**Institution Name:** Directorate General of Primary Health Care, MOH

**Document Title:** Congenital Hypothyroidism Guidelines for Neonatal Screening and Management

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Congenital Hypothyroidism
Guidelines for Neonatal Screening and Management

Second Edition
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Department of Woman and Child Health
Directorate General of Primary Health Care
Ministry of Health
Sultanate of Oman
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Department of Woman and Child Health
## ACRONYMS:

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>ACTH</td>
<td>Adrenocorticotropic hormone</td>
</tr>
<tr>
<td>BBA</td>
<td>Born Before Arrival</td>
</tr>
<tr>
<td>BFFP</td>
<td>Birthing Facility Focal Point</td>
</tr>
<tr>
<td>BP</td>
<td>Blood pressure</td>
</tr>
<tr>
<td>CH</td>
<td>Congenital hypothyroidism</td>
</tr>
<tr>
<td>DWCH</td>
<td>Department of Women &amp; Child Health</td>
</tr>
<tr>
<td>EPI</td>
<td>Expanded Program of Immunization</td>
</tr>
<tr>
<td>FSH</td>
<td>Follicle-Stimulating Hormone</td>
</tr>
<tr>
<td>FT4</td>
<td>Free thyroxine</td>
</tr>
<tr>
<td>IV</td>
<td>Intravenous</td>
</tr>
<tr>
<td>LH</td>
<td>Luteinizing hormone</td>
</tr>
<tr>
<td>MD</td>
<td>Medical Doctor</td>
</tr>
<tr>
<td>mg</td>
<td>Milligram</td>
</tr>
<tr>
<td>ml</td>
<td>Milliliter</td>
</tr>
<tr>
<td>mm</td>
<td>Millimeter</td>
</tr>
<tr>
<td>MO</td>
<td>Medical Officer</td>
</tr>
<tr>
<td>PEAS</td>
<td>Performance Evaluation Assessment Scheme</td>
</tr>
<tr>
<td>TBG</td>
<td>Thyroxine-Binding Globulin</td>
</tr>
<tr>
<td>TFT</td>
<td>Thyroid function Test(s)</td>
</tr>
<tr>
<td>TSH</td>
<td>Thyroid-Stimulating Hormone</td>
</tr>
<tr>
<td>TSH-R</td>
<td>TSH Receptor</td>
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<tr>
<td>μg</td>
<td>Microgram</td>
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PREFACE

The Ministry of Health of Oman (MOH) is committed to continue its efforts towards further reducing under five morbidity and mortality, through improving existing services and initiating new services, based on the identified needs. Congenital anomalies, genetic and metabolic disorders are recognized as major contributors to child morbidity and mortality in Oman. Many of the inherited disorders can be prevented and reduced through newborn screening and early intervention. This is in conjunction with other services such as preconception care and counseling that can help individuals in making informed decisions. Congenital hypothyroidism (CH) is one of such disorders that when recognized and treated early, long-term impacts of it in the form of poor mental and physical development can be prevented. Hence, considering the rewarding outcomes of preventing the conditions through an early screening and intervention, the Department of Woman and Child Health (DWCH) has launched a national screening program for congenital hypothyroidism.

Since 2005, all newborns are screened at birth through a blood sample collected from the umbilical vein in the hospital and through capillary blood sample for babies born outside hospital (approximately 2%). TSH concentration of 40 mIU/L was identified as a suitable cut off value for re-call of babies in the regular CH screening. Since launching the screening service, the program has gone through an evaluation process, and areas for improvement were recognized. Hence, the following guidelines and flow charts have been updated in order to address arising issues starting from blood sample collection, dispatch, retrieving tests, clearly specifying roles and responsibilities of providers at each level of health care level, counseling parents and follow up management of the detected cases, and finally documenting and reporting to DWCH.

I must express that apart from the great efforts of staffs of DWCH, several literature reviews on the latest evidence-based recommendations on screening for CH, many clinician’s inputs have gone into the updating of this guideline. Therefore, we request all health care providers to make the best use of the guidelines.
CHAPTER 1: INTRODUCTIONS, SCOPE, PROCESS, DEFINITIONS
1.1 INTRODUCTION
Congenital hypothyroidism occurs at an incidence of one case in every 3,000 to 4,000 births in most geographic areas of the world. Late detection in the neonatal period may result to mental retardation and poor physical development of the child. Considering the feasibility of preventing CH through early screening and intervention, many countries have initiated a routine screening program which in found to be cost effective. Following the pilot study conducted in Oman in 2004, the MOH of Oman initiated a National Neonatal Screening Program for CH in 2005. To evaluate the functioning of the systems and services, Performance Evaluation Assessment Scheme (PEAS) was carried out in the year 2008. The objective of the evaluation was to identify deficiencies and rectify them. Although the evaluation indicated an overall efficiency of the system, it also highlighted the need for greater elaboration in the guidelines on: the protocols, documentation and data accumulation and summation, and parental counseling, communication and education. Therefore, the guidelines need to be updated regularly to address the above issues.

The development of these guidelines has taken place in perspective of recent literature review on the latest evidence-based recommendations on CH screening, followed with a review by a panel of national experts including the National Laboratory Medicine Committee. As well as, a feedback from the National Health Service Screening programs, using Newborn Blood Spot for CH Initial Clinical Referral Standards and Guidelines as documented from the British Society for Pediatric Endocrinology and Diabetes; 2013 (revised in Jan 2016) was considered particularly with their evidence on screening program based on neonatal blood TSH.

These guidelines cover MOH policies; sample collection procedures; stages of screening process; follow-up of results and case management; parental counseling; laboratories and related logistics and specifies the roles and responsibilities of health care providers at various health care levels.

1.2 SCOPE:
The following guidelines and flow charts have been updated in order to address arising issues related to congenital hypothyroidism starting from blood sample collection, dispatch, retrieving tests, clearly specifying roles and responsibilities of providers at each level of health care level, counseling parents and follow up management of the detected cases, and finally documenting and reporting to DWCH.
1.3 PURPOSE:
The purpose of the guideline is to provide the most up-to-date and evidence-based clinical framework for the optimal management of congenital hypothyroidism for all health-care providers involved including general practitioners, family physicians, pediatricians, nurse practitioners, radiologists and laboratories.

1.4 DEFINITIONS:
I. All cases with repeated (venous blood sample) TSH ≥ 40 mlU/L should be diagnosed as hypothyroidism and treatment to be started immediately.

II. CH not suspected (a negative screening result for CH), if the neonatal blood TSH concentration on the second sample is as follows:
- <20 mlU/L (day 1-6) or
- < 10 mlU/L (7-14 days) or
- < 5 mlU/L (> 14 days)

III. Suspected CH, If the TSH concentration in the second sample is as follows:
- ≥20 - ≤ 40 mlU/L (day 1-6) or
- ≥10 - ≤ 20 mlU/L (7-14 days) or
- ≥5 - ≤ 10 mlU/L (> 14 days).

IV. If the cord or neonatal blood TSH concentration is < 2.4 mlU/L for 1-6 days old baby, or < 0.6 mlU/L for older babies and children; FT4 should be requested. If its concentration is below the normal range or in the low-normal range for age, the baby should be suspected to have central hypothyroidism.

1.5 POLICY FRAMEWORK:
Congenital hypothyroidism (CH) screening of neonates is a health service that is provided to all newborns in all health care facilities of the Sultanate of Oman, which include Ministry of Health (MOH) hospitals, extended health centers, sister governmental institutions and private health institutions throughout Oman. The following should be noted:

1. While screening is provided at all levels of health care systems, therapeutic management and follow up are provided at the tertiary and secondary health care levels.
2. The components of neonatal CH screening and management service include:
Congenital Hypothyroidism Guideline for Neonatal Screening and Management

- Screening through measuring cord blood thyroid stimulating hormone (TSH).
- Retesting of neonates who have elevated TSH through measuring neonatal blood TFT.
- Handling and follow-up of inconclusive or invalid samples.
- Initiating treatment for confirmed CH cases.
- Educating and counseling parents of neonates with CH.

3. Cord blood samples will be collected and immediately sent to the laboratory within 5 days.

4. Focal point laboratory in the regional hospital and maternity staff nurse in charge are responsible to trace the result of TSH and act immediately when TSH is elevated.

5. Result of TSH should be documented in white duplicate copy before dispensing the copies to parent’s institutions.

6. Result of TSH should be considered in all late discharge of neonates from Special Care Baby Unit (SCBU).

7. If TSH results are elevated or inconclusive the test will be repeated to confirm the results.

8. All cases with elevated TSH of ≥ 40 mlU/L will be referred to secondary hospital for treatment, then to tertiary hospital for follow up and further management.

9. Parents of confirmed cases of CH will be counseled on the nature of the disease and its impact on child development and Health education material will be provided to them.

10. Follow up and management plans will be discussed and agreed upon with parents.

11. Confirmed cases of CH will be immediately notified on the congenital anomaly and genetic disorder notification form (H/P-4) available in AL-Shifa 3+.

12. Recall & confirmation of the congenital hypothyroidism cases can be arranged internally in the hospital (examples of recall and notification forms used in some of hospitals and governorates, annex 5-7.)
CHAPTER 2: BLOOD COLLECTION AND PROCESSING
2.1 UMBILICAL BLOOD SAMPLING
   i. Collect 3 ml of cord blood with a 5 ml syringe within 2-3 minutes of birth.
   ii. Transfer the blood to a 5 ml plain glass tube with red cap.
   iii. Inform parents about the test and that they will be notified if test results are abnormal.
   iv. Ensure that documents accompanying specimen are appropriate, accurate, and complete.
   v. Transport blood to the hospital laboratory (Lab.) at room temperature.
   vi. If the health facility can’t process the blood samples, then it should store it at 4°C and transport it later to the regional lab.

2.2 VENOUS BLOOD SAMPLING
In the case of invalidity of cord blood sample, a repeat venous blood sample should be drawn from the baby and sent to the lab. Please follow the same procedures for sample collection and documenting the reason for invalidity of cord specimen with caution for the difference in TSH cut-off value.

2.3 SPECIAL CONSIDERATIONS

2.3.1 Born Before Arrival (BBA)
Collect 2-3 ml of blood sample by venous-puncture (neonatal blood, not cord blood and not placental blood) while the baby is in hospital before discharge and send it to the hospital laboratory as early as possible.

2.3.2 Home delivery
Collect blood sample by venous-puncture at the first contact and send it to a laboratory with facilities for TSH testing as soon as possible. Please note that even if the baby showed up late (later than 6 days) the test should also be done to avoid further damage by hypothyroidism.

2.3.3 Pre-term, low birth weight babies, and neonates from multiple births, particularly in case of monozygotic twins.
It is recommended to repeat the Thyroid Function Test (TFT) at 2 weeks after the first screening test for all preterm neonates of less than 30 weeks of gestation and those with a birth weight less than 2000 grams, as there might be a delayed rise in TSH due to immaturity of pituitary–thyroid feedback mechanism. Neonates born between 30-37 weeks of gestation have almost similar TSH values as compared to 37 weeks; however, in addition to the basal blood for TSH, another TSH check is required before discharging the baby from the hospital.

2.3.4 Very sick Neonates:
For example, TSH should be repeated at 2-4 weeks after birth for the neonates in SCBU, neonates with cardiac disease and those who are on Dopamine administration.

I. Neonates with hypothalamic/pituitary disorders (with central hypothyroidism): Cord TSH is not a good indicator of central hypothyroidism. If central hypothyroidism is suspected as TSH is in lower side for the lab reference (Table 1 & Table 2), then clinician should refer the case to pediatric endocrinologist for further evaluation of the whole anterior pituitary hormones. That includes assessment, such as FSH, LH, ACTH paired with cortisol and growth hormone.

II. In certain conditions TSH, should be repeated after one year then annually, along with FT4 and thyroid antibodies for all Down syndrome cases (referred to guideline for medical management of children and young people with Down syndrome) for whom, their parents should be informed and a note made in the child’s health record.
CHAPTER 3: STAGE OF PROCESS
3.1 THE SCREENING PROTOCOLS

I. The initial screening sample – TSH analysis is performed on a cord blood sample.

II. Samples with TSH ≥ a preliminary threshold (analytical cut off) of 40 mlU/L are followed by immediate action and notification of the Nurse-in-Charge or Nurse Coordinator who will notify the concerned clinician for re-calling the baby and re-sending a new neonatal blood sample for TSH and FT4.

III. It is the responsibility of the laboratory to ensure that a second sample for the newborn will be sent to the laboratory. For this purpose, also a notification form is filled by the Laboratory-in-Charge or Senior Pathologist to notify the Pediatric Endocrinologist Team (or Pediatrician) for the finding of suspected high TSH.

IV. Second sample – It is preferable to send the second neonatal venous blood sample at least 24-48 hr. after delivery (to avoid the immediate post-delivery TSH surge) and must be before 7-days.

V. Analysis is timed to permit referral of screen positive results within 2-4 working days of sample receipt. Re-testing also acts as confirmation of correct sample identification (Figure 1: screening protocol flow diagram).

3.2 CATEGORIZATION OF INITIAL SCREENING RESULT

I. Babies in whom the cord blood TSH concentration is <40 mlU/L on the initial screening sample should be considered to have a negative screening result for CH. Report CH not suspected.

II. Babies in whom the cord blood TSH concentration is ≥ 40 mlU/L on the initial screening sample should be considered to have a positive screening result for CH. Report and refer as CH suspected with notification and re-call of the baby, Screening protocol flow diagram (Figure 1).
III. To increase the negative predictive value of the screening protocol, no borderline TSH value will be considered in the protocol and all babies with cord blood TSH concentration ≥40 mIU/L on the initial screening sample should be re-called for confirmation or exclusion of CH.

IV. On detecting cord blood TSH concentration ≥40 mIU/L, a second sample is to be taken preferably 2-7 days after the initial sample. Although it is better to have the blood sample around the age of 7 days, however earlier blood is usually collected while the baby is in the hospital to avoid any missing of the blood collection (practicability and convenience).

3.3 REPEATED TEST:

I. If repeated TSH ≥ 40 mIU/L start treatment immediately and urgent referral to pediatric endocrinologist has to be done.

II. The baby should be considered to have a negative screening result for CH. Report CH not suspected if the neonatal blood TSH concentration on this second sample is as follows:

- <20 mIU/L (day 1-6) or
- < 10 mIU/L (7-14 days) or
- < 5 mIU/L (> 14 days)

III. The baby should be considered to have suspected CH If the TSH concentration in this second sample is as follows:

- ≥20 - ≤ 40 mIU/L (day 1-6) or
- ≥10 - ≤ 20 mIU/L (7-14 days) or
- ≥5 - ≤ 10 mIU/L (> 14 days).

IV. Proper re-check for TSH and FT4 and clinical assessment by pediatrician/endocrinologist is recommended for the final decision on thyroid state.
V. If FT4 concentration is below the normal range for age (reference range of lab), regardless of TSH concentration start treatment immediately with clinical follow up.

VI. If the cord or neonatal blood TSH concentration is < 2.4 mlU/L for 1-6 days old baby, or < 0.6 mlU/L for older babies and children; FT4 should be requested. If its concentration is below the normal range or in the low-normal range for age, the baby should be suspected to have central hypothyroidism. The baby should be referred to endocrinologist for further clinical management and follow up with consideration of measurement of other pituitary hormones, particularly FSH, LH, prolactin, and ACTH (and cortisol), in order to see whether central hypothyroidism (if confirmed) is isolated or part of panhypopituitarism. Because of the risk of inducing adrenal crisis if ACTH deficiency is present, do not begin treatment of central hypothyroidism until normal ACTH/cortisol function is documented.
3.4 INTERPRETATION OF THYROID FUNCTION TESTS

For the interpretation of TFT it is preferable to refer to the normal/reference ranges for age that are usually reported by the laboratory performing the tests. Unfortunately, there is no specific reference ranges in many populations, including Omanis, however, the following ranges can be used for guidance during interpretation stage.

Table 1: Age-based normal values for thyroid function test

<table>
<thead>
<tr>
<th>Age</th>
<th>TSH mlU/L</th>
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<tbody>
<tr>
<td>Day of birth</td>
<td>2.43–24.3</td>
</tr>
<tr>
<td>1 day – 6 days</td>
<td>0.58–5.58</td>
</tr>
<tr>
<td>7 days – 30 days</td>
<td>0.58–5.57</td>
</tr>
<tr>
<td>31 days – 90 days</td>
<td>0.58–5.57</td>
</tr>
<tr>
<td>3 months - 6 month</td>
<td>0.58–5.56</td>
</tr>
<tr>
<td>6 months – up to 1 year</td>
<td>0.57–5.54</td>
</tr>
<tr>
<td>1 year - 2 years</td>
<td>0.57–5.51</td>
</tr>
<tr>
<td>2 years - 5 years</td>
<td>0.56–5.41</td>
</tr>
<tr>
<td>5 years - 8 years</td>
<td>0.55–5.31</td>
</tr>
<tr>
<td>8 years - 12 years</td>
<td>0.53–5.16</td>
</tr>
<tr>
<td>12 years - 15 years</td>
<td>0.52–5.05</td>
</tr>
<tr>
<td>15 years - 18 years</td>
<td>0.51–4.93</td>
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Table 2: Interpretation of thyroid function test in different thyroid related disorders

<table>
<thead>
<tr>
<th>Disorder</th>
<th>TSH</th>
<th>FT4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary hypothyroidism</td>
<td>H</td>
<td>L</td>
</tr>
<tr>
<td>Primary hyperthyroidism</td>
<td>L</td>
<td>High N to H</td>
</tr>
<tr>
<td>Central/hypothalamic/pituitary hypothyroidism</td>
<td>L, N, H*</td>
<td>L</td>
</tr>
<tr>
<td>Euthyroid sick syndrome</td>
<td>L, N, H*</td>
<td>L to low-N</td>
</tr>
<tr>
<td>TSH adenoma or pituitary resistance</td>
<td>N to H</td>
<td>H</td>
</tr>
<tr>
<td>Compensated hypothyroidism</td>
<td>H</td>
<td>N</td>
</tr>
<tr>
<td>Thyroxine-binding globulin (TBG) deficiency</td>
<td>N</td>
<td>N (Low Total T4); H TBG</td>
</tr>
</tbody>
</table>

H: High; L: low; N: normal.
*Result can be normal, low, or slightly raised.
3.5 REFERRAL OF BABIES WITH POSITIVE SCREENING RESULTS

I. The laboratory shall recommend referring babies with positive screening results for CH the same or next working day for immediate detailed examination.

II. Referral is to a Pediatric Endocrine team (regional specialist team) or to a clearly identified lead Pediatrician with a special interest in CH or experience of managing these patients to start treatment and refer to tertiary care levels for further management and adjustment of doses from initial treatment (Annex 3).

III. Appropriate mechanisms must be in place to ensure CH suspected babies have entered into the diagnostic pathway.

IV. Clinicians should work to a common protocol and have access to the full range of diagnostic investigations recommended in the same hospital or in a referral tertiary care hospital or a specialized center.

V. The first clinical appointment with the Pediatrician must take place on the same day or the next day (and must be within less than one week) after parents are informed of their baby’s positive screening result.
3.6 PRETERM/PREMATURE NEONATES AND LOW BIRTH INFANTS

I. Premature neonates and low birth weight infants (< 2,000 g) should undergo a second screening [a] one month after birth, [b] when their body weight reaches 2,500 g, or [c] at discharge from the hospital, even if data in the first mass screening at (2 weeks after the first screening test) is normal.

II. Infants with delayed TSH elevation in the second screening in the presence of low FT4 should undergo a detailed examination.

III. Hypothyroxinemia in low-birth-weight infants should not be treated with levothyroxine sodium (L-T4).
3.7 COMMUNICATION FLOWS

I. Laboratories shall notify a positive screening test, verbally (should call immediately) and in writing by notification form, to the Pediatric Endocrinology team, the Head of Women and Child Health Section and the health professional responsible for communicating the results. This initiates the clinical referral of screen positive cases (Figure 1: screening protocol flow diagram).

II. The result should be communicated by an informed health professional.

III. The health professional at parent institution should arrange and ensure that details of the time and date of the appointment with the Pediatrician have been fulfilled.

IV. The outcome of the first appointment should be reported in the baby’s hospital file and to the newborn screening laboratory.

V. The MOH – CH team has to be notified of every high TSH value that is confirmed to be due to CH on the Congenital Anomalies and Genetic Disorders Notification Form (H/P-4), so that the case will be recorded in the annual national registry for CH.
3.8 CLINICAL EVALUATION AND CONFIRMATORY DIAGNOSTIC TESTS

I. The clinician responsible for assessing the baby with a positive screening result shall take a clinical history and perform a clinical exam. *(See Note 1)*

*Note 1: Babies with CH are more likely to have associated anomalies, particularly congenital heart defects and hearing loss and require careful neonatal examination and follow up. A complete history, including maternal thyroid status (previous history of thyroid dysfunction, maternal anti-thyroid medications), maternal diet (e.g. vegan or other low iodine diet) and family history should be obtained.*

II. Diagnostic tests considered essential in the baby are:

a) Free T4 (plasma or serum)

b) TSH (plasma or serum) *(See note 2)*

*Note 2: Diagnosis using FT4 and TSH should be performed on plasma or serum sample using the appropriate age-related reference range as defined by the laboratory in relation to the equipment used.*
3.9 DESIRABLE ADDITIONAL DIAGNOSTIC TEST

I. Appropriate imaging techniques (radioisotope and/or ultrasound scans) may help to establish whether the thyroid gland is:
   a) Normally situated and normal in size and shape
   b) Normally situated but abnormal in size and shape
   c) Ectopic
   d) Absent

(See note 3)

Note 3: A radioisotope scan and an ultrasound examination may establish the cause of the child’s CH and indicate whether the condition is likely to be permanent. Initiation of treatment should not be delayed whilst waiting for an isotope scan, which can be performed up within 7 days after starting therapy. An ultrasound scan can be performed at any stage and investigation need not be confined to the neonatal period. These investigations may increase the awareness of potentially related problems such as deafness and can provide information about recurrence risk. Recurrence is unusual in the case of thyroid dysgenesis but there is likely to be autosomal recessive inheritance with a 1:4 recurrence risk for families of babies with thyroid dyshormonogenesis. Both isotope scanning and thyroid ultrasound in neonates require specialist skills and can generate misleading results.

The thyroid uptake has to be done for patients with repeated neonatal venous TSH concentration ≥20 mlU/L (day 1-6). For hospitals with Al-Shifa-3 plus IT system to send an urgent E-referral to the Nuclear Medicine Department for thyroid uptake scan and if not available to send a fax (Annex 3). In addition, the referring team must call and notify the Nuclear Medicine Department. Please note that the thyroid scans can be done during working hours only. In case of long national holiday, the treatment to be started as per this policy and the thyroid uptake scan to be performed after the age of three years and following stopping the thyroxine for one month.

II. In addition, the following test may be helpful:
a) Thyroglobulin

This test is available at the Royal Hospital, and requests for babies with CH can be performed there.

(See note 4)

**Note 4:** Plasma thyroglobulin needs to be measured on a sample taken prior to the start of treatment; this must not delay initiation of treatment. If plasma thyroglobulin is detectable then there must be some thyroid tissue present. Concentrations will be undetectable in thyroid agenesis.
3.10 ADVISABLE TESTS TO BE DONE FOR THE MOTHER

Diagnostic tests that are considered to be advisable to be performed for the mother to exclude interference in the infant’s TSH measurement and to exclude thyroid dysfunction in the mother include:

a) Free T4 (plasma or serum)

b) TSH (plasma or serum)

These investigations should be extended to include an assessment of TSH Receptor Antibody (TSH-R Antibody) status in the mothers with a current or previous history of autoimmune thyroid disease.

3.11 TREATMENT

I. A baby in whom a diagnosis of CH has been made should commence treatment with oral levothyroxine (no later than the first 2 weeks of life or immediately after confirmatory serum TSH results in infants identified in a second routine screening test) by:

   a) CH suspected on initial screening sample
   Acceptable standard: 17 days of age (100% of infants)
   Achievable standard: 14 days of age (100% of infants)

   b) CH suspected on a repeat blood spot sample that follows a borderline TSH
   Acceptable standard: 24 days of age (100% of infants)
   Achievable standard: 21 days of age (100% of infants)

II. The starting dose of oral levothyroxine should be 10-15 μg/kg/day, with a maximum dose of 50 μg/day. The objective of treatment is to normalize TSH within the first month. The dose of levothyroxine may need to be reduced if TSH is suppressed or if the baby is showing signs of overtreatment.

   Babies with significant endogenous thyroid hormone production may need smaller initial doses.

   (See note 5)
Note 5: Treatment with levothyroxine should lead to normalization of free T4 and a 50% reduction in TSH within days. However, TSH normalization can take weeks and timing does not correlate well with the administered levothyroxine dosage or the severity of the underlying diagnosis. The aim of treatment is therefore to increase free T4 close to the upper half of the age-specific reference range within the first 2 weeks of treatment and to normalize the TSH within the six months. Most of the time TSH will normalize within two weeks, however, few cases will need longer time, especially agenesis. Free T4 concentrations may exceed the normal reference range at the time of TSH normalization but significant elevation should be avoided. Regular dose adjustments may be required.

III. Only licensed solutions and tablets of levothyroxine should be used (as per MOH rules in this regard). Suspensions may be unreliable. Parents should be shown how to administer preparations and accompanying written information should be provided.

IV. Once levothyroxine treatment has been started, TSH and thyroid hormone concentration should be checked at an appointment with a Pediatrician at approximately 2 weeks, 4 weeks, 8 weeks, 3 months, 6 months, 9 months and 12 months after treatment is started, and thereafter as indicated. More intensive biochemical monitoring may be required. 
(See note 5)

V. Assessment of permanence of hypothyroidism. In cases where the cause or persistence/permanence of hypothyroidism has not been confirmed.
3.12 REEVALUATION

I. Re-evaluation of the thyroid axis in cases in which no etiological diagnostic assessment was carried out during early infancy and/or when treatment was started in the context of the infant being ill (e.g., preterm). Re-evaluation is also mandatory when initial evaluation has shown a normally located gland, with or without goiter, in neonates with positive thyroid antibodies, in children who have required no increase in L-T4 dose since infancy, and in children in whom no enzyme defect has been identified, either because no molecular genetic investigations have been carried out or because investigations have proved negative for all mutations tested.

II. The outcome should be fed back to the regional endocrine center to facilitate regional and national audit.
CHAPTER 4. FOLLOW UP OF RESULTS, RECALL, AND COMMUNICATION
Guidelines on the follow up of results, recall of positive cases and communication with parents.

4.1 DEFINITION OF CONGENITAL HYPOTHYROIDISM:

I. All cases with cord blood TSH values of ≥ 40 mlU/L and repeat (neonatal venous blood sample) TSH value of ≥ 20 mlU/L (day 1-6) or ≥10 mlU/L (≥ day 7) in the second sample should undergo detailed examination by the Pediatric (Endocrinology) Team to confirm CH.

II. All cases with repeat (venous blood sample) Free T4 value less than 10 Pmol/L should be treated as case of CH irrespective of TSH value, or normal clinical findings, and start treatment immediately. (If FT4 concentration is below the norm for age (according to lab reference range), regardless of TSH concentration start treatment immediately).
4.2 FOLLOW UP OF THE RESULTS AND RECALL:

I. All tests should be recorded in the maternity register by the maternity staff nurse.

II. The maternity staff nurse should also fill the ‘Newborn screening for CH form, and send it on daily basis to the hospital laboratory focal person (Annex 1).

III. The laboratory focal person should ensure that the numbers of samples received are as per the form and that all samples received are suitable for processing. If the sample is invalid, the maternity staff nurse must be informed to recollect the blood sample and send it for repeat test, while the neonate is still admitted in the birthing facility.

IV. In the case of discharge, the birthing facility focal point will trace the case with the assistance of Regional Focal Point and primary health care facility to do so. This can be done by faxing the CH screening form to the Regional Focal Point who will collaborate with Parent Institution Focal Point in tracing the neonate.

V. If parent institution is unable to trace and recall the neonate by the end of 3 weeks, then they should report to Regional Focal Person.

VI. In the case of abnormal results, recall the neonate for a repeat test. This should be preferably done by the pediatrician. Please make use of the standard script provided, for recalling the case.

VII. Make sure to note down the result of the screening in the Child Health Record and Hospital Information System.

VIII. Report the final feedback to the Regional Focal Point.

IX. Notify all confirmed cases of CH on the Congenital Anomalies and Genetic Disorders Notification Form (H/P-4).
X. The Regional Focal Point will send quarterly and annual reports on the number of neonates screened and detected of CH screening to the Department of Women and Child Health, MOH.

XI. Regional Pediatricians should do biochemical markers (TSH, FT4) and clinical examination in terms of developmental assessment for any CH in follow up appointment.

XII. Follow the instruction guidance in roles and responsibilities of focal points in respective locations in (Annex 4).
4.3 CLINICAL ASSESSMENT AND MANAGEMENT

4.3.1 Clinical features of Congenital Hypothyroidism

Clinical features of CH may not be fully apparent at birth and might take time to become recognizable. However, the following features are considered the main clinical features of CH:

- Large tongue,
- Hoarse cry,
- Facial puffiness,
- Umbilical hernia,
- Hypotonia,
- Mottling,
- Cold hands and feet,
- Lethargy,
- Large anterior or posterior fontanels,
- Delayed linear growth,
- Goiter.

- Other nonspecific signs: Prolonged, un-conjugated hyper-bilirubinemia (jaundice), prolonged gestation (> 42 weeks), feeding difficulties, delayed passage of stool, hypothermia or unexplained respiratory distress in full term infants.
4.3.2 Communication with parents:
Communication with parents is essential for ensuring proper follow up and management of cases.

- Inform/ explain to the parents:
  1) About the test performed and the results obtained, if available.
  2) If the test has to be repeated, reasons for doing so.
  3) If the results are not ready at the time of discharge, how to obtain them later.

- Make sure to document the results in the Child Health Record.
- If you had to repeat the test because the result is doubtful, call the parents using the standard script provided below.
- Document details of follow up communication including date, name of person communicating the information and name of person receiving the information.

**Standard script for telephonic conversation with the parents of neonate with positive test results**

- Introduce yourself, greet mother and ask about her health and the baby.
- Ask, “Do you remember that your baby’s blood was tested for thyroid function test, hormone levels (TFT).”
- Wait for response and say, “We would like to retest his/her blood because the result is doubtful”.
- Ask, “how soon you can come and bring your baby for the re-test”.
- If she is not proposing to come soon, tell her “it is important to come soon because your baby may require treatment after the test result”.
- Request her to come with the baby to perform the test and proceed with the needed management.
4.3.3 Parent’s education, counseling and support:

All parents of cases with confirmed CH should be counseled by a specialist (e.g. Pediatrician) at the initiation or soon after initiation of treatment, as follows:

- Issue the parent brochure and ask parents to read it before counseling.
- Provide counseling as per standard guidelines (see below),
- Let the parents ask any other questions if they wish.
- Check the understanding of parents at the end of counseling.
- Refer the parents to a family who is successfully managing a child with CH (if available and agreed by both families).

4.3.4 Counseling in hypothyroidism: (five A) construct

Assess

I. Assess details of screening and confirmatory tests and re-confirm that treatment is necessary.

II. Ask about clinical symptoms and signs: constipation, prolonged jaundice, coarseness of skin.

III. Listen to mother's concerns and build confidence with her by reassurance.

Advice

Give the following information (please refer to annex2)

I. Thyroid gland: its position and function in the body (production of thyroxin).

II. Thyroxin hormone: can be given by mouth, it is an effective treatment.

III. The child may require lifelong treatment.

IV. The disease will have good outcome if treated without interruption.

Ask parents for any queries answer and assure accordingly

Agree

Agree with the client on next steps:

- To start the treatment with thyroxin.
• To do thyroid ultra sound/scan (if not done).

**Assist**

Assist in the management plan as follows:

• Prescription for medication.
• Give brochure on hypothyroidism and request her to read.

**Arrange**

• Arrange scan appointment if not done.
• Give appointment for follow up visits.
Figure 1: Screening Protocol Flow Diagram

Initial cord blood TSH M IU/L

- TSH <60 mIU/L, negative screening. No action needed
- Neonate was discharged home
- BF/Nurse in charge maternity to recall baby to repeat test at nearest institution

If baby contact is unknown,
- BF/N to notify the focal person at parent institution to trace & recall baby to repeat test at nearest institution and to arrange for pediatric appointment
- If baby contact is still unknown, focal person at parent institution to notify Regional focal person (head of MCH)

Pediatric/local or regional hospital
- Physician at OPD
- To collect venous sample
- Of TSH & T4 and start treatment with L-thyroxine

Venous blood sample at 2-7 days.
- Start treatment with L-thyroxine

Action cut-off TSH ≥20 mIU/L (day 2-6) or ≥10 mIU/L (≥7 days) mIU/L

- TSH < 10 mIU/L
- Report CH not suspected, discontinue treatment.
- No further action

- TSH 10-20 mIU/L
- Repeat TSH & T4 sample
- TSH level

- TSH >20 mIU/L
- TSH borderline
- Report CH suspected, refer

Focal person laboratory notify results to:
- Focal person at parent institution to recall baby and arrange urgent ped. Apt. for further evaluation and continuation of treatment
- Pediatric endocrinologist/pediatrician

Note:
- For complete information and result interpretation refer to text as appropriate.
- If the child has clinical signs suggestive of congenital hypothyroidism treatment should be started even if TFT values are normal. If TFT results are not in conformity with the expected levels while on treatment suspect non-compliance to treatment.
4.4 MANAGEMENT:

If the initial cord TSH value $\geq 40$ mIU/L, and re-called venous serum is suspected for CH with TSH value $\geq 20$ mIU/L provide initial management as follows:

I. Explain to the parents about the initial test result, initial treatment and the need to confirm by further tests.

II. Collect blood for TSH and Free T4 and send to lab.

III. **Start treatment on a temporary basis with L-thyroxin 10-15 μg/kg/day once given in the morning.**

IV. Review the case with TFT results.

V. **If repeated TSH is <10 mIU/L discontinue treatment.**

VI. If Free T4 is low less than 10 mIU/L or below normal range for age irrespective of TSH value continue treatment with L-Thyroxin at a dose of 10-15 μg/kg/day.

VII. Following initiation of treatment, If the repeated TSH is >10 mIU/L and Free T4 value is <15 Pmol/L, check for the compliance of medication. Repeat TFT in 2 weeks if picture remains to be the same refer the case to endocrinologist.

VIII. The dose should be titrated according to the biochemical values of free T4 and TSH.

**All confirmed cases of hypothyroidism should be managed as follows:**

I. Commence treatment with L-thyroxin 10-15 μg/kg/day if Free T4 value is more than 5 Pmol/L.

II. Commence treatment with L-thyroxin 50 μg/kg/day if Free T4 value 5 Pmol/L or less.

III. Repeat TFT in 2 weeks and adjust dose to maintain TSH below 10 mIU/L and Free T4 at upper half of normal value [normal Free T4 value (11-24 Pmol/L).]

IV. Continue treatment if the child has clinical signs suggestive of CH even if TFT values are normal.

V. Suspect non-compliance to treatment If TFT results are not in conformity with the expected levels while the child is on treatment.

VI. All confirmed cases must be notified to DWCH via the Congenital Anomalies and Genetic Disorders Notification Form (H/P-4).
4.5 FOLLOW UP OF CASES WITH CONGENITAL HYPOTHYROIDISM:

All children under treatment should be followed up rigorously as follows. The child should have TSH and FT4 done at all follow-up visits. The child should also be evaluated for clinical signs of hypothyroidism.

I. The first follow up visit: 2 weeks after starting the treatment.
   a. If there is a facility for thyroid scan, it should be arranged immediately.
   b. If there is no facility for a thyroid scan, treatment should commence immediately.

II. Second follow up visit: 4 weeks after first visit.

III. Third follow up visit: 8 weeks after second visit.

IV. Fourth follow up visit: 3 months after the third visit.

V. Subsequent visits: at 6 months, 9 months and 12 months (i.e. 3 monthly) until 4 years of age.

VI. Follow up visits: at six monthly intervals if the disease is under control.

4.6 CASE RE-EVALUATION:

All children under treatment should be re-evaluated at 3 years as below:

I. If thyroid scan was not done during the neonatal period, it should be done after completing 3 years of age. Thyroxin should be stopped for one month before the thyroid scan.

II. Perform TSH, FT4 and FT3 (Child should be off treatment for 4 weeks before the test).

III. If thyroid ultrasound and scan, TSH, FT4 and FT3 are normal and child has no clinical signs discontinue treatment and notify.

IV. If child has clinical signs of hypothyroidism continue treatment even if test results are normal.
CHAPTER: 5. LABORATORY PROTOCOLS
5.1 RECEPTION OF SPECIMENS AND ACCOMPANYING DOCUMENTATION

5.1.1 Specimens received for screening are checked for:
   I. Quantity of blood is sufficient (>2 ml)
   II. Blood collected is in the correct container (plain container – clotted blood)
   III. There are no leakages
   IV. The container is unbroken
   V. The age of the specimen is acceptable (<3 days and has been stored at 4°C).
   VI. That the specimen is not in any other way invalid.

5.1.2 The documents accompanying the specimen:
   I. Are legible
   II. Patient identification is complete
   III. Dates, time of sampling etc. are complete.

5.1.3 Notification of problems associated with the specimen or documentation:
   I. Specimen submitter or birthing facility focal point (BFFP) is notified about any problems associated with the sample/documentation within 24 hours of receipt.
   II. The BFFP is informed of the reason for the invalidity of the specimen so that a repeat sample from the subject can be initiated as soon as possible.
   III. A written record is kept of each incident of non-compliance with the specimen or documentation protocol.
   IV. A copy of the record of sample or documentation non-compliance is sent to the BFFP.

5.1.4 Sample Entry
After verification of sample integrity and compliant documentation, each specimen will be entered into the laboratory computer and assigned a unique laboratory number according to standard laboratory protocols for the receipt of all laboratory specimens.
5.2 ANALYTICAL PROCEDURE

I. The specimen is centrifuged and the serum separated and stored at 4°C if to be assayed for TSH within 3 days, otherwise keep frozen until ready for analysis.

II. The specimen will be analyzed in the normal way following the procedures prescribed in the Standard Operating Procedures (SOP) for TSH analysis along with other clinical specimens.

III. Any abnormal result will be repeated on the original sample for TSH.

IV. If the TSH is high the BFFP of the birthing facility from where the sample was collected and sent, will be notified immediately in order to facilitate a follow-up blood specimen collection and dispatch (see Positive Sample Follow-up Procedure).

V. All required Quality Control (QC) samples would be run in conjunction with the test samples.

VI. Only when all QC samples are in compliance with acceptable criteria will the test results be accepted and released.

VII. All test results and QC results will be maintained on the host computer (test results) and on the instrument file (QC results).

VIII. A hard copy of all test results along with unique identifying number will be retained in the laboratory.

IX. A copy of all cord blood TSH results will be sent to the BFFP.
5.3 SAMPLE FOLLOW-UP PROCEDURE

5.3.1 Blood Sample:

I. When a blood sample is found positive i.e. a test result on a cord blood that exceeds the cut-off limit (currently ≥ 40 mIU/L) the test will be repeated on the same (first) sample.

II. If the TSH is ≥ 40 mIU/L on the repeated test sample, the birth facility focal point is to be contacted immediately and a request to made for a repeat (second) sample.

III. When the repeat (second) sample is obtained following an initial confirmed positive result and the repeat TSH is still high ≥ 20 mIU/L (day 1-6) or ≥ 10 mIU/L (≥ day 7) in the second sample, interpretation should be made with consideration of free T4 values. The TSH and Free T4 results will be documented and the BFFP immediately informed by phone and in writing using the prescribed documentation for follow-up.

5.3.2 Reporting of all normal TSH results

I. Results will be issued as soon as verified and within the prescribed period (no later than 5 days of receipt of blood sample).

II. The reports are to be sent to the BFFP by mail (internal or external) unless otherwise requested by the birthing facility focal point and a feedback to be sent to the regional focal point.
CHAPTER 6. DATA MANAGEMENT
6.1 DATA ACCUMULATION AND SUMMATION:

The delivery health facility carries the responsibility of keeping records of cases and dispatching them appropriately to respective health care facility. The following section highlights the process and necessary requirements.

Documentation, accumulation, and summation data includes:

1. Number of live born
2. Number of TSH tests performed
3. Number of results tracked
4. Numbers confirmed
5. Numbers lost with documentation of reasons
6. Date of diagnosis (confirmation after the second blood sample).

Appropriate follow up data should be reported/sent to:

- MCH/Child Health coordinator (Regional Focal Person)
- DWCH to maintain data base on CH screening (quarterly report):
Table 3: Report on Neonatal Screening for Congenital Hypothyroidism (quarterly report):

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Final case disposition (affected, not affected, lost to follow-up) from the secondary care should include:

- Date of evaluation to confirm screening results.
- Date of diagnosis/case disposition.
- Date of initiation of Treatment/intervention (if applicable).
- Test results on which diagnosis was based.
- Name of person who communicates the diagnosis information.
- For diagnosed cases (i.e. affected), referral and follow up information to the primary care.
- For cases with uncertain diagnosis, clinical surveillance and action plan to achieve case resolution.
- Identification of the person recording/entering the information.

NB. A monthly report of the identified cases of high TSH level in the birthing institutions should be sent to the parent institution to keep it in their records.
# DOCUMENT HISTORY AND VERSION CONTROL

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<td>Team for Updating Congenital Hypothyroidism Guidelines, Child Health Team, Department of Woman &amp; Child Health</td>
<td>June 2010</td>
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<td>02</td>
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<td>Child Health Team, Department of Woman &amp; Child Health</td>
<td>May/2021</td>
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**Written by**: Department of Women and Child Health in collaboration with Department of Child Health, Royal Hospital

**Reviewed by**: Dr. Fatma Al-Hinai
Dr. Jumana Al-Abdwani

**Approved by**: Dr. Said Al-Lamki
REFERENCES

- NHS Screening programmes, newborn blood spot, congenital hypothyroidism, initial clinical referral standards and guidelines. British Society for Paediatric Endocrinology and Diabetes; 2013 UK Newborn Screening Programme Centre; revised Jan 2016.
- UK Guidelines for the use of TFT, Association for Clinical Biochemistry, British Thyroid Association, and British Thyroid Foundation; Jul 2006.
ANNEXURES
Annex 1: Neonatal screening for congenital hypothyroidism and follow-up system for newborns tested for TSH. Newborn screening for congenital hypothyroidism form

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*All the information should be completed by the labor room staff, then send to the lab. on daily 24 hours basis. (source of information is the maternity register)*

*The last 2 shaded columns are for lab use, who will fill the needed data and then fax it to the regional focal point in the next 48 hours.*

In the delivery units the regional focal persons will fax it to all parents institutions focal persons

In the region *the EPI focal persons will note down the value of TSH on the child health record during the first visit of the child in the child health clinic.*

*EPI focal persons will recall the babies who need a repeat sample & venous sample will be collected in the parent institution/delivery hospital. write down the lab. request form and fill the special neonatal TSH request form label as neonatal TSH–missed & send to lab.*

In the hospital laboratory The laboratory focal person should continue updating the list of newborn tested for TSH-missed, send the new list to the regional focal persons after obtaining the latest results
Annex 2: information for counseling parents of a child with hypothyroidism

What is congenital hypothyroidism?

Congenital hypothyroidism is a disorder that affects infants from birth (congenital), resulting from the severe deficiency of thyroid function (hypothyroidism), usually due to failure of the thyroid gland to develop correctly. Sometimes the thyroid gland is absent or ectopic (in an abnormal location). As a result, the thyroid gland does not produce enough thyroxine/T4 after birth. This may result in abnormal growth and development, as well as slower mental functions.

The thyroid is a gland that is located in the neck and is part of the endocrine system. This gland is responsible for secreting a hormone called thyroxine (T4) which plays a vital role in normal growth and development in children. This gland, is controlled by the pituitary gland. It works very much like a thermostat. The brain senses the amount of T4 and then signals the thyroid with another hormone, thyroid-stimulating hormone (TSH), or thyrotropin to produce more or less T4. When the thyroid gland produces enough T4, no extra stimulation is needed and the TSH level remains at a normal level. When there is not enough T4, the TSH rises. These characteristics of the T4 and TSH hormones allow for the screening of newborns to assess if the infant has normal or abnormal thyroid functions.
Why a child develops congenital hypothyroidism?

In most hypothyroid babies, there is no specific reason why the thyroid gland did not develop normally, although some of these children have an inherited form of this disorder. The parents should not feel the blame, as CH is NOT caused by any life style pattern or behavior of the family.

What are the symptoms of congenital hypothyroidism?

Often these babies appear perfectly normal at birth that is why screening is so vital. However, some may have one or more of the symptoms such as puffy face, swollen tongue, hoarse cry, low muscle tone, cold extremities, persistent constipation, lack of energy, excessive sleep, not growing etc.

What tests are done for confirming congenital hypothyroidism?

The thyroid functions or TFT including TSH and FT4 are confirmatory tests. A thyroid scan may be done to determine the location, or absence of the thyroid gland. Sometimes the scan may be done when the baby is three years old if it cannot be done before starting treatment.

How does one treat congenital hypothyroidism?

Treatment for CH is replacement of the missing thyroid hormone in tablet form. It is extremely important that these tablets are taken daily for life because, thyroxine (T4) is essential for all body functions. In general, the average starting dose for Levothyroxine (synthetic T4) or L-thyroxine in a newborn is between 25

and 50 mcg per day or 10 to 15 μg/kg of body weight. This value increase is dependent upon the individual needs of the child. The tablet can be crushed, and then administered in a small amount of breast milk while the child is still an infant.
Please be aware that L-thyroxine should not be mixed with Soy formula or with iron supplements as these products interfere with absorption. Blood tests will be done on a regular basis to ensure that the hormone levels are in a normal range. Thyroid hormone is necessary for normal brain and intellectual development and such development can be delayed when there is a lack of L-thyroxine.

**What type of medical attention should the child receive?**

Frequent visits to the doctor will be necessary with blood drawn to check if the laboratory values show normal thyroid levels. Once normal levels are reached, the blood tests will become less frequent. Generally, children are seen every 2 - 3 months, for the first three years, once normal levels have been established.

The goal is to maintain the concentration of Free T4 in the mid to upper half of the normal range (11-24 Pmol/L) for the first years of life. The TSH level should be maintained within the normal reference range for infants. The treatment for hypothyroidism is safe, simple, and effective. Successful treatment, however, depends on life-long daily medication with close follow up of hormone levels.

Making this procedure of taking medication on a routine basis needs to become a part of the lifestyle of the child in order to assure optimal growth and development.

**Will other children have the disorder?**

There is a small chance that the next child may have the same problem and will need to be screened after birth.

**What is the outcome for a baby with hypothyroidism?**

There is no cure but the serious effects of the disorder can be lessened and often prevented if medical treatment is started early and continued for life. There are a small proportion of children who have temporary (transient) CH for a period of time after birth. It is impossible to
distinguish these transient hypothyroid babies from those with true CH and so these infants will be treated as well. The child will need to be reviewed and retested after 3 years treatment to decide if the child will need lifelong treatment. In any case treatment should NOT be discontinued before 3 years. With early replacement of adequate thyroid hormone and proper follow up and care, the outcome would be favorable.
**Annex 3: Contact details of the Tertiary centers**

<table>
<thead>
<tr>
<th>Name of the Hospital/Center</th>
<th>Contact number</th>
<th>Fax number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Royal Hospital Laboratory</td>
<td>24599736 / 24599717</td>
<td>Dept Fax: 24599817</td>
</tr>
<tr>
<td>Nuclear medicine, Royal Hospital</td>
<td>Dept no: 24627069 / 24627066 / 24627067 / 24627072</td>
<td>Dept Fax: 24627085</td>
</tr>
<tr>
<td>National Diabetes &amp; Endocrine Center</td>
<td>24211272, 242112301, 24211297</td>
<td>24211270</td>
</tr>
<tr>
<td>Sultan Qaboos University Hospital</td>
<td>24144328/26 24144263</td>
<td>24144204</td>
</tr>
</tbody>
</table>
Annex 4: Roles and responsibilities of focal points in respective locations

Focal point in the labor room:

- Fill the details of all newborns, born within the last 24 hours in the enclosed form (Annex 1).
- Send the form to the lab of the same health institution.
- In case if the lab is in another health institution use fax to report to the lab.
- Repeat the test if required and if the baby still in the hospital.

Focal point in the Lab.:

- Fill in the section of above form (Annex 1) related to the TSH of the same cohort of newborn within 48 hours and send it to the regional focal point.
- Newborns with cord TSH values ≥40 mIU/L or invalid samples, please report as soon as possible to the focal point in the labour room and if the baby is discharged report to the regional focal point.
- Complete the data regarding TSH values and send it to the regional focal point.
Regional focal point (MCH / child health coordinator):

- Locate from the forms the parent institution of newborns with cord TSH value $\geq 40$ mIU/L or with the invalid samples that must be repeated.
- Fax the form to the focal point to the respective parent institution to take action.
- To send the CH quarterly report to the DWCH (Table 3).

Focal point at the parent institution:

- Receive the form from the regional focal point and call the families of the babies who need to have a repeat TSH blood sample because of invalid samples. This sample will be a venous sample and details should be entered in the usual lab request form.
- Arrange an immediate referral of the baby who has cord TSH $\geq 40$ mIU/L to the Pediatrician for the initiation of treatment and for repeating TSH sample.
### Annex 5: Congenital Hypothyroid screen - recall request

<table>
<thead>
<tr>
<th>Sultanate of Oman</th>
<th>Ministere of Health</th>
<th>The Royal Hospital</th>
<th>Directorate of Laboratory Medicine and Pathology</th>
<th>Forms Manual</th>
<th>Page 55 of 62</th>
</tr>
</thead>
<tbody>
<tr>
<td>FM/CHEM/IMUN/20</td>
<td>Congenital Hypothyroid Screen - Recall Request</td>
<td>Approved by:</td>
<td>Revision: 1</td>
<td>Effective date:</td>
<td></td>
</tr>
</tbody>
</table>

To Sister in Charge, Ward………………… Date………………
From:…………………………….. Title……………….
Baby of …………………………………………………………….DOB………………
Hospital # …………………………… Specimen #……………………………………
Date of Specimen………………

**CBTSH (if appropriate)………. mIU/l (≥ 40)**

Released on …………………

<table>
<thead>
<tr>
<th>TEST</th>
<th>Tick as required</th>
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<tbody>
<tr>
<td>No sample was received for this baby</td>
<td></td>
</tr>
<tr>
<td>Insufficient sample was received</td>
<td></td>
</tr>
<tr>
<td>The baby’s cord blood TSH ≥ 40 mIU/L</td>
<td></td>
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</tbody>
</table>

Has this request been phoned Y/N. By whom……………………………………
If yes, to whom……………………………..Ward………
Follow-up TFT results

<table>
<thead>
<tr>
<th>TSH…mIU/L</th>
<th>Reference Range (0.35– 17.2 7 – 14 days)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(0.35 – 5.0 15 days – 1 year)</td>
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</table>

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<thead>
<tr>
<th>FT4…pmol/L</th>
<th>Reference Range (11 – 37 7 – 14 days)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(10 – 24 15 days – 1 year)</td>
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</tbody>
</table>

**Comment:…………………………….

Further follow up required Y/N………
Signed…………………………………… Date:……………………
<table>
<thead>
<tr>
<th>Sultanate of Oman Ministry of Health</th>
<th>Forms Manual Page 56 of 62</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Royal Hospital</td>
<td>Cord Blood TSH – Confirmation and Notification Form</td>
</tr>
<tr>
<td>Directorate of Laboratory Medicine and Pathology</td>
<td>Approved by: Revision: 1 Effective date:</td>
</tr>
</tbody>
</table>

FM/CHEM/IMUN/21
Annex 6: Cord Blood TSH – Confirmation and Notification Form

Dr.………………………….
Date:……………………………
Senior Consultant Paediatric Endocrinologist, Royal Hospital

Subject: Final report on raised cord blood TSH

The following is the final report on
B/O……………………………………………………………………………………………
HOSPITAL ID……………………SPECIMEN ID………………………………
BORN ON………………………………AT……………………………………..HOSPITAL
CORD BLOOD TSH RESULT………………miU/L (≥ 40)

FOLLOW-UP RESULTS
PATIENT NAME…………………………………………………………………………………
HOSPITAL ID……………………SPECIMEN ID………………………………
TSH………………….miU/L (0.35 – 17.2 7 – 14 days)
(0.35 – 5.0 15 days – 1 year)
FT4…………………. pmol/L (11 – 37 7 – 14 days)
(10 – 24 15 days – 1 year)

DATE OF SAMPLE:………………….DATE REPORTED………………………
CONCLUSION:………………………………………………………………………………
…………………………………………………………………………………………
…………………………………………………………………………………………
…………………………………………………………………………………………
Signature of Senior Consultant Chemical Pathologist or Deputy
…………………………………….. Date: / /
Annex 7: TSH Follow-up form- Nizwa Hospital /medical laboratory services

High TSH cord blood ≥ 40 mIU/L from …../…… To …../……

<table>
<thead>
<tr>
<th>Patient ID</th>
<th>Sample ID</th>
<th>Patient name</th>
<th>Requesting location</th>
<th>Lab comment</th>
<th>Receiving time</th>
<th>Released date</th>
<th>TSH cord blood</th>
<th>Neonatal Venous TFT sent</th>
<th>Follow up Result of TFT</th>
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