

**Reportable**

**IN THE SUPREME COURT OF INDIA  
CIVIL ORIGINAL JURISDICTION**

**Writ Petition (Civil) No 131 of 2013**

**Dr Narendra Gupta**

**... Petitioner(s)**

**Versus**

**Union of India & Ors**

**... Respondent(s)**

**J U D G M E N T**

**Dr Dhananjaya Y Chandrachud, CJI**

1. A public interest litigation has been instituted by Dr Narendra Gupta in 2013 highlighting the fact that in the States of Bihar, Chhattisgarh and Rajasthan, in particular, “unnecessary hysterectomies” were carried out under the Rashtriya Swasthya Bima Yojana as well as other government schemes related to healthcare. The petition also highlights the involvement of private hospitals in performing such hysterectomies. The Union Ministry of Health and Family

Welfare<sup>1</sup> is the first respondent, while the States of Bihar, Rajasthan and Chhattisgarh are impleaded as the second, third and fourth respondents respectively. Based on his field work, the petitioner has brought to our notice the fact that women, who should not have been subjected to hysterectomies and to whom alternative treatment could have been extended, were subjected to hysterectomies, seriously endangering their health in the process. The petitioner also submitted that most women who were subjected to hysterectomies of this kind belonged to the Scheduled Castes, Scheduled Tribes, or Other Backward Communities.

2. On 13 December 2022, this Court directed the Secretary, MoHFW to examine the grievance which was raised in the petition and to file a response after collating relevant information.
3. Before we advert to the status report which has been filed by the Union of India, it must be recorded, at the outset, that from the counter affidavits filed by the States of Rajasthan, Bihar and Chhattisgarh, it emerges that there is a considerable degree of substance in the facts which have been highlighted in the petition. For instance, the affidavit filed by the State of Bihar indicates that steps were taken by the district authorities in Kishanganj, Madhubani, Samastipur and Saran to enquire into complaints regarding unnecessary hysterectomies. Finding that many of the allegations in regard to the performance of unnecessary hysterectomies were true,

1 "MoHFW"

the State has taken consequential action. It issued a circular *inter alia* directing that empanelled hospitals must obtain permission from the concerned insurance provider before conducting hysterectomies on women aged forty or below. This Court has been apprised of the fact that several hospitals have been blacklisted and de-empanelled from the Rashtriya Swasthya Bima Yojana pursuant to the investigation conducted in the state. In certain cases, First Information Reports have been filed.

4. The State of Rajasthan has placed on the record the steps which were taken by the District Collector, Dausa for constituting committees to enquire into the alleged incidents. The State of Rajasthan framed the Rajasthan Government Clinical Establishments (Registration and Regulation) Rules 2013. The State of Chhattisgarh constituted a High Powered Committee which found that the hysterectomies in the state could not be termed as “wholly unneeded.”
5. The right to health is an intrinsic element of the right to life under Article 21 of the Constitution. Life, to be enjoyed in all its diverse elements, must be based on robust conditions of health. There has been a serious violation of the fundamental rights of the women who underwent unnecessary hysterectomies.
6. In 2022, MoHFW issued guidelines titled “Guidelines to Prevent Unnecessary

Hysterectomies,”<sup>2</sup> which have been forwarded to all the States and Union Territories for compliance. The Guidelines were formulated after a series of consultations with different stake holders. The Guidelines indicate that while in developed countries hysterectomies are typically conducted amongst pre-menopausal women above the age of forty-five years, in India, community based studies have consistently found rising hysterectomy rates among young women, ranging from twenty-eight to thirty-six years of age. Field based studies have indicated that unnecessary hysterectomies are performed in cases where medical or non-invasive treatment would have been sufficient. The evidence indicates a higher risk among poor, less educated women, particularly in the rural areas.

7. Paragraphs 5.1.3 to 5.1.5 of the affidavit filed by the Secretary, MoHFW are set out below:

“5.1.3. Data from National Family Health Survey-4 (2015-16) estimates hysterectomy prevalence to be 3.6% amongst women aged 36-39 years, 9.2% amongst women aged 40-49 years and the median age for hysterectomy is 37 years.

5.1.4 Notably, two-thirds of the procedures were conducted in private facilities.

5.1.5 A working paper from the National Health Authority on early trends from AB-PMJAY indicates that 2% of the claims submitted by women were for hysterectomy. Notably, six states – Chhattisgarh, Uttar Pradesh, Jharkhand, Gujarat, Maharashtra and Karnataka – generated three quarters of all hysterectomy claims.”

8. In 2019, a national consultation on unnecessary hysterectomies identified three important challenges:
- a. The need for appropriate clinical and population level guidelines;
  - b. Availability of appropriate information on and treatment of gynaecological morbidity at the primary level; and
  - c. The critical need to monitor and regulate the appropriate use of hysterectomies, particularly for treatment of benign gynaecological conditions and amongst younger women.
9. Chapter 3 of the Guidelines provides guidance on prevention of unnecessary hysterectomies. It refers to the role of programme managers and also refers to the role of different levels of public health facilities. The Guidelines note that reporting of hysterectomies, cases conducted for women less than 40 years of age and the cause of the hysterectomy have to be incorporated in the existing screening checklist. To achieve this, the Guidelines propose the setting up of Hysterectomy Monitoring Committees at District, State and National levels. Chapter 3 also deals with District, State and National Hysterectomy Monitoring Committees in the following terms:

**“District Hysterectomy Monitoring Committees**

A District Hysterectomy Monitoring Committee must be set up in each

district to enable effective monitoring. The committee must be set up under the chairpersonship of District CMO. NCD Nodal, District RCH Nodal Officers/ Maternal Health Nodal Officers, other key government personnel at the district level, representatives from FOGSI (both public and private sector), representatives from development partners etc. The monitoring committee is expected to:

- Issue necessary orders to both public and private sectors to submit a line list of all women who underwent hysterectomy every month. The line list must include information on parameters such as:
  - Age
  - Parity
  - Occupation
  - Indication of hysterectomy
  - Previous medical/surgical history
  - Hysterectomy route:
    - Abdominal
    - Vaginal
    - Laparoscopic
  - Any other surgery done along with hysterectomy:
  - Past treatment history:
  - HPE:
- Every quarter the district committee must audit cases with following indications and issue necessary instructions if required:
  - Hysterectomy with/ without BSO in women <35 yrs. of age

- Hysterectomy with BSO in women < 40 yrs. of age
- All cases where no indication for doing the procedure is mentioned in the records
- All cases where no records of treatment prior to hysterectomy (in papers or in history) are available
- Discrepancy between mentioned indication and HPE report or Any severe morbidity/mortality due to hysterectomy
- Annexure 3 provides detailed guidelines on how to conduct audits of hysterectomies
- Arrange necessary trainings and sensitization sessions for both public and private sector professionals.

### **State Hysterectomy Monitoring Committees**

A State Hysterectomy Monitoring Committee must be set up in each State to enable effective monitoring. The committee must be set up under the chairpersonship of State Principle Secretary. State level DPH (Director Public Health) will be the nodal Officer & NCD State program officer, RCH/FW/MH programme officers will be the other key government personnel at the state level, representatives from FOGSI (both public and private sector), representatives from development partners etc. The monitoring committee is expected to meet once in every six months and review district level data to ensure that unnecessary hysterectomies can be avoided. The State Hysterectomy Monitoring Committees must also arrange necessary trainings and sensitization sessions for both public and private sector professionals and district officials.

### **National Hysterectomy Monitoring Committees**

A National Hysterectomy Monitoring Committee must be set up to enable effective monitoring and ensure necessary policy decisions at the National level. The monitoring committee would comprise of officials from NCD, ICMR, MH Officers under the chairpersonship of Additional Commissioner & Mission Director, NHM and is expected to meet once in every six months and review State level data to ensure that unnecessary hysterectomies can be avoided. The national committees must also

arrange necessary trainings and sensitization sessions for both public and private sector professionals and district officials. Most importantly national committees must review the landscape and take necessary policy decisions as required.”

10. The Ayushman Bharat Pradhan Mantri Jan Arogya Yojana which provides an annual health cover of Rs. 5 lakhs per family has been extended to cover twelve crore families across the nation. The scheme covers the treatment of 1949 procedures, including hysterectomies under 27 different specialties. As of 16 March 2023, 45,434 hospital admissions were authorized under this scheme for hysterectomy related treatments. Two Standard Treatment Guidelines have been developed for fourteen procedures relating to hysterectomies. The Union government has set out the details of procedures and State/UT-wise details of authorized hospital admissions for the purpose of hysterectomies under the Scheme.
11. Besides setting out the provisions of the Guidelines, the status report filed by the Union government indicates the steps which were taken by the States of Chhattisgarh and Bihar while dealing with the performance of unnecessary hysterectomies.
12. The Union government has proposed an action plan in its status report, which is set out below:

#### “E. PROPOSED ACTION PLAN



10. Setting Up of Grievance Portal - It is pertinent to mention here that the Rasthriya Swasthya Bima Yojana (RSBY) has been subsumed in PMJAY with the launch of Ayushman Bharat-Pradhan Mantri Jan Arogya Yojana (AB-PMJAY) on 23.09.2018. The PMJAY website hosts a grievance portal for its beneficiaries. An additional grievance portal would also be maintained by National Health Authority especially designed for PMJAY beneficiaries of hysterectomies.

The proposed portal will be activated for hysterectomy beneficiaries within a period of three months. Any grievance received on the portal will be monitored by the National Hysterectomy Monitoring Committee.

11. Formation of Committees – The Ministry will endeavour to form a National Hysterectomy Monitoring Committee, as proposed under the Guidelines within 4 to 6 weeks. Simultaneously the states will also be continuously advised to expedite formation of the state and district level committees so that the implementation of the National Guidelines can be properly monitored and supervised.”

13. The Guidelines which have been adopted by MoHFW to prevent unnecessary hysterectomies must be adopted by all the States and Union Territories. MoHFW shall engage with all the States and Union Territories to ensure that the Guidelines are adopted expeditiously. We direct that:
- a. All States and Union Territories shall adopt the Guidelines within three months and report compliance to MoHFW;
  - b. All the States and Union Territories shall implement the Guidelines without delay and report compliance to MoHFW; and
  - c. All the States and Union Territories shall ensure that all public and private hospitals within their territories are made aware of the existence and

importance of the Guidelines.

The Guidelines, for convenience of reference, are annexed to this judgment as Annexure A to facilitate compliance.

14. Ms. Kawalpreet Kaur, counsel appearing on behalf of the petitioner, has urged two submissions which seek to supplement the Guidelines. Firstly, it has been submitted that under the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana, where a hysterectomy is performed on a woman below the age of forty years, the requirement of the procedure has to be certified by at least two doctors. The suggestion is that this requirement should be extended to other cases as well, irrespective of the age of the woman undergoing a hysterectomy.
15. Responding to the above submission of Ms Kawalpreet Kaur, Ms Aishwarya Bhati, Additional Solicitor General, submits that once the full data on hysterectomies is duly captured on the portal of MoHFW and the National, State, and District Level Committees are constituted, a considered decision will be taken by the Union of India on this aspect. The Additional Solicitor General submitted that while certain States already have such a procedure in place, the network of government hospitals may not be adequate enough to implement such a regulation across India even if it were made. Moreover, the ASG urged that there is a real danger that this may result in the denial of treatment to women who are genuinely in the need of it. It has been submitted that since the situation is evolving, the Union of

India would take a considered view once adequate data is available.

16. We accept the submission.
17. The Guidelines mandate that the National Committee should review the landscape and take necessary policy decisions, as required, once in every six months.
18. The second suggestion which has been urged on behalf of the petitioner is that the state should take steps for blacklisting hospitals where hysterectomies were carried out without medical necessity and without obtaining the informed consent of the patient. In this context, it was urged that as a first line of treatment, other non-invasive methods should be adopted and, in any event, the woman who is undergoing the hysterectomy should be properly informed about the reason and likely consequences of the hysterectomy, bearing on the health of the patient.
19. We are in agreement with the submission that all the States and Union Territories must take stringent action for blacklisting hospitals once it is detected that any unnecessary hysterectomy was carried out or that the procedure was taken recourse to without the informed consent of the patient. We direct that necessary action be taken in accordance with law.
20. Since steps have been taken by the Union government in framing the Guidelines in 2022 and the States of Chhattisgarh, Bihar and Rajasthan have indicated to the Court of the steps which were taken to detect unnecessary hysterectomies and to

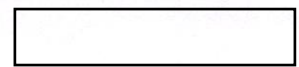
deal with them, we see no further reason to keep the petition alive.

21. The Union government shall take all necessary steps in accordance with the Guidelines to effectuate the public interest which is sought to be achieved.
22. We appreciate the assistance which has been rendered to the Court by Ms Kawalpreet Kaur, counsel appearing on behalf of the petitioner and Ms Aishwarya Bhati, Additional Solicitor General.
23. The petition is disposed of in terms of the above directions.
24. Pending applications, if any, stand disposed of.

.....CJI.  
[Dr Dhananjaya Y Chandrachud]

.....J.  
[J B Pardiwala]

New Delhi;  
April 05, 2023  
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**ANNEXURE-A**

**GUIDELINES TO PREVENT  
UNNECESSARY  
HYSTERECTOMIES**

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**MINISTRY OF HEALTH & FAMILY WELFARE**

**MATERNAL HEALTH DIVISION**

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## INTRODUCTION

Hysterectomy, the surgical removal of the uterus, is the most common non-obstetric gynaecological surgery amongst women in reproductive age group. The most common medical indications for hysterectomy include fibroids, abnormal uterine bleeding, uterine prolapse, chronic pelvic pain and premalignant and malignant tumours of uterus and cervix. Hysterectomy with Oophorectomy (Removal of ovaries) leads to surgical menopause which may further lead to menopausal symptoms such as hot flashes, vaginal dryness, urinary incontinence, sexual dysfunction and long term consequences like osteoporosis and CVS diseases. Oophorectomy worsens the symptoms of early menopause.

In developed countries, hysterectomy is typically conducted amongst premenopausal women above age 45 years. In India, there is increasing concern about patterns of hysterectomy at a population level. Community-based studies have consistently found rising hysterectomy rates amongst young women, ranging from 28 to 36 years. Further, evidence indicates a higher risk amongst poor, less educated women in rural areas. Field-based reports have also suggested that there are unnecessary hysterectomies performed in cases where medical or non-invasive treatment would have been sufficient. There are also reports of potential coercion for financial benefit under health insurance schemes and concerns pertaining to lack of information provided to women on side effects.

Data from the National Family Health Survey-4 (2015-16) estimates hysterectomy prevalence to be 3.6% amongst women 30-39 years and 9.2% amongst women 40-49 years. The median age at hysterectomy was 37 years (amongst women who were 40-49 at the time of survey). Two-thirds of procedures were conducted in private facilities. Excessive menstrual bleeding or pain was self-reported as the leading indication for hysterectomy, followed by fibroids and uterine disorder. Prevalence varied greatly across states, with prevalence from 20-23 percent of women in ages 40-49 in Andhra Pradesh and Telangana—close to high-income countries—yet at a considerably low median age. Data also show variation across states indicating uneven availability of treatment for women for common gynaecological disorders at primary health care level<sup>1</sup>. NFHS 5

A working paper from the National Health Authority on early trends from Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB-PM-JAY) indicates that 2% of claims submitted for women were for hysterectomy. Six states (Chhattisgarh, Uttar Pradesh, Jharkhand, Gujarat, Maharashtra and Karnataka)

<sup>1</sup> Desai S, Shukla A, Nambiar D, Ved R. Patterns of hysterectomy in India: a national and state-level analysis of the Fourth National Family Health Survey (2015-2016) [published correction appears in BJOG. 2020 Oct;127(11):e122. Shuka, A [corrected to Shukla, A]]. BJOG. 2019;126 Suppl 4(Suppl 4):72-80. doi:10.1111/1471-0528.15858

had overall high number of claims under PM-JAY and also generated three-quarters of all hysterectomy claims. The median age of claims submitted for hysterectomy under PM-JAY was 44 years. The most common package covered was hysterectomy with salpingo-oophorectomy, suggesting that up to half of claimants may have undergone removal of the ovaries, which in turn may render women vulnerable to a range of side effects.

A national consultation in 2019 on unnecessary hysterectomy identified three important challenges for women's health:

- \* The need for appropriate clinical and population-level guidelines on hysterectomy
- \* Availability of appropriate information on and treatment of gynecological morbidity at the primary care level
- \* A critical need to monitor and regulate the appropriate use of hysterectomy, particularly for treatment of benign gynecological conditions and amongst younger women.

The purpose of this document is to:

1. Provide guidance to public health programme managers on measures to address unnecessary hysterectomy at the facility level, including focus on monitoring and awareness generation activities at the community level.
2. Provide clinical guidelines on common conditions that constitute key indications for hysterectomy. To focus on providing treatment pathways for abnormal uterine bleeding/dysfunctional uterine bleeding, lower abdominal pain, vaginal discharge, abnormal looking cervix and uterovaginal prolapse, drawing from existing government guidelines, evidence reviews and expert consultation.



## COMMON INDICATIONS FOR HYSTERECTOMY

Evidence reviews and expert consultations have highlighted the following common indications for Hysterectomy in our country:

- Abnormal Uterine Bleeding/ Dysfunctional Uterine Bleeding
- Vaginal Discharge
- Lower abdominal pain/Pelvic Inflammatory Disease (PID)
- Abnormal looking cervix
- Uterocervicovaginal Prolapse

### ABNORMAL UTERINE BLEEDING

Abnormal uterine bleeding (AUB) is a broad term that describes irregularities in the menstrual cycle involving frequency, regularity, duration, and volume of flow outside of pregnancy. Up to one-third of women will experience abnormal uterine bleeding in their life, with irregularities most commonly occurring at menarche and perimenopause. A normal menstrual cycle has a frequency of 24 to 38 days, lasts 7 to 9 days, with 5 to 80 ml of blood loss. Variations in any of these 4 parameters constitute abnormal uterine bleeding. Older terms such as oligomenorrhea, menorrhagia, and dysfunctional uterine bleeding should be discarded in favour of using simple terms to describe the nature of the abnormal uterine bleeding. Revisions to the terminology were first published in 2007, followed by updates from the International Federation of Obstetrics and Gynaecology (FIGO) in 2011 and 2018. The FIGO systems first define the abnormal uterine bleeding, then give an acronym for common aetiologies. These descriptions apply to chronic, nongestational AUB. In 2018, the committee added intermenstrual bleeding and defined irregular bleeding as outside the 75th percentile.

Abnormal uterine bleeding can also be divided into acute versus chronic. Acute AUB is excessive bleeding which requires immediate intervention to prevent further bloodloss. Acute AUB can occur on its own or superimposed on chronic AUB, which refers to irregularities in menstrual bleeding for most of the previous 6 months.

**TABLE Potential causes of abnormal uterine bleeding according to the PALM-COEIN classification<sup>5</sup>**

<b>Polyp</b>	<b>Structural pathology measurable through imaging or histopathology</b>
<b>Adenomyosis</b>	
<b>Leiomyoma</b>	
<b>Malignancy &amp; hyperplasia</b>	
<b>Coagulopathy</b>	<b>Bleeding unrelated to structural abnormalities</b>
<b>Ovulatory disorders</b>	
<b>Endometrial dysfunction</b>	
<b>Iatrogenic</b>	
<b>Not otherwise classified</b>	

### **UTEROCEVICAL AND UTEROVAGINAL PROLAPSE**

Uterine prolapse occurs when pelvic floor muscles and ligaments stretch and weaken and no longer provide enough support for the uterus. As a result, the uterus slips down into or protrudes out of the vagina. Uterine prolapse can occur in women of any age. But it often affects postmenopausal women who have had one or more vaginal deliveries. Mild uterine prolapse usually doesn't require treatment. But if uterine prolapse starts interfering with the routine activities and disrupts the normal life then benefit occurs from the treatment. The management of uterovaginal prolapse is age and fertility related. Not everyone requires hysterectomy. The conservative surgical operations are gaining more popularity. Several sling operations are available now.

### **VAGINAL DISCHARGE**

Vaginal discharge is one of the most common presenting symptoms of women to a doctor's office. It may be pathological or physiological. It may affect women of any age group. Even when it is pathological, it may be treated by means of antibiotics prescribed to the woman and often times also to her partner. However persistent vaginal discharge despite treatment requires further investigation. Vaginal discharge which is not treated or inappropriately treated can start interfering with the routine activities, affect the woman's ability to work and also give rise to more severe forms of pelvic infections, often leading women to opt for hysterectomy specially in the underdeveloped sectors of the country where referral centers are not easy to approach. It is very important both for the patient and the health care provider to understand that hysterectomy is not a treatment of vaginal discharge.

### **LOWER ABDOMINAL PAIN:**

Lower abdominal pain or pelvic pain are common complaints compelling women to visit the health care provider. This pain may be acute or chronic. Most commonly it is the chronic pelvic pain, the causes of which may be difficult to diagnose, hence making treatment difficult. Owing to this often both the health care provider and the patient resort to hysterectomy as the final answer. The most common cause of chronic pelvic pain in women is Pelvic Inflammatory Disease (PID). Treatment of PID is mostly outpatient and non-surgical requiring a prolonged course of antibiotics. Only a few patients presenting with acute symptoms like high grade fever and increased blood counts may require admission. Conservative surgery may be needed only in cases with pelvic abscess.

**Pre-cancerous Lesions of Cervix / Unhealthy Cervix:**

Chronic cervicitis or pre-cancerous cervical lesions may often lead to an unhealthy looking cervix with chronic discharge, which may be treated by medical management or cervical ablation or excisional techniques. Hence, an unhealthy looking cervix requires evaluation to rule out cancerous or precancerous lesions but does not require hysterectomy in all cases.

# **PROGRAMMATIC GUIDANCE**

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## PROGRAMMATIC GUIDANCE

**The purpose of this section** is to provide programme managers guidance on prevention of unnecessary hysterectomy by raising awareness among health providers regarding alternative methods of treatment available for gynaecological diseases as well as in the community regarding indications of hysterectomy and disadvantages of unnecessary hysterectomy. While the burden of hysterectomies varies across states, variation in national patterns suggests a lack of uniform services available to treat gynaecological morbidity. Hitherto the health system has focused largely on obstetric and family planning services, aligned with the aim to reduce maternal mortality and address unmet need for family planning. Accordingly, financial and human resources at all levels, including outreach services, were primarily related to pregnancy, delivery, post-partum care and family planning. As of now, other than Community Health Centres, District Hospitals and Medical Colleges, there are limited services in public health facilities to treat or appropriately refer women with gynaecological complaints. Women often undergo surgery for gynaecological conditions may possibly respond to medical or non-surgical interventions. The lack of services for such conditions have many reasons including high obstetric case-loads, a shortage of Medical officers and specialists, and on account of limited knowledge among service providers on updated methods of non-surgical methods for treatment.

Programme officers are expected to ensure training of all cadres of workers including the ones at the frontline, supply of medicines and other logistics, enable the delivery of high quality services at primary and secondary care levels including provision of NCDs at HWC's and create the mechanism for community awareness and facilitate the conduct of medical and social audits.

**The role of programme managers** in reducing unnecessary hysterectomy is to:

1. Communicate the range of interventions to be provided at each level of the health system for gynecological as well as obstetric ailments and thereby eliminate unnecessary hysterectomy
2. Build capacity of secondary and primary level service providers (Medical Officers, Staff Nurses, CHOs, LHV/ANMon women's health needs for gynecological services
3. Ensure that the PHC team at Health and Wellness Centers is able to make appropriate referrals and ensure that medicines prescribed at the higher levels is dispensed at HWC-SHC (If available) and that continuum of care is maintained
4. Enable improved public understanding of the various gynecological problems a woman may develop, the plethora of medical management and non- surgical interventions available to treat them, the consequences of unnecessary hysterectomy and guide women on care-seeking for gynecological morbidity through building community awareness

5. Ensure awareness regarding publicly financed health insurance like PMJAY amongst those who are eligible for the scheme and are required to undergo indicated hysterectomy in order to reduce out of pocket expenditure and thus provide financial protection.

## Role of Different Levels of Public Health Facilities

The role of HWCs/SC/PHC/CHC/SDH/DH/MC according to conditions leading to/associated with Hysterectomy, have been listed for the common conditions:

- 1a. Abnormal Uterine Bleeding (Menorrhagia with **normal** sized uterus) with/without dysmenorrhoea
- 1b. Abnormal Uterine Bleeding (Menorrhagia with **enlarged** uterus)
- 1c. Abnormal Uterine Bleeding: Metrorrhagia, Oligomenorrhoea, Amenorrhoea followed by irregular bleeding in high risk group (obese, hypertensive, diabetic or a family history of endometrial or cervical cancer), AUB in women above 40 years of age  
**OR** Persistent dysmenorrhoea
2. Abnormal Vaginal Discharge ± Pelvic pain ± Backache
3. Utero-cervical prolapse
4. Lower abdominal pain
5. Abnormal or unhealthy cervix
6. Post – hysterectomy care in women who have undergone hysterectomy at age less than 45 years.
7. Emergency hysterectomy performed to treat uncontrolled PPH

**Annexure 1 provides details** on what is expected at each level of the health system (HWCs/SC/PHC/CHC/SDH/DH/MC) for common gynaecological symptoms, the role of the service provider at each level, and details of services including essential drugs and diagnostics to be provided at the level of the facility.

## Community Awareness

It is essential that facts about hysterectomy are available to the community. Existing platforms such as Village Health, Sanitation and Nutrition Committees, Women's Self-Help Groups, Mahila Arogya Samities, and Rogi Kalyan Samities at PHC, CHC and district hospitals could be used to disseminate information through frontline workers such as ASHA and MPW- F. Discussions should focus on removing myths and misconceptions in the community and raising awareness on menstrual hygiene practices, prevention of PID's and STD, safe sex practices, other gynaecological problems in women, risk factors for genital tract malignancies and plenty of treatment modalities available for treatment as well as the role of hysterectomy in these conditions. Emphasis should be laid on the fact that hysterectomy is not the first choice of treatment for most conditions. This section of the document provides guidance on developing programs to build community awareness on unnecessary hysterectomy. It focuses on providing basic facts on hysterectomy and components of a communication strategy.

### Basic Facts on Hysterectomy

It is essential that facts about hysterectomy are available to the community and community health workers in particular. **Annexure 2** provides clear, simple information on hysterectomy that can be used to raise community awareness.

### Communication strategies

#### Existing agencies that can help build awareness in the community:

1. Village Health, Sanitation and Nutrition Committee in each village
2. Women's Self Help Groups linked to each Anganwadi
3. Mahila Aarogya Samitis
4. Mother's group in each Anganwadi
5. Standing Committee on Health in every gram panchayat
6. School Management Committees in every school
7. Rogi Kalyan Samitis at PHC, CHC and district hospitals
8. Other community based organizations
9. Ward and gram sabhas
10. District Health Societies

#### Principles for community awareness on hysterectomy prevention:

1. Community awareness building should be done in local language and IEC materials must be developed accordingly
2. All FAQs must be translated into local language. Print material, videos and apps can be used. Apps must be free to use once downloaded and usable offline. They can provide information on menstrual hygiene and hysterectomy related information for both service providers and women
3. LNG IUS must be promoted as a low cost non-surgical alternative to hysterectomy where ever feasible
4. Testimonies of women who experienced adverse effects after hysterectomy  
Testimonies of caregivers who witnessed adverse effects following hysterectomy
5. Professional Testimonies of doctors, Counsellors, Journalists, Teachers etc

#### You can make a difference by:

- Removing myths and misconceptions in the community
- Avoiding unnecessary Hysterectomies
- Campaigning for preventing unnecessary Hysterectomy

The training for all levels may be conducted through existing NCD platform.



**Key components of a communication strategy to address unnecessary hysterectomy**

**Designing a Communication Strategy<sup>2</sup>**

1. Key Messages	Literature Review; Formative Research	Findings from formative research can be used to develop and design customized and standardized messages for behaviour change.
2. Target Population	<p>a. <b>Policy Makers</b> - sensitization and advocacy with policy makers for creating policies and institutional mechanisms to prevent unnecessary hysterectomy (bureaucrats, executives etc.)</p> <p>b. <b>Service providers</b> - sensitization and advocacy with service providers (such as doctors, RMPs, Nursing Homes etc.) for uptake of desired practices of change</p> <p>c. <b>Community</b> -</p> <ul style="list-style-type: none"> <li>• <u>Women</u>: the women and her immediate family members are made aware of, and are encouraged to follow desired practices of change</li> <li>• <u>Influencers</u>: (relatives, peer, fellow villagers, doctors, RMPs, nursing homes, labour contractors, employers etc.) are made aware of, and are encouraged to promote the dissemination and uptake of desired practices of change.</li> </ul>	
3. Platforms	<ul style="list-style-type: none"> <li>• Workshops, Seminars (for policy makers, executives, service providers etc.)</li> <li>• Community level Events and Institutions (such as VHSNDs, AWCs, SHGs, Gram Sabha, Health Centres, Schools/ School Management Committees/ PTAs etc.)</li> <li>• Labour Chowks, Brick Kilns, Sugar Factory/ Farms, Railways Stations, Bus Stations etc.</li> </ul>	
4. Medium	a. Docudrama (Video-based Approach)	<ul style="list-style-type: none"> <li>• Use community based video production or employ professionals to produce small docudramas.</li> <li>• Videos produced can be screened at the various platforms (above) or sent through WhatsApp, or broadcasted on local TV</li> <li>• PICO projectors, smart phones, and TAB can be used for screening videos</li> </ul>
	b. IVR (Community Radio)	<ul style="list-style-type: none"> <li>• Use a combination of push and pull call system</li> </ul>

<sup>2</sup> Indicative only

		<ul style="list-style-type: none"> <li>• Allow the user to call on a Toll Free Number and listen to pre-recorded FAQs or record her queries.</li> </ul>
	c. Wall Painting/ Flip charts/ Dangles, Flyers etc. (Conventional Approach)	<ul style="list-style-type: none"> <li>• Wall paintings at railways stations, labour chowk, PHC, etc.</li> <li>• Specific posters for each level of Facilities.</li> </ul>
	d. TV, Radio, Social Media, WhatsApp	<ul style="list-style-type: none"> <li>• Whats App can become an effective medium of dissemination</li> </ul>
<b>5. Change Agents</b>	<ul style="list-style-type: none"> <li>• Frontline workers of various government departments (ASHA, ANM, AWW etc.)</li> <li>• Community institutions (Women's groups, Farmers groups, Gram Panchayat, School Management Committees etc.)</li> <li>• Doctors, RMPs, Labour Contractors, Labour Employers</li> </ul> <p>** Influencers like RMPs, labour contractors and employer can be highly effective if sensitized and encouraged to undertake the role of change agent.</p>	
<b>6. Monitoring and Evaluation</b>	<ul style="list-style-type: none"> <li>• Identify suitable indicators of monitoring and evaluation of the communication interventions like : No. of Hysterectomy cases conducted &lt; 40 years and cause of hysterectomy. Design a system of continuous tracking of practices and trends around women's health and unnecessary hysterectomy.</li> </ul>	

## Monitoring & Evaluation

Reporting of hysterectomy like; No. of Hysterectomy cases conducted < 40 years and cause of hysterectomy need to be incorporated in the existing NCD screening checklist. Data pertaining to Hysterectomies must be regularly monitored at both State and District levels. Data from both public and private sector needs to be monitored and government institutions, medical professionals from both public and private sector as well as other stakeholders must come together to make this monitoring a success.

### District Hysterectomy Monitoring Committees

A **District Hysterectomy Monitoring Committee** must be set up in each district to enable effective monitoring. The committee must be set up under the chairpersonship of District CMO, NCD Nodal, District RCH Nodal Officers / Maternal Health Nodal Officers, other key government personnel at the district level, representatives from FOGSI (both public and private sector), representatives from development partners etc. The monitoring committee is expected to:

- Issue necessary orders to both public and private sectors to submit a line list of all women who underwent hysterectomy every month. The line list must include information on parameters such as:
  - Age
  - Parity
  - Occupation
  - Indication of hysterectomy
  - Previous medical/surgical history
  - Hysterectomy route:
    - Abdominal
    - Vaginal
    - Laparoscopic
  - Any other surgery done along with hysterectomy:
  - Past treatment history:
  - HPE:
- Every quarter the district committee must audit cases with following indications and issue necessary instructions if required:
  - Hysterectomy with/ without BSO in women <35 yrs. of age
  - Hysterectomy with BSO in women < 40 yrs. of age
  - All cases where no indication for doing the procedure is mentioned in the records
  - All cases where no records of treatment prior to hysterectomy (in papers or in history) are available
  - Discrepancy between mentioned indication and HPE report
  - Any severe morbidity/mortality due to hysterectomy

**Annexure 3** provides detailed guidance on how to conduct audits of hysterectomies

- Arrange necessary trainings and sensitization sessions for both public and private sector professionals.

### **State Hysterectomy Monitoring Committees**

A **State Hysterectomy Monitoring Committee** must be set up in each State to enable effective monitoring. The committee must be set up under the chairpersonship of State Principle Secretary. State level DPH (Director Public Health) will be the nodal Officer & NCD State program officer, RCH/FW/MH programme officers will be the other key government personnel at the state level, representatives from FOGSI (both public and private sector), representatives from development partners etc. The monitoring committee is expected to meet once in every six months and review district level data to ensure that unnecessary hysterectomies can be avoided. The State Hysterectomy Monitoring Committees must also arrange necessary trainings and sensitization sessions for both public and private sector professionals and district officials.

### **National Hysterectomy Monitoring Committees**

A **National Hysterectomy Monitoring Committee** must be set up to enable effective monitoring and ensure necessary policy decisions at the National level. The monitoring committee would comprise of officials from NCD, ICMR, MH Officers under the chairpersonship of Additional Commissioner & Mission Director, NHM and is expected to meet once in every six months and review State level data to ensure that unnecessary hysterectomies can be avoided. The national committees must also arrange necessary trainings and sensitization sessions for both public and private sector professionals and district officials. Most importantly national committees must review the landscape and take necessary policy decisions as required.

# CLINICAL PROTOCOLS

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This section focuses on clinical protocols for management at the level of ANMs and at the level of CHOs/ Medical Officers

## **VARIOUS MANAGEMENT MODALITIES AVAILABLE FOR HYSTERCTOMY**

This section deals with various treatment modalities available for common indications of hysterectomy namely Abnormal Uterine Bleeding/ Dysfunctional Uterine Bleeding, Uterocervicovaginal Prolapse, Vaginal Discharge, Pelvic Inflammatory Disease (PID) & Abnormal Cervix

### **MODALITIES OF MANAGEMENT AVAILABLE FOR AUB/ DUB**

Choice of treatment for AUB/DUB depends on clinical stability, suspected aetiology of bleeding, desire for future fertility and underlying medical problems. The two main objectives of managing acute AUB are:

- 1.) To control the current episodes of heavy bleeding
- 2.) To reduce menstrual blood loss in subsequent cycles

Medical therapy is considered the preferred initial treatment.

Medical management:

Medical treatment options for DUB include tranexamic acid, nonsteroidal anti-inflammatory drugs (NSAIDs), combined oral contraception pill, progestogen, danazol and gonadotropin-releasing hormone analogues (GnRH-a). Another medical method for the treatment of DUB is the levonorgestrel-releasing intrauterine system (Mirena®). It was originally developed as a contraceptive method , but it has been proven quite effective in the treatment of DUB, so the device acquired approval for that indication too.

Surgical methods: In cases of AUB resistant to medical treatment, physicians should offer to women surgical treatment. In such patients, one could choose between endometrial ablation techniques and hysterectomy, taking into consideration patient's age, physical condition, and will.

**Detailed treatment modalities for AUB/ DUB are annexed (Annexure 4).**

## **MODALITIES OF MANAGEMENT AVAILABLE FOR UTERO VAGINAL PROLAPSE**

Uterovaginal prolapse is also not a direct indication of hysterectomy specially in younger age group. In elderly age group hysterectomy is the better option. There are new modalities of conservative surgeries in the form of various sling operations which have been recommended in order to avoid hysterectomy.

### **Various sling operations are -**

- Shirodkar sling
- Purandare cervicopexy
- Khanna sling
- Soonawalla sling
- Joshi sling
- Virkud sling
- Others

### **There are also different types of reconstructive surgeries:**

- Fixation or suspension using your own tissues (uterosacral ligament suspension and sacrospinous fixation)—Also called “native tissue repair,” this is used to treat uterine or vaginal vault prolapse. It is performed through the vagina. The prolapsed part is attached with stitches to a ligament or to a muscle in the pelvis. A procedure to prevent urinary incontinence may be done at the same time.
- Colporrhaphy—Used to treat prolapse of the anterior (front) wall of the vagina and prolapse of the posterior (back) wall of the vagina. This type of surgery is performed through the vagina. Stitches are used to strengthen the vagina so that it once again supports the bladder or the rectum.
- Sacrocolpopexy—Used to treat vaginal vault prolapse and enterocele. It can be done with an abdominal incision or with laparoscopy. Surgical mesh is attached to the front and back walls of the vagina and then to the sacrum (tail bone). This lifts the vagina back into place.
- Sacrohysteropexy—Used to treat uterine prolapse when a woman does not want a hysterectomy. Surgical mesh is attached to the cervix and then to the sacrum, lifting the uterus back into place.
- Surgery using vaginally placed mesh—Used to treat all types of prolapse. Can be used in women whose own tissues are not strong enough for native tissue repair. Vaginally placed mesh has a significant risk of severe complications, including mesh erosion, pain, infection, and bladder or bowel injury. This type of surgery should be reserved for women in whom the benefits may justify the risks.

## **MODALITIES OF MANAGEMENT AVAILABLE FOR PRE-CANCEROUS LESIONS OF CERVIX / UNHEALTHY CERVIX:**

### **Cervical screening is recommended in:**

- All symptomatic women giving history of chronic leucorrhoea, postcoital bleeding or unhealthy appearance of cervix should be investigated with VIA or Pap smear.
- Age 30-65 years
- All HIV infected women as soon as the infection is diagnosed
- Women having symptoms and visible growth, plaque that bleeds on touch: Cervical biopsy from the growth/lesion
- Women having infective discharge: Antibiotics. Follow up after 7 days.

### **Medical Treatment for cervical infection**

- Cefixime, 400 mg orally single dose plus Azithromycin, 1g orally single dose 1 hour before food
- Treatment of partner
- Getting HIV, VDRL test
- Follow-up after 7 days
- When there is no infection conduct the following tests

### **Evaluation**

#### **1) Visual Inspection (Visual Inspection after acetic acid (VIA), or Lugol's iodine (VILI))**

- Visual inspection of cervix after painting it with 4-5% acetic acid for 1 minute and turn yellow after application of iodine. If VIA is negative assure the woman. Repeat VIA every 5 years
- If VIA test is positive (shows dense white, opaque acetowhite lesions in transformation zone) - colposcopy and directed biopsy should be done.

#### **2) Pap smear / Liquid-Based Cytology (LBC) (if available)**

- Send the smears to pathologist requesting for results as per Bethesda system (2001). Review the result of smear.
- With ASCUS cytology do colposcopy or VIA, followed by biopsy if suspicious areas are identified. Alternatively, it can be triaged with repeat cytology at one year.
- Women with cytology report LSIL should preferably undergo colposcopy and directed biopsy.
- Women with cervical cytology report of ASC-H or HSIL should be advised to undergo colposcopy and directed biopsy.

Women with cytology report of atypical glandular cells should be evaluated with colposcopy and directed biopsy along with endocervical and endometrial sampling.



**3) HPV testing:** for high-risk HPV type if available and affordable. Negative HPV test with other tests is more assuring and can help prolong the repeat screen interval to 5 years.

### **Treatment of CIN on Histopathology of biopsy specimen**

- Women having low-grade (ASCUS / LSIL) Pap smear and **CIN 1** on histology should be advised to continue with 1 yearly follow up with VIA/Pap smear under supervision.
- Women with high grade (ASC-H, HSIL) smear abnormalities and CIN 1 histology should be advised cytology after 6 months or immediate treatment depending on their compliance and desire.
- If high grade smear abnormality persists for 12 months and no lesion is seen on colposcopy a diagnostic excision should be performed.
- With **CIN 2/3**, if colposcopy is adequate, both excision and ablation are adequate modalities of treatment. Excision is preferred to ablation.
- Excision is recommended if recurrent CIN, endocervical involvement or colposcopy is inadequate.
- Immediate hysterectomy for CIN2/3 is unacceptable.
- Hysterectomy can be an alternative to repeat excision/ cone biopsy is feasible.
- If biopsy shows invasive cancer at any time, staging and management according to the stage of disease should be done in the appropriate center.

### **MODALITIES OF TREATMENT AVAILABLE FOR VAGINAL DISCHARGE**

Vulvo vaginal infections are among the most frequent disorders for which patients seek care from gynecologists. By understanding the pathophysiology of these diseases, and having an effective approach to their diagnosis, physicians can institute appropriate antimicrobial therapy to treat these conditions and reduce long-term sequelae.

#### **Common Causes:**

- Vaginitis can be of three types: Trichomonal, candidial vaginitis. Bacterial vaginosis. Mixed.
- Cervical infection due to gonorrhoea and Chlamydia infection.
- Genital herpes.

#### **Normal vaginal discharge:**

Normal vaginal secretions are floccular in consistency, white in color, and usually located in the dependent portion of the vagina (posterior fornix).

#### **Treatment:**

- Depends on accurate diagnosis based on symptoms and examination findings
- Once diagnosed can be managed with antimicrobials
- If clinical examination is suggestive of enlarged uterus, adnexal mass or tenderness in pelvis then patient should be referred for ultrasonography.

- Exclude HIV infection, diabetes mellitus, immunosuppressive conditions, steroid therapy in cases of recurrent infection and refer to higher center.

#### **MODALITIES OF TREATMENT AVAILABLE FOR LOWER ABDOMINAL PAIN (D/TPID):**

Reproductive age group women often present with chronic lower abdominal pain associated with low backache, vaginal discharge and painful menstruation which can be treated by medical treatment. One of the common causes of lower abdominal pain is Pelvic inflammatory disease (PID). It is caused by microorganisms colonizing the endocervix and ascending to the endometrium and fallopian tubes. Other causes of pain may be endometriosis, adenomyosis, pelvic adhesions, adnexal mass or fibroid uterus.

#### **Diagnosis**

- Should be based on history and examination.
- Traditionally, the diagnosis of PID is based on a triad of symptoms and signs, including pelvic pain, cervical motion and adnexal tenderness, and the presence of fever.
- Ultrasonography may be advised in cases with palpable masses in the pelvis or incases with acute tenderness.

#### **Treatment of Lower Abdominal Pain:**

- Treatment is directed to the cause.
- Treatment of infection.
- Medical treatment for endometriosis, (OCP/ progestogens-MPA/Dienogest ,GnRHa)
- Laparoscopic adhesiolysis, fulguration of endometriotic lesions, etc.
- Sometimes the woman may not have any gynecological cause for pelvic pain.
- Other medical conditions such as gastrointestinal infections or infestations or abdominal TB could be responsible which can be treated with appropriate antimicrobial agents.
- Correct Anemia, under nutrition & Improve general health

## Annexure 1

Table: Responsiveness at various levels of care

## 1a. AUB - Menorrhagia with normal sized uterus, with or without dysmenorrhoea

Level	Human Resource/ Service Provider	Medicines (Essential List of Medicines)	Point of Care Diagnostics
Community +Sub centre	<p><b>ASHA/MAS:</b></p> <ul style="list-style-type: none"> <li>Annual screening of women using checklist for Abnormal Uterine Bleeding (AUB).</li> <li>Oral iron and calcium with D<sub>3</sub> supplementation. (Daily requirement of Oral Iron-60mg elemental iron and daily requirement of Calcium-500mg.</li> </ul> <p><b>ASHA/ANM:</b></p> <ul style="list-style-type: none"> <li>Ensure follow up of women taking treatment for Abnormal Uterine Bleeding during home visits.</li> </ul>		
HWC/PHC/Non FRU CHC	<p><b>CHO</b></p> <ul style="list-style-type: none"> <li>✓ Refer all women with Heavy Menstrual Bleeding to PHC for initial assessment.</li> <li>✓ Dispensing and follow-up in subsequent cycles.</li> </ul> <p><b>Medical Officer(MO)</b> Initial assessment (history taking, examination including per speculum and bimanual examination by SN) at first visit of all women with AUB .</p> <ul style="list-style-type: none"> <li>✓ Refer women to Gynaecologist if               <ol style="list-style-type: none"> <li>menorrhagia + enlarged firm/ irregular uterus or</li> <li>metrorrhagia or</li> <li>intermenstrual bleeding or</li> <li>menorrhagia + normal uterine size if woman &gt; 40 yrs.</li> <li>acute menorrhagia or</li> <li>severe anaemia</li> <li>tenderness on uterine motion</li> <li>restricted uterine mobility</li> <li>adnexal mass or fullness</li> </ol> </li> <li>✓ Tele-consultation with Gynaecologist for management of women &lt; 40 yrs. with menorrhagia and normal uterine size without</li> </ul>	<p>If women fit into category 1a after assessment at PHC and are advised medical management by PHC MO (MBBS), then dispense following drugs in subsequent cycles:</p> <ul style="list-style-type: none"> <li>Tab. Tranexamic Acid 500 mg</li> <li>Combined Oral Contraceptive</li> <li>Iron (Oral) 60 mg elemental iron /day.</li> <li>Tab. Diclofenac 100 mg</li> <li>Tab. Mefenamic acid 500 mg</li> <li>Oral MPA(Medroxy Progesterone Acetate)</li> <li>Tab. Nor-Ethisterone acetate 5 mg</li> <li>Inj DMPA 150mg/ml</li> <li>LNG IUD</li> </ul>	Hb (initial and when needed during follow up)

Level	Human Resource/ Service Provider	Medicines (Essential List of Medicines)	Point of Care Diagnostics
	severe anaemia. Refer to Gynaecologist for relapse or persistent complaints after three months of medical treatment.	(Levonorgestrel intrauterine device). (by MBBS MO only)	
<b>Community Health Centre/S DH/DH/ Tertiary care</b>	<b>Gynaecologist</b>	<ul style="list-style-type: none"> <li>• Tab. Tranexamic Acid 500 mg</li> <li>• Combined Oral Contraceptive</li> <li>• Iron (Oral) 60 mg elemental iron /day</li> <li>• Parenteral Iron (20mg/ml, total dose of 100mg/day)</li> <li>• Tab. Diclofenac 100 mg</li> <li>• Tab. Mefenamic acid 500 mg</li> <li>• Oral MPA(Madrox Progesterone Acetate)</li> <li>• Tab. Nor-Ethisterone acetate 5 mg</li> <li>• Inj DMPA 150mg/ml</li> <li>• LNG IUD</li> <li>• SERM: Tamoxifen-20mg /Day Raloxifene-60mg/Day Bazedoxifene-20mg/Day Ospemifene-</li> </ul>	<ul style="list-style-type: none"> <li>✓ USG</li> <li>✓ Hb</li> <li>✓ Coagulation profile</li> <li>✓ Sickling profile</li> <li>✓ Thyroid profile</li> <li>✓ S. Ferritin</li> </ul> <p>If Gynaecologist is available at CHC:</p> <ul style="list-style-type: none"> <li>✓ Endometrial aspiration/sampling if needed</li> <li>✓ D&amp;C if needed</li> <li>✓ Endometrial Ablation (Non-hysteroscopic)</li> <li>✓ Hysterectomy if needed</li> </ul>

Level	Human Resource/ Service Provider	Medicines (Essential List of Medicines)	Point of Care Diagnostics
		60mg/Day  <ul style="list-style-type: none"> <li>Inj.GnRH analogues (Gonadotropin Releasing Hormone) eg. Inj. Leuprolide 3.75mg monthly.</li> </ul>	

### 1b. Abnormal Uterine Bleeding (Menorrhagia with enlarged uterus)

Community / Sub Health Centre	<b>ASHA/MAS:</b> <ul style="list-style-type: none"> <li>Annual screening of women using checklist for AUB</li> <li>Oral iron and calcium with D<sub>3</sub> supplementation. (Daily requirement of Oral iron-60mg elemental iron and daily requirement of Calcium-500mg.</li> </ul> <b>ASHA/ANM:</b> <ul style="list-style-type: none"> <li>Ensure follow up of women taking treatment for AUB during home visits.</li> </ul>	
HWC/ Primary Health Centre/UPH C	<b>CHO</b> <b>MO</b>	<ul style="list-style-type: none"> <li>✓ Tab. Tranexamic Acid 500 mg</li> <li>✓ Refer to centre where Gynaecologist and USG are available.</li> <li>✓ Provide care (including dispensing drugs if MBBS MO) during subsequent months to women whose medical treatment has been started by gynaecologist or who have undergone surgical management for AUB.</li> <li>✓ Oral/ Parenteral Iron therapy if needed.</li> </ul>

Community Health Centre/ Sub Division Hospital /District Hospital/ Hospital/ Tertiary Care / Medical College	Gynaecologist	<ul style="list-style-type: none"> <li>• Tab. Tranexamic Acid 500 mg</li> <li>• Combined Oral Contraceptive</li> <li>• Iron (Oral) 60 mg elemental iron /day</li> <li>• Parenteral Iron (20mg/ml, total dose of 100mg/day)</li> <li>• Tab. Diclofenac 100 mg</li> <li>• Tab. Mefenamic acid 500 mg</li> <li>• Oral MPA(Medroxy Progesterone Acetate)</li> <li>• Tab. Nor-Ethisterone acetate 5 mg</li> <li>• Inj DMPA 150mg/ml</li> <li>• LNG IUD</li> <li>• SERM: Tamoxifen-20mg /Day Raloxifene-60mg/Day Bazedoxifene-20mg/Day Ospemifene-60mg/Day</li> <li>• Inj.GnRH analogues (Gonadotropin Releasing Hormone)</li> <li>• Tab Ulipristal (As Contraceptive-30mg/Day and non-contraceptive-5mg/Day)</li> </ul>	
			<ul style="list-style-type: none"> <li>✓ USG</li> <li>✓ Hb</li> <li>✓ Coag profile</li> <li>✓ Sickling</li> <li>✓ Thyroid Profile</li> <li>✓ S. Ferritin</li> <li>✓ Endometrial aspiration/Sampling if needed</li> <li>✓ PCV transfusion if needed</li> <li>✓ D&amp;C if needed</li> <li>✓ Hysteroscopy / guided biopsy</li> <li>✓ Hysterectomy if needed</li> </ul>

**1c AUB -Metrorrhagia, Oligomenorrhoea, Amenorrhoea- irregular bleeding in high risk group (obese, hypertensive,diabetic, family history of endometrial /cervical cancers), AUB in women > 40 years of age, OR Persistent dysmenorrhea**

Community / Sub Health Centre	<p><b>ASHA/MAS:</b></p> <ul style="list-style-type: none"> <li>Annual screening of women using checklist for AUB</li> <li>Oral iron and calcium with D<sub>3</sub> supplementation. (Daily requirement of Oral iron -60mg elemental iron and daily requirement of Calcium- 500mg.</li> </ul> <p><b>ASHA/ANM:</b></p> <ul style="list-style-type: none"> <li>Ensure follow up of women taking treatment for AUB during home visits.</li> </ul>		
HWC/ Primary Health Centre/UPH C	<p><b>CHO MO</b></p>	<p>✓ UPT</p> <p>✓ Refer to centre where Gynaecologist and USG is available.</p>	
Community Health Centre/ Sub Division Hospital /District Hospital/ Tertiary Care / Medical College	<p><b>Gynaecologist</b></p>	<ul style="list-style-type: none"> <li>Tab. Tranexamic Acid 500 mg</li> <li>Combined Oral Contraceptive</li> <li>Iron (Oral) 60 mg elemental iron /day</li> <li>Parenteral Iron (20mg/ml, total dose of 100mg/day)</li> <li>Tab. Diclofenac 100 mg</li> <li>Tab. Mefenamic acid 500 mg</li> <li>Oral MPA(Medroxy Progesterone Acetate)</li> <li>Tab. Nor-Ethisterone acetate 5 mg</li> <li>Inj DMPA 150mg/ml</li> <li>LNG IUD</li> <li>SERM: Tamoxifen-20mg /Day Raloxifene-60mg/Day Bazedoxifene-20mg/Day Ospemifene-60mg/Day</li> <li>Inj.GnRH analogues (Gonadotropin Releasing Hormone)</li> </ul>	<ul style="list-style-type: none"> <li>USG</li> <li>Hb</li> <li>Sickling</li> <li>Thyroid Profile</li> <li>S. Ferritin</li> <li>Coag profile</li> <li>Endometrial aspiration/Sampling if needed</li> <li>PCV transfusion if needed</li> <li>D&amp;C if needed</li> <li>Hysteroscopy / guided biopsy</li> <li>Conservative surgical management for Pre-malignant lesions</li> <li>Hysterectomy if needed (including surgical management of endometrial malignancy chemo / radiotherapy follow up as recommended)</li> </ul>

		<ul style="list-style-type: none"><li>• Tab Ulipristal (As Contraceptive- 30mg/Day and non-contraceptive- 5mg/Day)</li></ul>	
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## 2. Abnormal Vaginal Discharge ± Pelvic pain ± Backache

<b>Community / Sub Health Centre</b>	<b>ASHA/MAS:</b> ✓ Distribution of Oral Iron, Calcium with D3 tablets and condoms. ✓ Ensure follow up to check for resolution of Infective vaginal discharge / acute PID. Encourage treatment of the partner.		
<b>HWC/ Primary Health Centre/UPH C</b>	<b>CHO MO</b>  If CHO is a lady, provide follow up care in subsequent visits to women who have taken initial care at higher level.  History and examination including per speculum and bimanual examination Ensure treatment of partner	<ul style="list-style-type: none"> <li>• Kit-1,2,6</li> <li>• Condoms</li> <li>• Injectable Ceftriaxone</li> <li>• Tab Calcium ±Vit D</li> <li>• Iron (Oral) (60mg elemental iron/Day)</li> <li>• Parenteral Iron if needed</li> <li>• (20mg/ml, total dose of 100mg/Day)</li> </ul>	<ul style="list-style-type: none"> <li>✓ Hb</li> <li>✓ VDRL/HBsAg/HIV</li> <li>✓ VIA</li> </ul>
<b>Community Health Centre/ Sub Division Hospital /District Hospital/ Tertiary Care / Medical College</b>	<b>Gynaecologist</b>	<ul style="list-style-type: none"> <li>• Kit-1,2,6</li> <li>• Condoms</li> <li>• Inj. Cefotaxime (1gm/12 hourly and can be extended up to 2gm/12 hourly) /Cefoperazone</li> <li>• Inj. Metronidazole</li> <li>• Inj. Clindamycin</li> <li>• Tab Calcium ±Vit D</li> <li>• Iron (Oral)</li> <li>• Parenteral Iron</li> <li>• Treatment of partner</li> </ul>	<ul style="list-style-type: none"> <li>✓ Hb</li> <li>✓ VDRL/HBsAg/HIV</li> <li>✓ Vaginal discharge examination (Hanging drop and Gram stain)</li> <li>✓ USG</li> <li>✓ VIA</li> <li>✓ Pap smear</li> <li>✓ Colposcopy, SOS biopsy</li> <li>✓ LLETZ(Large loop Excision of the Transformation Zone)</li> <li>✓ Cryotherapy</li> <li>✓ Thermocoagulation</li> </ul>

## 3. Prolapse

<b>Community</b>	<b>ASHA/MAS and ANM:</b> ✓ Lifestyle modification, healthy diet, smoking cessation. ✓ Early treatment for chronic cough and constipation. ✓ Promote institutional delivery for proper intra-natal care. ✓ Reinforce need for postnatal exercises ✓ Explain Kegel's exercises for early prolapse.		
<b>Sub Health Centre/HWC/ Primary Health Centre/UPHC</b>	<b>CHO MO</b>	<ul style="list-style-type: none"> <li>• Lifestyle modification</li> <li>• 1<sup>st</sup> and 2<sup>nd</sup> degree prolapse - Pelvic floor exercises</li> <li>• Pessary insertion if necessary by MO or SN after tele-consultation with Gynaecologist</li> <li>• Physiotherapy for backache</li> </ul>	
<b>Community Health Centre/ Sub Division Hospital /District Hospital/ Tertiary Care / Medical College</b>	<b>Gynaecologist</b>	<ul style="list-style-type: none"> <li>• Lifestyle modification 1<sup>st</sup> and 2<sup>nd</sup> degree - Pelvic floor exercises</li> <li>• 3<sup>rd</sup> degree – Pessary / Surgical intervention ( VH with Mc Call's with AP repair OR conservative surgery if lady wants to preserve childbearing or is &lt; 40 years of age)</li> <li>• Surgical management of Vault prolapse and associated Stress Urinary Incontinence</li> <li>• Physiotherapy for backache</li> </ul>	<b>USG</b>

## 4. Lower Abdominal Pain

<b>Community / Sub Health Centre</b>	<b>ASHA/MAS:</b> <ul style="list-style-type: none"> <li>• Distribution of Oral Iron and Calcium with D3 tabs</li> <li>• Deworming</li> <li>• IEC for prevention of diarrhoeal diseases</li> <li>• Counselling regarding Partner treatment for PID</li> </ul>		
<b>HWC/ Primary Health Centre/UPH C</b>	<b>CHO MO</b> Refer to Gynaecologist if <ul style="list-style-type: none"> <li>✓ no response to treatment or</li> <li>✓ relapse of symptoms within 6 months or</li> <li>✓ if associated with fever/ vomiting/ abdominal distension/ breathing difficulty/ abdominal lump/TB in patient or a family member/ within 6 weeks of delivery or within a month of abortion</li> </ul>	<ul style="list-style-type: none"> <li>• Kits-1,2,6</li> <li>• Condoms</li> <li>• Tab Calcium ±Vit D</li> <li>• Injectable antibiotics (Cefotaxime)</li> <li>• Tab Metronidazole</li> <li>• Iron (Oral)</li> <li>• Parenteral Iron</li> </ul>	<ul style="list-style-type: none"> <li>✓ Urine routine and microscopy</li> <li>✓ Stool examination</li> </ul>
<b>Community Health Centre/ Sub Division Hospital /District Hospital/ Tertiary Care / Medical College</b>	<b>Gynaecologist</b>	<ul style="list-style-type: none"> <li>• Kit-1,2,6</li> <li>• Condoms</li> <li>• Inj. Cefotaxime /Cefoperazone</li> <li>• Inj. Metronidazole</li> <li>• Inj. Clindamycin</li> <li>• Tab Calcium ±Vit D</li> <li>• Iron (Oral)</li> <li>• Parenteral Iron</li> <li>• ATT for genital TB</li> </ul>	<ul style="list-style-type: none"> <li>✓ USG</li> <li>✓ Urine routine and microscopy</li> <li>✓ Stool examination</li> <li>✓ GI endoscopy</li> <li>✓ Laparoscopy and SOS surgical intervention</li> </ul>

**5 Abnormal/ Unhealthy cervix**

<b>Community / Sub Health Centre</b>	<b>ASHA/ANM/MAS:</b> ✓ Warning symptoms suggestive of cervical cancer. ✓ Importance of screening for cervical cancer. ✓ Protective effect of condoms on Cervical Intra-epithelial lesions. ✓ Safe sex practices		
<b>HWC/ Primary Health Centre/UPH C</b>	<b>CHO MO</b>		VIA PAP Smear
<b>Community Health Centre/ Sub Division Hospital /District Hospital/ Tertiary Care</b>	<b>Gynaecologist</b>		✓ VIA ✓ Pap smear ✓ Cervical biopsy (may be sent to higher centre for reporting) ✓ HPV testing ✓ Colposcopy ✓ Cervical biopsy (may be sent to higher centre for reporting) ✓ LEEP, LLETZ, Cryosurgery ✓ Management of Cervical cancer (Surgery or Radiotherapy)

**6 Post hysterectomy follow up of woman who had Hysterectomy before 45 years of age**

<b>Community + Sub Health Centre</b>	<b>ASHA/MAS:</b>		
	<ul style="list-style-type: none"> <li>✓ Distribution of oral Iron and Calcium with D3</li> <li>✓ IEC about Post-menopausal problems and care.</li> <li>✓ Counselling on important of regular exercise and healthy diet.</li> </ul>		
<b>HWC/PHC/Non FRU CHC</b>	<b>CHO MO</b>	<ul style="list-style-type: none"> <li>• Tab Calcium ± Vit D</li> <li>• Iron (Oral)</li> <li>• Parenteral Iron</li> <li>• Vaginal Estrogen creams</li> </ul> <p>after tele-consultation with the Gynaecologist</p>	<ul style="list-style-type: none"> <li>• Hb</li> <li>• Lipid Profile</li> <li>• S. creatinine</li> </ul>
<b>Community Health Centre/ Sub Division Hospital /District Hospital Tertiary Care / Medical College</b>	<b>Gynaecologist</b>	<ul style="list-style-type: none"> <li>• Tab Calcium ± Vit D</li> <li>• Iron (Oral)</li> <li>• Parenteral Iron</li> <li>• Vaginal Estrogen creams</li> <li>• Oral Estrogen - Progesterone for HRT if indicated</li> <li>• Bisphosphonates</li> <li>• Tab Tibolone (2.5mg/day)</li> </ul>	<ul style="list-style-type: none"> <li>• USG</li> <li>• Hb</li> <li>• Thyroid Profile</li> <li>• Lipid Profile</li> <li>• S. creatinine</li> <li>• ECG</li> <li>• Bone Mineral Density testing</li> </ul>

**Annexure 2****Basic Facts on Hysterectomy****About Hysterectomy**

Uterus is a midline pelvic organ of the female reproductive system where the fetus develops during pregnancy. The surgical procedure of removal of the uterus is called hysterectomy. Hysterectomy is a major surgery done by a trained gynaecologist under regional or general anaesthesia. An abdominal hysterectomy involves removal of the uterus through an incision in the lower abdomen. When hysterectomy is performed through an incision in vagina it is called a vaginal hysterectomy. Laproscopic Hysterectomy is where the uterus and cervix are removed completely with the help of laproscope & laproscopic instruments through small incisions on the abdomen.

- A total hysterectomy is the removal of the uterus and cervix.
- When a hysterectomy includes removal of both the ovaries and fallopian tubes, the procedure is called hysterectomy with Bilateral Salpingo-Oophorectomy.

**Hysterectomy with or without Oophorectomy**

The various indications for ovarian removal at the time of hysterectomy include genital tract malignancies (ovarian cancer, uterine cancer, cervical cancer, metastasis from non-genital tract malignancies), removal of ovaries and tubes in women genetically susceptible to ovarian cancer, ectopic pregnancy, ovarian abscess, ovarian endometriosis etc. In many non-cancerous conditions oophorectomy is performed with the aim of reducing the possibility of ovarian cancer in the future. Risk, benefits, and alternatives need to be discussed with the patient before surgery. Patients must be informed of the possible complications and the long-term effects of decreased hormone levels due to ovarian removal.

**Unnecessary hysterectomy**

There is a fear that hysterectomy is done without reason. Patients can seek more than one opinion before taking decision. Many gynaecological conditions can be managed conservatively without the need for surgical intervention and hysterectomy should always be reserved as the last option. Few cases where hysterectomies can be avoided are

- Abnormal uterine bleeding
- Fibroid
- Completion of family
- Precondition for employment

- Fear of cancer

### **Hysterectomy as a method of treatment**

Hysterectomy can be performed in various conditions such as treatment of uterine cancer, ovarian cancer, some cases of cervical cancer, and various common noncancerous gynaecological conditions like abnormal uterine bleeding, fibroids, adenomyosis, endometriosis, uterovaginal prolapse, chronic pelvic pain etc. that lead to varying levels of pain, discomfort, uterine bleeding and emotional stress amongst women. A hysterectomy is a major operation with a long recovery time and is only considered after less invasive treatments have been tried. Although hysterectomy is often the definitive treatment for many gynaecological conditions, nonsurgical alternatives should always be attempted in elective cases.

Conditions for which hysterectomy can be done after all nonsurgical options have been tried

- a. Uterine fibroids (lumps in uterus) that cause pain, bleeding or other problems
- b. Thickening of the uterus – adenomyosis, endometrial hyperplasia etc.
- c. Uterine prolapse, which is a sliding of the uterus from its normal position into the vaginal canal
- d. Cancer of the uterus, cervix, or ovaries
- e. Abnormal vaginal bleeding\*
- f. Chronic pelvic pain

A hysterectomy may not be the best option for all women. It shouldn't be performed on women who still want to have children unless no other alternative are possible. Luckily, many conditions that can be treated with a hysterectomy may also be treated in other ways. For instance, hormone therapy can be used to treat endometriosis. Fibroids can be treated with other types of surgery that spare the uterus.

### **Hysterectomy should always be the last option.**

### **Complications and Side effects**

- **Immediate** Complications include heavy bleeding during or after surgery, risk of blood transfusion, damage to surrounding organs and blood vessels like the bladder, urethra, uterine artery and nerves, blood clots in the legs and lungs, breathing problems or problems due to anaesthesia
- Short term-fevers and chills, persistent nausea and vomiting, infection at the incision site, excessive bleeding, requirement of blood transfusion, difficulty with bowel function, difficulty voiding, pain which is not resolving, Injury to adjacent organs (bowel, bladder, ureter), Injury to nerves, chest pain, difficulty breathing, lower extremity, or calf pain and anesthesia related complications.

- Long-term- Bladder dysfunction due to cystocele formation (bladder prolapse through the vaginal wall), stress incontinence (Involuntary passage of urine), formation of enterocele and rectocele (bowel and rectum prolapsing through the vaginal wall), vaginal vault prolapse.
- Long term effects of decreased hormone levels- **surgically induced menopause** including hot flashes (sudden feeling of warmth in the upper body which is usually most intense over the face, neck and chest), night sweats, insomnia, vaginal dryness, recurrent UTI, mood changes, irritability, increased bone loss leading to osteoporosis and cardiac disease.

### Changes women can expect after a hysterectomy

- The women attains a surgical menopause so there will be no menstrual periods. If the ovaries have been removed along with a hysterectomy, there may be menopausal symptoms like hot flashes, sweating, vaginal dryness, mood swings etc as well as increased chances of developing osteoporosis, dyslipidemia, cardiovascular diseases, stroke etc.
- If ovaries are retained, menopause is experienced at a younger than average age.
- There will be a symptomatic relief of symptoms.
- Some women may experience mood changes after hysterectomy. There may be grief and possibly depression over the loss of fertility, loss of interest in food & lethargy.
- Some women have vaginal dryness or lack of interest in sex after a hysterectomy, especially if the ovaries have been removed.
- If both ovaries are removed, this may put the woman at higher risk for certain conditions such as: bone loss, heart disease, and urinary incontinence (leaking of urine)<sup>1</sup>.

### Issues relating to menstruation

Menstruation is required to be managed in a healthy and hygienic manner. One of the huge challenges in our society is the inability to deal with blood flow hygienically during menstruation. A large number of hysterectomies are done to get rid of menstruation without application of safer medical methods of treatment. Here, good counselling by a provider and a trained counsellor becomes very important. ASHA, Anganwadi worker and ANM can all popularize this by using a campaign format.



**Annexure 3****Guidance on Conducting Audits of Hysterectomies**

Medical audits are utilised to monitor the appropriate use of specific procedures. In the case of hysterectomy, ensuring regular audits may be necessary in areas where unnecessary use is suspected. The guidance below explains the process and use for an audit.

**Who should conduct the assessment?**

Setting up of a Hysterectomy Audit Committee - Medical audit is best conducted by more than one person e.g. a technical expert and someone with social sciences expertise. A guideline for practitioners will help them to provide services that are ethically and technically correct in the social setting in which the patient exists and practitioner practices.

**What can form part of the audit for unnecessary hysterectomy?****1. Patient Profile**

- a. Age
- b. Number of living children
- c. Socio economic status
- d. Education
- e. Cultural beliefs
- f. Occupation
- g. Area of residence
- h. Distance from hospital

**2. Eligibility of patients for hysterectomy**

- Is the indication for hysterectomy matching with the signs and symptoms of the actual disease from history taking, clinical examination, pathological and radiological findings?
- Is the patient really eligible for hysterectomy – age group, cause, menstrual symptoms marital status, desirous of fertility etc.
- Is the patient prepared for anaesthesia and hysterectomy – medically and psychological fit?

**3. Use of alternative and effective medical treatment**

- If the condition was benign (not cancer), were alternative non-surgical / medical treatments tried
- Was counselling on alternative treatment modalities done
- What was the alternative treatment provided and for how long was it used e.g.
  - Polyp : Polypectomy
  - Adenomyosis : LNG IUS/Oral hormonal therapy/Others
  - Leiomyoma – Myomectomy/Hysteroscopic resection/Uterine artery

- embolization/GnRH analogues / Ulipristal acetate /Inj. DMPA /LNG IUS
- Endometrial Hyperplasia - High dose Progesterone
- CIN: Conization/LEEP/LLETZ
- Treatment of Coagulopathy
- AUB due to Ovulatory dysfunction: Progesterone therapy
- Utero-vaginal prolapse - Pessary
- Obstetrical Haemorrhage : Uterine artery embolization/ Compression sutures/ Uterine balloon tamponade
- Was the effectiveness of alternative treatment assessed before deciding on hysterectomy
- If yes, was it documented in the patient's case notes with necessary supportive documents

#### 4. Choice of surgical method

- What was the rationale for selecting the type of surgical procedure
- Was the patient made aware about risks and outcomes of the selected procedure?
- Was comparison of costs of recommended procedures done - abdominal, vaginal and laparoscopic hysterectomy?

#### 5. Ethical issues

- Was the decision on selecting the treatment method, particularly if a surgical procedure was recommended, based on involved and informed consent of the patient
- Was primary care for the gynaecological condition available to the patient
- Was choice of second or expert opinion available to the patient
- Was there any conflict of interest by the provider i.e. was provider opinion influenced by personal interest e.g. learning more about a procedure ( training situations ) or earning monetary benefit from patient or insurance agency
- Whether the audit is interfering with professional freedom of the practitioner or with doctor patient relationship in that particular setting

#### 6. How was the Hysterectomy conducted?

Was it performed abdominally, vaginally or laparoscopically?

Approach will depend on indications for surgery, nature of disease, surgeon and patient preferences

#### 7. Why was the hysterectomy conducted?

The reasons can range from benign conditions of the uterus to malignancies of the genital tract as well as obstetric reasons

#### Common Gynaecological Reasons

- Uterine fibroids - depends on site, size and symptom
- Chronic pelvic infection
- Chronic pelvic pain
- Abnormal Uterine Bleeding:
  - Polyps
  - Adenomyosis, endometriosis
  - Endometrial causes - Malignancy, Hyperplasia and other
  - Cancer of the ovaries, cervix, fallopian tubes.
  - Premalignant lesions of cervix.
  - Iatrogenic
- Utero-vaginal prolapse

#### Obstetric Reasons

- Atonic Post-partum Haemorrhage with/without Placenta praevia
  - Traumatic Post-Partum Haemorrhage
  - Adherent placenta with/without Placenta praevia
  - Sepsis
  - Rupture Uterus
  - Intractable post-partum haemorrhage
8. Were there intra-operative or post-operative complications during/following hysterectomy and were these documented?
9. Was there need for correction of anaemia by blood transfusion/ parenteral iron?
10. Was the Hysterectomy covered by an insurance scheme?
11. What was the cost incurred due to hysterectomy, including related interventions/treatment before, during and after the procedure?

**Annexure 4****VARIOUS MODALITIES OF TREATMENT AVAILABLE FOR AUB/ DUB****1. Medical treatment for dysfunctional uterine bleeding**

Medical treatment options for DUB include tranexamic acid, nonsteroidal anti-inflammatory drugs (NSAIDs), combined oral contraception pill, progestogen, danazol and gonadotropin-releasing hormone analogues (GnRH-a). The effectiveness of the reported medical therapy for DUB has been evaluated and reviewed in systematic reviews in the Cochrane Library.

**Tranexamic acid**

Antifibrinolytic tranexamic acid has proven to be more effective than placebo, NSAIDs, progestogen in the luteal phase of menstrual cycle, or ethamsylate when subscribed to women with DUB, without any serious adverse effects. A reduction in menstrual flow by 34–59% has been reported by Wellington and Wagstaff, which is quite impressive. However, this drug is mainly indicated for acute or short-term use and not as a definite treatment for DUB.

The main problem with the administration of tranexamic acid for the treatment of DUB is the potential risk of thromboembolic disease due to its antifibrinolytic effect. Although this is always an issue, especially in cases of severe anemia, it seems that the risk does not reach a statistical significance.

**Nonsteroidal anti-inflammatory drugs**

Prostaglandins are found in high concentrations in the endometrial shedding. Nonsteroidal anti-inflammatory drugs inhibit prostaglandin synthesis and decrease menstrual blood loss. NSAIDs are quite effective in cases of DUB compared to placebo, but they are less effective than either tranexamic acid, danazol, or levonorgestrel intrauterine system.

**Combined oral contraceptive pill**

The combined oral contraceptive pill is another effective alternative treatment for DUB, offering at the same time contraception to women. It reduces menstrual blood loss, but there are not enough data to determine its value in comparison to other drugs. So, it seems reasonable to offer a combined oral contraceptive pill (COC) in young women suffering from DUB who also seek for contraception at the same time.

## **Progestogens**

The administration of progestogens for the treatment of anovulatory DUB was always a tempting alternative for physicians, in order to restore the natural cycle of endometrial growth and shedding. The oral luteal phase progestogens do not seem to be more advantageous over other hormonal medical treatments or levonorgestrel-releasing intrauterine device. A long-term administration of progestogen is sometimes followed by severe side effects, such as water retention and hirsutism, depending on the type and dose of progestin.

## **Danazol-gonadotropin-releasing hormone analogues**

Danazol and the GnRH analogues were found as highly effective agents for DUB compared to other medical treatments. However, the administration of danazol or GnRH-a is limited due to their strong side effects. Long-term administration of danazol may cause hirsutism while GnRH-a is associated with irreversible bone loss when used for more than 6 months. Thus, their utility is restricted mainly for short-term use, especially in cases of severe anemia, until further treatment is decided.

### **2. Levonorgestrel-releasing intrauterine device**

Another medical method for the treatment of DUB is the levonorgestrel-releasing intrauterine system (Mirena®). It was originally developed as a contraceptive method, but it has been proven quite effective in the treatment of DUB, so the device acquired approval for that indication too.

Its efficacy is based on the continuous local release of the progestogen (levonorgestrel) within the uterine cavity, which suppresses endometrial growth. Studies report reduction of blood loss in menstrual cycles up to 97%, with its maximum efficacy 1 year after insertion. The majority of women with Mirena bleed only for 1 day or experience just spotting during their period, while 15% of them become amenorrhoeic.

There are two trials comparing levonorgestrel intrauterine device (IUD) with medical treatment, two trials to transcervical resection of the endometrium and three trials comparing Mirena® with balloon ablation. Mirena was found superior to cyclical progestogens and mefenamic acid, but is significantly less effective than endometrial ablation in reducing blood loss. Interestingly, levonorgestrel IUD was found more cost effective than hysterectomy in Hurskainen et al.'s trial.

### **3. Surgical treatment for dysfunctional uterine bleeding**

In cases of DUB resistant to medical treatment, physicians should offer to women an alternative surgical treatment. In such patients, one could choose between endometrial ablation techniques and hysterectomy, taking into consideration patient's age, physical condition, and will.

Dilatation and curettage, which is offered as an alternative treatment option in women with excessive blood loss during menstrual periods, results in a temporary reduction of blood loss for the first month after the procedure, therefore it should not be proposed and performed in women suffering from DUB.

### **Endometrial ablation techniques**

Since Ashermann in 1948 described for the first time the association between amenorrhea and dilatation and curettage for termination of pregnancies, several investigators have studied the possibility of a controlled destruction of the basal layer of the endometrium in order to treat abnormal uterine bleeding.

Several methods have been developed from the early 1980s for the ablation of the endometrium and have been studied in cohort studies and randomized controlled trials. Basically, all these methods are divided in two large groups with a criterion, the need of direct visualization of the endometrial cavity.

### **First-generation endometrial ablation techniques**

First-generation endometrial ablation techniques are based on direct visualization of the endometrial cavity with a hysteroscope. Three methods were developed since the late 1980s, and their efficacy were studied and compared to other techniques by many investigators. Before the application of each technique, endometrial thinning was necessary by using GnRH-a or danazol.

#### **Hysteroscopic laser ablation**

The first laser method was a neodymium-YAG laser, which destroyed the endometrium through a hysteroscope. Observational studies have reported a satisfaction rate up to 97% and amenorrhea rates ranging between 25% and 60% after hysteroscopic laser ablation (HLA). Failure rates varied between 7% and 21% in the same studies. There is only one prospective randomized trial comparing laser ablation with transcervical resection of the endometrium reporting 23% amenorrhea rate and 90% satisfaction rate. Despite the promising results of its use, the equipment's high cost and extended learning curve remain obstacles for its wide application.

#### **Transcervical endometrial resection**

The wide use of a resectoscope in gynaecological operations allowed its application as a method for treatment of DUB. Transcervical endometrial resection (TCRE) has been shown to be an effective and safe method for treating DUB. TCRE was tested in nonrandomized prospective studies, which reported a satisfaction rate between 85% and 87% and an amenorrhea rate varying up to 46%. TCRE is comparable to other hysteroscopic endometrial ablation techniques in terms of amenorrhea and satisfaction rates. Direct visualization of the endometrial cavity and the possibility of treating concomitant endometrial pathology at the time of endometrial ablation remain the major advantages of the method.

#### **Rollerball endometrial ablation**

The technique was developed in 1989 in Australia by Vancaillie and soon became quite popular due to its relative simplicity and excellent results. Studies report comparable results from its application to the other two first-generation ablation techniques (satisfaction rate up to 94% and amenorrhea rate varying between 29% and 35%). Rollerball endometrial ablation requires less operative time and shorter learning curve compared to TCRE and HLA.

Studies evaluating first-generation ablation techniques revealed quite impressive results regarding their effectiveness, treating three fourths of the women suffering from DUB, who would otherwise proceed to hysterectomy in terms of definite treatment. They are acknowledged to be the "gold standard" by which other, newer procedures are judged.

HLA and rollerball ablation are considered safer methods than TCRE, while resection of the endometrium caused more of the serious and possibly fatal complications, which include uterine perforation and bleeding, bowel injury, visceral burn, and hyponatremic encephalopathy with cerebral edema.

### **Second-generation endometrial ablation techniques**

Many endometrial ablation devices have been developed in the early 1990s for the treatment of DUB and categorized as second-generation ablation techniques. Their application did not require the use of a hysteroscope, so the advantage of a direct visualization of the endometrial cavity no longer existed. Therefore, endometrial biopsy prior to ablation is a mandatory prerequisite.

Every method consists of a different device which, by different means (hot liquid, laser, bipolar energy, ultrasound, microwaves, heating balloons, or cryoablation), causes selective destruction of the endometrial layer. These devices require less skills of the surgeon, as they are very simple to use, so the learning curve is smaller. The operation time is shorter, the anesthesia/analgesia can become minimal, and the complication rate is reduced.

In some of these techniques, a preoperative thinning of the endometrium with GnRH-a or danazol is not necessary, in contrast to all first-generation ablation techniques.

### **Thermal balloon endometrial ablation**

The technique consists of a balloon for insertion in the endometrial cavity and a generator. After insertion, the balloon is filled with hot liquid that causes a destructive thermal effect to the surrounding endometrium.

The Thermablate thermal balloon was developed in 2004, and since then, various authors have studied the application results of this device. Amenorrhea rate ranges between 22.2% and 35% with a failure rate varying between 3% and 5.5% .

### **Endometrial ablation by hysteroscopic instillation of hot saline (hydrotherm ablator)**

This technique, although applied hysteroscopically, is categorized as a second-generation endometrial ablation technique. Externally heated saline of 90°C is infused into the uterine cavity through the external sheath of a diagnostic hysteroscope. The pressure used for the infusion is less than 45 mmHg, thus preventing flow through the fallopian tubes. Under direct hysteroscopic view, the hot saline causes ablation of the endometrium. The application experience of the method is tested in several observational studies and in one randomized controlled trial compared to rollerball. Amenorrhea rates are reported up to 53%, cure rate up to 94%, and satisfaction rate up to 98% .

### **Microwave endometrial ablation (MEA)**

The microwave endometrial ablation system has been compared to first-generation ablative techniques (TCRE and rollerball) in randomized trials with similar results in terms of amenorrhea and satisfaction rates, even 10 years following surgery with low complication rates. There is also one randomized controlled trial comparing MEA and thermal balloon ablation, showing similar results in relation to menstrual scores and satisfaction.

### **Endometrial laser intrauterine thermal therapy (ELITT)**

The technique was developed by Donnez et al. in 1996 and causes endometrial ablation by laser photocoagulation . Preparation of the endometrium prior to laser application is considered necessary. The technique has been evaluated in a prospective observational study. Satisfaction rate was reported up to 90% at 12 months after treatment, while amenorrhea rate was 71% . There is only one randomized controlled trial comparing ELITT and TCRE, reporting at 12 months amenorrhea rates of 56% and 23%, respectively

### **Cryo-endometrial ablation**

Endometrial ablation is achieved by a cooling gas, which achieves a temperature of -90 to -100°C within the endometrial cavity. The treatment has been evaluated in prospective observational studies with encouraging results (amenorrhea 28% and satisfaction up to 91%) .

### **Bipolar impedance controlled endometrial ablation (Novasure)**

The device consists of a radio frequency generator and a single-use bipolar ablation probe. The probe consists of a three-dimensional expandable bipolar electrode, which comes in touch with the entire endometrial cavity, when opened. There is also a vacuum pump within the generator, which provides continuous suction of the endometrial lining and debris; therefore, preoperative preparation of the endometrium is not generally needed. The generator operates at 500 KHz and has a power cutoff limit of 50 Ω of tissue impedance. Once the myometrial layer is reached, immediately the tissue impedance increases to 50 Ω, and the generator automatically switches off.

This method has been evaluated in prospective observational studies and women reported a satisfaction rate of up to 87%, an amenorrhea rate of up to 58%, and a failure rate of up to 3% 1 year after treatment, while amenorrhea rate at 3 years postablation