gov.in/sites/default/files/2022-09/womensaftyDivMedicalOfficers_06082018_0%5B1%5D.pdf
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Annexure

Annexure 1:
Administration of BPG Injection

The steps of administration of BPG injection are as follows:

- Penicillin sensitivity test should be conducted before administering BPG. Please note that BPG is a safe drug to administer and confirmed penicillin allergy, only occurs in less than 3% of the population.
- Keep an emergency tray ready at sites providing treatment services using BPG.
- Administer into ventrogluteal, dorso-gluteal area of buttock or vastus lateralis of thigh, alternating on each administration (BPG should not be given into the Deltoid muscle of the upper arm)
- Deliver medication at slow, steady rate, preferably over 2-3 minutes
- Never administer BPG via intravenous administration; take special precautions to avoid intravascular injection
- Avoid intramuscular injection of these suspensions near major nerves or blood vessels because this could cause neurovascular damage
- Observe Patient for Signs of Anaphylactic Shock: discomfort in breathing, shock, itchy rashes, or hives.

In case of Anaphylactic Shock:

- Call for help, contact emergency services if required
- Assess Airway, Breathing and Circulation; perform CPR if necessary
- Inject Adrenaline intramuscularly (0.5ml for adult, 0.3ml for elderly); repeat in 5-10 minutes until response is adequate; recommended dilution for adrenaline is 1:1000 (1 mg/ml)
- Check BP and pulse every 5-10 minutes
- Give Hydrocortisone, 250 mg intramuscular
- Give Chlorpheniramine, 10–20 mg or Diphenhydramine, 50–100 mg intramuscular
- Transfer patient to hospital or nearest emergency ward
- Repeat Adrenaline if necessary
- Record all details of treatment; Give a copy to the hospital as well as the patient

Annexure 2:
Laboratories actively performing Mpox testing

1. ICMR-National Institute of Virology, Pune
2. NCDC Lab, New Delhi
3. Government Medical College, Trivandrum, Kerala
4. Kasturba Hospital for Infectious Disease, Mumbai, Maharashtra
5. Gauhati Medical College, Gauhati, Assam
6. Gandhi Medical College, Secunderabad, Telangana
7. All India Institute of Medical Sciences (AIIMS), Delhi
8. Bangalore Medical College & Research Institute, Bangalore, Karnataka
9. National Institute of Virology (NIV) Field Unit, Kerala
10. All India Institute of Medical sciences, Nagpur
11. King Institute of Preventive Medicine and Research (KIPM&R), Chennai
12. ICMR – National Institute of Research in Bacterial Infection, Kolkata
13. SMS Medical College, Jaipur
14. Govt. Medical College, Amritsar
15. King George's Medical University (KGMU), Lucknow
16. B.J. Medical College, Ahmedabad
17. Govt. Medical College, Thrissur
18. Govt. Medical College, Kozhikode
19. Sher-e-Kashmir Institute of Medical Sciences, Srinagar
20. Zoram Medical College, Mizoram
21. Maulana Azad Medical College, New Delhi
22. Institute of Post Graduate Medical Education & Research (IPGMER), Kolkata

Annexure 3:
Operations for Screening and Management of Syphilis

Screening and Confirmation for Syphilis

The STI clients, HRGs (including population under P&OCS) and at-risk BPs can be screened for syphilis using Dual RDT/ RPR/VDRL kits. The algorithms for screening and confirmation of syphilis are mentioned in the Table A.

Table A. Algorithms for Screening and Confirmation of Syphilis

Algorithm	Kits used for Screening	Sites for Screening	Kits used for Confirmation for syphilis-reactive cases	Sites for Confirmation
Reverse Algorithm	Dual RDT	Screening sites (CBS, Mobile Outreach, DSRC, POCS)	RPR/VDRL	ICTC/ District/Sub-District Hospital/ Medical College
Traditional Algorithm	RPR/VDRL	ICTC/ District/Sub-District Hospital/Medical College	TPHA, TP-ELISA*	District Hospital/ Medical College

**Not mandatory*

The following operational aspects needs to be considered while providing syphilis services in TI/LWS settings:

Scenario 1. When Screening with Dual RDT Kits

- The syphilis screening under TI/LWS settings can be conducted using Dual RDT kits through CBS and Mobile Outreach. The detailed algorithm is mentioned in Figure A.

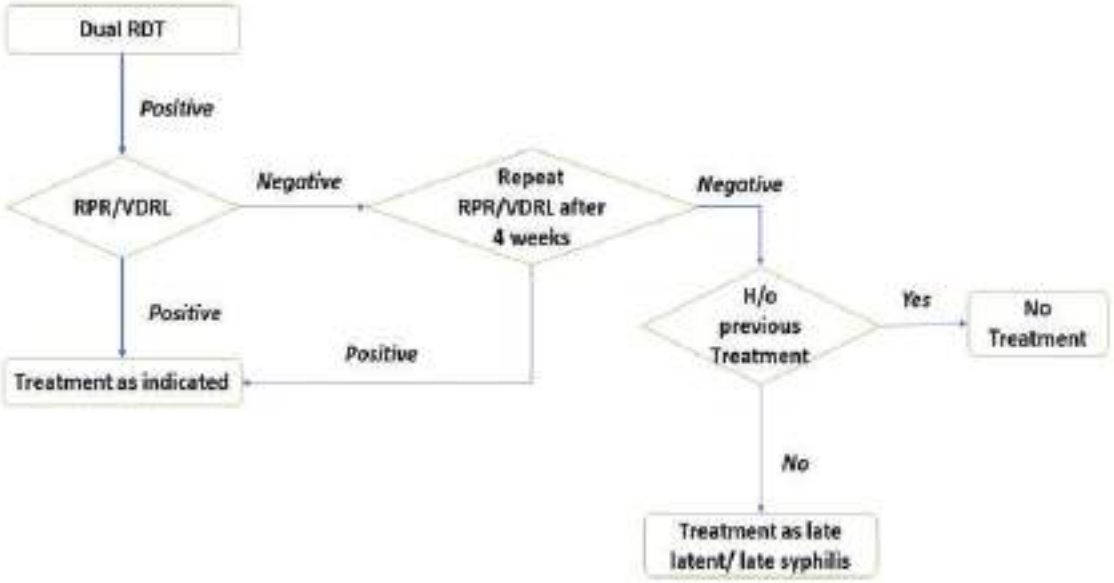

Figure A. Testing and Management Algorithm for Syphilis using Dual RDT kits

- When RPR/VDRL testing is not possible for confirmation (e.g., in P&OCS), the treatment decision can be taken on the basis of history of potential high-risk exposure, history of syphilis treatment, and clinical discretion of the treating physician.

Scenario 2: When Screening with RPR/VDRL kits

- In absence of Dual RDT kits, the clients can be referred from TI/LWS sites to ICTC/ District/Sub-District Hospital/Medical College for RPR/VDRL screening.
- The confirmation for Syphilis using TPHA is not mandatory. The decision for management of Syphilis can be taken on the basis of history of potential high-risk exposure, history of syphilis treatment, comparison of RPR/VDRL titers with previous values and clinical discretion of the treating physician.

These scenarios can also be used for screening of syphilis in STI clinics (including DSRCs)

Management of Syphilis

- All screened reactive/confirmed cases can be treated in TI/LWS settings using STI color-coded kit 3 or 4 under the guidance of trained medical officer.
- When the treatment cannot be done at TI/LWS sites, the patient should be referred to the nearest DSRC/identified facility for further management.
- All partners of syphilis-reactive cases should be notified and screened for syphilis.

Note:

1. Injection BPG is the first choice of treatment for management of syphilis.
2. Injection BPG will be administered by a trained medical officer in a facility with availability of emergency tray.
3. All patients will undergo skin allergy testing before BPG administration.

Follow-up

- All cases will be followed up after 3 months of completion of treatment.
- The RPR/VDRL titers will be tested and compared with the baseline value. If the titers are stagnant or increasing or there is clinical evidence of syphilis, repeat complete treatment.
- The patients once tested reactive with Dual RDT kits for syphilis will be screened with RPR/VDRL in follow-up visits (for routine bi-annual screening).
- The at-risk PLHIV will be routinely screened for syphilis using RPR/VDRL kits only

The details on follow-up screening are mentioned in Table B.

Table B. Follow-up regular screening for syphilis

Result of Dual RDT Screening	Confirmation	Follow-up
HIV (-); Syphilis (-)	-	• Regular Screening using Dual RDT every 6 months
HIV (+) only	HIV Positive	1. ARTC Referral and Linkage 2. Regular Screening of at-risk PLHIV for Syphilis with RPR/VDRL every 6 months
	HIV Negative*	• Regular Screening using Dual RDT every 6 months or as per the protocols
Syphilis (+) only	Syphilis Positive (using RPR/VDRL)	• Management at DSRC • Treatment Monitoring after 3-6 months • Regular Screening using RPR/VDRL every 6 months
	Syphilis Negative (using RPR/VDRL)	Repeat RPR/VDRL after 4 weeks: i) RPR/VDRL turns positive → Treatment at DSRC → Treatment Monitoring after 3 months → Regular Screening using RPR/VDRL every 6 months ii) RPR/VDRL remains negative → Treatment at DSRC (if needed as per algorithm) → Regular Screening using RPR/VDRL every 6 months

*As per the National HIV Testing algorithm

Please note that these operational aspects for screening and management of syphilis can be used in other settings providing STI and RTI services (including DSRC).

National AIDS Control Organisation

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