



सत्यमेव जयते



National Guidelines for Screening of Hypothyroidism during Pregnancy



Maternal Health Division
Ministry of Health & Family Welfare
Government of India

December 2014

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लव वर्मा
सचिव
LOV VERMA
Secretary



भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Department of Health & Family Welfare
Ministry of Health & Family Welfare

Preface



The RMNCH+A programme is the cornerstone of the National Health Mission and provision of quality maternal health care services is an important component within the RMNCH+A strategy.

With improved service delivery and access to care, it is now time to expand the range of services provided and these guidelines are an important step in this direction. One of the essential components of maternal health programmes is to ensure that all pregnant women get a wide range of quality ante-natal care services with the ultimate goal of reducing maternal mortality and morbidity. The aim of these guidelines is to screen at-risk pregnant women for hypothyroidism, facilitating early diagnosis and treatment thereby reducing maternal, fetal and neonatal complications.

I appreciate the efforts of the Maternal Health Division of this Ministry in drafting these guidelines after a wide range of consultations. I am certain that Mission Directors and Programme Officers of all States will ensure wide dissemination of these guidelines and its implementation in our public health facilities.



(Lov Verma)



C.K. Mishra, IAS

Additional Secretary &

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Ministry of Health & Family Welfare
Nirman Bhavan, New Delhi - 110011

Dated: 17th November, 2014

Foreword



The National Rural Health Mission was launched in 2005 with reduction in MMR being one of its key goals. The National Health Mission, 2013 carries forward the goals and objectives on NRHM. When we look back, we see the tremendous progress we have made in improving maternal and neonatal health however, we are also mindful of the fact that a lot more needs to be done. It is in this context that the Ministry of Health & Family Welfare has brought out National Guidelines for Hypothyroidism in an endeavor to broaden the scope of ante-natal care services being provided across levels of care.

Whilst India is known to be a relatively iodine sufficient belt, iodine deficiency is still prevalent in certain geographical pockets. In addition to this, iron deficiency is common in India which contributes to hypothyroidism. The effects of hypothyroidism on maternal and fetal well-being are well documented. Early diagnosis and treatment of hypothyroidism are known to reduce maternal and fetal morbidity and improve neonatal well-being. Therefore, these guidelines for screening and treatment of hypothyroidism in pregnancy are a timely measure to address a gap in the services provision.

I also acknowledge the efforts of the Maternal Health Division particularly Dr. Himanshu Bhushan, Deputy Commissioner I/C who has brought together experts from across the country and ensured that the guidelines are comprehensive.

These guidelines are an invaluable tool for health care workers providing maternal health services. I am certain that proper use of these guidelines by all States and UTs in ante-natal clinics will bring about improved maternal and child health outcomes.

C.K. Mishra



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Foreword



Untreated hypothyroidism during pregnancy is associated with adverse effects for the mother and the baby. Hypothyroidism during pregnancy could result in abortion (especially in early pregnancy), recurrent pregnancy losses, anaemia, pre-eclampsia, gestational diabetes, abruptio placenta, postpartum hemorrhage, increased rate of caesarean sections due to fetal distress and in some cases myopathy and congestive heart failure.

Hypothyroidism results in preterm births, intrauterine growth restriction, intrauterine fetal demise, respiratory distress and increased perinatal mortality in newborns. It could lead to cognitive, neurological and developmental impairment as the thyroid hormone is critical for fetal brain development.

In view of the above, there was a acute need to have national guidelines for screening and treatment of hypothyroidism during pregnancy. The tireless efforts by the Maternal Health Division with support from technical experts from various institutes and development partners have enabled us in drafting of these guidelines for implementation across the country.

I hope that these comprehensive guidelines on screening for hypothyroidism in pregnancy will help in improving the scope and quality of ANC services being provided under the Mission and provide a stepping stone for improved maternal and child health in India.


(Dr. Rakesh Kumar)



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Programme Officer's Message



Routine ante-natal care is pivotal in reducing maternal death rates and miscarriages as well as birth defects, low birth weight, and other preventable health problems. Although access to routine ante-natal care has been steadily improving across the country, it is now time to expand the range of services being provided and screen for disorders like hypothyroidism and diabetes during pregnancy that are proven to adversely affect maternal, fetal and neonatal health.

In India, there are no universally accepted guidelines for screening of hypothyroidism and much of the evidence is in piecemeal. The present set of guidelines are comprehensive in scope beginning with areas of concerns, target population, screening and treatment protocols as well as operational aspects of the programme. There is a judicious mix of technical, programmatic and service provider's perspective while framing these guidelines.

I would like to express that these guidelines would not have been possible without the constant encouragement from Mr. C.K Mishra, AS&MD & Ms Anuradha Gupta, Ex AS& MD. Dr. Rakesh Kumar, Joint Secretary (RMNCH+A) headed the expert group meeting and gave valuable inputs in framing this guideline.

I would like to acknowledge the contribution of all members of the Expert Group in developing the content of these technical and operational guidelines. I would also like to acknowledge my colleagues in MH Division especially Dr. Dinesh Baswal, DC (MH) and development partner's for their valuable efforts and inputs in developing this document

It is hoped that these guidelines will be used optimally by Programme managers to update knowledge and skills of managers and service providers to enable them to implement this intervention successfully and at scale and thereby help in accelerating the decline of maternal and neonatal morbidity and mortality.

Himanshu Bhushan
12.12.14

(Dr Himanshu Bhushan)

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LIST OF ABBREVIATIONS

AMC	Annual Maintenance Contract
ANC	Antenatal Care
ANM	Auxiliary Nurse Midwife
ASHA	Accredited Social Health Activist
ATA	American Thyroid Association
AV	Audio Visual
CEmONC	Comprehensive Emergency Obstetric and Neonatal Care
CHC	Community Health Centre
CHF	Congestive Heart Failure
DPM	District Programme Manager
FT4	Free T4
Gol	Government of India
HMIS	Health Management Information Systems
IEC	Information Education Communication
IFA	Iron Folic Acid
ITS	Indian Thyroid Society
IUGR	Intrauterine Growth Restriction
JSSK	Janani Shishu Suraksha Karyakram
LHV	Lady Health Visitor
LT	Laboratory Technician

MC	Medical College
MCTS	Mother and Child Tracking System
MO	Medical Officer
NHM	National Health Mission
OH	Overt Hypothyroidism
OPD	Out Patient Department
PHC	Primary Health Centre
PNM	Perinatal Mortality
PW	Pregnant Women
RA	Rheumatoid Arthritis
RCH	Reproductive and Child Health
RCT	Randomised Control Trials
SCH	Subclinical Hypothyroidism
SLE	Systemic Lupus Erythematosus
SN	Staff Nurse
TOT	Training of Trainers
TPO	Thyroid Peroxidase Antibodies
TSH	Thyroid Stimulating Hormone
VHND	Village Health Nutrition Day
WHO	World Health Organization

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1. Introduction



Primary maternal hypothyroidism is defined as the presence of elevated Thyroid Stimulating Hormone (TSH) levels during pregnancy.



Hypothyroidism can be Overt (OH) or Subclinical (SCH). In overt hypothyroidism, S.TSH levels are elevated and S.T4/Free T4 (FT4) levels are low. S.TSH \geq 10mIU/l is taken as OH irrespective of FT4 levels. In SCH, the TSH level is elevated (\leq 10mIU/l) with normal Serum T4/FT4.

Positive thyroid antibody titers suggest autoimmune thyroid disease. Euthyroid patients with positive Thyroid Peroxidase Antibody (TPO) titers have high chances of developing hypothyroidism.

The foetus is dependent on maternal trans-placental thyroid hormone supply in the first trimester. This, along with other factors, leads to an increased thyroid hormone demand during pregnancy. To meet the increased demands, the thyroid hormone production increases by 50%.

India is known to be a relatively iodine sufficient belt, however, iodine deficiency is still prevalent in certain pockets like the hilly regions and foothills. Moreover, iron deficiency is common in India, and this also contributes to hypothyroidism. Autoimmune thyroiditis contributes significantly towards hypothyroidism in iodine sufficient regions and may be associated with other autoimmune disorders.

1.1 Consequences of untreated hypothyroidism

Untreated hypothyroidism in pregnancy is associated with adverse maternal effects. During pregnancy, it is known to result in miscarriages (in early pregnancy), recurrent pregnancy losses, anaemia, pre-eclampsia, gestational diabetes, abruptio placentae, postpartum haemorrhage, increased caesarean sections due to fetal distress, and rarely myopathy and even congestive heart failure (CHF) in severe cases.

Hypothyroidism results in preterm births, intrauterine growth restriction, intrauterine fetal demise, respiratory distress and increased perinatal mortality (PNM). In newborns, it leads to cognitive, neurological and developmental impairment. Thyroid hormone is critical for fetal brain development.

2. Evidence

2.1 International evidence

The estimated prevalence of hypothyroidism in pregnancy is 2-3%. Of these, 0.3-0.5% is OH and 2-2.5% is SCH. Studies have demonstrated 60% risk of fetal loss and 22% risk of gestational hypertension with untreated OH. A firm association between OH and adverse risk to the maternal-fetal unit has been demonstrated. The miscarriage rate in SCH is 6% vs 3.6% in euthyroid women. A two-to threefold increased risk of pregnancy-related complications was demonstrated in untreated women with SCH.

American Thyroid Association's (ATA 2011) recommendation is neither for nor against universal screening in the first trimester. It recommends treatment of OH (TSH > trimester specific values with low T4 or TSH > 10 irrespective of T4) and SCH with positive TPO antibodies. ATA also recommends regular TSH monitoring of euthyroid TPO positive pregnant women (PW) throughout pregnancy. SCH in PW who have not been treated initially should be monitored every 4 weeks with serum TSH and FT4 approximately, until 16–20 weeks of gestation and at least once between 26 and 32 weeks gestation.

The Endocrine Society (2012) does not recommend universal screening of all PW but encourages TSH in "high risk" individuals and low dose thyroxine to target TSH to <2.5mIU/l. It recommends repeating the screening in the second trimester if initial screening is normal. The Cochrane Review 2013, of four randomised control trials (RCTs), concludes that levothyroxine treatment may benefit asymptomatic PW with low thyroxine levels. However, some

studies have shown that limiting screening to “high risk” groups will miss out 30% women with overt or SCH (Vaidya B et al 2007). Till date, universal screening has not been demonstrated to result in improved population outcomes. No recommendations have been given from World Health Organization (WHO) regarding thyroid screening in pregnancy.

2.2 National evidence

Prevalence of hypothyroidism in pregnancy in the Indian population is 4.8-12%. Reported prevalence by Sahu et al 2010 was 6.47% with 4.58% as OH. Another Indian study has reported the prevalence of hypothyroidism to be 12%, of which 3% was OH and 9% was SCH. TPO antibodies are positive in around 50% pregnant women in SCH, as compared to 7% in euthyroid pregnant women.

Incidence of hypothyroidism in women with recurrent pregnancy loss up to 12 weeks is 4.1-16.6%. The miscarriage rate in SCH is 12-21%, while in OH, it is 21%. The rate of stillbirth is 0-16.6% for SCH and 4.2% for OH. The incidence of pre-eclampsia has been reported as 16% for OH and 22% for SCH. The incidence of abruption placentae is 16% for OH and 5% for SCH. Intrauterine Growth Restriction (IUGR) prevalence is 25% in OH and 8% in SCH, while the incidence of pre-term delivery is 33% with OH and 11% with SCH.

Indian Thyroid Society (ITS) recommends screening of TSH levels in all PW at the time of their first visit, ideally during pre-pregnancy evaluation or as soon as pregnancy is confirmed, although evidence for this is limited from studies that have already been carried out.

2.3 Universal vs high risk approach for screening

Universal screening has not been recommended till now in any country due to paucity of data and most of the available guidelines recommend screening of high-risk PW.

2.4 Need for national guidelines

Evidences shown above are in pieces and there is no standard protocol that is being followed in the country for screening and treating hypothyroidism in pregnancy. There was, therefore, a need to develop national guidelines.

For this purpose, an expert group was constituted drawing a panel of experts (obstetricians, endocrinologists and public health specialists) to formulate guidelines for the country.

3. Technical guidelines for screening and treatment of hypothyroidism in pregnancy

High risk factors for hypothyroidism

- Residing in an area of known moderate to severe iodine insufficiency (according to area mapping)
- Obesity (pre-pregnancy/first trimester Body Mass Index (BMI) ≥ 30 kg/m²) [BMI= weight in kg/height in m²]
- History of prior thyroid dysfunction or prior thyroid surgery
- Symptoms of thyroid dysfunction or the presence of goiter
- History of thyroid dysfunction in first degree relative (parents/siblings/ children)
- History of diagnosed mental retardation in family/previous births
- Known case of autoimmune diseases like Type I diabetes/Systemic Lupus Erythematosus (SLE)/Rheumatoid Arthritis (RA)/Addison's disease/Coeliac disease, etc.
- à History of recurrent miscarriages, pre-term delivery, intrauterine demise, pre-eclampsia/eclampsia, abruption placentae
- History of infertility (inability to conceive after one year of unprotected intercourse)
- Use of amiodarone or lithium, or recent administration of iodinated radiologic contrast



AIM

To reduce maternal morbidity and serious complications during pregnancy and childbirth



OBJECTIVE

To reduce maternal, fetal and neonatal complications associated with hypothyroidism by screening PW at risk for hypothyroidism.

To reduce the burden of complications due to hypothyroidism during pregnancy through early diagnosis and treatment.

3.1 Target population

Screening for hypothyroidism is recommended in high risk PW.

3.2 Diagnostic criteria in pregnancy

TSH levels during pregnancy are lower as compared to TSH levels in a non-pregnant state. Pregnancy-specific and trimester-specific reference levels for TSH are as follows:

Ist trimester - 0.1-2.5mIU/l; IInd trimester - 0.2-3mIU/l; IIIrd trimester - 0.3-3mIU/l.

Hence, in pregnancy, SCH is defined as a serum TSH between 2.5 and 10mIU/L with normal FT4 concentration and OH is defined as serum TSH>2.5-3mIU/l with low FT4 levels. TSH>10mIU/l irrespective of FT4 is OH.

3.3 Methodology for Diagnosis

- **Blood/sample collection:** Venous blood samples should be taken with other antenatal care (ANC) investigations in a single sitting
- **Equipment:** Auto-analyser/semi auto-analyser
- **Analysis:** Samples will be analysed using Chemiluminiscence assay/auto-analyser/semi auto-analyser

3.4 Protocol for management of hypothyroidism

→ **Drug of choice for treatment is Levothyroxine.**

Levothyroxine Sodium is available in market as 'tablets' in different strengths. Levothyroxine is to be taken orally, in the morning empty stomach, The patient should be asked not to take anything orally for at least half an hour after intake of the medicine.

The strength required for this programme is 25, 50, 100 µg. It has to be supplied in moisture tight packages and should be stored as room temperature. Exposure to direct sun light or heat should be avoided at all times

Levothyroxine Sodium belongs to category A for use during pregnancy and can be used safely during pregnancy and lactation without any adverse effect on mother or fetus.

Important Note

- If dose is missed on one day, the patient may take the same as soon as she remembers and should not eat anything for the next half hour
- If she misses the tablet altogether, she should take double the dose on the next morning
- A complete bottle of Levothyroxine tablets to be provided to patients (25/50/75/100 mcg)

- Contraindications – nil
- **Side effects of treatment** – in the suggested/recommended doses, this drug does not have any side effect.

Treatment Plan:

- Treatment plan is given in flow chart on next page.
- All treatment steps are based on S. TSH level.

- If TSH level is <2.5 in first trimester and <3 in second and third trimester, no further management is required and pregnant woman will continue routine pregnancy care
- If TSH is between 2.5/3 to 10, PW will be started on 25 μg of levothyroxine per day
- If TSH is >10 , PW will be started on 50 μg of levothyroxine per day
- If initial TSH was less than 10, treatment is to be stopped after delivery but if it was >10 , treatment will continue in same dose after delivery.
- If PW is already taking treatment before this pregnancy, treatment will continue during pregnancy with same target range.
- Once treatment has started, TSH levels should be repeated after 6 weeks of starting date of treatment
- Dose of thyroxine should be adjusted depending upon TSH levels

TSH level	Current dose	Increase to
First Trimester		
>2.5	25	50
>2.5	50	75
>2.5	75	100
>2.5	100	125
Second/Third trimester		
>3	25	50
>3	50	75
>3	75	100
>3	100	125

- Target range of TSH to be kept on follow-up after starting treatment
- In first trimester – TSH should <2.5
- In second/third trimester – TSH should <3
- At all times, TSH <0.1 should be avoided by decreasing the dose

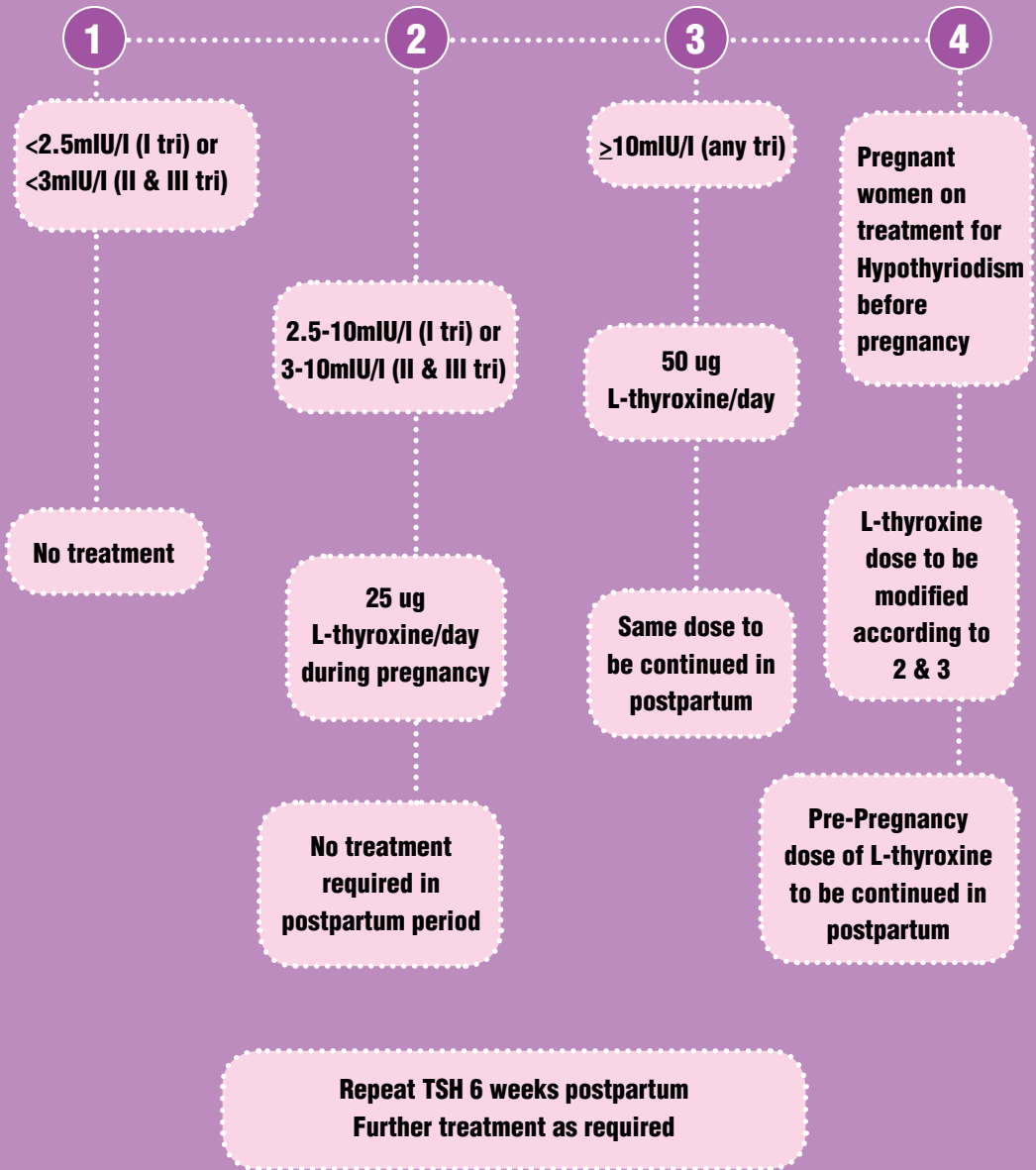
If TSH is less than 0.1, treatment should be decreased as given below:

TSH level	Present dose	Change to
<0.1	50	25
<0.1	75	50
<0.1	100	75
<0.1	25	12.5

Treatment Delivery

- Adequacy of hypothyroid treatment will be monitored by repeat TSH after 6 weeks of initiation of treatment and dose will be titrated accordingly. Once the dose is titrated, women may follow up at the concerned Community Health Centre (CHC)/Primary Health Centre (PHC) to get the next packet of Levothyroxine tablets.
- Levothyroxine treatment is to be started by physician/specialist at DH/MC or any facility that fulfills the prerequisite criteria of implementation.
- Deliver uncomplicated cases at PHC/CHC under supervision of Medical Officer (MO).
- Refer cases with associated complications at a higher centre for delivery under the supervision of an obstetrician.
- Postpartum treatment will be continued at recommended doses for those with TSH>10mIU/l.
- For women with TSH between 3-10mIU/l, treatment to be discontinued after delivery.
- Women diagnosed with hypothyroidism before pregnancy and on treatment to resume pre-pregnancy doses after delivery. TSH to be repeated 6 weeks postpartum and further treatment to be done accordingly.

Flow Chart for Treatment of Hypothyroidism in Pregnancy and postpartum period based on S.TSH Values



4. Operational aspect of the programme

4.1 Level of implementation

The current programme shall be rolled out in a phased manner

Phase 1: Medical Colleges

Phase 2: District Hospitals (DHs), CHCs, PHCs – before scaling up to DH/CHC/PHCs, states need to analyse outcomes of the programme implementation at the medical college levels.

States with infrastructure capabilities/resources may implement this programme at DHs and CHCs earlier (with Phase 1) if feasible at the facilities fulfilling the prerequisite criteria.

4.2 Selection of facility

- States are free to choose the number of districts where the programme will be implemented
- A health facility chosen for implementation of programme should have all the pre-requisites in place

4.3 Pre-requisites for health facility appropriate for programme implementation

- Specialist/Obstetrician/Physician
- Chemiluminescence assay system/auto-analyser
- Good quality referral linkage
- Single point sample collection clubbed with ANC investigations
- Availability of drugs
- The service provider and programme officer must be oriented and trained about the programme

4.4 Strategy for implementation

- All high risk PW attending ANC out patient department (OPD) shall be screened for hypothyroidism at the first antenatal visit
- Treatment to be instituted by treating obstetrician/physician

- Patients coming from the periphery may be followed-up by the obstetrician/physician/MO at their concerned CHC/PHC and cases with associated medical/obstetric complications would be referred to Physicians/Obstetricians at Medical College (MC)/District Hospital (DH)
- Deliver uncomplicated cases at PHC/CHC under the supervision of MO
- Refer cases with associated complications at the higher centre for delivery under supervision of obstetrician.

4.5. Role of health personnel at different levels of health facility

Village/Village Health Nutrition Day (VHND)/Sub-centre

- Accredited Social Health Activist (ASHA)/Auxiliary Nurse Midwife (ANM) - To identify pregnant women at risk for hypothyroidism and mobilise and counsel them for timely testing and follow up

PHC/corresponding urban centre/CHC

- MO/Staff Nurse (SN)/ANM/Laboratory Technician (LT) to undertake activities as per their training and defined jobs
- Identification/counselling/testing for hypothyroidism
- Medical management with Levothyroxine
- Refer PW with hypothyroidism and associated medical/obstetric complications to physician/obstetrician at MC/DH
- Monitor adequacy of hypothyroid treatment by repeat TSH after 4-6 weeks of initiation of treatment and titrate dose accordingly
- Deliver uncomplicated cases at PHC/CHC under supervision of MO Refer cases with associated complications at the higher centre for delivery under supervision of obstetrician
- Continue postpartum treatment at recommended doses for those with TSH>10mIU/l.
- Maintaining records, monitoring and follow up

Level III:

A) DH and all Comprehensive Emergency Obstetric and Neonatal Care (CEmONC) centres

- All jobs as defined under Level II
+
- Specialist/Gynaecologist/MO: management of all types of complicated cases

B) MC and other Super-speciality centres

- Comprehensive management of pregnancy with hypothyroidism including all referral cases

Community linkages

- ASHAs and ANMs are the key persons connecting PW in the community with health facilities, and therefore, they have an important role in detection and follow up of PW diagnosed with hypothyroidism.
- Testing for hypothyroidism for high risk PW should be an integral part of existing ANC.
- PW diagnosed with hypothyroidism should be monitored during ANC as per the advice of the treating doctor and in the post natal period, as defined under follow up protocol.
- In case of any complication or for delivery of PW with hypothyroidism, referral facility under *Janani Shishu Suraksha Karyakram* (JSSK) should be made available.
- ANM and outreach workers from sub centre/PHC should periodically visit all those mothers on treatment for hypothyroidism in their area and ensure that they follow the advice of the medical management.
- MOs at PHCs should make sure that periodic visits are made as per schedule by PW diagnosed with hypothyroidism and that there are no dropouts.
- In case a pregnant woman who has been diagnosed with hypothyroidism is moving out of the area, a detailed report should be given to her regarding the management plan so that she is able to follow up and continue her treatment wherever she goes.
- She should be tracked through Mother and Child Tracking System (MCTS) and the concerned District Programme Manager (DPM) should be informed by the doctor/designated officer who had been treating her about her migration along with the duly filled in migration form.

4.6 Capacity building of health personnel

Activity	General orientation about programme including awareness & Information Education Communication (IEC)	Counselling and motivation	Knowledge and skills for testing For hypothyroidism	Medical management (Levothyroxine therapy)	Maintaining records & follow up
Health personnel					
ASHA	√	√			√
ANM/SN/ Lady Health Visitor (LHV)	√	√			√
LT			√		√
MO	√	√		√	√
Ob/ Gyn and Specialist	√	√		√	√
State/ District Programme Manager & Facility in-charges	√				√

4.7 Training/Orientation

Key points & topics to be covered

- General orientation about programme including awareness and IEC
 - Counselling and motivation
 - Knowledge about the importance of iodine/iodised salt in diet, iodine rich food, role of iodine in the prevention of thyroid disorders in pregnancy
 - Benefits of iodine and possible adverse effects if adequate iodine is not taken
 - Consequences of uncontrolled hypothyroidism in pregnancy
 - Knowledge and skills for testing of hypothyroidism using semi- auto-analyser/auto-analyser (Chemiluminiscence assay)
 - Medical management:
 - When and how to initiate Levothyroxine therapy and titration of dose
 - When and how to administer Levothyroxine tablets specially in relation to meals
 - Importance for regularity and compliance
 - Referral of a case with complications to a higher facility
 - Maintaining records & follow up
- When and how to administer Levothyroxine tablets specially in relation to meals
 - Importance for regularity and compliance
 - Referral of a case with complications to a higher facility
 - Maintaining records & follow up
- Programme manager and Facility in charge/ASHA/ANM/SN/LHV/LT/MO/Ob-Gyn (one day orientation either separate or can be included with any other training)



Batch size

- Stand-alone training for hypothyroidism might not be needed and the orientation programme can be done during existing review meetings at state/district/blocks/PHCs or can be combined with any other training programme
- If separate training is to be organised, one batch can have 50-100 trainees from all cadres
- One batch of trainees will consist of
 - Programme manager
 - ANM/SN/LHV
 - MO/Ob-Gyn
- District Training In-charge will accordingly prepare training plan and calendar
- ASHA to be trained separately during any ongoing training programme.

Training site

Prerequisites:

- Seminar/Conference Room with a capacity of around 100 participants
- Audio visual (AV) aids and other training aids

Any DH/CHC which has the above prerequisites/ is able to arrange the above prerequisites can be chosen as a training site

Trainer

- Ob-Gyn, Physician/ Endocrinologist to be included as Trainers as per their availability and area of expertise
- Half day Training of Trainers (TOT) should be organised for 20-25 Trainers at the state level

Training material

- Government of India (GoI) guidelines on hypothyroidism
- Any other teaching or training material synchronised with GoI guidelines



5. Key points

- Screen all PW at risk for Hypothyroidism
- Treat if TSH value is above the defined upper limit for the specific trimester (2.5mIU/l for first and 3mIU/l for second and third trimesters)
- Levothyroxine 25µg/day for TSH between upper limit and 10mIU/l and 50µg/day for TSH>10mIU/l
- Repeat TSH after 4-6 weeks to assess response
- Specialist referral required only for women with associated complications
- Postpartum treatment to continue in women with TSH>10mIU/l

6. Records and registers

- Reporting of Pregnancy with Hypothyroidism should be synchronised with MCTS/Health management Information Systems (HMIS)/Reproductive and Child Health (RCH) portal for reporting purpose
- Health personnel at various levels should keep/maintain records as defined under the programme for various levels as indicated below:
 - Monthly Pregnancy with Hypothyroidism Reporting Format for State and District programme managers (Annexure 3)
 - Monthly Pregnancy with Hypothyroidism Reporting Format for Health Facility (Annexure 4)
- Use of SMS and mobile phones may be promoted for collection of information/data regarding Pregnancy with Hypothyroidism.

7. Monitoring and quality assurance

State and district programme managers to ensure:

- Constant supply of Levothyroxine and its distribution
- Timely completion of training
- Periodic evaluation of technical skills of LT
- Include Pregnancy with Hypothyroidism in state IEC plans
- Monitoring the outcome and progress

8. Outcome measures to be assessed

- Number/percentage of PW who tested positive for hypothyroidism out of total ANC
- Number/percentage of PW with hypothyroidism requiring referrals for further management, out of the total number diagnosed as Pregnancy with hypothyroidism

9. Budget

- Infrastructure: any additional infrastructure not required
- Human resource: no separate human resource required
- Equipment/Instruments:
 - i. Auto-analyser or Semi auto-analyser
- Reporting forms:
 - i. Monthly hypothyroidism reporting format for State and District Programme Managers (Annexure 3)
 - ii. Monthly hypothyroidism reporting format for Health Facility (Annexure 4)
 - iii. Migration form for PW with hypothyroidism (Annexure 5)

Case load for hypothyroidism programme

1. In India, the prevalence of hypothyroidism has been reported between 4.8% to 12%. For calculation purpose it has been taken as 10%.

Budget estimates and provision for the following needs to be done by the state/district programme officer

1. Levothyroxine

Out of the total number of screened PW, 10% can be diagnosed hypothyroid positive. Two full bottles of 100 tablets shall be given to each positive patient needing treatment.

2. Provision of Auto-analyser or Semi auto-analyser

- In the first year, medical colleges/DHs are expected to have Chemiluminiscence assay/auto-analyser/semi auto-analyser equipment, therefore, no such equipment will be provided in Phase 1. However, if there is any gap, budget provision for purchase of equipment to be done.
- One Chemiluminiscence assay/auto-analyser/semi auto-analyser can be provided to CHCs and PHCs in Phase 2. Gap assessment to be done and the budget estimate to be indicated in the Project Implementation Plan (PIP).
- Before procuring new equipment, availability of the existing auto-analyser/semi auto-analyser through a regular programme needs to be accounted for.

Training

One day orientation/training can be organised. Stand-alone training is not required. This can be part of any other ongoing training or can be held during state/district/block review meetings.

Note

- Every district programme officer needs to undertake advanced planning and budget estimates for universal screening of hypothyroidism in the district
- State programme officer needs to reflect the budgetary requirement either in the state or National Health Mission (NHM) PIP
- Necessary equipment/supplies, either cash or in kind, needs to be made available in advance to all health facilities in the district.
- Any procurement should be done through competitive and transparent bidding.
- Certification by the manufacturer for meeting the requirement of specifications and variations, if any, by comparing the results from a regularly calibrated auto-analyser for precision and accuracy needs to be clearly mentioned for auto-analyser supplied
- Process of standardisation of auto-analyser also needs to be mentioned in the manufacturer's certificate
- Wherever applicable, annual maintenance contract (AMC) should be in built against all major procurements

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Annexure 1: Effect of Hypothyroidism on Pregnancy

Deficiency of thyroid hormone in pregnancy can lead to

- Miscarriage
- Hypertension or fits during pregnancy
- LBW baby
- IUD
- Preterm birth
- Respiratory distress and consequent hospitalisation
- Possibility of a birth defect or low IQ baby
- Excessive bleeding during delivery



**Follow the advice of your
doctor or health worker**

**Have a healthy mother and a
healthy baby**

Annexure 2: High Risk Factors for Hypothyroidism

It you have one of the following symptoms then you may be suffering from thyroid hormone deficiency

- Have you been treated for thyroid or operated?
- Is your area iodine deficient or are you a resident of a hilly area?
- Was your baby born with medical intervention or treatment?
- Are you overweight?
- Are you diabetic?
- Have you had a miscarriage?
- Did you suffer from or experience intrauterine death (IUD)?
- Have you experienced hypertension in earlier pregnancy or have you suffered from fits?
- Have you experienced early rupture of membrane in earlier pregnancy?
- Does any child or member of your family have low IQ?
- Are you undergoing radiotherapy for any disease?
- Have you ever been administered iodine or lithium dye?

Annexure 3: Reporting Format at State and District level

Monthly Pregnancy with Hypothyroidism Reporting format for State & District Programme managers for month of, year

Name of State:

Name of District:

Estimated no of Pregnant Women:

No of deliveries:

Total no of ANC conducted (including all 4 ANC visits) in reporting month:

No of new cases of Hypothyroidism in pregnancy diagnosed in the reporting month:

Please indicate category of high risk and no. identified against each in the reporting month

No of new cases of Hypothyroidism in pregnancy on treatment in the reporting month:

Cumulative no of cases of Hypothyroidism in pregnancy on treatment in the reporting month:

Supplies (Levothyroxine) available in all districts- Yes/No

Whether Chemiluminiscence assay for TSH evaluation available in all districts- Yes/No

If No, identify district & reflect requirement in PIP

Note:

Districts will report to their States

Information will be compiled at State level for sending information to GOI

Annexure 4: Reporting Format at Health Facility level

Monthly Pregnancy with Hypothyroidism Reporting Format for Health Facility

Name of the Health facility: Month: Year:.....

Name of State:

Name of District:

Total no of deliveries:

Total no of ANC conducted (including all 4 ANC visits) in reporting month:

No of new cases of Hypothyroidism in pregnancy diagnosed in the reporting month:

Please indicate category of high risk and no. identified against each in the reporting month

No of new cases of Hypothyroidism in pregnancy on treatment in the reporting month:

Cumulative no of cases of Hypothyroidism in pregnancy on Levothyroxine therapy in the reporting month:

No of cases of Hypothyroidism in pregnancy referred for management to higher facility:

Whether adequate supplies (Levothyroxine) were available throughout the month at reporting facility - Yes/No

Whether Chemiluminiscence assay for TSH evaluation available in all districts- Yes/No

If No, indicate requirement:

Note:

Facility will send report to the District

Information will be compiled at District level for sending information to State

Annexure 5: Migration Form

Migration form for PW with Hypothyroidism

Name:

Husband's/Father's Name:

Present Address:

Health Facility attended:

Migration Address:

Address of Health Facility to be attended:

Diagnosis of Hypothyroidism (indicate category of high risk):

Date

Period of gestation: weeks

Treatment given:

Information about migration given to:

Name:

Designation:

Mobile no/Telephone no:

Place of work:

Signature of Doctor

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Notes

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