

# Thyroid Disease in Pregnancy

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**Executive Lead:** Name and title

**Status:** Approval date:

Ratified by:

Review date:

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## History

Issue	Date Issued	Brief Summary of Change	Author
1			
2			

For more information on the status of this document, please contact:	
Policy Author	
Department/Directorate	
Date of issue	
Review due	
Ratified by	
Audience	

## Executive summary

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**See also: Any relevant trust policies/guidelines or procedures**

## 1. Introduction

1.1 Hypothyroidism (overt and subclinical) is common in women of reproductive age and can be associated with adverse maternal and fetal outcomes. Optimal control in the first trimester seems to be most important. Whilst accepting that the evidence base regarding the implications of subclinical hypothyroidism and benefits of treatment are conflicting, we here offer guidance on its management in pregnancy. Most women with hypothyroidism will be able to have midwifery-led care.

## 2. Scope

2.1 This guidance is relevant to: all midwives, obstetricians, neonatologists and endocrinologists involved in the care of pregnant women.

## 3. Purpose

3.1 The purpose of this document is to set out which women should be screened for thyroid disease in pregnancy and how women with new or existing thyroid disease should be cared for.

## 4. Explanation of Terms Used

4.1 List and define the meaning of terms (where required). This may be included as a Glossary.

## 5. Duties and responsibilities

5.1 General roles and responsibilities for implementation and operation of the policy.

5.2 This section may have subheadings to cover the range of duties held by individuals and/or committees within the Trust.

## 6. Policy

### 6.1 Pregnancy specific normal ranges for TFTs

There are no gestation specific reference ranges applicable to our local population and our analysers.

	TSH (mU/L)	Thyroxine (pmol/L)	Tri-iodothyronine (pmol/L)
Non-pregnant	0.27-4.2	12-22	3.1-6.8
First trimester	0-5.5	10-16	3-7
Second Trimester	0.5-3.5	9-15.5	3-5.5
Third trimester	0.5-4	8-14.5	2.5-5.5

From 'Handbook of Obstetric Medicine (5<sup>th</sup> Ed)', C Nelson-Piercy, 2015

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## 6.2 Summary – Screening for hypothyroidism

Who to screen at booking (request 'TSH')	<p>Previous hyperthyroidism/Graves'</p> <p>Previous postpartum thyroiditis</p> <p>Previous thyroid surgery</p> <p>Family history of thyroid disease (1st-degree)</p> <p>Type 1 diabetes</p> <p>Adrenal failure</p> <p>Previous therapeutic head or neck irradiation</p>
Screening abnormal (TSH > 4.78 mU/L)	Book into next obstetric antenatal clinic where they can be advised to commence levothyroxine.
History of postpartum thyroiditis	BadgerNet referral to 'obstetric endocrine'. Will be seen in the obstetric endocrine clinic.

## 6.3 Summary – Hypothyroidism

Women who previously had hyperthyroidism / Graves'	<p>BadgerNet referral to 'obstetric endocrine' who will advise whether they will be seen in the joint clinic or the maternal medicine clinic.</p> <p>Refer to perinatal high-risk list for discussion (e-mail antenatal screening midwife).</p> <p>Check maternal TSH receptor antibodies once in pregnancy.</p>
Hashimoto's thyroiditis	BadgerNet referral to 'obstetric endocrine'. Will be seen in the obstetric endocrine clinic.
Monitoring: when to check TSH.	<p>When find out pregnant (GP to arrange)</p> <p>Booking appointment</p> <p>14-week appointment</p> <p>26-28 weeks (with the antibody screen and FBC)</p> <p>And 4 weeks after any change in dose</p>
Once booking bloods reviewed by community midwife	Send GP Hypothyroid in Pregnancy letter (Appendix)
TSH ≤ 2.5 mU/L	Continue current levothyroxine dose
TSH > 2.5 mU/L	<p>Dose of levothyroxine needs to be increased by approximately 25%</p> <p>Community midwife to call patient and message through BadgerNotes and e-mail to GP (see Appendix)</p> <p>GP to repeat TFTs after 4 weeks</p>
TSH > 10 mU/L or levothyroxine dose > 200mcg	Discuss with maternal medicine consultant or endocrine consultant.

Place of birth	Midwife Led Birth environment unless other risks including previous possible or proven Graves' disease
Postnatal	Continue current treatment Repeat TFTs at GP 6-week postnatal check
Neonate	See Neonatal Thyroid Disease guideline

#### 6.4 Summary – Hyperthyroidism

Fetal Heart monitoring	Document the fetal heart rate at all antenatal visits after 24 weeks. If abnormal please discuss with senior medical staff.
Growth scans – routine growth scan NOT recommended unless there are additional features:	Other obstetric growth risk factors Previous neonate with Graves' disease Sustained fetal tachycardia of uncertain cause
Possible or likely GRAVES NORMAL TFTS at booking. On antithyroid medication	BadgerNet referral to 'obstetric endocrine'.  Refer to perinatal high-risk list for discussion (e-mail antenatal screening midwife).  Confirm diagnosis re possible / confirmed GRAVES  Continue current antithyroid medications; Consider dose reduction to lowest dose.  Repeat TFT's depending on details / respond PRN.  Confirm postnatal plan re ongoing treatment (Endocrinology team)  Monitor fetal growth clinically and refer if concerns  Monitor fetal heart rate, refer if persistently over 160  Check maternal TSH receptor antibodies once in pregnancy.
NORMAL TFTS at booking. No current antithyroid drugs.	BadgerNet referral to 'obstetric endocrine' who will advise whether they will be seen in the joint clinic or the maternal medicine clinic.  Refer to perinatal high-risk list for discussion (e-mail antenatal screening midwife).

	<p>Review history, exclude Graves disease if possible.</p> <p>If possible or confirmed GRAVES see above.</p> <p>Repeat TFT's every trimester</p> <p>Check maternal TSH receptor antibodies once in pregnancy.</p>
Abnormal TFT's consistent with HYPERTHYROID status, at anytime	<p>Discuss with obstetric/endocrine senior medical staff within 3 days (best with original endocrine team responsible for previous and ongoing thyroid care)</p> <p>Management dependant on details.</p> <p>Check maternal TSH receptor antibodies once in pregnancy – liaise with neonatal teams accordingly.</p> <p>Refer to perinatal high-risk list for discussion (e-mail antenatal screening midwife).</p>
Place of birth	Labour ward
Postnatal	<p>Usual obstetric care</p> <p>Continue current plan and treatment</p> <p>Repeat maternal TFTs at 2 and 6 weeks. Document thyroid plan and follow up-usually endocrinology and GP</p>
Neonate	See Neonatal Thyroid guideline. Babies are at risk of either HYPO and or HYPERTHYROIDISM

## 6.5 Hypothyroidism

### 6.5.1 Care Pathway

In general, women with known hypothyroidism will continue under midwifery-led care pathways, who will arrange routine monitoring of thyroid function. Changes in dose will be requested from the patient's GP. They will not usually need obstetric appointments unless there are other concerns in pregnancy or markedly abnormal blood tests.

Women with Hashimoto's will be seen in the joint obstetric endocrine clinic.

New diagnoses of hypothyroidism in pregnancy will have an antenatal clinic appointment with their named consultant to discuss treatment.

### 6.5.2 Risks

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Overt hypothyroidism is associated with increased risks of pregnancy induced hypertension, pre-eclampsia, postpartum haemorrhage, miscarriage, preterm labour, low birth weight and neurocognitive effects in offspring (lower IQ (7 points), delay in motor skill development, language and attention at 7-9 years).

It is unclear what target for TSH levels gives the best outcomes. Therefore, for simplicity, a target of < 2.5mU/L is used in this guideline for those with hypothyroidism on levothyroxine.

The evidence regarding subclinical hypothyroidism (raised TSH with normal T3/4) is inconsistent with some studies showing smaller associations with the above risks but others do not bear out the risks. It is uncertain if thyroid hormone replacement is of benefit in women with subclinical hypothyroidism.

### 6.5.3 Screening

The following women are at increased risk of hypothyroidism and should be screened at their booking appointment:

- Previous hypothyroid or hyperthyroid disease (women with a **history of hyperthyroid disease or Graves' disease** should also have TSH receptor antibodies (TRAbs) checked & should be referred to the joint endocrine clinic). They should also be added to the perinatal high-risk list (e-mail the antenatal screening midwife).
- Previous postpartum thyroiditis
- Previous thyroid surgery
- Family history thyroid disease (first-degree family member)
- Type 1 diabetes, adrenal failure
- Previous therapeutic head or neck irradiation

Check **TSH** with routine booking bloods.

Screening women with **TSH >4.78mU/L** should have an appointment in the next ANC with their named consultant where they can be advised to start treatment with levothyroxine.

The discussion at this appointment should cover:

- Possible risks of hypothyroidism and subclinical hypothyroidism
- Uncertainty of benefit of treatment of subclinical hypothyroidism

If **TRAbs** are positive the newborn baby will need neonatal review and this should be noted on Badgernet. These cases should be referred to the perinatal high-risk list.

#### 6.5.3.1 Levothyroxine dosing guidance for new diagnosis of hypothyroidism

Raised TSH (>4.78mU/L) and low T4: 1.6mcg/kg/day

Raised TSH with normal T4: 1mcg/kg/day

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Take on an empty stomach. Ideally an hour before breakfast. Separate from iron, antacids, pregnancy vitamins and calcium supplements by 4 hours.

#### 6.5.4 Pre-existing Hypothyroidism

Women already taking levothyroxine should contact their GP as soon as they know they are pregnant to check their TSH. Women will be advised of this when they complete the maternity booking form on the trust website.

#### 6.5.5 Monitoring

##### **Aim for TSH < 2.5mU/L.**

Increase dose by around 25% if required (in multiples of 25mcg).

Overtreatment has a possible association with preterm delivery and behavioural difficulties (one study).

TSH should be checked 4 weeks after any change in dose.

If the dose is > 200mcg then endocrine input should be sought.

Women should have TSH checked approximately every 4-6 weeks until 18 weeks gestation but to reduce the burden on women these should coincide with visits to the hospital:

- Positive pregnancy test (GP)
- Booking appointment
- 14-week appointment
- 26-28 weeks (with the antibody screen and FBC)

In line with the relevant SOP these results should be reviewed by the community midwifery team within 10 days.

Once the booking blood results have been checked the community midwife will send the GP the Hypothyroidism in Pregnancy letter which sets out the expectations for the pregnancy (see appendix).

The need for a change in dose should be communicated to the patient by the community midwife by phone and followed up with a message on Badgernotes (standard template in appendices). The midwife should also inform the GP by e-mail so that the GP can increase the dose and arrange repeat TFTs 4 weeks later (standard template letter in appendices).

#### 6.5.6 Postnatal

After delivery the GP should be asked check TSH at the 6-week check and adjust the levothyroxine dose accordingly. The need for this should be included in the postnatal discharge letter.

#### 6.5.7 Place of Birth

In general, hypothyroidism should not influence a woman's choice for place of birth (midwifery-led birth unit, home birth or labour ward). However, women with a history

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of hyperthyroidism, Graves' disease or who are TRAb positive should be advised to birth on the Labour Ward or in the Abbey Birth Centre to allow early neonatal review.

## 6.6 Hyperthyroidism

Current or previous hyperthyroid disease should be referred at booking through BadgernNet to 'obstetric endocrine'. They should have TSH, T3, T4 and TSH receptor antibodies (TRAbs) checked at booking. All referrals will be reviewed by an endocrinology consultant and a plan of care made. Women on antithyroid medication will be seen in the joint obstetric endocrine clinic. Women with normal thyroid function and not on antithyroid medication may be seen in either the joint obstetric endocrine clinic or the maternal medicine clinic.

These cases should also be added to the perinatal high-risk list (e-mail the antenatal screening midwife).

### 6.6.1 Risks

Overt hyperthyroidism is associated with increased risks of pre-eclampsia, heart failure, pre-term labour, stillbirth, and intrauterine growth restriction. Graves' disease is associated with fetal and neonatal hyperthyroidism.

### 6.6.2 Management

- 6.6.2.1 Low TSH in pregnancy - If a subnormal serum TSH concentration is detected during pregnancy hyperthyroidism must be distinguished from normal physiology including hyperemesis gravidarum associated changes (typically low TSH and raised T4). A diagnosis of Graves' disease may be supported by evidence of autoimmunity, a goitre and presence of TSH receptor antibodies (if known as testing not usually recommended).
- 6.6.2.2 Growth scans – routine growth scan NOT recommended unless there are additional features or clinical details increasing the risk for growth restriction (other obstetric growth risk factors, previous neonate with Graves' disease, sustained fetal tachycardia of uncertain cause)
- 6.6.2.3 Fetal Heart monitoring – ALL women with past or current history of hyperthyroid disease should have the fetal heart rate monitored and documented at all antenatal visits after 24 weeks (midwife or doctor visits). If abnormal please discuss with senior medical staff.
- 6.6.2.4 Anti-thyroid medication – if needed use lowest possible dose to maintain maternal thyroxine levels in the upper pregnant reference range. Review and adjust dose as pregnancy advances.
- 6.6.2.5 Propylthiouracil (PTU). Less PTU reaches breast milk and for this reason PTU is the first line treatment for women of reproductive age who require treatment. However, for women on carbimazole, changing agent in pregnancy is NOT

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recommended. Both drugs cause agranulocytosis and women should be warned to report a sore throat and attend for a full blood count as soon as possible. This reaction is unpredictable and the risks of this are not an indication to change agent routinely in pregnancy.

- 6.6.2.6 Subtotal thyroidectomy - rarely indicated in pregnancy, may be required for women with adverse reactions to antithyroid therapy or requiring high doses of antithyroid therapy or those who are not adherent to treatment and have uncontrolled hyperthyroidism. Timing usually best in the second trimester, discuss details with senior medical staff.
- 6.6.2.7 Thyroid receptor stimulating or binding antibodies (TSH receptor antibodies) cross the placenta and can stimulate the fetal thyroid. Currently we recommend checking TSH receptor antibody levels once in pregnancy. The values do not influence antenatal care or management. If raised this should be highlighted to the Fetal Medicine MDT.
- 6.6.2.8 Radioactive iodine should NEVER be given to a woman who may be pregnant. Expert opinion is recommended if this occurs. Women who have had previous treatment with radioactive iodine should be considered to still have the antibodies for Graves' disease and assessed as previously described including normal recommendations for thyroxine replacement, if needed.

### 6.6.3 Place of birth

Because the baby requires specific neonatal review, additional observations with possible interventions we recommend birth in hospital. If the mother is taking treatment this should be on the main labour ward however if there is no current medication at any time in the pregnancy consideration can be given to birth on the Abbey Birth Centre.

### 6.7 Hyperemesis gravidarum and testing for hyperthyroidism

Thyroid function - routine assessment of TFTs is not indicated unless there are other signs of thyroid disease (eye, significant goitre or other additional thyroid disease concerns).

Without a previous history of thyroid disease or autoimmunity acute presentation with hyperthyroidism is rare. Rarely will the biochemical thyroid derangement seen in hyperemesis require specific treatment. If further advice is necessary, please discuss with senior medical staff.

#### 6.7.1 Postpartum thyroiditis

There are insufficient data to recommend routine screening of women for postpartum thyroiditis. Women with symptoms (including anxiety and mood disorders) which may be non-specific should however, have testing of thyroid function.

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Women who are known to be thyroid peroxidase antibody-positive should be considered at high risk for postpartum thyroiditis and consideration given to screening with TSH level measurements perhaps at 2 weeks, 2 months and then every 6 months for 1 year.

Women with postpartum thyroiditis have an increased risk of developing permanent primary hypothyroidism in the following five to 10-year period. Annual TSH levels are recommended in these women.

#### 6.7.2 Thyroid nodules and cancer

Women with thyroid nodules or other thyroid concerns should be discussed and referred as appropriate for expert endocrinology opinion. Further details of this area are beyond the scope of this guideline.

#### 6.7.3 Iodine nutrition during pregnancy

Women of childbearing age should have an average iodine intake of 150 µg per day (this is the amount in Pregnacare). During pregnancy and breast-feeding women should increase their daily iodine intake to 250 µg on average. This should not exceed 500 µg per day.

## 7. Training

- 7.1 Explain the training arrangements (including where relevant, training arrangements for staff at all levels).

## 8. Stakeholder Engagement and Communication

- 8.1 The development of this guideline involved obstetricians with a specialist interest in foeto-maternal medicine, endocrinologists with a special interest in obstetric endocrinology, specialist midwives and neonatologists.

## 9. Approval and Ratification

- 9.1 Define the process for gaining approval for your policy
- 9.2 Explain the ratification process for your policy at the relevant committee.

## 10. Dissemination and Implementation

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- 10.1 -Information to be provided to GPs to cover normal range of TFTs in pregnancy and why women will be contacting them at conception.
- 10.2 Standardised templates to communicate TSH results for women with hypothyroidism requiring a change in dose of levothyroxine.
- 10.3 BadgerNet will be updated to prompt booking midwife to ask about family history of thyroid disease.

**11. Review and Revision Arrangements**

- 11.1 Review every 3 years by lead for the hypothyroid antenatal clinic and the lead for the joint obstetric endocrine clinic.
- 11.2 Review should be triggered earlier if any new relevant national guidelines are introduced, or should there be a significant change in the evidence base.

**12. Document Control and Archiving**

- 12.1 Detail the process for uploading new, approved versions of the policy onto the intranet, and archiving arrangements.

**13. Monitoring compliance with this Policy**

Measurable Policy Objective	Monitoring/ Audit method	Frequency of monitoring	Responsibility for performing the monitoring	Monitoring reported to which groups/ committees, inc responsibility for reviewing action plans
e.g. All policies will be reviewed by their authors at least annually to ensure that they remain valid and in date	Compliance audit of sample of policies (including Review History)	Annual	Associate Director of Quality	Management Executive

**14. Supporting References / Evidence Base**

- 14.1 Lazarus J, Brown RS, Daumerie C, Hubalewska-Dydejczyk A, Negro R, Vaidya B. 2014 European thyroid association guidelines for the management of subclinical hypothyroidism in pregnancy and in children. Eur Thyroid J. 2014 Jun;3(2):76-94. doi: 10.1159/000362597. Epub 2014 Jun 7. PMID: 25114871; PMCID: PMC4109520.

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- 14.2 De Groot L, Abalovich M, Alexander EK, Amino N, Barbour L, Cobin RH, Eastman CJ, Lazarus JH, Luton D, Mandel SJ, Mestman J, Rovet J, Sullivan S. Management of thyroid dysfunction during pregnancy and postpartum: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2012 Aug;97(8):2543-65. doi: 10.1210/jc.2011-2803. Erratum in: J Clin Endocrinol Metab. 2021 May 13;106(6):e2461. PMID: 22869843.
- 14.3 Okosieme O, Gilbert J, Abraham P, Boelaert K, Dayan C, Gurnell M, Leese G, McCabe C, Perros P, Smith V, Williams G, Vanderpump M. Management of primary hypothyroidism: statement by the British Thyroid Association Executive Committee. Clin Endocrinol (Oxf). 2016 Jun;84(6):799-808. doi: 10.1111/cen.12824. Epub 2015 Jun 25. PMID: 26010808.
- 14.4 Alexander EK, Pearce EN, Brent GA, Brown RS, Chen H, Dosiou C, Grobman WA, Laurberg P, Lazarus JH, Mandel SJ, Peeters RP, Sullivan S. 2017 Guidelines of the American Thyroid Association for the Diagnosis and Management of Thyroid Disease During Pregnancy and the Postpartum. Thyroid. 2017 Mar;27(3):315-389. doi: 10.1089/thy.2016.0457. Erratum in: Thyroid. 2017 Sep;27(9):1212. PMID: 28056690.
- 14.5 Thyroid disease in pregnancy and the newborn guideline. Version 3.2. October 2018. University Southampton NHS Foundation Trust

## **APPENDIX 1: EQUALITY IMPACT ASSESSMENT**

### **Equality Impact Assessment Summary**

**Name and title:**

**Policy:**

<p><b>Background</b></p> <ul style="list-style-type: none"> <li>Who was involved in the Equality Impact Assessment</li> </ul>
<p><b>Methodology</b></p> <ul style="list-style-type: none"> <li>A brief account of how the likely effects of the policy was assessed (to include race and ethnic origin, disability, gender, culture, religion or belief, sexual orientation, age)</li> <li>The data sources and any other information used</li> <li>The consultation that was carried out (who, why and how?)</li> </ul>

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**Key Findings**

- Describe the results of the assessment
- Identify if there is adverse or a potentially adverse impacts for any equalities groups

**Conclusion**

- Provide a summary of the overall conclusions

**Recommendations**

- State recommended changes to the proposed policy as a result of the impact assessment
- Where it has not been possible to amend the policy, provide the detail of any actions that have been identified
- Describe the plans for reviewing the assessment

## **APPENDIX 2: CHECKLIST FOR THE REVIEW AND APPROVAL OF DOCUMENTS**

To be completed (electronically) and attached to any document which guides practice when submitted to the appropriate committee for approval or ratification.

**Title of the document:**

**Policy (document) Author:**

**Executive Director:**

		Yes/No/ Unsure/ NA	<u>Comments</u>
<b>1.</b>	<b>Title</b>		
	Is the title clear and unambiguous?		
	Is it clear whether the document is a guideline, policy, protocol or standard?		
<b>2.</b>	<b>Scope/Purpose</b>		
	Is the target population clear and unambiguous?		
	Is the purpose of the document clear?		
	Are the intended outcomes described?		
	Are the statements clear and unambiguous?		
<b>3.</b>	<b>Development Process</b>		
	Is there evidence of engagement with stakeholders and users?		
	Who was engaged in a review of the document (list committees/ individuals)?		
	Has the policy template been followed (i.e. is the format correct)?		
<b>4.</b>	<b>Evidence Base</b>		
	Is the type of evidence to support the document identified explicitly?		
	Are local/organisational supporting documents referenced?		
<b>5.</b>	<b>Approval</b>		
	Does the document identify which committee/group will approve/ratify it?		
	If appropriate, have the joint human resources/staff side committee (or equivalent) approved the document?		
<b>6.</b>	<b>Dissemination and Implementation</b>		
	Is there an outline/plan to identify how this will be done?		
	Does the plan include the necessary training/support to ensure compliance?		
<b>7.</b>	<b>Process for Monitoring Compliance</b>		

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		Yes/No/ Unsure/ NA	<u>Comments</u>
	Are there measurable standards or KPIs to support monitoring compliance of the document?		
<b>8.</b>	<b>Review Date</b>		
	Is the review date identified and is this acceptable?		
<b>9.</b>	<b>Overall Responsibility for the Document</b>		
	Is it clear who will be responsible for coordinating the dissemination, implementation and review of the documentation?		
<b>10.</b>	<b>Equality Impact Assessment (EIA)</b>		
	Has a suitable EIA been completed?		

**Committee Approval (insert name of Committee)**

If the committee is happy to approve this document, please complete the section below, date it and return it to the Policy (document) Owner

Name of Chair	Date

**Ratification by Management Executive (if appropriate)**

If the Management Executive is happy to ratify this document, please complete the date of ratification below and advise the Policy (document) Owner

**Date:** n/a

APPENDIX 1 – Badgnernotes entry for women with hypothyroidism requiring an increased dose of levothyroxine.

I have now had the opportunity to review your thyroid function blood tests. Your TSH was xx mU/L. For optimal control we would like the TSH to be less than 2.5mU/L. Would you therefore please arrange with your GP to increase your dose of levothyroxine. A message has also been sent to your GP to inform them.

You will also need to arrange a repeat blood test to check your thyroid function with your GP 4 weeks after you start taking the increased dose.

APPENDIX 2 – GP communication regarding women with hypothyroidism requiring an increased dose of levothyroxine.

Patient Name:  
Date of birth:  
NHS number:

This lady is currently xx weeks pregnant. Her TSH is xx mU/L. The ASPH guidelines for hypothyroidism in pregnancy set a target of < 2.5mU/L and suggest increasing the dose of levothyroxine by approximately 25% until this is achieved.

Would you please increase her dose of levothyroxine and arrange repeat testing in 4 weeks?

APPENDIX 3 – GP communication for women with hypothyroidism with booking blood results.

Patient Name:  
Date of birth:  
NHS number:

This lady has hypothyroidism and is pregnant. Her community midwife team will arrange for her thyroid function to be checked at booking, 14 weeks and 28 weeks. The ASPH guidelines for hypothyroidism in pregnancy set a target of <2.5mU/L to reduce the risk of complications associated with hypothyroidism.

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If the TSH level is > 2.5mU/L we will inform the patient by phone and through BadgerNet, we will also notify yourselves. We would appreciate if you would arrange to increase the dose of levothyroxine by approximately 25% and to check her thyroid function 4 weeks after the change in dose.

Postnatally we would appreciate if her thyroid function could be checked at 6 weeks and any dose adjustments made in response to that result.

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