

CLINICAL AUDIT

Monitoring of  
**Thyroid Replacement  
Therapy**



Valid to September 2012



# Introduction

## This audit is designed to:

- Identify ways in which your monitoring of thyroid replacement therapy can be improved,
- Stimulate reflection on your monitoring of patients on thyroid replacement therapy,
- Benchmark your identification of patients on thyroid replacement therapy,
- Compare your monitoring for patients on thyroid replacement with monitoring recommendations.

## Background

Thyroxine (thyroxine sodium, levothyroxine) is the drug of choice for maintenance thyroid replacement therapy. The usual maintenance dose is 100–200 mcg daily given as a single dose (BNF, 2005). However, a recent study reported that only half of patients on thyroid replacement therapy attending the outpatients department of an American hospital received the recommended monitoring. Adverse events related to the replacement therapy were more common in those who did not receive the recommended monitoring (Stelfox, 2004).

## Choice of test for monitoring

Thyroid stimulating hormone (TSH) measurement is the most sensitive test of thyroid excess or deficiency for people with stable thyroid function and intact hypothalamic-pituitary function. However, for people with unstable thyroid function serum free thyroxine (FT4) is more sensitive than TSH. Thyroid status is unstable during the commencement of therapy for hypothyroidism and hyperthyroidism (NACB, 2002).

People who may have poor adherence to their thyroid replacement regimen need both TSH and FT4 for monitoring as they may have a combination of high TSH following a period of missed medication and a high FT4 because of recent thyroxine intake prior to the test.

## TSH levels

TSH levels are evaluated against a reference range which includes the TSH levels of 95% of the euthyroid population. As is usual in this type of reference range, 5% of the euthyroid population will have levels outside this range. For some people with TSH levels within the reference range, this level will in fact be abnormal for them. TSH levels should therefore be interpreted in combination with the clinical picture.

People who are taking too much thyroxine will have suppressed levels of TSH. Suppressed levels of TSH are associated with an increased risk of atrial fibrillation, cardiovascular disease and fractures.

People who have been treated for thyroid cancer benefit from having a suppressed TSH, because TSH is thought to promote tumour recurrence.

## Reflex testing

Laboratories retain blood samples for varying lengths of time, making it possible for the GP or in some cases, the laboratory to add additional tests without the need for another blood test.

Based on the TSH result, some laboratories may add FT4, FT3, or thyroid antibodies. To assist with additional tests being added appropriately, it is important you indicate on the laboratory request form that the patient is on thyroid replacement therapy.

The practice of reflex testing varies between laboratories, so it is important you do not rely on the laboratory to add extra tests.

## bpac<sup>nz</sup> recommendations for monitoring

Recommendations for monitoring of most people on maintenance thyroid replacement therapy, who are not known to have disturbance of hypothalamic-pituitary function are:

1. After 6–8 weeks of thyroxine therapy TSH is the initial test required for monitoring of thyroid function, unless there are concerns about adherence to the treatment regimen.
2. Once stable, TSH levels should be measured annually.
3. In most cases, TSH levels should be kept within the reference range.

## References

1. Stelfox HT et al. An evaluation of the adequacy of outpatient monitoring of thyroid replacement therapy. *J Eval Clin Pract* 2004;10:525-30.
2. BNF, March 2005. Number 49. ([www.bnf.org](http://www.bnf.org)).
3. Demers LM, Spencer CA. The National Academy of Clinical Biochemistry Laboratory Medicine Practice Guidelines. Laboratory support for the diagnosis and monitoring of thyroid disease. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2002. ([http://www.nacb.org/Impg/thyroid\\_imp\\_pub.stm](http://www.nacb.org/Impg/thyroid_imp_pub.stm)) accessed 24 September 2005.
4. Investigating Thyroid Function. bpac<sup>nz</sup> October 2005. (<http://www.bpac.org.nz>).

# Plan

## Indicators

For people who are not known to have disturbance of hypothalamic-pituitary function and have been on thyroid replacement therapy for longer than three months:

1. TSH test has been performed in the previous year.
2. TSH is usually the sole initial test of thyroid function.
3. TSH result is within the reference range.

## Criteria

1. The notes record that a TSH has been performed within the previous year.
2. The notes record that TSH level was requested as the initial sole test of thyroid function.
3. The notes record that the most recent TSH level recorded for each patient is within the reference range.

## Standards

1. TSH test has been performed in the previous year in at least 80% of patients.
2. TSH was requested as the initial sole test of thyroid function in at least 80% of patients.
3. The TSH result was within the reference range for at least 80% of patients.

# Data

## Which patients are included?

This audit should include patients who have been on thyroid replacement therapy for longer than three months and are not known to have disturbance of hypothalamic-pituitary function.

## Identifying patients

Search your computer notes for patients taking:

- Thyroxine (thyroxine sodium, levothyroxine).

Discard patients

- Who have been taking thyroxine for less than three months, or
- Are known to have disturbance of hypothalamic-pituitary function

## Sample size and type

Hypothyroidism is more common in women, with an estimated prevalence of overt hypothyroidism of 0.5% in women aged 40 to 60 years, rising to 2% in women aged 70 to 80 years. Therefore, numbers of eligible patients will vary according to your practice demographics. Try to identify at least 20 patients for this audit.

## What data should be collected?

Record the following details for each patient on the data recording sheet (Appendix one):

- Has the patient had a TSH requested in the last year?
- Was TSH the sole initial test of thyroid function requested when thyroid function was last assessed? If other measures of thyroid function were reported check your requesting data to see if these were requested by you or added as reflex testing by the laboratory.
- Was the most recent TSH level within the reference range?

## Data analysis

Calculate the percentage of patients that reach each criterion.

Compare these percentages to the standards set in advance by the practice team. Standards are suggested in this protocol, but may also be set at a practice / practitioner level. Discussion amongst peers may be useful in establishing standards.

# Data sheet – cycle 1

## Audit: Monitoring of thyroid replacement therapy

Date of data collection: \_\_\_\_\_

Patient Number	Has the patient had a TSH requested in the past year?	Was TSH the sole initial test of thyroid function?	Was the most recent TSH within the reference range
	YES/NO	YES/NO	YES/NO
1			
2			
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25			
26			
27			
28			
29			
30			
Total (Yes)			
% (Yes)			

# Data sheet – cycle 2

## Audit: Monitoring of thyroid replacement therapy

Date of data collection: \_\_\_\_\_

Patient Number	Has the patient had a TSH requested in the past year?	Was TSH the sole initial test of thyroid function?	Was the most recent TSH within the reference range
	YES/NO	YES/NO	YES/NO
1			
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28			
29			
30			
Total (Yes)			
% (Yes)			

# Identifying opportunities for CQI

## Taking action

The first step in taking action is to identify where gaps exist between expected and actual performance and decide on priorities for change.

Once priority areas for change have been decided on, an action plan should be developed to implement any changes.

The plan should assign responsibility for various tasks to specific members of the practice team and should include a timeline.

It is important to include the whole practice team in the decision-making and planning process.

It may be useful to consider the following points when developing a plan for action (RNZCGP 2002).

### **1. Problem solving process**

- What is the problem or underlying problem(s)?
- Change it to an aim.
- What are the solutions or options?
- What are the barriers?
- How can you overcome them?

### **2. Overcoming barriers**

- Identifying barriers can provide a basis for change.
- What is achievable? – find out what the external pressures on the practice are and discuss ways of dealing with them in the practice setting.
- Identify the barriers.
- Develop a priority list.
- Choose one or two achievable goals.

### **3. Effective interventions.**

- No single strategy or intervention is more effective than another, and sometimes a variety of methods are needed to bring about lasting change.
- Interventions should be directed at existing barriers or problems, knowledge, skills and attitudes, as well as performance and behaviour.

# Review

## Monitoring change and progress

It is important to review the action plan against the timeline at regular intervals with the practice team. It may be helpful to discuss the following questions:

- Is the process working?
- Are the goals for improvement being achieved?
- Are the goals still appropriate?
- Do you need to develop new tools to achieve the goals you have set?

Following the completion of the first cycle, it is recommended that practices complete the first part of the CQI activity summary sheet (Appendix 1).

## Undertaking a second cycle

In addition to regular reviews of progress with the practice team, a second audit cycle should be completed in order to quantify progress on closing the gaps in performance.

It is recommended that the second cycle be completed within 12 months of completing the first cycle. The second cycle should begin at the data collection stage. Following the completion of the second cycle it is recommended that practices complete the remainder of the CQI activity summary sheet.

### Claiming MOPS credits

This audit has been endorsed by the RNZCGP as a CQI Activity for allocation of MOPS credits. General practitioners taking part in this audit can claim credits in accordance with the current MOPS programme. This status will remain in place until **September 2012**.

To claim MOPS points, you can indicate completion of the audit on the annual claim sheet, or alternatively you can go to the RNZCGP website, and claim your points at “MOPS online” at [www.rnzcgp.org.nz](http://www.rnzcgp.org.nz). You receive 10 credits per audit cycle.

As the RNZCGP frequently audit claims you should retain the following documentation, in order to provide adequate evidence of participation in this audit:

1. A summary of the data collected  
**and**
2. A Continuous Quality Improvement (CQI) Activity summary sheet (included as Appendix 1).

# Appendix 1: RNZCGP Summary Sheet – CQI Activity

<b>DOCTORS NAME</b>	
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The activity was designed by (please tick appropriate box):

- RNZCGP
- Organisation e.g. IPA/PHO/BPAC (name of organisation) bpac<sup>nz</sup>
- Individual (self)

<b>TOPIC</b>	<b>Monitoring of thyroid replacement therapy</b>
Describe why you chose this topic (relevance, needs assessment etc):	

## FIRST CYCLE (10 Credits)

<b>1. DATA</b>	<b>Information collected</b>
Date of data collection:	
Please attach:	
<ul style="list-style-type: none"><li>▪ A summary of data collected <b>or</b></li><li>▪ If this is an organisation activity, attach a certificate of participation.</li></ul>	

<b>2. CHECK</b>	Describe any areas targeted for improvement as a result of the data collected.

<b>3. ACTION</b>	Describe how these improvements will be implemented.

<b>4. MONITOR</b>	Describe how well the change process is working. When will you undertake a second cycle?

## SECOND CYCLE (10 Credits)

<b>1. DATA</b>	<b>Information collected</b>
Date of data collection:	
Please attach: <ul style="list-style-type: none"><li>▪ A summary of data collected <b>or</b></li><li>▪ If this is an organisation activity, attach a certificate of participation.</li></ul>	
<b>2. CHECK</b>	Describe any areas targeted for improvement as a result of the data collected.
<b>3. ACTION</b>	Describe how these improvements will be implemented.
<b>4. MONITOR</b>	Describe how well the change process is working.
<b>COMMENTS</b>	

This audit has been endorsed by the RNZCGP as a CQI Activity for allocation of MOPS credits. This status will remain in place until September 2012. See page 9 for further information about claiming MOPS credits.

## AUDIT CHECKLIST

Date:

1  Audit Planning

### FIRST CYCLE

2  Data collected

3  RNZCGP Summary Sheet completed

4  MOPS Credits claimed

### SECOND CYCLE

5  Data collected

6  RNZCGP Summary Sheet completed

7  MOPS Credits claimed

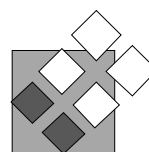
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