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### **Abbreviations**

ANM Auxiliary Nurse Midwife

ASHA Accredited Social Health Activist

**DH** District Hospital

**DPM** District Program Manager

LHV Lady Health Visitor

NFHS National Family Health Survey

**OBGYNs** Obstetrician and Gynecologists

PMW Post Menopausal Women

RMNCH+A Reproductive, Maternal Neonatal, Child Health and Adolescent

**SPM** State Program Manager

WHO World Health Organization

## Foreword and Acknowledgments



**Dr. Duru Shah** Principal Investigator

# STANDARDIZATION OF HEALTHCARE OF POSTMENOPAUSAL WOMEN IN INDIA

The menopausal period has an important role in the reproductive life of a woman and is associated with many physical and psychological problems. Life expectancy has been increasing, yet the age at menopause remains relatively unchanged, hence women are spending more of their lives in the post-menopausal period. Menopausal experiences in women from different parts of the world and from different ethnic groups provide evidence, that there are varied symptoms in various cultural and ethnic groups. For every region, people are geopolitically different from other people.

The Menopause Rating Scale (MRS) is a health-related quality- of- life Scale, developed in Germany (by The Berlin Center for Epidemiology and Health Research) in the early 1990s. Its intent was to measure the severity of aging symptoms and their impact on the quality of womens' lives and is a well-accepted tool for assessment of symptoms of menopause, both by WHO and the international community. Currently no validated Indian tool related to quality of life is available. Thus there is need for development of a screening tool which would be specific for the Indian Menopausal woman.

The aims of this tool would be needed to enable comparisons of symptoms of aging between different groups of women under different conditions, to compare the severity of symptoms over time, and to measure changes pre- and post-treatment.

Data from various developing countries has shown that as the proportion of older women increases, they continue to face poverty, social isolation, discrimination and violence.

Chronic diseases remain the main cause of morbidity and mortality among older women. However, accurate data on the different causes of morbidity and mortality data are lacking. These information-gaps are a constraint in identifying appropriate interventions to improve the health, gender equality and rights for older women. Thus screening for Non-communicable diseases (NCD's) as they occur in this age group is also very important. WHO STEPS approach is a widely used tool for NCD's screening. In this project we have also developed the IMS Tool for NCDs based on the WHO STEPS approach, which is specific for Indian Menopausal women.

Hence the current project is based on preparation of screening tools for screening of severity of menopausal symptoms and NCD in Indian Menopausal Women based on the locally validated MRS and WHO STEPS tools.

The Indian Menopause Society was keen to prevent morbidities due to Non-Communicable diseases in post-menopausal women, so that women could live good quality lives beyond their menopause. Hence it was decided to create questionnaires or screening tools, which captured the symptoms of women related to menopause. And a screening tool to assess the presence of common diseases like hypertension, diabetes, cancer, osteoporosis and mental health has been developed to correlate the symptoms of such disorders through relevant investigations. We hope that the screening tools would later be used by Asha workers to decide which women needed extra care, and would sensitize them to evaluate the health of post-menopausal women based on their symptoms.

This would give our health authorities a basis to evaluate post-menopausal womens' health. A well-developed questionnaire to record symptoms, was created by a group of senior physicians from Mumbai who deal with such medical problems on a day to day basis. Guidance and assistance of an International WHO expert Dr. Arvind Mathur was sought to plan this project.

This Project has been made possible through a huge grant from the IMS Foundation set up by the Indian Menopause Society. I would like to acknowledge the Advisory Board Members of the Foundation and the various Presidents and Members of the Board of the Indian Menopause Society for their support and assistance during this project, especially Dr. Rama Vaidya, Dr. Rashmi Shah, Dr. Preeti Galvankar and Dr. Jyoti Unni.

I also wish to thank Dr. Sadhana Tayade, Joint Director, Directorate of Health services, Govt. of Maharashtra, Dr. Vipin Itankar, Honourable Chief Executive Officer, Latur Zilla Parishad; Dr. G. G Parage, District Health Officer, Latur; Dr. S Dhage, Civil Surgeon Latur;

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I acknowledge the help of Mr. Ajey Bhardwaj and team of Avni Health Foundation for their guidance and support throughout the Project.

I do hope that this labour of love put in by so many people, helps to prevent morbidities in post-menopausal women and adds quality and dignity to their lives.

Dr. Duru Shah

Principal Investigator, The IMS Project 26th June, 2019 Han Wenobause Society

# Guidance Note on Rolling Out Indian Menopausal Women (IMW) Program

#### **Backgroundand Introduction**

Menopause is defined as the time of cessation of ovarian function resulting in permanent amenorrhea<sup>1</sup>. The NFHS-2 (2005-06) report defines menopause as the absence of menstruation for six or more months. Hence menopause can be called as a transition phase from the reproductive to the non-reproductive phase in a woman's life. It is nature's protective phenomenon against reproductive morbidity and mortality in the ageing female population.

The life expectancy in India has taken a quantum jump from 30 years in 1940s to 61 years in 1990s. According to the WHO health statistics (2011), in India an average female life expectancy is 68 years and is projected an increase to 73 years by 2021. The unprecedented increase in human longevity in the 20th century has resulted in the phenomenon of population ageing, thus many women are likely to live for more than two decades beyond menopause, in an estrogen deficient state<sup>2</sup>.

It sets the stage for ageing and accelerates the process of non-communicable disorders. The natural menopausal age of a woman serves as a biomarker for subsequent disease prediction and mortality<sup>3</sup>. The most common complaints of postmenopausal women severe enough to affect normal lifestyle include sleep disturbances, muscle or joint pain, hot flushes, night sweats, depression and anxiety.

Thereis extensive work on menopause and its related symptoms done across the world especially in western countries, however not much has been done in the developing countries. A review of the India scenario shows that RMNCH+A program, National programme for the healthcare of the elderly, National Rural Health Mission, National Health Mission, and the modules on the role of ASHA's in non-communicable diseases do not refer to the issues of post-menopausal women. There have been studies

<sup>&</sup>lt;sup>1</sup> Howkins J, Bourne G. Perimenopause, menopause, premature menopause and postmenopausal bleeding. In: Paduvidri VG, Daftary SN, editors. Shaw's Textbook of Gynaecology. 14th ed. India: Elsevier; 2008. p. 37.

Nisar N, Sohoo NA. Frequency of menopausal symptoms and their impact on the quality of life of women: A hospital based survey. J Pak Med Assoc. 2009;59:752-6. [PubMed]

<sup>&</sup>lt;sup>3</sup> Cooper GS, Sandler DP. Age at natural menopause and mortality. Ann Epidemiol. 1998;8:229-35.

documenting the age at which Indian women attain menopause and the factors that influence the phenomenon. The estimated mean age of menopause is 46 years in India<sup>4</sup>.

In 1998 there were approximately over 477 million postmenopausal women in the world and the number is projected to rise to1.1 billion by the year 2025<sup>5</sup>. According to the Indian Menopause Society, there were about 65 million Indian women over the age of 45 years in the year 2006. Approximately 130 million Indian women are expected to live beyond menopause by 2015<sup>6</sup>; therefore, the menopausal health demands a higher priority in the Indian scenario<sup>7</sup>.

As the issues surrounding postmenopausal women are many and need specific psychological and medical management, Indian Menopause Society through this project is leading the work related to IMW and is focusing its attention on the policy framework, definition, identification, and providing management health services to postmenopausal women residing both in the urban and rural India.

#### **Guidance note**

The present note is based on the inputs and deliberations held based on the initial work done by the Indian Menopause Society (IMS) through its project "To develop a community based screening tool for the screening Menopausal symptoms and Non-Communicable diseases in Indian postmenopausal women". By involving the ministry of health and family welfare at the National and State levels, the purpose of this note is to make available a draft policy for menopausal women of India, firming up of the training quidelines, easy to use tools for identification, and menopause management quidelines.

#### **Guidance objectives**

- **1.** To help establish operational mechanisms/modalities for screening and identification of women above the age of 40 years for Menopause associated conditions.
- 2. To disseminate information on the tools for identification, and menopause management guidelines, data collection tools, data/information flow and use of data in analysis.

<sup>&</sup>lt;sup>4</sup> Meeta, Digumarti L, Agarwal N, Vaze N, Shah R, Malik S. Clinical practice guidelines on menopause: An executive summary and recommendations. Journal of Mid-Life Health. 2013;4(2):77-106. doi:10.4103/0976-7800.115290.

<sup>&</sup>lt;sup>5</sup> http://www.healthline.com/health/menopause/facts-statistics-infographic#1

<sup>&</sup>lt;sup>6</sup> Kaulagekar A. Age of menopause and menopausal symptoms among urban women in Pune, Maharashtra.JObstetGynecol India. 2011;61:323-6.

New Delhi: Indian Menopause Society; Making Menopause Easier. Available from: http://www.indiatogether.org/ 2006/0ct/were-menopause.htm

3. To give a readymade plan and way forward for the Ministry of Health and Family welfare, who can then use the materials created and tested for firming up the Indian policy for menopausal women and training for health care providers delivering menopausal services.

#### Who benefits from the guidance

The note will be useful for sensitization of ASHAs, ANMs, LHVs, medical officers, district Health Officers, DPM, SPM, OBGYNs at DH and Medical colleges and programme managers who are routinely engaged in delivery of health interventions. Policy makers may be sensitized toward the health of the ageing woman and thus promote the concept of menopausal medicine and design programmes to foster positive healthcare utilization amongst ageing or menopausal women. Private sector providers may also find this useful in instituting menopause specific interventions or clinics and referral of PMWs to relevant specialists.

# Menopause – Technical Details

### Clinical Terminologies

#### 1. Natural or spontaneous menopause

It is recognized to have occurred after 12 months of amenorrhea for which there are no obvious pathological and physiological causes. It is a retrospective diagnosis. It occurs due to depletion of ovarian follicles resulting in near complete, but natural diminution of ovarian hormone secretion. There is no independent biological marker for menopause.

#### 2. Pre-menopause

It is often used to refer the entire reproductive period, up to the final menstrual period.

#### 3. Peri-menopause

It is the period immediately prior to and up to 1 year after the final menstrual period. It may last for 3-5 years. The characteristics are increased blood levels of FSH, anovulatory cycles, significantly reduced fertility and erratic menstrual periods, and onset of symptoms. This term is used interchangeably with menopausetransition.

#### 4. Menopause transition

It is the term coined by Stages of Reproductive Aging Workshop (STRAW) group, and during this period, disturbed menstrual cycle and endocrine changes are observed.

#### 5. Post-menopause

It is the span of time dating from the final menstrual period, regardless of whether the menopause was spontaneous or iatrogenic.

#### 6. Senescence

It is the period after the age of 60 years.

#### 7. Premature menopause

It is the spontaneous menopause occurring two standard deviations (SDs) below the mean estimated age for the reference population. Traditionally, it is considered to be below the age of 40 years.

#### 8. Induced menopause

Cessation of menstruation that follows bilateral oophorectomy or iatrogenic ablation of ovarian function.

#### 9. Early menopause

It is the time span between the spontaneous or iatrogenic menopause occurring between the age of 40 years and the accepted typical age of menopause for a given population.

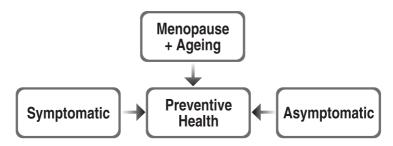
#### 10. Delayed menopause

It is not defined but may be important in terms of the increased problems associated with the hyperestrogenism and is used in this guideline. It is two SDs above from the natural average age of menopause in a given population. It may beconsidered to be beyond 54 years\*. (\*We need population-based studies to derive at the cut off values.)

#### 11. Post-menopausal bleeding (PMB)

It is the occurrence of vaginal bleeding following a woman's final menstrual cycle and not on cyclical hormone therapy. However, vaginal bleeding that occurs 6 months after amenorrhea should be considered suspicious and warrants investigation.

Every woman needs an individualized health plan management. Women may display with menstrual problems, menopausal symptoms or may show symptoms or maybe asymptomatic. The health worker at the community level may refer the woman based on the symptoms or knowledge of time of the last menstrual cycle.



## Diagnosis of Menopause

Menopause is diagnosed retrospectively by history. Markers for diagnosis of menopause arepreferably restricted for use in special situations and for fertility issues. Levels of (FSH) Follicular Stimulating Hormone > 10 IU/L are indicative of declining ovarian function. FSH levels > 20 IU/L are diagnostic of ovarian failure in the peri-menopausal age group with vasomotor symptoms (VMS) even in the absence of cessation of menstruation. FSH levels > 40 IU/L done 2 months apart is diagnostic of menopause. Anti-mullerian hormone becomes undetectable, inhibin levels fall, and antral follicular count and ovarian volume decreases at menopause. Menstrual irregularity is the only objective marker to define and establish the menopause transition.

# Clinical Guidelines for Identification and Management of Symptoms of Menopause, issues related to Menopause Transition, and Ageing

#### A. Fertility

- **a.** After the age of 30 years, if a woman does not conceive naturally within 6 months, the couple should have an infertility work-up.
- b. In women with a single ovary, previous ovarian surgery, poor response to Gonadotropins, previous exposure to chemotherapy or radiation, or unexplained infertility should undergo ovarian reserve testing even before the age 30 years and in all women it is done beyond ≥ 30 years.
- c. In women > 40 years who do not conceive within 1 to 2 cycles of controlled ovarian hyper stimulation, (IVF) *In vitro* Fertilization should be considered.
- d. The only effective treatment for ovarian ageing is oocyte donation. A woman with decreased ovarian reserve should be offered oocyte donation as an option as pregnancy rates associated with this treatment are significantly higher than those associated with controlled ovarian hyper stimulation or *In vitro* fertilization with a woman's own eggs.
- **e.** The risk of spontaneous pregnancy loss and chromosomal abnormalities increases with age, and the couple need to be counseled on this aspect.
- f. Preconception counseling with an emphasis on optimal general health, screening for medical conditions such as hypertension, diabetes, and pregnancy-related risks should be addressed for women of more than 40 years.

#### **B.** Contraception

- a. Pregnancies in elderly women are associated with higher maternal and perinatal morbidity and mortality, increased risk of fetal malformations. This can also lead to psychological and potential domestic and social consequences.
- b. For women, above the age of 35, careful personal and family history, and accurate measurement of blood pressure (BP), breast examination, screening for diabetes, and lipid profile should be performed while selecting the method of contraception.

- c. Sterilization is highly effective, safe and a single act, case fatality rate with tubectomy is 1-2/100,000 procedures. However, it is a permanent method. Vasectomy is even safer except for minor complications.
- d Oral contraceptives pills (OCPs) are effective, easy to use, and reversible. Lowdose OCPs have non-contraceptives health benefits with an increased safety profile.
- e. Healthy women of normal weight, non-users of tobacco, doing well on a combination contraceptive pill can continue this method until the age of menopause and up to a year or two later, after analyzing the risks and benefits.
- **f.** If oral contraceptives are continued before major surgery, heparin prophylaxis should be considered.
- g. Administration of OCPs in normal eumenorrheic women has no effect on Bone density (BMD) and bone metabolism. Conversely, depot medroxyprogesterone acetate (DMPA) is associated with bone loss, which returns to normal, after stopping DMPA. Yet, caution needs to be exercised in women at a high-risk of osteoporosis. Short- or long-term use of DMPA in healthy women should not be considered as an indication for dual X-ray energy absorptiometry (DXA) or other tests that assess BMD.
- h Change over from oral contraceptive to Hormone Therapy (HT) is carried out at an arbitrary, age of 45-50 years or if serum FSH: (LH) Luteinizing Hormone ratio of > 1, FSH > 30 IU/L.
- i Progesterone only contraceptive is an ideal method in women with a past history of venous thromboembolism (VTE) and gallstones. Limitations are erratic and scanty periods. The levonorgesterol Intra Uterine System (LNG-IUS) this is correct apart from being used as a hormonal contraception is most effective hormonal therapy for heavy menstrual bleeding and for treating bleeding disturbances associated with endometrial hyperplasia.
- j. Intra-uterine contraceptive devices (IUCDs) are effective, but sometimes can cause menorrhagia and dysmenorrhea.
- **k.** Emergency contraception is an effective emergency method, but it is not as effective and consistent as the use of other contraceptives.

#### C. Perimenopausal bleeding

- a. PMB is defined as uterine bleeding occurring after at least 1 year of amenorrhea. Its incidence is about 10-15%. Common cause are anovulatory bleeding, leiomyoma, endometrial polyp, endometrial hyperplasia, and endometrial cancer (EC)
- b. Endometrial tissue sampling should be performed in patients with (AUB) Abnormal
   Uterine Bleeding who are older than 40 years
- c. TVS is the primary screening test for AUB, and Magnetic resonance imaging (MRI) should be considered when the diagnosis is inconclusive. Sonohysterography is superior to transvaginal ultrasonography (TVS) can be done in the detection of intracavitary lesions.
- d. Persistent bleeding with a previous benign pathology, such as proliferative endometrium, requires further testing to rule out focal endometrial pathology or a structural pathology, such as a polyp or leiomyoma.
- **e.** Management depends on the cause, cost benefit analysis of therapy and the patient's choice

#### D. Post Menopausal Bleeding (PMB)

- a. Common cause is due to atrophic changes in the vagina and the endometrium. There is a 10-15% chance of having EC. Conversely, 90% of the EC in the post-menopausal period present with PMB. Hence, immediate evaluation is required.
- **b.** A detailed clinical and drug history is important as some over the counter drugs like 'Ginseng' can cause PMB.
- **c.** A through clinical examination is carried out to rule out cervical, vulval and vaginal cancer, atrophic vaginitis, urinary, and anal causes for bleeding.
- **d** Women with PMB may be assessed initially with Trans Vaginal scan, an endometrial biopsy.
- e. Endometrial thickness is measured using endometrial echo on a long-axis transvaginal view of the uterus. Women with an endometrial thickness of . 4 mm in transvaginal scan do not require endometrial sampling unless they are at a high-risk for endometrial carcinoma or bleeding is episodic. If endometrial thickness is > 4 mm, it is important to consider endometrial sampling. In women with homogeneous and normal morphology, women on HT and hypertensive

medication, the acceptable combined thickness is 6 mm. If the endometrial biopsy tissue is reported as insufficient for diagnosis, and endometrial thickness is less than 4 mm, follow-up is sufficient. Recurrent episodes warrant further investigations.

- **f.** A focal increased echogenicity or a diffuse heterogeneity in the endometrium even in a thin endometrium warrants further investigations.
- **g.** Out-patient endometrial sampling devices such as Pipelle and out-patient hysteroscopy can be carried out wherever possible.
- **h** Dilatation and curettage and fractional curettage are useful in low resource settings.

#### E. Quality of life (QOL)

- a. QOL as it relates to menopausal women is usually referring to health-related QOL,taking into account a woman's symptoms. Commonly used are *Menopause Rating Scale*, Greene Climacteric Scale, Women's Health Questionnaire, and Utian Quality of Life Scale.
- b. When evaluating drug therapies, besides safety, and efficacy, it is important to know the effect of the drug on QOL. Some studies show that low dose hormonal replacement therapy (HRT) significantly improves overall measures of QOL in early menopause.
- c. Some studies show that low dose HT significantly improves overall measures of QOL. HT had mixed effects on QOL among older women from the (HERS) Heart and Estrogen/Progesterone Replacement Study trial, whereas the Women's Health Initiative (WHI) trial investigators found that estrogen plus progestin did not have a clinically meaningful effect on HRQOL. An Indian study has shown an improvement in QOL in women receiving Tibolone.

#### F. Vasomotor Symptoms (VMS)

a. VMS present as hot flushes, cold sweats, and night sweats. It may be reported in the menopause transition, reach maximum intensity during the first 2 years postmenopause and then decline over time. VMS generally last for 6 months to 2 years, although some may experience for 10 years or longer. Other causes of flushing before planning treatment need to be excluded.

- b. Grading of VMS is important to plan management, follow-up and for research. Grades of hot flashes are classified as: Mild – feeling of heat without sweating; moderate – feeling of heat with sweating; and severe – feeling of heat with sweating and palpitation that disrupts usual activity.
- c. Life-style modifications may be recommended to reduce mild VMS. The most effective treatment for VMS is Hormonal Therapy. Low dose oral contraceptive pills can be used in the menopause transition phase for relief of symptoms. Non-hormonal prescription agents may relieve VMS, but have their own side-effects. These can be considered when HT is contraindicated or not desired.
- **d.** Complimentary and alternative treatments should be advised with caution as the data are still insufficient especially in moderate to severe VMS.

#### G. Urogenital symptoms

- a. The prevalence of urogenital symptoms in the post-menopause in the IMS study was 15%. It presents as vaginal dryness in 32%, pruritus vulvae 10-17%, dyspareunia, and urinary urgency 10%.
- b. It is due to urogenital atrophy as a result of declining estrogen levels and may also present as recurrent urinary tract infections. Though it affects the QOL, women in general do not complain about it; hence, suggestive questions need to be posed during history taking.
- c. Physical signs of vulvovaginal atrophy are variable and include reduced vulval fat, reduced vaginal rugae, and blood flow leading to a pale appearance; a change from moderately acidic range (pH 3.5-5.0) to a neutral range (pH 6.0-8.0) in vaginal pH, there is a shift in the vaginal maturation index.
- d Vaginal lubricants can be recommended for subjective symptom improvement of dyspareunia. Vaginal moisturizers can be offered for vaginal dryness and dyspareunia. Lifestyle modification, bladder drill, and pelvic floor exercises are recommended for urinary incontinence. Estrogen therapy (ET) maybe recommended.

#### H. Sexual problems

a. A woman's sexual response to her partner is significantly related to her baseline feelings for the partner, their relationship qualities, and partner's age and health. Sexual dysfunction is multifactorial and needs to be addressed accordingly.

- **b.** Vaginal atrophy with ageing leads to dyspareunia. Dyspareunia leading to sexualdysfunction is corrected by local ET.
- c. Acquired sexual desire disorder in some women responds to testosterone therapy. Testosterone preparations meant for males should not be prescribed for women. Tibolone is a good option; since, it contains androgenic activity and can be used to treat libido problems.

#### I. Abnormal Menopause

#### a. Premature menopause (POF)

- i. The National Family Health Survey (1998-99), collected information from a sample of more than 90,000 married women aged between 15 and 49 and covering 99% of India's population living in 26 states. 3.1% of the women are already in menopause by the age of 30-34, and the incidence rises to 8% for the age bracket of 35-39. At age of 48-49 years 66% of the women are amenorrheic. This is probably an overestimate for the study did not differentiate between natural, surgical or secondary causes.
- ii. Menopause occurring at an age less than 2 SD below the mean estimated age for the reference population is called as premature menopause.
- iii. Women receiving chemotherapy/radiotherapy (pelvis) should be cautioned about iatrogenic premature menopause. Hysterectomy alone can sometimes cause early menopause.
- iv. Diagnosis is established by hormone analysis repeated 1 month apart. Serum FSH levels > 40 U/mL are diagnostic of POF.
- v. Appropriate counselling, life-style modification and Hormone replacement therapy (HRT) form the mainstay of treatment. HRT should be started as early as possible in women with POF and continued till age of natural menopause. Androgen replacement should be considered for women with persistent fatigue, loss of libido in spite of estrogen replacement.
- vi. Women with untreated premature menopause are at increased risk of developing osteoporosis, cardiovascular disease dementia, cognitive decline, and Parkinson's and all-cause mortality.

#### b. Induced menopause

i. The exact prevalence of surgical menopause is not known, but varies in the rural to urban areas and across states.

- ii. Hysterectomies along with bilateral oophorectomy performed at a young age are responsible. This trend of unwarranted hysterectomies and surgical castration for fear of cancer by the professional and the women should be discouraged.
- iii. There is wide diversity in awareness, about public health problems and QOL among both physicians and population. There is a great need of awareness program about consequence of surgical menopause risk/benefit and in prevention of problems due to surgical menopause. Women who need oophorectomy before menopause should be counseled about the risk of surgical menopause.
- iv. The physicians should have appropriate knowledge to recognize menopausal symptoms and whenever in doubt should get the test (FSH > 40 IU/mL, E2 < 40 pg/mL.
- v. Hormone Therapy (HT) should be considered in women less than 50 who have undergone surgical menopause. Routine HT is not recommended for surgical menopause in post-menopausal women as primary prevention for chronic conditions.

#### J. Non-communicable diseases

#### a. CVD

- i. The incidence of CVD in Indian women has been noted to have significantly risen. The projected death's from CVDs by 2020 is estimated to be 42% of the total deaths. The prevalence rate of stroke is 545.1/100,000 persons. The case fatality rate is 41% in 30 days. The prevalence of hypertension is 20.4-22% in the urban area and 12-17% in rural area. From the Indian Million Death Study 2009, CVD emerges as the major cause of mortality, 16.8% in the rural and 28.6% in the urban area.
- ii. Risk factors for coronary heart disease: Pre-mature menopause, hypertension, dyslipidemia, homocystenemia, lipoprotein (a), high-risk C-reactive protein (CRP), obesity, sedentary life-style, smoking, and metabolic syndrome.
- iii. Risk factor for deep vein thrombosis: Personal or family history of clot, if so, when and why? Prolonged immobilization-surgery or while pregnant or on the contraceptive pills. Any tests to confirm the clot history of the treatment with anticoagulants.

- **iv.** Risk factors for stroke: Hypertension, diabetes, smoking, obesity, atrial fibrillation, asymptomatic carotid stenosis, and hyperlipidemia.
- v. Prevention and management
  - 1. Life-style interventions
  - 2. Encourage optimal Blood Pressure (BP) < 120/80 through lifestyle approaches</p>
  - **3.** Pharmacotherapy if BP . 140/90 to avoid end-organ damage, more so in diabetes
  - **4.** Use thiazide diuretics unless there is an absolute contraindication. Optimal lipid targets
  - 5. Low density lipoprotein (LDL) < 100 mg/dL, high density lipoprotein (HDL)</li>50 mg/dL, triglycerides < 150 mg/dL, non- HDL cholesterol < 100 mg/dL</li>
  - 6. High-risk: Initiate statin if LDL > 100 mg/dL 7. Inter-mediate risk: Initiate statin if LDL > 130 mg/dL
  - 8. Aspirin in high-risk women (75-162 mg/day)
  - Routine use of aspirin in women < 65 years of age is not recommended for Myocardial Infarct (MI) prevention
  - **10.** HT is not indicated solely for primary or secondary cardio protection
  - 11. Do not use antioxidant supplements for CVD prevention
  - **12.** Do not use folic acid, with or without B6 or B12 supplements for CVD prevention

#### b. The metabolic syndrome: Insulin resistance (IR)

- i. Also known as IR syndrome and syndrome X, affects an average of 40% of the Indian women. The prevalence reported in the peri-menopause in India is 22.2% rising to 32.2% to 48% in the post-menopause. It is 1.5- 2 times more common in women than in men.
- ii. Clinical conditions associated include type 2 diabetes, CVD, polycystic ovary syndrome (PCOS), non-alcoholic fatty liver, obstructive sleep apnoea, and certain cancers. It is also a prominent feature of the metabolic syndrome.
- iii. Diagnosis of metabolic syndrome: Abdominal obesity defined as > 35 inches in females; serum triglycerides > 150 mg/dL; BP > 130/85 mmHg; and fasting plasma glucose > 110 mg/dL.

- iv. Effect of HT: Reduced IR, abdominal obesity, new-onset diabetes, lipids, BP, adhesion molecules, and procoagulant factors in women without diabetes and reduced fasting glucose and IR in women with diabetes. The effects were diminished by the addition of progestin
- v. Dietary recommendations are to reduce exposure to insulin both as a result of dietary stimulus and through decreased IR. Exercise improves insulin sensitivity, aiming for a minimum of 30 min of moderate physical activity/ exercise per day.

Indications for intervention by Body mass index (BMI) category			
Category	Intervention		
Underweight (18.5):	Encourage balanced diet and exercise		
Healthy (18.5-24.9):	Encourage balanced diet and exercise		
Overweight (25-26.9):	Lifestyle (diet, exercise, and behavior therapy)		
Overweight (27-29.9):	Lifestyle plus drug therapy if co morbidities* exist		
Obese class 1 (30-35):	Lifestyle plus drug therapy		
Obese class 2 (35-39.9):	Lifestyle plus drug therapy, plus surgery if co morbidities* exist		
Obese class 3 (above 40):	Lifestyle, drug therapy and surgery		

<sup>\*</sup>co morbidities: Hypertension, diabetes and hyperlipidemias, BMI: Body mass index

#### c. Diabetes Mellitus

- i. The prevalence in hospital based multi-centric study by the IMS in postmenopausal woman was 12%. In India, Type 2 DM occurs a decade earlier than the Caucasians. More than 50% of the subjects are undiagnosed.
- ii. Risk factors: Advancing age, obesity, family history, hypertension, dyslipidemia, personal history of gestational DM or impaired glucose tolerance, PCOS, and physical inactivity.
- iii. Screening: Opportunistic screening for all women above the age of 30 years, every 3 years for younger women with risk factors. Diabetic women should be screened for hypertension, dyslipidemia, microalbuminuria, and undergo yearly eye check.

iv. The goal in management is to maintain the HbA1c around < 7% and control risk factors for CVD. It may be indicated to evaluate the endometrium by transvaginal scan before starting HT.

#### d. Thyroid disease

- i. The prevalence from hospital-based data in post-menopausal women for hypothyroid in India is 3-7%.
- ii. Hypothyroidism is much more common in older than younger individuals. Symptoms and signs include lethargy, constipation, dry skin, alopecia, memory impairment, and depression. The individual is often obese and may have elevated cholesterol. The prevalence of hypothyroidism is approximately 5% in otherwise healthy individuals. Thyroid-stimulating hormone (TSH) is a good screening test.

#### e. Anaemia

Anaemia is common in the elderly people in India. Prevalence of irondeficiency anaemia, vitamin B12 deficiency, and folate deficiency is common, and should be an integral part of management of menopause.

#### f. Dementia

- i In 2010, there were 2.1 million women. While the numbers are expected to double by 2030, costs would increase 3 times. Prevalence of dementia overall is 0.6-3.5% in rural India and 0.9-4.8% in Urban India.
- ii. Risk factors of dementia are family history, genetic factor apolipoprotein E (APOE), minimal cognitive impairment (MCI), CVD risk factors, physical inactivity, diabetes, hypertension, dyslipidemia, smoking, obesity, autoimmune diseases, depression and stress, social engagement and diet, head trauma and traumatic brain injury, and age
- iii. Risk factors for Alzheimer's disease: Age, family history, genetic factor APOE, MCI, CVD risk factors, physical inactivity, diabetes, hypertension, dyslipidemia, smoking, obesity, auto-immune diseases, depression and stress, social engagement and diet, and head trauma and traumatic brain injury.
- **iv.** Polypharmacy and thyroid disease are two examples of reversible causes of memory loss in older adults.
- v. It affects core mental functions like memory, communication and language, ability to focus and pay attention, reasoning and judgment, activities of daily

living, and visual perception. Impairment of any two functions is suggestive of dementia. Many dementias are progressive, hence introduction of accessible diagnostic and early stage dementia care services such as memory clinics is recommended

- **vi.** An objective marker is examination of (CSF) cerebrospinal fluid for amyloid beta or tau protein and phosphorylated tau protein concentration.
- vii. HT or ET is not currently recommended for reducing risk of dementia developing in post-menopausal women or retarding the progress of diagnosed AD. For best preservation of memory and cognition, women should be advised about the importance of good overall health, good cardiac and vascular health, exercise, maintenance of active mind, avoidance of excessive alcohol consumption, and measures to reduce risk of diabetes and hypertension.

#### g. Sleep

- i. A detailed assessment of menopausal symptoms should always include questions about sleep pattern. Sleep questionnaires or sleep diaries can be useful to assess sleep in detail
- ii. If insomnia is identified, medical or psychiatric causes of insomnia should be ruled out and if present, treated accordingly. If specific neurological or breathing disorders are suspected, further investigations and referrals to specialists should be initiated. Adverse life-style factors, social factors, and risk factors should be considered and treated accordingly.
- iii. If insomnia is resistant to life-style modifications, then hypnotics, benzodiazepines or melatonin agonists can be used in the short-term, but there is no definite or convincing evidence to suggest its efficacy. These should only be prescribed by supervision or after liaison with psychiatrists or sleep experts Sleep hygiene measures and life-style modifications should be recommended as first line of treatment. Psychological treatments such as (CBT) Cognitive Behavioral Therapy should also be considered.

#### h. Osteoporosis

i WHO defines osteoporosis as "a systemic skeletal disease characterized by low bone mass (measured as BMD) and microarchitectural deterioration of bone tissue with a consequent increase in bone fragility and susceptibility to fracture and involves the wrist, spine, hip, pelvis, ribs or humerus." The

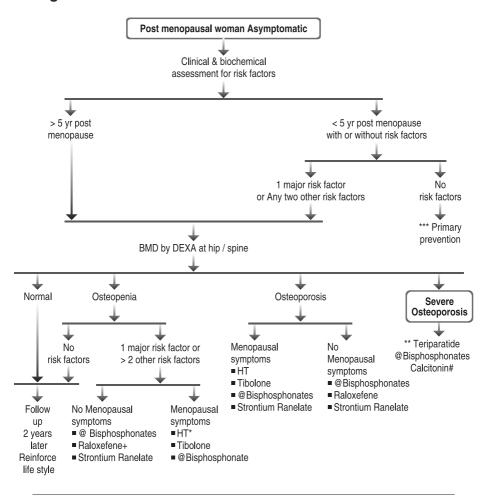
- National Institute of Health definition is "a disease characterized by decreased bone strength and propensity to fall."
- ii. The diagnosis of an osteoporotic fracture, the clinical end-point of osteoporosis is by the presence of fragility fracture (clinical or by investigation) and or by BMD (DXA is Gold Standard Test). Its value is expressed from the mean in an age-matched population (Z-score). A Zscore below 2 is regarded as abnormal and should be referred to as "low for age."
- iii. Osteoporosis is classified as primary and secondary
  - 1. Primary osteoporosis is seen in post-menopausal women in whom there is no specific pathogenetic mechanism other than age. There is an accelerated bone loss at the rate of 2-5% per year due to declining estrogens levels and is seen in the first 5-7 years after menopause. Later age-related bone loss occurs at a rate of 1% per year in both sexes and affects the cortical and trabecular bone.
  - Secondary osteoporosis is due to specific causes. A low Z-score in a post-menopausal woman indicates the need to evaluate for secondary osteoporosis.
- A fragility fracture has been defined by the WHO as "a fracture caused byinjury that would be insufficient to fracture normal bone: The result of reduced compressive and/or torsional strength of bone."
- Osteoporosis is asymptomatic unless a fracture occurs. Early diagnosis in the asymptomatic period and timely management of osteoporosis will prevent the associated morbidity and mortality. Opportunistic screening for women above 40 years is suggested.
- Major risk factors defined by WHO are advancing age, prior fragility fracture, low Body Mass Index (BMI), family history of fracture, smoking, and more than three drinks of alcohol per day.
- Environmental factors include nutrition (calcium intake using the quick dietary calculator, protein) physical activity and sunlight exposure, which are important modifiable risk factors in India. Relevance of risk of falling increases with ageing.

- For secondary osteoporosis, high-risk disease subgroups are chronic glucocorticoid users and patients with rheumatoid arthritis, collagen vascular disease, or inflammatory bowel disease, hypogonadism, thyroid dysfunction, type 2 diabetes.
- Women presenting with fracture complain of severe pain, which is sudden in onset with minimal trauma, or chronic pain localized to the mid back, may radiate to the abdomen. Generalized bone pain indicates osteomalacia or metastasis.
- Physical examination should include the height and weight annually, check for balance and gait, get up, and go test by asking the women to get up from the chair without using their arms. Kyphosis and dowgers hump is seen in the late stage of osteoporosis.

#### Indications for DXA:

- All post-menopausal women more than 5 years of menopause.
- Women with fragility fractures.
- Post-menopausal women less than 5 years of menopause with risk factors.
- Women in menopause transition with secondary causes.
- Radiological evidence of osteopenia and presence of vertebral compression fracture.
- Before initiating pharmacotherapy for osteoporosis.
- To monitor therapy the interval to the next test should depend on the calculated individual risk and would mostly be scheduled between 1 year and 5 years later.
- Emerging indications are to measure total body fat and lean tissue mass.
- Screen post-menopausal women for secondary osteoporosis if history or examination show systemic disease or low Z-scores on DEXA
- Management The target is primary prevention (population-based), intervention, and rehabilitation (individualized). Measures include Balanced diet, adequate physical activity, exposure to sunlight, avoidance of bone depleting agents such as tobacco, alcohol, etc, intake of calcium supplements (800mg), Vitamin D, low sodium and adequate protein (1 g/kg body weight).

#### **Management Flow Chart**



@Bisphosphonates - for 5 yrs

- Review after 5 years
- Consider continuation after a drug holiday

Raloxelene - effective on vertebral fractures

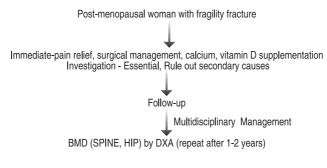
- # Calcitonin
  - Analgesic effect
  - Useful for vertebral#
  - Short term use upto 3 months.
- \*\*Teriparatide Can be used upto 2 yrs

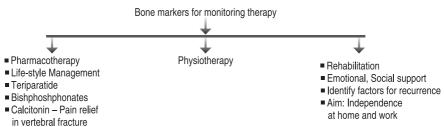
\*Hormone therapy

To be used within 10 yrs of menopause

- Pre initiation work up
- Individualize therapy

\*\*\*Primary Prevention for all – Nutrition, Lifestyle Modification, Adequate Vitamin D and Calcium, Excercise, Avoid bone depleting agents





Frailty-related falls and fractures follow unintentional weight loss, self-reported exhaustion, weakness (grip strength), slow motor performance (walking speed), and low physical activity. Women's health-care programs targeting post-menopausal women's comprehensive care can contribute a lot by educating women as to take care of their musculoskeletal health through life-long commitment to proper nutrition, exercise, and understanding about issues related to prevention of falls.

#### i. Osteoarthritis

- i. Age, weight, female sex, quadriceps weakness, and overloading of the knee joint (climbing stairs, squatting posture, etc.,) are the main contributors than menopause per se in the incidence of osteoarthritis. Those contributing factors should be addressed on a priority basis.
- ii. Epidemiological studies of a potential role for estrogens in osteoarthritis showed firstly, estrogen deprivation at the menopause seems to be associated with increases in the frequency of knee, hip, and finger osteoarthritis, and in the severity of hip osteoarthritis and secondly, HT for the menopause may decrease the incidence and progression of hip and knee osteoarthritis.
- iii. Perimenopausal women can be advised about HT and they should be aware of the fact that only long-standing (>5 years) use of HT can be beneficial. Once osteoarthritis sets in, there is no protection from HT and osteoarthritis

- takes its own course. In such cases, osteoarthritis should be treated on its own merits.
- iv. First two stages of osteoarthritis can be addressed by life-style modification, pharmacotherapy, and physical therapy. Third and fourth stages need surgical intervention for which total knee replacement is the gold standard.

#### j. Eye

- i. Blindness was more likely with increasing age and decreasing socioeconomic status, and in female subjects and in rural areas. The causes of blindness include cataract, refractive error, preventable corneal disease, glaucoma, complications of cataract surgery, and amblyopia.
- ii. There is increased risk of dry eye in with age due to decreased tear production.
  Menopause also contributes to the ocular surface impairment due to hormonal imbalance.

#### k. Cancer

#### **Breast Cancer**

- i. In India, breast cancer is the second most common cancer with an estimated 115,251 new diagnoses and the second most common cause of cancerrelated deaths with 53,592 breast cancer deaths in 2008. The agestandardized incidence rate for breast cancer in India is 22.9 per 100,000, one-third that of Western countries and the mortality rates are disproportionately higher.
- ii. Non-modifiable risk factors for breast cancer are age, family history, benign breast disease, BRCA – Breast Cancer) 1 or 2 carriers, early menarche (<12 years), late age at menopause (after age 55), increased breast density, and a chest irradiation between ages 25 years and 55 years.
- iii. Modifiable risk factors are age at first child, breast-feeding, parity, obesity, physical activity, and menopausal HT. The risk of breast cancer may be lowered to some extent by lifestyle changes, working on modifiable risk factors, and diligent use of HRT. The best way to protect one's self is through early detection.
- iv. Early results of trial by WHO in India (JNCI 2011) (Journal of the National Cancer Institute) and studies for cost effectiveness of screening in Indian women support that CBE is an effective way and survival can be improved by up to 16% at half the cost by use of CBE

■ In India, breast cancer incidence peaks before the age of 50 years, and a recent review of the evidence in younger women (aged 39-49 years) based on 8 trials conducted between 2001 and 2008, suggests that mammographic screening is also beneficial in this younger age group. Mammography screening for women aged 40-69 years leads to approximate 12-15% reduction in breast cancer mortality. However, cost affectivity and false positives are the other limitations in the use of mammography in India. Currently MRI screening in combination with mammography is targeted to high-risk patients, which includes: BRCA 1 or 2 mutation carriers, untested women who have a first degree relative with a BRCA 1 or 2 mutation, women with lifetime risk of breast cancer of 20-25% or more, received radiation treatment to the chest between ages 10 and 30 or women with Li-Fraumeni syndrome or Cowden syndrome.

#### Cervical cancer

- i. Cervical cancer is the leading cause of cancer death in women in both rural and urban areas. The cervical cancer death rate of 16/100,000 reported in the million woman death study 2012 suggests that a 30-year-old Indian woman has about 0.7% risk of dying from cervical cancer before 70 years of age in the absence of other diseases.
- ii. India contributes to over 25% of the disease burden and more than 26% of the deaths due to cervical cancer world-wide. More than 75% of the cases presenting in the late stage of the disease renders poor prospects for survival and cure. About 1, 34, 420 new case are being diagnosed every year. However, currently only 4.9% of urban women aged 18-69 years are screened every 3 years (WHS India -World Health Surveys. Geneva: WHO; 2003) and 2.3% of rural women aged 18-69 years are screened every 3 years (WHS India).
- iii. Risk factors: HPV-Human Papilloma Virus, sexual intercourse at an early age, multiple sexual partners, sexual partners who have had multiple partners, HIV positive status, and smoking.
- iv. Screening tests such as Visual inspection, Visual inspection with acetic acid (VIA) and Visual inspection with Lugol's iodine are useful at community and low resource setting. Conventional screening uses PAP Papinacolou smear (both conventional and liquid base cytology and HPV DNA testing at secondary and tertiary level. Screening methods may be sometimes

inconclusive in menopausal women whose transformation zone is inside the cervical canal or due to atrophic changes. Hence, choosing the appropriate test is important. In the event of availability of low-cost and rapid HPV testing as primary screening test every 5 years up to the age of 65 is recommended.

v. Behavioural changes to reduce the risk of cervical cancer include limiting the number of sexual partners, delaying initial age of sexual intercourse, and avoiding sexually transmitted disease. The association of cigarette smoking with cervical cancer should also be emphasized.

#### Stomach cancer

- i In women aged 30-69 years, the second most common fatal cancers were stomach (14.1%). Stomach cancer rates were higher in rural than in urban areas of India due to increased prevalence of chronic *Helicobacter pylori* infection.
- ii. Symptoms include loss of appetite or feeling full all the time, loss of weight, pain or discomfort in abdomen, Persistent indigestion or nausea, bloated belly and constant fatigue.

#### Cancer endometrium (EC)

- i. EC is commonly occurs in post-menopausal women. Overall morbidity and mortality of EC is low because most patients present at an early stage because of abnormal bleeding or PMB.
- ii. A strong influence of modifiable risk factors such as increasing obesity, life expectancy, and adjuvant tamoxifen use for breast cancer has been attributed. Also factors that are those associated with increase in endogenous estrogens or HT with estrogens
- **iii.** Adenomatous and atypical hyperplasias are the common precursors of endometrial carcinoma.
- iv. Unopposed ET in women with an intact uterus increases the risk of EC 2- to 10fold, and risk increases with duration of use. Cyclic or continuous progestin given along with estrogens reduces the risk of EC.
- v. Relative risk of EC with obesity is 3.0 in women 21-50 lb overweight and 10 in women more than 50 lb overweight.
- vi. Women taking tamoxifen for more than 2 years have a 2.3- fold to 7.5-fold relative risk of EC.

- vii The lifetime risk of EC for women with hereditary non-polyposis colorectal cancer (HNPCC) and for women who are at high-risk for HNPCC is as high as 60%.
- viii.It is recommended that, at the time of menopause, women at average risk should be informed about risks and symptoms of EC, and strongly encouraged to report any unexpected bleeding or spotting.
- ix. For those with increased risk and special situations such as on HT, genetic risk, and on tamoxifen therapy should have a complete diagnostic evaluation for abnormal bleeding. Women diagnosed with EC should have the benefit of multidisciplinary team approach.

#### Cancer ovary

- i. The general or lifetime risk of ovarian cancer is 1.4%. The most common sign of ovarian cancer is enlargement of the abdomen caused by accumulation of fluid or a large ovarian mass. However, many women have bloating or weight gain in the abdominal area, making this sign non-specific.
- **ii.** In women over 40, persistent and unexplainable digestive disturbances indicate the need for a thorough evaluation for ovarian cancer, including a carefully performed pelvic examination and ultrasound.
- iii. Risk factors include having first degree relative with ovarian cancer (mother, sister or daughter), Personal H/o breast cancer < 40 years or age, Personal H/o breast cancer < 50 and one or more close relative with breast or ovary cancer at any age or having 2 or more close relative with breast cancer < 50 years of age or ovarian cancer at any age. Recommendation for screening is dependent on the risk status of women.</p>
- iv. A heightened awareness of the symptoms of early ovarian cancers on the parts of the patients and practitioners may help to reduce the delay in diagnosis and hopefully result in an improvement in outcome of some progress.
- v. For general population annual pelvic examination, PAP smear, and transvaginal sonography are recommended as a part of post-menopausal surveillance.
- vi. For Primary prevention: despite limited data available on efficacy of prophylactic oophorectomy in decreasing the risk of ovarian cancer in mutation carriers, it is recommended to be considered in BRCA mutation carriers who have completed childbearing.

#### Vulvar cancer

- i. Cancer of the vulva is a rare disease that accounts for approximately 5% of gynaecological cancers. The median age of onset is approximately 65-70 years for invasive cancer and approximately 45-50 years for carcinoma in situ.
- ii. Risk factors for vulvar cancer include the following: Human Papilloma Virus (HPV), previous genital warts, greater number of sexual partners, current smoking, abnormal PAP smear, diabetes, obesity, chronic vulvar pruritus, and poor personal hygiene have also been suggested as contributing to risk. Protected intercourse, monogamy, and adequate hygiene of the external genitalia protect against vulvar cancer.
- iii. Annual examinations should be performed to check for vulvar cancer. Highrisk patients should be examined every 6 months. White lesions and chronic ulcerative lesions should be biopsied for evaluation.

# Assessment Requirements for Post-Menopausal Women

#### A. General considerations

Clinical examination includes a holistic approach to health, rather than simply looking for features of menopause in isolation and this leads to diagnose the latent and overt NICD. A thorough assessment of the health-related problems helps in formulating treatment plan. Examination can be broadly divided into three main categories:

- a. General physical examination: Examination of respiratory, cardiovascular system, skin, eyes, oral cavity and bones may detect common age-related problems.
- **b.** Breast examination: This should be carried out regularly due to an increased risk of breast cancer as women get older
- **c.** Pelvic examination: This is performed to assess for complications of menopause, such as urogenital atrophy and must include PAP smear.

#### **B.** Assessment

- 1. Detailed history
- 2. Evaluate women's need
- **3.** Evaluation of women's individual risk factor: cardiovascular, respiratory, malignancy, fragility fractures
- 4. Assess general condition of patient
- 5. Physical examination:
  - a. Pulse
  - b. BP [Optimal BP (<130/85) to be rechecked every 2 years; Normal level (<140/90 mmHg) to be checked yearly; Greater than 140/90 mmHg need second measurement to confirm diagnosis of hypertension]</p>
  - c. Auscultation of the heart and lungs
  - d. Height
  - e. Weight

- f. Waist circumferences
- g. Calculate BMI
- h. Breast examination
- i. Pelvic examination

#### C. Investigations

These are necessary to establish the diagnosis, determine etiology, and screen for complication. Some investigations may be necessary to perform for diagnosis or to help in formulating a treatment plan.

Recommended laboratory tests:

- 1. Complete blood picture
- 2. Urine test routine
- 3. Fasting glucose level
- 4. Lipid profile
- 5. Serum TSH
- 6. Vitamin D3 and B12
- 7. Stool for occult blood
- 8. PAP smear
- 9. Transvaginal ultrasound
- 10. Mammogram/ultrasound
- 11. Eye checkup intraocular pressures, refractive index, and retina

#### Test performed solely on indication:

Test	Indication
FSH	Premature menopause, women on OC pills, women who had hysterectomy, doubt as to the cause of secondary amenorrhea or hot flushes, women on patches to rule out accumulation
Estradiol	Premature menopause, women on OC pills, women who had hysterectomy, doubt as to rule out the cause of secondary amenorrhea or hot flushes

Test	Indication
Test to assess increased risk of thrombosis	Where there is relevant past or family history, women with previous history of unexplained thromoembolic episodes anti thrombin III, Tissue factor pathway inhibitor activity, protein C and protein S are to be estimated. Lupus anticoagulant, anticardiolipin antibodies should also be assessed
Endometrial biopsy	Post-menopausal bleeding, recent irregular bleeding, previous use of unopposed estrogen in the presence of uterus
Bone mass measurement	For specific indication. Refer Flow chart 2
LFT	When relevant as with suspected liver disease or recent history of liver disease
Urodynamic study	To diagnose and differentiate on the severity and type of incontinence before planning surgery
ECG, 2D Echo, Stress test	CVD assessment
25, OH, vitamin D	Rule out secondary causes of osteoporosis

 ${\sf FSH:} \ \ {\sf Follicular} \ \ {\sf stimulating} \ \ {\sf hormone}, \ \ {\sf LFT:} \ \ {\sf Liver} \ \ {\sf function} \ \ {\sf tests}, \quad {\sf ECG:} \ \ {\sf Electrocardiogram},$ 

CVD: Cardiovascular disease, 25, Ohn vitamin D 25, hydroxy vitamin D

### Management Options for Post-menopausal Women

#### A. Counselling

- **a.** The art of medical counselling and translating the statistics in simple language is an important part of the consultation.
- b. The objectives of counseling include addressing women's questions and concerns, providing patient education, and enhancing the patient's confidence in the decision making. If a therapy is chosen, the patient and clinician should agree on the goals, risks, and benefits, whether they are short-term (menopause symptom relief), long-term (primary or secondary prevention of diseases associated with aging), or both.
- **c.** The clinician should review the decisions about menopause management with the patient at subsequent visits.

#### **B. Dietary Prescription**

- a. Although there is no special diet that women going through the menopause need to follow, it's particularly important that they have a healthy, balanced diet with regular meals, as irregular eating can make certain symptoms worse, such as feeling tired.
- b. Starchy foods should make up just over a third of the diet. Potatoes are a great source of fibre. Leave the skins on where possible to keep in more of the fibre and vitamins. Try to choose wholegrain or whole meal varieties of starchy foods, such as brown rice, and brown, whole meal or higher-fibre white bread. They contain more fibre (often referred to as "roughage"), and usually more vitamins and minerals than white varieties.
- c. It's advised to eat at least five portions of a variety of fruit and vegetables each day. They are a vital source of vitamins and minerals. People who eat at least five portions a day have a lower risk of heart disease, stroke and some cancers. For example, just an apple, banana, pear or similar-sized fruit, a large slice of

- pineapple or melon is one portion, three heaped tablespoons of cooked vegetables or pulses is another portion.
- d. It's especially important to get enough calcium in your diet, as it's vital for bone health. Good sources of calcium include milk and dairy foods, such as cheese and yoghurt, which also contain protein.
- e. With ageing, we need more protein as it plays a vital role in helping the body recover from illness, infections and surgery. Good sources of protein include beans, fish, eggs and meat. They also contain a range of vitamins and minerals.
  - i. Meat is a good source of iron, zinc and B vitamins especially vitamin B12.
  - **ii.** Try to eat lean cuts of meat and skinless poultry whenever possible to cut down on fat. Always cook meat thoroughly.
  - iii. Oily fish is also rich in omega-3 fatty acids.
  - iv. Aim for at least two portions of fish a week, including one portion of oily fish.
  - v. Nuts and seeds are also great sources of protein. Plain unsalted nuts are high in fibre and a good alternative to snacks high in saturated fat or sugar, but they still contain high levels of unsaturated fats, so eat them in moderation.
- d. Some fat in the diet is essential but should be limited to small amounts. It's important to get most of fat from unsaturated oils and spreads to help lower cholesterol. Too much saturated fat can increase the amount of cholesterol in the blood, which increases your risk of developing heart disease, while regularly consuming foods and drinks high in sugar increases your risk of obesity and tooth decay.

#### C. Exercise prescription

- a. Physical exercise helps to maintain a healthy weight, improves bone density, coordination and balance, muscle strength and joint mobility, lipid profiles, genitourinary problems, relieves depression, and induces sleep. Euphoria created with activity promotes her QOL.
- **b.** Combination of exercises, diet, and yoga helps the post-menopausal women to increase her metabolic rate and maintain a healthy weight.
- **c.** Social interactions either in an exercise program or otherwise, help the postmenopausal women to improve mood, relieve depression, and anxieties.

#### D. Immunization prescription

- a. Hepatitis B vaccination (HBV) is indicated for all unvaccinated adults at risk for HBV infection and all adults seeking protection from HBV infection including postexposure prophylaxis. The expert group of Association of Physicians of India recommends vaccination of the entire community at risk during an outbreak situation
- **b.** Two doses of varicella vaccine are strongly recommended in adults at increased risk for exposure of varicella

#### E. Pharmacotherapy

#### Complementary and alternative therapies

- a. Non-hormonal prescription agents may relieve Vasomotor (VMS) but have their own side effects. These can be considered when HRT is contraindicated or not desired. Complementary and alternative treatments should be advised with caution as the data is still insufficient, especially in moderate to severe VMS.
- b. Awareness should be created regarding the phytoestrogens and lycopene rich foods in the Indian diet.
- c. It is recommended to educate about the effects of locally used herbs in the Indian context that very little human data is available on the usefulness of these formulations and side-effects of the herbs have not been studied. It is important to read labels to determine isoflavone content and to warn them that in India, there are no regulations to ensure the content or quality of such products.

# Hormone Therapy (HT) for Post-menopausal Women

#### **Terminology**

- **a.** HT covers therapies including estrogens, progestogens, combined therapies, androgens, and tibolone.
- **b.** Terminology used in HT: HT, HT; ET; Estrogen progesterone therapy (EPT), EPT; and androgen therapy (AT).
- **c.** Indications for post-menopausal HT: symptom relief for VMS, urogenital atrophy, and bone.
- d. Patient characteristics that may be favourable for estrogen/androgen combination: Surgical menopause continued VMS despite estrogen replacement, decreased wellbeing despite estrogen replacement, and acquired sexual desire dysfunction.

#### Indications for HT

- a. VMS: Progesterones or Low dose oral contraceptive pills can be used in the menopause transition phase for relief of symptoms
- b. Urogenital atrophy: Vaginal ET is most effective. Low dose vaginal preparations are as effective as systemic therapy. Some women on oral ET may require additional local therapy Recurrent attacks of atrophic vaginitis require the use of the smallest effective dose over a period of time. After control of acute symptoms, the dose of local estrogen can be tapered for long-term maintenance therapy. Treatment may be continued indefinitely, although safety data from studies do not go beyond 1 year
- c. Osteoporosis: EPT/ET may be used for prevention and treatment of in the early postmenopause in symptomatic women unless there is a contra-indication. ET/EPT prevents all osteoporotic fractures even in low risk population, it increases lumbar spine BMD up to 7.6% and femoral neck BMD up to 4.5% over 3 years. It reduces the risk of spine, hip, and other osteoporotic fractures by 33-40%.

However, HT should not be started solely for bone protection after 10 years of menopause. Extended use of HT in women with reduced bone mass is an option after considering the risk benefit analysis compared to the other available therapies for osteoporosis. The bone protective effect is lost after stopping HT.

- **d.** POF or early menopause: HT should be offered, and it can be recommended until the age of natural menopause
- e. Depressive symptoms: Estrogen can be prescribed to enhance mood. The effect appears to be greater for perimenopausal symptomatic women than for postmenopausal women.
- f. Possible benefits include: Decrease in the risk for type 2 diabetes, decreases the abdominal obesity, protective effect on osteoarthritis, short term benefit on verbal memory when initiated soon after surgical menopause, reduces the neovascular macular lesions, in the early menopausal period improves QOL by its effects on vasomotor and urogenital symptoms, improvement on sleep, and mood.
- g. Breast cancer: Women who have general risk can be prescribed HT according to their need after a detailed history, examination, and counseling. They should be provided information about breast cancer risk with HT as per evidence. Women who are at highrisk also can be prescribed HT after risk benefit analysis. HT does not appear to influence the clinical pattern of benign breast disease in a postmenopausal woman. Use of HT in breast cancer survivors is debatable. It is recommended to use nonhormonal therapies.
- h. Women with cervix, ovary, and EC endometrial cancer can be given HT if needed.

#### HT use

- a. All preparations including low dose, non-oral routes of estrogen are effective in symptom control and in preserving bone mass. In women with hypertriglyceridemia, obesity, glucose intolerance, history of deep vein thrombosis, and tobacco users, nonoral route should be the preferred.
- b. Hormone Therapy given to women below the age of 60 or within 10 years of menopause, the risks are rare.

Classification of frequency of drug reactions according to WHO and CIOMS – The Council for International Organizations of Medical Sciences:

Very common > 1/10; common (frequent) > 1/100 and < 1/10; uncommon (infrequent) > 1/1000 and < 1/100; rare > 1/10,000 and < 1/100; and very rare < 1/10,000.

Harmful Effect: Based on WHO: number of excess events on HT vs. placebo per 10,000 women per year of HT use between the age group of 50–59 years

Disease	Estrogen	WHO/CIOMS definition of risk	Estrogen + progesterone	WHO/CIOMS definition of risk
VTE	4	Rare < 1/10,000 and < 1/1,00	11	Rare >1/10,000 and <1/1000
Stroke	1	Rare > 1/10,000 and < 1/1,000	4	Rare >1/10,000 and <1/1000
Breast Cancer			5	Rare >1/10,000 and <1/1,000
CVD			5	Rare >1/10,000 and <1/1,000

WHO: World Health Organization, VTE: Venous thromboembolism, CIOMS: CVD: Cardiovasular disease

Benefits: Based on WHO: Number of less events on estrogen versus placebo per 10,000 women per year of HT use between the age group of 50 years and 59 years

Disease	Number of less events with estrogens
Myocardial infarction	12
Breast cancer  Number of less events with E/E+P	8
Total deaths	10
Adverse events	18
Fractures	5
Colorectal cancer	6

E: Estrogen, P: Progesterone

#### Absolute contraindications of HT

Active endometrial and gynaecological hormone dependent cancers, active breast cancer, estrogen progestogen receptor positive cancers, known or suspected pregnancy, undiagnosed, abnormal vaginal bleeding, severe active liver disease with impaired/abnormal liver function, estrogen dependent venous thrombosis, and inherent increased risk of thromboembolism.

#### **Precautions**

- a. Progesterone in adequate dose should be supplemented along with oralestrogens in women with uterus. Progesterone supplement for endometrial protection is not needed along with the use of vaginal estrogen
- **b.** Estrogen alone is given in hysterectomized women
- c. Endometrial surveillance is not necessary in low risk asymptomatic woman. Unscheduled bleeding should be investigated by an ultrasound and endometrial biopsy
- d Pre-HT work-up and an annual follow-up are essential when prescribing HT. The dose and duration of use of HT should be individualized and a risk-benefit assessment carried out annually. A full gynaecological assessment is mandatory prior to starting HT and at regular intervals thereafter. Self-breast examination is advised monthly and CBE at least annually. Mammogram/US, where available should be carried out 1-3 yearly if the initial mammogram is normal.

#### **Duration of use**

- a. Premature menopause-HT can be prescribed up to the natural age of menopause; further continuation of therapy is a shared decision between the woman and the physician according to the indication and the need.
- b. Natural menopause: Safety data of EPT therapy with CEE+MPA is 3-5 years with ET safety data for use is 7 years of treatment with 4 years follow-up. Role of extended use of HT is a shared decision between the woman and the physician and may be considered in cases of recurrence of symptoms after stopping therapy, in cases of management of osteoporosis when other therapies are contraindicated (Grade A).
- **c.** Stopping HT: May be abrupt or the dose and duration may be tapered off gradually.

#### Potency and non-oral routes

- a. Minimum effective dose is the principle to be followed while prescribing HT. The potency needed by the woman may change over time. After starting standard dose therapy, dose can be lowered and maintained accordingly. Low dose and ultralow dose therapy are effective in relieving symptoms and increasing bone mass.
- b. Transdermal estrogen has a neutral effect on triglycerides, CRP, and sex hormone binding globulin and is preferable for use in women with hypertriglyceridemia, obesity, glucose intolerance, high-risk of deep vein thrombosis, and tobacco users.

#### HT and CVD

HT should not be prescribed for primary or secondary prevention of CVD. However, healthy women within 10 years of menopause tend to have a lower risk. HT increases VTE risk by 2- fold. Standard dose oral HT increased stroke risk by about one third in generally healthy postmenopausal women. Low dose ET may not increase the risk of stroke.

#### HT and BREAST CANCER

#### Estrogen alone

- a. Estrogen alone increases percentage mammographic density, not as much as estrogen and progesterone together. Estrogen increases the risk of breast cancer after more than 5 years of use, particularly in recently post-menopausal women
- **b.** Use of estrogen for less than 5 years may reduce the risk especially in women who start HT many years after menopause.

#### Estrogen + progesterone (E+P)

- a. E+P particularly with synthetic progesterones increase the risk of invasive breast cancer within 3-5 years of initiation and increases progressively beyond that time.
- **b.** Emerging data from 2 independent studies report that progesterone (micronized progesterone/dydrogesterone) with estrogen does not increase the risk if given for less than 5 years
- **c.** The risk returns to approximately that of non-users within 3 years of cessation

**Tibolone**: It reduces the risk of breast cancer in post-menopausal women. It increases the risk of breast cancer recurrences.

Raloxifene: It decreases the risk of development of breast cancer.

# Maximum benefits, minimum side-effects of HT can be achieved by judicious use

- a. Age of initiation: Ideally therapy begins within 10 years of menopause or below
   60 years of age "window of opportunity."
- **b.** Low dose: Use of low-dose estrogen with low-dose progestin when appropriate.
- **c.** Route of administration: Transdermal administration has reduced risk of blood clotting (VTE risk) compared to oral administration.
- **d.** Progestin: Side-effect profile of various progestins may play a clinical role in selecting the optimum treatment regimen. Natural progesterone is a choice.
- e. Tissue selective estrogen complex (TSEC): Newer formulations of combination therapy of estrogen and selective estrogen receptor modulators are soon to be available.

#### **Tibolone**

- a. Tibolone is a selective tissue estrogenic activity regulator. It is a synthetic steroid compound, which has estrogenic, progestogenic, and androgenic properties. It has an estrogenic effect on bone, inhibiting bone resorption by reducing osteoclastic activity.
- **b.** Tibolone is approved in 90 countries to treat menopausal symptoms and in 45 countries to prevent osteoporosis.
- c. Tibolone is effective in treating VMS and improves urogenital atrophy
- d. It improves mood and libido
- e. Tibolone is prescribed in a single daily dose of 2.5 mg orally. A lower dose of 1.25 mg has been found to be equally effective for most indications, including osteoporosis. It should be prescribed 1 year after amenorrhea
- f. Tibolone reduces the risk of vertebral and non-vertebral fracture in older osteoporotic women. Tibolone prevents bone loss and is as effective as standard doses of conventional post-menopausal HT. Tibolone increases lumbar spine and total hip BMD to a statistically significantly greater extent than Raloxifene

- g. It does not increase the risk of VTE and CVD events
- h It does not induce endometrial hyperplasia or carcinoma in post-menopausal women Tibolone may be preferable to HRT in symptomatic menopausal women with mammographically dense breast tissue
- Tibolone may be used as add back therapy with GnRH analogs for VMS and to maintain BMD
- j. Tibolone may be used in women with myomas and endometriosis.
- **k.** Tibolone should be used with caution in women over 60 years and should not be used in those who have strong risk factors for stroke

#### Selective estrogen receptor modulators

- a. Selective estrogen receptor modulators, e.g. Raloxifene at 60 mg daily improve and preserve bone density at the spine (2.6%) and hip (2.1%) after 4 years with a simultaneous reduction by 76% in the risk of invasive breast cancer.
- **b.** Antifracture efficacy on the hip is lacking (Grade A).
- c. Raloxifene has been shown to be beneficial in reducing new vertebral fracture risk by 69% in post-menopausal women with osteoporosis and 47% in postmenopausal women with osteopenia over 3 years (Grade A).
- **d** Raloxifene can be used as therapy for the prevention and treatment of osteoporosis especially for women with an increased risk of breast cancer
- e. Raloxifene and estrogen are associated with a similar increased risk of VTE. Other sideeffects include hot flushes, which are more likely in the perimenopausal period, and leg cramps.

#### **Economics of menopause management**

a. Indian health-care system is one of the most privatized systems where individual has to pay for health insurance. It is indeed very important to enrol in any of the good health insurance schemes for a secure future. Health-care insurance provides a cushion against medical emergencies. Most companies stop enrolment after 65-70 years of age.

- **b.** Menopause management is associated with significant direct and indirect costs.
  - i. Direct costs include physician's visits, specialist's visit and traditional pharmacotherapy or alternative and complimentary medicines modality.
  - ii. Indirect costs include laboratory testing, management of adverse events, loss of productivity at home and at work, and treatment of associated medical disorders.
- c. Menopause is a time of significant changes, which often have a negative impact on QOL. However, it is possible to live well with menopause. Adopting a healthy life-style is costeffective.

### Setting up a Menopause Program

#### At Community Level / DH / CHC

Constitution of IMW Committee at State Level under the State Health and Family Welfare Department

#### Identification of District/s

By State Director/State Programme Manager and IMS

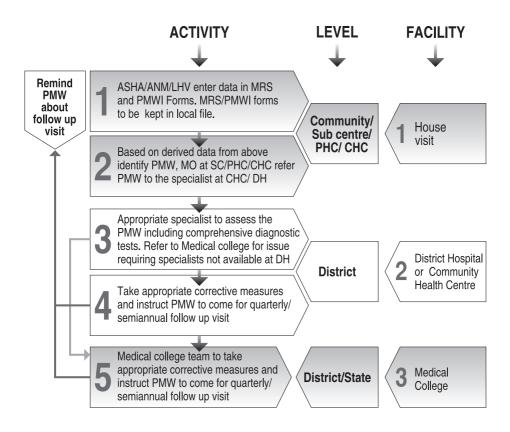
## **Training of Trainers at Selected District/s**

By State Programme Manager with resource persons

### **Training of Trainees**

By State Programme Manager with resource persons

## Implementation - Process Flow Chart



# Time Lines & Incentives Suggested (To be proposed by GOI/State)

Activity	Time Required	Time line Transaction Cost payment suggested	Incentive funding	Source of
Training of trainers – Medical officers at DH and CHC, DHO	1 day training			
Training of the ASHA, ANM and LHV	1 day training			
Interview of Menopausal women and collection of data of all women in the SC/PHC/CHC	3 months			
Referral of the PMW to the CHC /District Hospital / Medical College Simultaneous to interview Investigation, counseling, treatment and follow up	2 months/six monthly/ annual			

#### Note:

- The purpose of this project is to identify post menopausal women and refer them for appropriate counseling, investigation, and management.
- To sensitize healthcare service providers to medical conditions undergone by menopausal women.

#### Conducting workshops for training

- a. Prepare the agenda and arrange materials for the Workshop
- **b.** Select the District & sites (District Hospital and/or Community Health Centre) where IMW program is to be implemented

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- **c.** Letters from the DHS to go to District Hospitals and/or Community Health Centre program implementation sites.
- **d** Select and inform a point person at the district level.
- e. Letter to the medical and health officers working at selected centres for attending the workshop
- f. Arrangement of Workshop \*
  - \* Arrangement for state level workshop
  - a. Convener DHO
  - **b.** Venue decide, Suitable Training banner to be prepared and put up at the venue.
  - c. Participants No.: 30. Separate program for D-CMO, District nodal officer, OBGYN at DH, Block MOs and ANMs, ASHAs, LHVs, PHNs, Staff nurse, AWW etc as trainees.
  - **d** Agenda
  - e. Seating of participants with adequate spacing
  - f. Folder with diary and pen
- g. Computers, LCD projector, sketch pens, drawing sheets, (big), clip board , white board etc
- h. All the presentations as planned to be serially saved on the desk top of the computer
- Explain to the participants how to fill up data collection tools and what process to be followed for referral at community and district level
- j. In practice session MRS and PMWI forms to be given to participants for filling up.
- **k.** Presentation of each group on- difficulties encountered in filling up the forms, any suggestions, additions or omissions
- I. A live planned session (role-play) on interview with the women to be screened.

### Data Collection Tools

St	ate District
Da	te / / Form Serial Number
<u>P</u>	ost-Menopausal Women Interview Form
G	eneral Information
1.	Name:
2.	Age:
3.	Marital Status:
4.	If married, number of family members in household:
5.	Address:
6.	Residence:
	ral/Urban (a person residing in municipality area is considered urban and a rson residing in panchayat area is considered rural).
7.	Date and time of interview:
8.	Contact no:
9.	Educational status:
10	Occupation:
11	. Years spent in school:
12	Per capita family income:

#### **SECTION A**

1.	When was your last period?
	mm yy
	Age
	Year Month
2.	What was your age at the time of your last period?
	Years
3.	Do you have erratic periods?
Ye	s 1 / No 2
SI	ECTION B
То	bacco use
Re	sponse
1.	Do you currently use any tobacco products?
	such as beedi, cigarettes, snuff, pan, gutka or hookah?
	Yes 1 / No 2
2.	If yes Do you currently use tobacco products daily?
	Yes 1 / No 2
3.	How old were you when you first started using tobacco?
	Years
4.	Do you remember when was the last time you used tobacco?
	Don't remember
	Years Months Weeks

5.	On average, how many times do you use each day? (Record for each type)
	Cigarettes
	Beedi
	Snuff
	Hookah
	Pan/ Gutka/ Betel nut
Ex	panded Tobacco Use
1.	In the past, did you ever use tobacco daily
	Yes 1 / No 2
2.	If Yes, How old were you when you stopped using tobacco daily?
	Years
3.	Cigarette/beedi smoking (in pack-years)
	On an average for how many packs of cigarettes/beedis did you smoke and that too for how many years?
	Number Years
Αl	cohol
Α .	Have you ever consumed drink that contains alcohol such as beer/wine/whiskey. Or Arrack/Mahua/Tharra?
	Yes 1 / No 2
A1	b) Have you consumed alcohol within the past 12 months?
	Yes 1 / No 2

A2)	In the past 12 months, how frequently have you had at least one drink? (READ RESPONSES)				
	5 or more days in a week 1-4 days per week	ek			
	1-3 days a month Less than once a	n month			
A3)	When you drink alcohol on average how many Number of during one day?	Irinks do you have			
	Don't know				
A4)	During each of the past 7 days, how many standard drinks of any alcoholic drink did you have each day?				
	Monday Tuesday				
	Wednesday Thursday				
	Friday Saturday				
	Sunday				
Diet					
Which o	category do you belong to - Vegetarian / Non-vegetarian?	V / N			
Do you	use dairy products?	Yes 1 / No 2			
If Yes ho	ow many times in a week?				
Do you	have five servings of fruits and vegetables per day?	Yes 1 / No 2			
How ma	any days in a week do you take fruits?				
How ma	any days in a week do you take vegetables?				
-	Are you taking any dietary supplements such as calcium, vitamins?  Yes 1 / No 2				
Hypert	ension				
Have yo	ou ever checked your blood pressure?	Yes 1 / No 2			
If yes he	ow many days ago?				
What is	your known highest blood pressure?				

Do you experience headache?	Yes 1 / No 2
Do you have throbbing sensation in head?	Yes 1 / No 2
Do you have palpitation?	Yes 1 / No 2
Do you experience giddiness / vertigo?	Yes 1 / No 2
Diabetes	
Have you ever checked your blood sugar?	Yes 1 / No 2
If yes how many days ago?	
Have you experienced loss or gain in weight?	Yes 1 / No 2
Have you experienced increased frequency/ Burning sensation during micturition?	Yes 1 / No 2
Have you experienced increased hunger or thirst?	Yes 1 / No 2
Have you ever taken any anti diabetic drug?	Yes 1 / No 2
If yes for how long?	
Cancer	
Have you ever experienced spotting/ foul smelling discharge from the vagina?	Yes 1 / No 2
Have you experienced post menopausal bleeding?	Yes 1 / No 2
Have you ever experienced post coital bleeding?	Yes 1 / No 2
On self examination of the genitalia have you felt a lump or a wart or localized thickening of the skin??	Yes 1 / No 2
On self palpation of the breast have you felt a lump in the breast or localized thickening of the skin?	Yes 1 / No 2
Have you noticed any discharge from the nipple or retraction of the nipple?	Yes 1 / No 2
Do you experience discomfort or pain in abdomen?	Yes 1 / No 2

Do you experience nausea, vomiting or				
blood in the sputum or in the vomitus?	Yes 1 / No 2			
Have you passed blood in the stools?	Yes 1 / No 2			
I have able and discuss				
Hypothyroidism				
Do you experience lethargy or slowing down of physical activity?	Yes 1 / No 2			
Do you suffer from chronic constipation?	Yes 1 / No 2			
Do you have frequent hair fall or alopecia or dry skin	Yes 1 / No 2			
Orthopaedics				
0.1110pa04.100	ı			
Have any elderly family members experienced unexplained fractures or falls?	Yes 1 / No 2			
Have you at any time had a fall/ fracture?	Yes 1 / No 2			
Montal Haalth				
Mental Health				
Do you feel sad or depressed often?	Yes 1 / No 2			
Do you feel you are forgetting things?	Yes 1 / No 2			
Do you feel confused or unfocused?	Yes 1 / No 2			
Dhysical activity and Clean				
Physical activity and Sleep	ı			
How many days in a week you do physical activity like walking or yoga?				
Does your work involve mostly sitting or standing or vigorous activitywithout walking	Yes 1 / No 2			
How many hours in a week are you exposed to sunlight (sunrise to 10 am / 4 pm to sunset)				
Do you have difficulty initiating or maintaining sleep?	Yes 1 / No 2			

#### **SECTION C**

#### **Examination**

Height (cms)	
Weight (kg)	
Waist circumference (cms)	
Blood Pressure (Systolic / Diastolic )	
Blood Sugar (Fasting + Post Glucose 75gms (2 hrs.))	
Serum Lipid (on 12 hours empty stomach)	
Total Cholesterol	
HDL	
LDL	
Triglycerides	
Serum Creatinine	
CBC	
Vitamin D3	

#### **SECTION D**

#### **Menopause Rating Scale (MRS)**

Which of the following symptoms apply to you at this time? Please, mark the appropriate box for each symptom. For symptoms that do not apply, please mark 'none'.

<u>Data collection tool is to filled up for all cases along with Section D and kept together</u> with <u>Data collection tool.</u>

S.No	Symptoms	None	Mild	Moderate	Severe	Very Severe
	Score	0	1	2	3	4
1	Hot flushes (Episodes of sweating)					
2	Cardiac Discomfort (unusual awareness of heart palpitations, heartbeat skipping, heart racing, Chest tightness)					
3	Sleep problems (difficulty in falling asleep, difficulty in maintaining sleep, waking up early).					
4	Depressive mood (feeling down, sad, on the verge of tears, lack of drive, mood swings)					
5	Irritability (feeling nervous, inner tension, aggressive					
6	Anxiety (feeling restless, panicky, and fearful)					
7	Physical and mental exhaustion (general decrease in performance, impaired memory, decrease in concentration, forgetfulness)					
8	Sexual problems (change in sexual desire, in sexual activity and satisfaction)					

9	Bladder problems (difficulty in urinating, increased need to urinate, bladder incontinence)			
10	Dryness of vagina (sensation of dryness or burning in the vagina, difficulty with sexual intercourse)			
11	Joint and muscular discomfort (pain or stiffness in the joints or muscles, rheumatoid complaints)			

## Referral Slip

Name of referring	g facility:			
Address:				
Name of patient:				
Father's/Husband	d's Name:			
Contact Number:	:			
Address:				
Referred on	/	/	(d/m/yr) with chief complaint	
of				

Signature of referring physician/health functionary

(Name/Designation/Stamp)

## Monthly Reporting

#### ASHA / ANM / LHV / SC / PHC / CHC / DH / Facility

Name of the Area Health facility	
Month	Year
Name of State	Name of District:
Total Women population of the area	
Number of Women 45+ years old identifie	ed in reporting month
Number of Data form completed in report	ing month
Number of MRS form completed in report	ting month
Based on data form total Number of wom or 2 questions against the items as listed	en with below issues: (A "Yes" response to 1 in the data form should be listed here)
Hypertension	
Diabetes	
Cancer	
Hypothyroidism	
Orthopaedics	
Mental Health	
Sleep issues	

Total No of cases referred for management to higher facility	With issues of	
Hypertension		
Diabetes		
Cancer		
Hypothyroidism		
Orthopaedics		
Mental Health		
Sleep issues		

### Register Maintenance

#### ASHA / ANM / LHV / SC / PHC / CHC / DH / Facility

Please create a register to include all the details listed below.

Age at Last period (m/yr)

Name: Father/Husband's Name Marital Status: Age If married, number of family members in household: Address: Residence: Rural/Urban (a person residing in municipality area is considered urban and a person residing in panchayat area is considered rural). Date and time of interview: Contact no: Educational status: Occupation: Years spent in school: Per capita family income: Last Period (m/yr)

#### **Broad Menopausal Issue identified based on Data Form**

- Hypertension
- Diabetes
- Cancer
- Hypothyroidism

- Orthopaedics
- Mental Health
- Sleep issues
- Referred to 1st Higher center for Menopausal issue on Date d/m/yr
- Women Visited 1st Higher center for Menopausal issue on Date d/m/yr
- Reason for non-visit
- Referred to 2<sup>nd</sup> Higher center for Menopausal issue on Date d/m/yr
- Women Visited 2<sup>nd</sup> Higher center for Menopausal issue on Date d/m/yr
- Reason for non-visit
- Referred to 3<sup>rd</sup> Higher center for Menopausal issue on Date d/m/yr
- Women Visited 3rd Higher center for Menopausal issue on Date d/m/yr
- Reason for non-visit
- 1st Follow up with Women on
- 2<sup>nd</sup> Follow up with Women on
- 3<sup>rd</sup> Follow up with Women on
- 4th Follow up with Women on
- 5<sup>th</sup> Follow up with Women on
- 6<sup>th</sup> Follow up with Women on

# Acknowledgements for References used

The above guideline has been prepared using the materials taken from the following sources. We thank the authors, teams of these sources for the same.

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