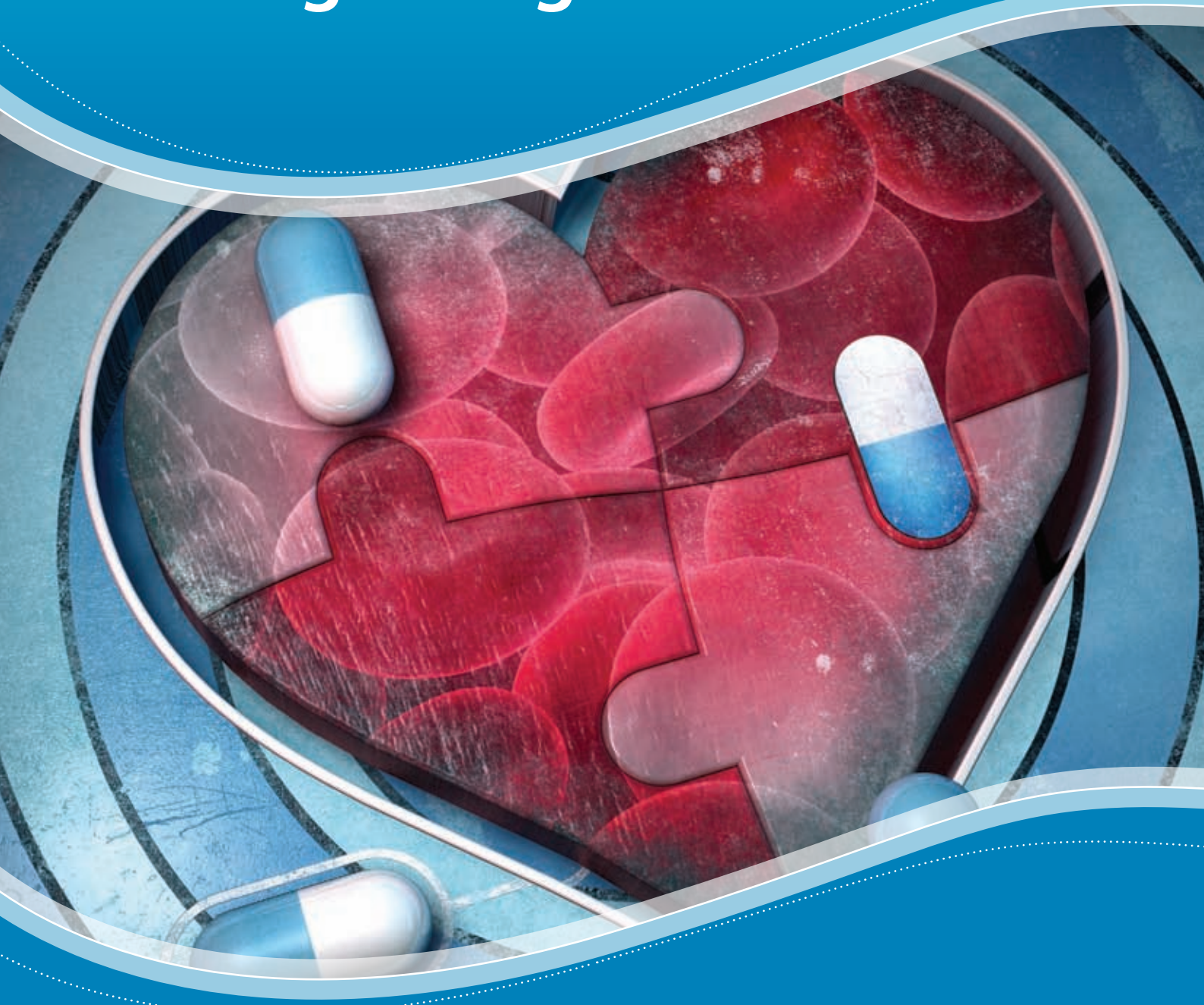


CLINICAL AUDIT

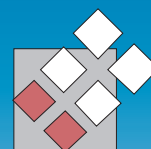
# Renal Function Testing in People Taking Dabigatran



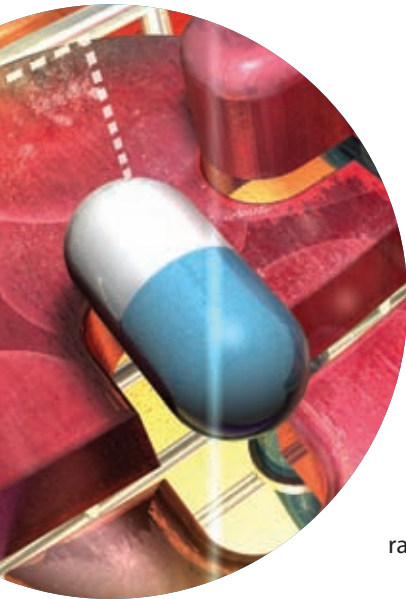
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 MOPs

Valid to December 2017



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## Background


Dabigatran is an oral anticoagulant used primarily to prevent stroke in people with non-valvular atrial fibrillation (AF). It is an alternative treatment option to warfarin and appears to be at least as effective as warfarin for preventing stroke in patients with AF. Dabigatran has a similar rate of bleeding events to warfarin.<sup>1</sup>

Dabigatran is indicated for people with non-valvular atrial fibrillation for:

- Prevention of stroke
- Prevention of systemic embolism
- Reduction of overall vascular mortality

For these indications, pharmacological treatment should be continued for life unless the patient's risk/benefit ratio changes.

Dabigatran is also registered for short-term use for the prevention of venous thromboembolism (VTE) after major orthopaedic surgery. It provides an oral alternative to low molecular weight heparin, such as enoxaparin.

 For further information on prescribing and monitoring dabigatran, see: "The use of dabigatran in general practice: a cautious approach is recommended", *BPJ* 38 (Sept, 2011).

### Dabigatran is excreted by the kidneys

Up to 80% of circulating dabigatran is excreted, unchanged, by the kidneys. Therefore, any reduction in renal function can affect the plasma concentration of the medicine.

As renal function declines with age and most people taking dabigatran will be taking it for life, regular monitoring of

renal health and function is essential to avoid serious adverse events, particularly bleeding. Creatinine clearance should be checked in all patients before treatment with dabigatran and patients with severe renal impairment (creatinine clearance < 30 mL/min) should not be prescribed dabigatran. Patients with impaired renal function (creatinine clearance 30 – 50 mL/min) should only be prescribed dabigatran with caution, and close monitoring will be required.

Any patient taking dabigatran, who has renal impairment or is at risk of developing renal impairment, should have their eGFR checked or creatinine clearance calculated at least annually during long-term treatment. The key criteria for renal assessment in people taking dabigatran are:

- Renal function must be assessed in all patients prior to the initiation of dabigatran
- For patients taking dabigatran, renal function should be rechecked in any clinical situation where a decline is suspected, e.g. dehydration, hypovolaemia and with some medicines, such as diuretics
- Renal function should be assessed at least annually in patients taking dabigatran aged over 75 years or with moderate renal impairment (creatinine clearance 30–50 mL/min)

## Recommendations

Patients taking dabigatran with the following risk factors should have had at least one renal function assessment within the previous 12 months:

- Age over 75 years
- Moderate renal impairment (30 – 50 mL/min)

## Audit plan

### Indications

Any patient with AF enrolled in primary care taking dabigatran for stroke prevention who is either over age 75 years or has moderate renal impairment.

### Criteria for a positive result

The patient is currently taking dabigatran and has had a creatinine clearance test in the previous 12 months.

1. Barrios V, Scobar C. New evidences for old concerns with oral anticoagulation in atrial fibrillation: focus on dabigatran. *Exp Op Pharmac* 2012;35(18):2649-61.

## Audit standards

As the risk of bleeding is significant and the consequences of a bleed can be severe, at least 90% of patients should meet the requirements of a positive audit outcome.

## Data

### Eligible people

Any person with AF who was prescribed dabigatran in primary care for stroke prevention, and is aged over 75 years OR has moderate renal impairment, is eligible for this audit.

### Identifying patients

You will need to have a system in place that allows you to identify eligible patients. Many practices will be able to identify patients by running a 'query' through their practice management software for patients who are currently taking dabigatran and then checking for read codes identifying renal impairment or checking patient notes for age or impairment. Depending on recording practices, the tests that were requested at the time of prescription or regularly since then can be found either within the query or from the patient notes.

### Sample size

The number of eligible patients will vary according to your practice demographic. If you identify a large number of patients, take a random sample of 30 patients whose notes you will audit (or the first 30 results returned).

### Data analysis

Use the data sheet below to record your data. Calculate your percentages by taking the number of people who are a "positive result" as per the audit criteria, divided by the total number of people audited (i.e. the 30 patients whose test choice was reviewed), multiplied by 100.

For example – 25 people were audited, 23 of whom had had their renal function tested in the previous 12 months. Therefore percentage is calculated as:  $23/25 \times 100 = 92\%$ .

## Identifying opportunities for CQI

### Taking action

The first step to improving medical practice is to identify the criteria where gaps exist between expected and actual performance and then to decide how to change practice.

Decide on a set of priorities for change and develop an action plan to implement any changes.

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

It may be useful to consider the following points when developing a plan for action:

### 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?

### 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

### 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. It may be helpful to consider 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 the doctor completes the first part of the CQI activity summary sheet.

### Undertaking a second cycle

In addition to regular reviews of progress, 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 doctors 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 **1st December, 2017**.

To claim points for MOPS or CPD online please enter your credits on your web records. Go to the RNZCGP website [www.rnzcgp.org.nz](http://www.rnzcgp.org.nz) and claim your points on 'MOPS online' for vocationally registered doctors, or 'CPD online' for general registrants. Alternatively MOPS participants can indicate completion of the audit on the annual credit summary sheet which is available from the College on request.

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
2. A Continuous Quality Improvement (CQI) Activity summary sheet

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[www.bpac.org.nz](http://www.bpac.org.nz)

## Data sheet – cycle 1

### Audit: Renal function testing in people taking dabigatran

Patient	Reason for requiring monitoring (i.e. > 75 years or moderate renal impairment)	Was their renal function checked in last 12 months (i.e. creatinine clearance or eGFR)?	
		Yes	No
1			
2			
3			
4			
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13			
14			
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24			
25			
26			
27			
28			
29			
30			
<b>Total Yes</b>			
<b>% Yes</b>			

Please retain this sheet for your records to provide evidence of participation in this audit:

## Data sheet – cycle 2

### Audit: Renal function testing in people taking dabigatran

Patient	Reason for requiring monitoring (i.e. > 75 years or moderate renal impairment)	Was their renal function checked in last 12 months (i.e. creatinine clearance or eGFR)?	
		Yes	No
1			
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27			
28			
29			
30			
<b>Total Yes</b>			
<b>% Yes</b>			

Please retain this sheet for your records to provide evidence of participation in this audit:

# RNZCGP Summary Sheet – CQI Activity

**DOCTORS NAME**

The activity was designed by (please tick appropriate box):

- RNZCGP
- Organisation e.g. IPA/PHO/BPAC (name of organisation)
- Individual (self)

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**TOPIC**

**Renal function testing in people taking dabigatran**

Describe why you chose this topic (relevance, needs assessment etc):

## FIRST CYCLE

**1. DATA**

Information collected

Date of data collection:

Please attach:

- A summary of data collected **or**
- If this is an organisation activity, attach a certificate of participation.

**2. CHECK**

Describe any areas targeted for improvement as a result of the data collected.

**3. ACTION**

Describe how these improvements will be implemented.

**4. MONITOR**

Describe how well the change process is working. When will you undertake a second cycle?

Please retain this sheet for your records to provide evidence of participation in this audit:

## SECOND CYCLE

### 1. DATA

Information collected

Date of data collection:

Please attach:

- A summary of data collected or
- If this is an organisation activity, attach a certificate of participation.

### 2. CHECK

Describe any areas targeted for improvement as a result of the data collected.

### 3. ACTION

Describe how these improvements will be implemented.

### 4. MONITOR

Describe how well the change process is working. Will you undertake another cycle?

### COMMENTS