NATIONAL SCREENING PROGRAMME FOR CONGENITAL HYPOTHYROIDISM

Ministry of Health Malaysia
2018
NATIONAL SCREENING PROGRAMME FOR CONGENITAL HYPOPHYROIDISM
FOREWORD

Congenital Hypothyroidism (CH) is one of the conditions occurring in newborns that could lead to morbidity. It is also one of the most common preventable cause of intellectual disability.

This condition may not be recognised or detected at birth, as infants may not have any apparent symptoms or signs. Treatment of children with CH should be as soon as possible, as late treatment will result in poor intellectual performance and delayed growth.

Thus, to ensure the growth and development of all children, Ministry of Health implemented the Congenital Hypothyroidism Screening Program for all newborns. Beginning 20 years ago in 1998 with only 5 hospitals, today more than 400 hospitals and clinics from both government and private health sectors are involved in the screening programme.

Revision of guidelines is a vital task, as each day, research shines new light on our understanding of human development and disease, technologies advance and new approaches are discovered. This current revision is in line with Paediatric Protocol, which includes revision of cut-off values and data collection format. This guideline for screening is meant for use by staff in hospital and health clinics.

I would like to congratulate the Child Health Sector from the Family Health Development Division for their hard work and commitment in ensuring this guideline is produced. My appreciation also to all who were involved in the development of this updated guideline.

Datuk Dr Noor Hisham bin Abdullah
Director General of Health
Ministry of Health Malaysia
FOREWORD

Congenital Hypothyroidism (CH) is one of the conditions requiring medical attention in newborns and the Ministry of Health initiated a screening programme in 1998 to ensure all newborn are screened for CH.

Congenital Hypothyroidism is a treatable condition and if addressed early, morbidity in the form of intellectual disability can be averted. The problem however lies in the fact that in most babies this condition may go unnoticed until they reach 2 months of age, and by then intellectual and growth impairment would have occurred. For these reasons, screening at birth was implemented to ensure early treatment is given.

The screening programme has been in place for 20 years and over the years increasing numbers of hospitals and health clinics have implemented the screening programme. Coverage for CH screening in participating hospitals is almost 100%, and over the years an average of 200 cases are identified and treated every year, thereby achieving the goal of the programme i.e. early detection and intervention of Congenital Hypothyroidism to prevent disability.

These achievements are the result of close networking and coordination between the Obstetric and Pediatric Departments, the laboratory staff and the staff in health clinics. The guidelines developed facilitate all involved to ensure smooth running of the programme and this guideline has been revised to ensure relevance by incorporating the new additions to CH screening in the Pediatric Protocol.

I would like to congratulate the Child Health Sector from the Family Health Development Division and all the technical group members for their hard work and commitment in ensuring this guideline is produced.

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1. INTRODUCTION

1.1 WHAT IS CONGENITAL HYPOTHYROIDISM

Congenital hypothyroidism (CH) is defined as thyroid hormone deficiency, which is present at birth. However, this condition may not be recognised or detected at birth, as infants may appear normal with no apparent symptoms or signs seen.

Thyroid hormone deficiency at birth can be caused by abnormality in thyroid gland development (dysgenesis) or disorder of thyroid hormone biosynthesis (dyshormonogenesis). These two abnormalities lead to primary hypothyroidism. While, deficiency of thyroid stimulating hormone (TSH) leads to secondary or central CH. Another category in CH is peripheral hypothyroidism, which results from defects of thyroid hormone transport, metabolism or action.

Congenital hypothyroidism can be classified as permanent or transient CH (Table 1). In permanent CH means there is a persistent deficiency of thyroid hormone and life-long treatment is required. Transient CH is defined as a transient abnormality of the thyroid function, which later normalises and may or may not require replacement therapy.

<table>
<thead>
<tr>
<th>Disorder</th>
<th>Prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Permanent disorder</strong></td>
<td></td>
</tr>
<tr>
<td>1. Thyroid dysgenesis (agenesis, hypoplasia, ectopia)</td>
<td>1: 4,500</td>
</tr>
<tr>
<td>2. Thyroid dyshormonogenesis</td>
<td>1: 30,000</td>
</tr>
<tr>
<td>3. Hypothalamic-pituitary hypothyroidism</td>
<td>1: 100,000</td>
</tr>
<tr>
<td>4. Generalised resistance to thyroid hormone</td>
<td>Very rare</td>
</tr>
<tr>
<td><strong>Transient disorder</strong></td>
<td></td>
</tr>
<tr>
<td>1. Transient hypothyroxinemia (mainly premature infants)</td>
<td>1:2000</td>
</tr>
<tr>
<td>2. Transient primary hypothyroidism (common in areas of iodine deficiency)</td>
<td>Variable</td>
</tr>
<tr>
<td>3. Transient hyperthyrotropinemia (predominantly seen in Japanese population)</td>
<td>Very rare</td>
</tr>
</tbody>
</table>

Often babies with congenital hypothyroidism appear normal at birth. However, the early features include umbilical hernia, constipation, prolonged jaundice, poor feeding, inactivity and delayed bone age. Late features of untreated congenital hypothyroidism are macroglossia, coarse features, dry skin and hair, hoarse cry, delayed development, poor growth and mental retardation.
1.2 IMPORTANCE OF CONGENITAL HYPOTHYROIDISM SCREENING

Congenital hypothyroidism cannot be clinically detected at birth and it is the most common preventable cause of mental retardation. The child is usually discovered to have congenital hypothyroidism at around 2-6 months of age and by this time there already may be consequent brain damage. Recent prospective studies show that screening neonates and treating affected babies within the first week of life results, on average, in normal or near normal intellectual performance and growth at 6-12 years. Hence without a screening programme, most children with CH cannot be detected early and will be at risk of mental retardation.

Two cost-benefit analysis conducted in France and in the United States revealed overall cost-benefit ratio is between 1: 8.9 – 13.8 for screening congenital hypothyroidism (Layde et al, 1979 & Dhondt et al, 1991).

1.3 DEVELOPMENT OF CONGENITAL HYPOTHYROIDISM SCREENING PROGRAMME

In the past, priorities of children health care in Malaysia were focused on infectious diseases and curative services. Improvement in economy status and changes in lifestyle has led to the increase awareness of preventive issues in healthcare. Thus in 1991, paediatricians in Malaysia started the initiative to make CH as a national screening programme. Five studies were done in various part of the nation to understand the local situation of CH. Data from four of the studies described the birth prevalence of CH in Malaysia (Table 2). From the data, the "pooled" rate is 1:3029.

<table>
<thead>
<tr>
<th>Birth prevalence</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 : 2410</td>
<td>Harun, 1992</td>
</tr>
<tr>
<td>1 : 2983</td>
<td>Ammar, 1997</td>
</tr>
<tr>
<td>1: 3666</td>
<td>Wu et al, 1999</td>
</tr>
<tr>
<td>1 : 3065</td>
<td>Mafauzy et al</td>
</tr>
</tbody>
</table>
Generally, the birth prevalence of congenital hypothyroidism appears to be higher in Malaysia when compared with Europe or America. There are three possible reasons for this higher prevalence:

1. Consanguinity, which is more common among certain ethnic groups in the region. However, the majority of cases are not due to inherited defects (thyroid dyshormonogenesis) but due to thyroid dysgenesis.

2. Transient primary hypothyroidism due to iodine deficiency. It is well recognised that iodine deficiency can affect the results of screening tests. Malaysia has, to varying degrees, the problem of iodine deficiency in Sabah and Sarawak and isolated district in Peninsular Malaysia.

3. This prevalence may possibly be reflecting the true genetic situation in the region.

In 1997, MOH initiated a national committee to look into the implementation of a national screening programme. A Health Technology Assessment was done to determine the safety, effectiveness and cost effectiveness of screening for CH. After one year of assessment, it was reported that a national screening programme for CH should be instituted. As a result, the national screening programme for CH officially started in October 1998 with the objective of screening all newborn for CH and managing them appropriately to prevent mental disability.

The first draft for national screening manual was prepared in October 1998 and the programme was commenced in three regional hospitals (Seremban, Klang, Ipoh) and one district hospital (Port Dickson). After 1 year, evaluation of the programme was done and MOH decided to further expand the programme throughout the whole nation. With the expansion of the programme more health facilities were involved (Table 3) and more newborn babies could be screened. To ensure that the programme ran smoothly a national guideline was developed named as ‘Protocol for National Screening for Congenital Hypothyroidism’, which was developed in the year 2000 and revised in 2011.

**Table 3: Number of health facilities involved in CH screening programme**

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of hospital &amp; clinic</th>
<th>Number of hospital with lab facility (analyser) for cord TSH</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Government</td>
<td>Private</td>
</tr>
<tr>
<td>1999</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>2005</td>
<td>75</td>
<td>NA</td>
</tr>
<tr>
<td>2008</td>
<td>104</td>
<td>16</td>
</tr>
<tr>
<td>2012</td>
<td>117</td>
<td>94</td>
</tr>
<tr>
<td>2015</td>
<td>385</td>
<td>139</td>
</tr>
</tbody>
</table>

*NA: Not Available
Compared to other countries, Malaysia has chosen cord blood sampling as the sample collection method, due to:

1. Mobility of mother after the delivery of their children
2. Limited home visits by medical staff in the post-natal period especially in the urban settings
3. Difficult to get parents respond for a preventive programme (where blood collection is done on an apparently normal child).
4. Allows for a much higher coverage of infants as almost > 85% of deliveries were conducted in the hospitals or by trained personal at home,
5. Reduces the cost of screening as the mechanism for blood sample collection will be linked to the established cord blood screening programme for Glucose-6-phosphate dehydrogenase (G6PD) deficiency
6. Cord blood sampling is simple, non-invasive and offers the earliest postnatal diagnosis

The test strategy adopted in Malaysia is primary TSH measurement supplemented by T4 determination in borderline samples. Infants with elevated TSH values, and those with borderline values & low FT4, are recalled for testing. This approach does run the possibility of missing secondary and tertiary hypothyroidism (1:100,000 births). However, it is the least expensive option with the lowest recall rates (0.03 – 0.85). This screening approach is especially in view of the development of newer TSH assays (enzyme linked immunoassays, chemiluminescent assays and fluoroimmunoassays) which offer greater sensitivity and better separation between normal and abnormal TSH values. Using a combined TSH and FT4 screening approach would be too expensive. Using a primary FT4 approach would involved a large recall of up to 2%.
2. NATIONAL CONGENITAL HYPOTHYROIDISM SCREENING PROGRAMME

2.1 Objective

a. General objective:
   All newborns with congenital hypothyroidism will be detected early and managed appropriately to prevent mental disability.

b. Specific objectives:
   i. To screen all newborns for congenital hypothyroidism
   ii. To ensure the use of appropriate screening technology which meets quality standards.
   iii. To ensure all newborns with congenital hypothyroidism will receive treatment within the first 2 weeks of life
   iv. To promote community awareness of congenital hypothyroidism

2.2 Methodology

a. Collection of Blood samples for TSH in Hospital
   i. Immediately after delivery, clean maternal side of the cord with sterile gauze and collect the blood sample. (Appendix 1)
   ii. Allow free flow of blood from the cord directly to the tube (if you need to ‘milk’, do it gently to prevent hemolysis)
   iii. The tube should be filled with a minimum of 3ml of blood. (Allow space for the cap to be pushed in)
   iv. Label the tube immediately. Complete investigation form.
   v. Send the sample to the laboratory with the form at the normal routine intervals within 24 hours.
   vi. For handling of blood samples at the laboratory; refer to Flowchart 1.
CONGENITAL HYPOTHYROIDISM
FLOW CHART FOR CORD BLOOD ASSAY

Collect cord blood into plain/heparinised or gel tubes.  
Sent samples to hospital laboratory within 24 hours.  
Keep sample at room temperature if sending to lab is delayed.

Sample unsuitable

Inform paediatric clinic immediately

Check sample and forms

Centrifuge sample

Testing done in the same hospital

No

Keep serum/plasma at 2-8°C not more than 72 hours

Send to testing laboratory

Analysis of specimen (Refer to work instruction)

Insufficient sample

Invalid

Validate results

Valid

Decision

Abnormal/borderline results

Normal results

Inform labour room staff

Inform paediatric clinic immediately

Dispatch results and form to Paediatric Clinic
b. Missed, Insufficient, Blood Clot Samples & Born Before Arrival Cases
   i. If for some reason the blood sample has not been taken from the cord then it
      should be taken from the baby as soon as possible after the third day of life. This is
      to avoid the TSH surge that occurs ½ hour after birth to about 72 hours of age and
      to ensure early treatment before 2 weeks of life for better prognosis.
   
      ii. Fill up the data collection form (Appendix 2) and send this to the Paediatric doctor
          in charge. In addition, give parents the instruction sheet and the date to return for
          a blood sample (after the 3rd day of life).
   
      iii. The Paediatric Department is responsible to collect the blood sample. The blood
           sample collected after the 3rd day of life should be venous sample of at least 2mls.

2.3 Filling Up of Investigation Form (Appendix 2)

Labelling and completion of the data collection form are as follow:
   i. Biodata of the newborn as in item 1-8 should be filled in by labour room staff
   
   ii. Items 9-10 are to be filled by the laboratory staff

2.4 Flow chart for investigation

Refer to flow chart 2 - 4
Flow chart 2: Screening for Congenital Hypothyroidism at Hospital with T4/TSH screening facilities

Cord blood sample collected at birth in labour room¹

Sent to screening hospital lab for TSH

Normal²,³ (< 20mU/L)

Borderline²,³ (20-60mU/L)

High TSH²,³ (> 60mU/L)

FT4 analysis
(on cord blood)

FT4 Normal²,³ (> 15pmol/l)

FT4 Low²,³ (≤ 15pmol/l)

Babies not discharged

Babies discharged

Missed cases

Recall babies urgently
- By phone
- Through nearest health clinic/office⁴

Refer baby to Paediatric Clinic⁵

Take blood for FT4/TSH⁶

Blood to lab for Se FT4/TSH

Result sent to Paediatric Clinic

Further management by Paediatrician

¹ Blood taken by staff who conducts the delivery. Investigation form for screening of TSH to be filled up by attending staff
² Result to be sent to paediatric clinic and compiled by staff in charge.
³ Lab to inform relevant officer/staff at Pediatric Clinic to recall for cases either by phone or to inform sisters/PHN at health districts/clinics.
⁴ Sister/PHN to recall babies.
⁵ Urgent referral and appointment to pediatric clinic
⁶ Blood to be taken at Paediatric Clinic

* For asphyxiated neonates, repeat screening test should be done after 3rd day of life when hemodynamically stable
Flow chart 3: Screening For Congenital Hypothyroidism at Hospital without T4/TSH Screening Facilities

1. Cord blood sample collected at birth in labour room
2. Sent to designated hospital/MKA screening lab for TSH

- Normal (< 20mU/L)
- Borderline (20-60mU/L)
- High TSH (> 60mU/L)

FT4 analysis (on cord blood sample)

- FT4 Normal (> 15pmol/l)
- FT4 Low (≤ 15pmol/l)

Babies not discharged
- Refer baby to Pediatric Clinic
- Take blood for FT4/TSH
- Result to Paediatric Clinic/designated staff
- Further management by Paediatrician

Babies discharged
- Recall babies urgently - By phone
  - Through nearest health clinic/office

Missed cases

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1 Blood taken by staff who conducts the delivery. Investigation form for screening of TSH to be filled by attending staff
2 Result sent to paediatric clinic & compiled by staff in charge.
3 Lab to inform relevant officer/staff at Pediatric Clinic/designated staff to recall cases or to inform sisters/PHN at health districts/clinics.
4 Sister/PHN to recall babies.
5 Urgent referral and appointment to pediatric clinic
6 Blood to be taken at Pediatric Clinic

* For asphyxiated neonates, repeat screening test should be done after 3rd day of life when hemodynamically stable
Flow chart 4: Screening For Congenital Hypothyroidism for Home/Health clinic/ Low Risk Birthing Centre Delivery

1. Cord blood sample collected at birth¹
2. Sent to lab hospital/health clinic
3. Spin and separate sample/storage
4. Sent to designated hospital/MKA screening lab for TSH

- Normal² (≤ 20mU/L)
- Borderline²,³ (20-60mU/L)
- High TSH²,³ (> 60mU/L)

5. FT4 analysis (on cord blood sample)
6. FT4 Normal (≥ 15pmol/l)
7. FT4 Low² (≤ 15pmol/l)

Inform Paediatric Department (designated staff)

- Recall babies urgently⁴
- Take blood for FT4/TSH⁵
- Blood to lab for Se FT4/TSH (MKA/screening hospital lab)

Inform abnormal results to designated staff and Paediatrician²,³

¹ Blood taken by staff who conducts the delivery. Investigation form for screening of TSH to be filled up by attending staff
² Lab to inform abnormal result to Paediatric Department (designated staff) to recall cases
³ All result to be sent to Paediatric Clinic and compiled by designated staff.
⁴ Designated staff to make arrangement to recall babies.
⁵ Blood to be taken at nearest hospital/health clinic.
2.4 Level of Cord TSH and FT4

Cord TSH level:

i. **NORMAL**: < 20mIU/L or use 97.5\textsuperscript{th} percentile value as determine by the local laboratory or laboratory that used the same analyser:
ii. **BORDERLINE**: 20- 60 mIU/L
iii. **HIGH**: > 60 mIU/L

Cord FT4 level:

i. **NORMAL**: > 15pmol/l
ii. **LOW**: ≤ 15pmol/l

2.5 Retesting of Patients (Confirmation) and management

Blood samples for confirmation (re-testing) should be venous samples and should be taken from the baby **after the 3\textsuperscript{rd} day of life**. This is to avoid the TSH surge that occurs from ½ hour after birth to 72 hours of age.

Babies for retesting are those with **high TSH** (> 60mIU/L) or **borderline TSH** (20-60mIU/L) with **low FT4** (≤ 15pmol/l).
3. MANAGEMENT OF CONGENITAL HYPOTHYROIDISM

3.1 Management Principles for Congenital Hypothyroidism

Hormonal therapy is available for congenital hypothyroidism. Every effort needs to be taken to confirm the diagnosis as soon as possible and to initiate treatment. With the cord blood screening programme most neonates with severe congenital hypothyroidism can be treated within the first 14 days of life.

The goal of therapy is to restore euthyroid state by maintaining a serum FT4 level at the upper half of the normal age-related reference range. Ideally serum TSH levels should be between 0.5-2.0mIU/L after the first month of life.

Subsequent review is at 4-6 weekly intervals during the first 6 months and at 2-3 monthly interval during the 6-18th month period to maintain serum FT4 levels in the normal range for age. Treatment is monitored by measuring FT4, TSH, bone age, growth parameters and psychomotor development. Parents need to be counseled that poor compliance in the infancy may cancel the benefits of screening.
Follow-up and Thyroid Function Tests

Suggested time interval for follow-up and thyroid function test is as in Table 4.

### Table 4: Time interval for follow-up and thyroid function test

<table>
<thead>
<tr>
<th>Age of patient</th>
<th>Intervals for Thyroid Function Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>After initiation of L-thyroxine</td>
<td>1-2 weeks (until normalization of results)</td>
</tr>
<tr>
<td>1- 6 months</td>
<td>1 - 2 monthly</td>
</tr>
<tr>
<td>6 months – 3 years</td>
<td>3 - 4 monthly</td>
</tr>
<tr>
<td>&gt; 3 years until growth is complete</td>
<td>6 - 12 monthly</td>
</tr>
</tbody>
</table>

- Should be more frequent if compliance is questionable or abnormal TFT values are obtained, and 4-6 weeks after any change in L-thyroxine dose/formulation

Follow-up Assessment

- Growth
- Development
- Mental and cognitive function
- Symptoms of over and under treatment
- Hearing test
- Bone age - normalization by 1-2 years
4.  MONITORING AND EVALUATION OF THE NATIONAL CONGENITAL HYPOTHYROIDISM SCREENING PROGRAMME

It would be useful to have a computerised register of all neonates screened but this may not be possible in all centres. The simplest way to keep data for monitoring of the programme is for the Paediatrician in charge to keep a copy of ALL the screening forms (i.e. for normal children and those found to have abnormal TSH results)

The data listed below is use for monitoring of the programme:

1. Number of birth registered by month (from the labour room book)
2. Number of cases screened by month
3. Outcome of screening sample results by month (TSH high, borderline and low)
4. Number of children recalled for testing by month (TSH high and TSH borderline with low FT4)
5. Number of cases confirmed as congenital hypothyroidism
6. Number of confirmed cases treated within 14 days of life

Various QA indicators were made to ensure the quality of National Congenital Hypothyroidism Screening Programme, refer Table 5.
Table 5: QA Indicators for National Congenital Hypothyroidism Screening Programme

<table>
<thead>
<tr>
<th>Monitoring Data</th>
<th>QA Indicator</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Coverage of screening programme</strong>&lt;br&gt;= No. of newborn screened (including BBA) per month x 100&lt;br&gt;No. of live births + BBA per months</td>
<td>&gt;99% for hospital</td>
<td>Reflect process in labour room</td>
</tr>
<tr>
<td><strong>2. Screening Sample rejection rate</strong>&lt;br&gt;= No. of rejected sample x100&lt;br&gt;Total no. of screened sample received</td>
<td>&lt; 1%</td>
<td></td>
</tr>
<tr>
<td><strong>3. Percentage of patients with abnormal results retested.</strong>&lt;br&gt;= No. of patients with abnormal results retested x 100&lt;br&gt;Total number recalled back</td>
<td>100%</td>
<td>Reflects process in Paeds.</td>
</tr>
<tr>
<td><strong>Patient with abnormal results</strong> = High TSH + Borderline TSH with low FT4</td>
<td> </td>
<td> </td>
</tr>
<tr>
<td><strong>4. Duration from birth to treatment of confirmed cases</strong>&lt;br&gt;&lt;14 days</td>
<td>100%</td>
<td> </td>
</tr>
<tr>
<td><strong>5. Total turn around time (for lab)</strong>&lt;br&gt;Time from collection of sample to despatch of result to Paediatric Department should be &lt;2 working days (to be monitored 6 monthly)</td>
<td>&gt;90%</td>
<td>Birth&lt;br&gt;Collection&lt;br&gt;Despatch to Lab&lt;br&gt;Received at lab&lt;br&gt;Analysis&lt;br&gt;Despatch to paeds</td>
</tr>
<tr>
<td><strong>6. External Quality Assurance Programme</strong></td>
<td>All Screening lab</td>
<td> </td>
</tr>
<tr>
<td><strong>7. Internal QC</strong>&lt;br&gt;Long term QC monitoring to report CV of IQc&lt;br&gt;Involving 1 year QC data/QC data of the same lot number and calculation of total error and MU</td>
<td>All Screening lab</td>
<td> </td>
</tr>
</tbody>
</table>
Table 6: Data collection at each screening center (Hospital/ KK /LRBC)

<table>
<thead>
<tr>
<th>Year</th>
<th>Month</th>
<th>J</th>
<th>F</th>
<th>M</th>
<th>A</th>
<th>M</th>
<th>J</th>
<th>J</th>
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<th>Total</th>
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<td></td>
<td>No. of live births at hospital/KK</td>
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<td>b</td>
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<td>No. live birth as BBA</td>
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<td>No. samples rejected</td>
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<td>No. samples with high TSH</td>
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<td>No. of confirmed cases treated &lt; 14 days</td>
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## Table 7: Definition Data collection at each screening center

<table>
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<tr>
<th>Variables</th>
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<tbody>
<tr>
<td>a. No. of live births at hospital/KK</td>
<td>No. of live births in participating hospital/clinics</td>
</tr>
<tr>
<td>b. No. live birth as BBA</td>
<td>No. of live births born before arrival to the hospital/clinic</td>
</tr>
<tr>
<td>c. No. samples screened</td>
<td>No. of cord blood samples screened</td>
</tr>
<tr>
<td>d. No. samples rejected</td>
<td>Cord blood samples unable to be processed by lab (analyser) *example: sample hemolysed/mucoid/inadequate/wrong lable/wrong container</td>
</tr>
<tr>
<td>e. No. normal TSH</td>
<td>No. of cord blood samples with TSH &lt; 20 mIU/L</td>
</tr>
<tr>
<td>f. No. samples with high TSH</td>
<td>No. of cord blood samples with TSH &gt; 60 mIU/L</td>
</tr>
<tr>
<td>g. No. samples with borderline TSH</td>
<td>No. of cord blood samples with borderline TSH 20 - 60 mIU/L</td>
</tr>
<tr>
<td>h. No. samples with borderline TSH and low FT4</td>
<td>No. of cord blood samples with borderline TSH 20 - 60 mIU/L and low FT4 &lt; 15pmol/L (on same cord blood sample)</td>
</tr>
<tr>
<td>i. No. needing retesting (f+h)</td>
<td>No. of cord blood samples with abnormal results which needed retesting (TSH &gt; 60mIU/L or borderline TSH and low FT4 &lt; 15pmol/L)</td>
</tr>
<tr>
<td>j. No. retested</td>
<td>No. of cord blood samples with abnormal results (TSH &gt; 60mIU/L or borderline TSH and low FT4 ≤ 15pmol/L) which were retested after 72 hours of life</td>
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<tr>
<td>k. Actual recall rate (j/c)x 100</td>
<td>No. needing retesting / total no. of cord blood samples x 100%</td>
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<tr>
<td>l. No. of confirmed cases</td>
<td>No. of cases confirmed to have Congenital Hypothyroidism</td>
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<tr>
<td>m. No. of confirmed cases treated &lt; 14 days</td>
<td>No. of confirmed congenital hypothyroidism who received treatment within 14 days of life</td>
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Table 8: Data collection at state level and national level

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<th>JUL</th>
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<th>OCT</th>
<th>NOV</th>
<th>DEC</th>
<th>Total</th>
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<td>c</td>
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<td>No. samples with high TSH (&gt;60mIU/L)</td>
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<td>i</td>
<td>No. samples with borderline TSH (20-60mIU/L)</td>
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<td>(private&amp;university)</td>
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<tr>
<td>j</td>
<td>No. samples with borderline TSH (20-60mIU/L) and low FT4 (≤15pmol/L)</td>
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<td>Total no of result collected</td>
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<td>(KCM)</td>
<td>(private &amp; university)</td>
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<td>(private &amp; university)</td>
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<tr>
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<td>(KCM)</td>
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<tr>
<td>5</td>
<td>No of confirmed cases treated &lt; 14 days</td>
<td>(KCM)</td>
<td>(private &amp; university)</td>
<td>(KCM)</td>
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<td>(private &amp; university)</td>
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<td>(private &amp; university)</td>
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<td>% treated &lt; 14 days of life</td>
<td>(KCM)</td>
<td>(private &amp; university)</td>
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<td>(private &amp; university)</td>
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<td>(private &amp; university)</td>
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<tr>
<td>7</td>
<td>No. of hospital with lab facility (analyser) for cord TSH</td>
<td>(KCM)</td>
<td>(private &amp; university)</td>
<td>(KCM)</td>
<td>(private &amp; university)</td>
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Table 9: Definition Data Collection at State and National Level

Definitions of variables

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<tr>
<th>Facilities</th>
<th>Definition</th>
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<td>(KKM)</td>
<td>For <strong>KKM</strong> hospital/clinics/ABC</td>
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<tr>
<td>(private&amp;university)</td>
<td>For <strong>PRIVATE and UNIVERSITY</strong> hospital/maternity centres/clinics</td>
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</table>

<table>
<thead>
<tr>
<th>Variables:</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>a</td>
<td>No. live births at hospital/KK</td>
</tr>
<tr>
<td>b</td>
<td>No. live birth as BBA</td>
</tr>
<tr>
<td>c</td>
<td>Total no. of live birth (a+b)</td>
</tr>
<tr>
<td>d</td>
<td>No. samples screened (total)</td>
</tr>
<tr>
<td>e</td>
<td>% samples screened</td>
</tr>
<tr>
<td>f</td>
<td>No. rejected samples</td>
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<td>g</td>
<td>No. normal TSH</td>
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<tr>
<td>h</td>
<td>No. samples with high TSH</td>
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<tr>
<td>i</td>
<td>No. samples with borderline TSH</td>
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<tr>
<td>j</td>
<td>No. samples with borderline TSH and low FT4</td>
</tr>
<tr>
<td>k</td>
<td>Total no of result collected</td>
</tr>
<tr>
<td>l</td>
<td>Missing results</td>
</tr>
<tr>
<td>m</td>
<td>No. of needing retesting (h+j)</td>
</tr>
<tr>
<td>n</td>
<td>No. Retested</td>
</tr>
<tr>
<td>o</td>
<td>Actual recall rate - (n/d) x 100</td>
</tr>
<tr>
<td>p</td>
<td>No. of confirmed cases</td>
</tr>
</tbody>
</table>

Variables:

- **a**: No. live births at hospital/KK
- **b**: No. live birth as BBA
- **c**: Total no. of live birth (a+b)
- **d**: No. samples screened (total)
- **e**: % samples screened
- **f**: No. rejected samples
- **g**: No. normal TSH
- **h**: No. samples with high TSH
- **i**: No. samples with borderline TSH
- **j**: No. samples with borderline TSH and low FT4
- **k**: Total no of result collected
- **l**: Missing results
- **m**: No. of needing retesting (h+j)
- **n**: No. Retested
- **o**: Actual recall rate - (n/d) x 100
- **p**: No. of confirmed cases

Definitions:

- **a**: No. of live births in participating hospital/clinics
- **b**: No. of live births born before arrival to the hospital/clinic
- **c**: Total no. of live births in the participating hospital/clinic (AUTOCALCULATED)
- **d**: No. of cord blood samples screened
- **e**: no. of samples screened/total no. of live birth in the participating hospital x 100% (d/c x 100) (AUTOCALCULATED)
- **f**: Cord blood samples unable to be processed by lab (analyser)
  *example: sample hemolysed/mucoid/inadequate/wrong label/wrong container
- **g**: No. of cord blood samples with TSH < 20 mIU/L
- **h**: No. of cord blood samples with TSH > 60 mIU/L
- **i**: No. of cord blood samples with borderline TSH 20 - 60 mIU/L
- **j**: No. of cord blood samples with borderline TSH 20 - 60 mIU/L and low FT4 ≤ 15pmol/L (on same cord blood sample)
- **k**: g+h+i (AUTOCALCULATED)
- **l**: (d-k) (AUTOCALCULATED)
- **m**: No. of sample with abnormal result which needed retesting (sample with TSH > 60mIU/L + samples with low FT4 ≤15pmol/L) (AUTOCALCULATED)
- **n**: No. of cord blood samples with abnormal results (TSH > 60mIU/L or borderline TSH AND low FT4 ≤ 15pmol/L) which were retested after 72 hours of life
- **o**: No. of needing retesting (abnormal result) / total no. of cord blood screened x 100%
- **p**: No. of cases with confirm diagnosis of Congenital Hypothyroidism
<table>
<thead>
<tr>
<th>Variables:</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>q  No of confirmed cases treated &lt; 14 days</td>
<td>No of confirmed congenital hypothyroidism who received treatment within 14 days of life</td>
</tr>
<tr>
<td>r  No. hospital &amp; klinik involved in blood sampling and return collection</td>
<td>No. of hospital participate in the screening program (collects TSH samples and submit returns)</td>
</tr>
<tr>
<td>s  No. of hospital with lab facility (analyser) for cord TSH</td>
<td>No. of hospitals with lab facilities (analyser for TSH)</td>
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</table>
Table 10: Data collection for confirmed case by states

Confirmed case report

STATE:  
YEAR:  
MONTH:

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<th>RN</th>
<th>DOB</th>
<th>Date of 1st sample / result</th>
<th>Date of repeat sample / result</th>
<th>Date of diagnosis</th>
<th>Date started treatment</th>
<th>Duration from birth to treatment</th>
<th>Remarks</th>
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</tbody>
</table>
Flow chart 6: Monthly reten flow from Hospital

Cord blood sample collected at birth in hospital

Sample sent to hospital lab

Result normal?

Yes

Hardcopy result send to program coordinator in paediatric department.

Result sent to district health office (PKD)

Distribution of result to respective KK

Results recorded in child’s health card and Buku Daftar KIB 101 Pindaan 2/2007

Monthly reten send to PKD

Monthly reten send to JKN before 10th of every month

Monthly reten send to BPKK before 15th of every month

No

Inform result immediately to program coordinator in paediatric department. Hardcopy result send to paediatric clinic

Inform result to respective KK

Recall babies for retesting

Retesting results

Hardcopy result send to program coordinator in paediatric clinic

Inform result to respective KK

Reten data from private sector
Flow chart 7: Monthly reten flow from Health clinic/Alternative Birthing Centre Delivery

1. Cord blood sample collected at birth in KK/ABC

2. Sample sent to hospital lab /MKA

3. 
   - Results normal?
     - Yes: Hardcopy of the result send to programme coordinator in KK
   - No: Inform result immediately to program coordinator in KK. Hardcopy result send to KK.

4. 
   - Hardcopy of the result send to programme coordinator in KK
   - Inform result immediately to program coordinator in KK. Hardcopy result send to KK.

5. Recall babies and refer to Paediatrician

6. Results recorded in child’s health card and Buku Daftar KIB 101 Pindaan 2/2007

7. Retesting results

8. Monthly reten send to PKD

9. Monthly reten send to JKN before 10th of every month

10. Reten data from private sector

11. Monthly reten send to BPKK before 15th of every month
5. RESPONSIBILITIES OF DEPARTMENTS INVOLVED

Administrative Department
1. Printing of investigation form

Obstetric Department/Labour Room
1. To assign staff responsible for coordination Congenital Hypothyroidism Screening
2. To indent investigation form and test tubes
3. Collection of specimen
4. Fill up investigation form
5. Dispatch of specimen to the laboratory
6. Record number of specimen taken/not taken (with reason)
7. BBA cases – explain to mothers regarding the screening, fill up the investigation form and to get appointment for mothers to take the baby to paediatric clinic
8. Antenatal education

Pathology Department
1. Purchasing of reagents and consumables
2. Receiving specimen and keep records
3. Perform laboratory investigation/procedure
4. Inform cases that need to be recalled (high/borderline TSH with low FT4 and rejected samples) to paediatric clinic/designated staff
5. Dispatch all results to Paediatric Clinic/designated staff
6. To participate in External Quality Assurance Programme

Paediatric Department
1. Coordination of the screening programme
2. Collection of all results
3. Recall of cases for high/borderline TSH with low FT4 and rejected samples
4. Further management of cases
5. Handle BA cases (liaise with post-natal ward)
6. Monitoring and evaluating of the programme with QA indicators
7. Annual return of the programme to State Health Department (via State Paediatrician)

State Health Department
1. To set up Congenital Hypothyroidism committee at state level
2. Assist in recalling babies and follow up
3. To establish mechanism for documenting results in Child Health Home-based Card
4. Monitoring and evaluation of the overall programme
5. Budget
6. Planning
7. To finalized return and submit to Family Health Development Division, MOH
8. Responsible for public health education
9. Responsible for training for screening programme (eg: blood collection)
APPENDIX

Appendix 1
Blood for TSH (Thyroid Stimulating Hormone) evaluation should be collected immediately after birth from the maternal side of the cord. From studies done in Singapore and Finland, it is noted that there is a rapid admixture of maternal blood and foetal blood in the placenta immediately after births. This means that the TSH from cord blood can be contaminated by maternal TSH levels. To overcome this problem, we would like cord blood to be collected for TSH in the manner described below:

Please note:
1. For vaginal deliveries, the 2nd metal clamp is applied to the umbilical cord as close to the vulva as possible. Only blood between the 1st and 2nd metal is to be collected for TSH. Even if the volume of blood is small (ie. <10mls), do not tempted to release the 2nd metal clamp.

2. For LSCS deliveries (where the plastic clamp is not used), please apply a 3rd metal clamp or artery forceps to the umbilical cord just before the placenta. Collect blood for TSH from the segment of cord between 2nd and 3rd metal clamps. Even if the volume of blood is small (ie. <10mls), do not tempted to release the 3rd metal clamp.
Appendix 2

Ref No.

CONGENITAL HYPOTHYROIDISM CORD BLOOD SCREENING TEST
HOSPITAL ____________

Items 1-8 are to be filled in by labour room staff

<table>
<thead>
<tr>
<th>Item</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Mother’s IC number:</td>
</tr>
<tr>
<td>2.</td>
<td>RN:</td>
</tr>
<tr>
<td>3.</td>
<td>Mother’s name:</td>
</tr>
<tr>
<td>4.</td>
<td>Home Address:</td>
</tr>
<tr>
<td>a)</td>
<td>Permanent address</td>
</tr>
<tr>
<td>b)</td>
<td>During confinement period/maternity leave</td>
</tr>
<tr>
<td>5.</td>
<td>Home Telephone No:</td>
</tr>
<tr>
<td>6.</td>
<td>Place of birth:</td>
</tr>
<tr>
<td>7.</td>
<td>DOB: Time</td>
</tr>
<tr>
<td>8.</td>
<td>Date sample taken:</td>
</tr>
</tbody>
</table>

Items 9-10 are to be filled in by laboratory staff:

<table>
<thead>
<tr>
<th>Item</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.</td>
<td>Date sample received:</td>
</tr>
<tr>
<td>10.</td>
<td>Result:</td>
</tr>
<tr>
<td>a)</td>
<td>TSH (mIU/l):</td>
</tr>
<tr>
<td>b)</td>
<td>FT4 (pmol/L)</td>
</tr>
</tbody>
</table>

Collection of blood samples for TSH in hospital

i) Immediately after delivery, clean the maternal side of the cord with a sterile gauze and collect the blood sample. (Appendix 1)

ii) Allow free flow of blood from the cord directly to the tube (if you need to ‘milk’, do it gently to prevent hemolysis).

iii) The tube should be filled with a minimum of 3 ml of blood. (Allow space for the cap to be pushed in)

iv) Label the tube immediately. Complete the investigation form.

v) Send the sample to the laboratory with the form at the normal routine intervals within 24 hours.

vi) See flow chart 1 for the handling of blood samples at the laboratory.

Flow of Investigations

- Cord blood sample collected at Birth
- Screening for TSH
- TSH < 20 mIU/l (Normal)
- TSH 20-60 mIU/l (Borderline)
- TSH > 60 mIU/l (High)
- Missed Cases
  - Do FT4
    - FT4>15 pmol/L*
    - FT4≤15 pmol/L*
  - No recall
    - Recall babies urgently for repeat TSH & FT4

*Note:
Lab is encouraged to determine their own 97.5th percentile (use log TSH for its determination) for TSH to be used as a cut off value.

Missed, Insufficient, Blood Clot Samples & Born Before Arrival Cases

i) If for some reason the blood sample has not been taken from the cord then it should be taken from the baby as soon as possible after the third day of life. This is to avoid the TSH surge that occurs from ½ hour after birth to about 72 hours of age and to ensure early treatment before 2 weeks of life for better prognosis.

ii) Fill up the data collection form (Appendix 2) and send this to the Paediatric doctor in charge. In addition give parents the instruction sheet and the date to return for a blood sample (after the 3rd day of life).

iii) The Paediatric Department is responsible to collect the blood sample. Blood samples collected after the 3rd day of life should be venous samples of at least 2 mls.
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