# An audit of two methods of anticoagulation monitoring in a general practice

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## ABSTRACT

**BACKGROUND AND CONTEXT:** Patients with atrial fibrillation (AF) and a five-year stroke risk >15% should be on long-term oral anticoagulant therapy with adjusted dose warfarin unless there is a clear contraindication.

**ASSESSMENT OF PROBLEM:** Ad hoc adjustments of warfarin dose and anticoagulation monitoring by a general practitioner is less efficient than a standardised protocol administered by the practice nurses. This study was a retrospective audit of patient anticoagulation control before and after a change in method of warfarin adjustment. Measures were frequency of testing, time spent in the therapeutic range and mean International Normalised Ratio.

**RESULTS:** Thirty-two patients were studied over a 12-month period. The method change resulted in important improvements in practice efficiency while maintaining the standard of anticoagulation control with no significant increase in frequency of venesection.

**STRATEGIES FOR IMPROVEMENT:** General practices still using ad hoc adjustments of warfarin therapy can adopt a standardised nurse-managed protocol to achieve greater efficiency without adversely affecting patient care.

**LESSONS:** A move from the heavily doctor-intensive ad hoc system to the entirely nurse-led system improved practice efficiency. The doctor was liberated from the process. The nurse no longer had to act as liaison with the doctor. The receptionist did not have to ask patients to ring back once the doctor had seen the results. Patients received their instructions more quickly and their care was not compromised.


**KEYWORDS:** Anticoagulation monitoring; warfarin; family practice.

## Background

Patients with atrial fibrillation (AF) and a five-year stroke risk of over 15% should be on long-term oral anticoagulant therapy with adjusted dose warfarin unless there is a clear contraindication to doing so.[1] The target International Normalised Ratio (INR) is 2.5, range 2.0–3.0.[2] The monitoring of anticoagulation represents a significant workload to general practices. A New Zealand (NZ) study from 2005 suggests that less than half of eligible patients in NZ receive anticoagulation.[3] If these figures are to be improved, then the workload associated with anticoagulation monitoring in general practice is set to increase. Efficient ways of managing this workload are required.

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### Outline of local context

This study took place in a rural Eastern Bay of Plenty general practice. At the time of the audit, there was one full-time GP and two practice nurses working 1.2 full-time equivalents. The enrolled population was 2430. Thirty-four percent of the practice was aged under 19 years and 20% aged 60 years or over. Forty-two percent of the patients identified themselves as Maori.

## Assessment of problems

### Approach taken

The traditional method of monitoring anticoagulation in our practice was similar to that used in

many general practices—a system often described in the literature as 'ad hoc adjustments'. Results from the venesection were faxed from the lab to the practice. The doctor decided if a dose adjustment was required and when the next test should be. The practice nurse would then contact the patient with the new instructions.

As the doctor involved in the dose adjustments, I took into considerations several factors other than the patient's past INR results. These included my impression of the patient's 'reliability in following instructions', transport and mobility issues.

In order to improve efficiency, we decided to devolve the clinical decision-making process to the practice nurses by adopting a standardised method for INR adjustment. Following an in-house clinical education meeting, we decided to implement the guideline produced by the British Columbia Health Service as this appeared well validated and easily understood.[4] For the first month of the new regime, all INR adjustments made by the nurse following the anticoagulation guidelines were checked by the doctor and no errors were found.

The change from a method that was 'tailor-made' by the doctor for each patient to a 'one size fits all' nurse-led method had resulted in important improvements in efficiency. Gains in practice efficiency are sometimes achieved at the expense of patient care. Our aim was to discover if any alteration had occurred in the standard of anticoagulation control or frequency of patient venesection.

## Measurement of problem

Using patients as their own controls, a retrospective audit was performed for a period of six months before (ad hoc arm) and six months after the change in practice (standardised arm). Patients who commenced or discontinued warfarin during the study period were excluded. Only those patients whose target INR was 2.0–3.0 were included. Only a small number of patients in the practice had a target range higher than this. They were patients with mechanical heart valves and, while they were managed using the same guidelines, their numbers were too small to allow any meaningful analysis.

### WHAT GAP THIS FILLS

**What we already know:** Most monitoring of anticoagulation occurs within the primary care setting. Some practices use ad hoc methods of warfarin dose adjustment which can be time-consuming and of untested effectiveness.

**What this study adds:** Switching from ad hoc adjustments to a standardised protocol improved our efficiency and maintained effectiveness.

The dates of testing and the INR results for the 12-month period were extracted from the practice management software and analysed in order to answer the following three questions:

1. **Has there been any change in the frequency of testing of INRs?** To establish this, the length of time between tests was measured for each patient for both study periods. A mean was calculated with a standard deviation to establish whether a significant change in the frequency of testing had occurred for each individual and for the group as a whole. Ninety-five percent confidence intervals were used in establishing significance.

2. **Has there been any change in the amount of time spent by the patients in the target range over the two study periods?** Establishing length of time within the therapeutic range is a complex issue. It can only be known for sure whether someone is within or outside the range on a particular day when an INR test has been performed. If two consecutive results are within the target range then an assumption is made that the patient has been in range for the entire interval between the tests. If consecutive results show one result in target and one out of target then a linear estimate is made of when the patient entered or exited the therapeutic range. Using these assumptions, the percentage of time within the therapeutic range was calculated for each patient for both study periods using 95% confidence intervals in establishing significance. A mean and standard deviation was calculated for the test group for both study periods to establish whether or not a significant change had taken place.

3. **Has there been a change in patient's mean INR?** In other words, did the change in system result in patients sitting in a different part of the therapeutic range? Ninety-five percent confidence intervals were used in establishing significance.

Approval from an ethics committee was not sought because this was an audit conducted by a health provider for the purpose of quality improvement.

### Results of assessment

Thirty-two patients formed the study group. Of those, 30 patients had AF and were on warfarin to reduce stroke risk and two were on warfarin to prevent recurrent deep vein thromboses. A summary of the data is presented in Table 1.

### Frequency of testing

In the 'ad hoc' arm the most frequently tested patient had an INR performed on average every four days and the least frequently tested patient averaged 46 days between tests. The frequency of testing ranged between seven and 45 days in the 'standardised' arm. Across the entire study period three patients showed a statistically significant decrease in the frequency of testing after changing to the 'standardised' model, and one patient showed a statistically significant increase in frequency. The remaining 28 patients showed no statistically significant change in frequency of testing.

The mean number of days between tests for the 'ad hoc' arm as a whole was 18 days and for the 'standardised' arm 17 days. This increased frequency of testing in the 'standardised' arm was not statistically significant.

### Time in the therapeutic range

In the 'ad hoc' arm the patient with the poorest control spent only 32.1% of the time within the therapeutic range (of 2.0–3.0) while the best controlled patient was in this range for 93.9% of the time. Comparable figures for the 'standardised' arm were 32.2% and 100%.

The mean percentage time spent in the therapeutic range for the 'ad hoc' arm was 65.3 (SD 15.7%) and for the 'standardised' arm 69.3 (SD 17.6%). This difference is not statistically significant.

### Mean INR

Individual patients had their mean INR compared over the two study periods. Two patients had significantly different mean INRs under the different systems; one higher and one lower. The other 30 patients showed no statistically significant change in mean INR.

## Strategies for quality improvement

### Frequency of testing

It is important to measure frequency of testing when examining different methods of anticoagulation monitoring to ensure that one method does not demonstrate superior results simply by virtue of more or less regular testing. The results show no significant change in frequency of testing between the two methods of INR monitoring allowing an equitable comparison. Frequency of testing is also an important measure of patient care. Many patients find venesection uncomfortable and inconvenient. For this reason, and to minimise cost, we would not wish to test for good anticoagulation control more frequently than is necessary.

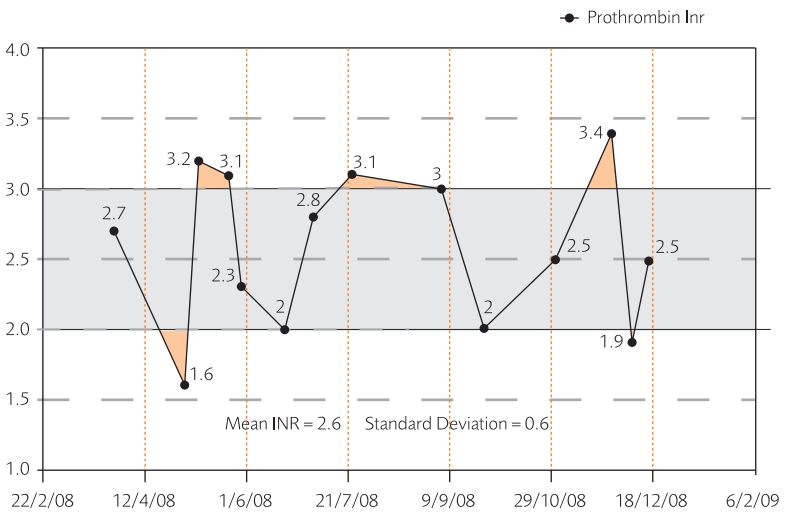
### Time in the therapeutic range

The individual variation between patients, with the best controlled patients spending three times as long in the therapeutic range as the poorest controlled, is a stark reminder of the importance of individual patient factors (be they biological, social or behavioural) in the control of anticoagulation. Those individuals who showed poor control in the first arm of the study were the same individuals showing poor control in the second arm of the study. Patient to patient variability was noticeably greater than any variability demonstrated between the two methods of anticoagulation monitoring.

*Table 1. Summary of results*

| | Ad hoc arm | | | Standardised arm | | |
|---|---|---|---|---|---|---|
| **Patient Number** | **% time in therapeutic band** | **INR (95% CI)** | **Days between tests (95% CI)** | **% time in therapeutic band** | **INR (95% CI)** | **Days between tests (95% CI)** |
| **1** | 75.2 | 2.2 ± 0.1 | 13 ± 3 | 88 | 2.6 ± 0.1 | 14 ± 2 |
| **2** | 93.9 | 2.2 ± 0.3 | 11 ± 6 | 93.3 | 2.3 ± 0.1 | 18 ± 4 |
| **3** | 92.5 | 2.5 ± 0.4 | 20 ± 6 | 86.3 | 2.5 ± 0.2 | 29 ± 12 |
| **4** | 93.1 | 2.4 ± 0.4 | 19 ± 14 | 100 | 2.4 ± 0.2 | 45 ± 19 |
| **5** | 53.6 | 2.7 ± 0.1 | 15 ± 8 | 72.5 | 2.9 ± 0.3 | 15 ± 3 |
| **6** | 84.4 | 2.3 ± 0.1 | 16 ± 3 | 76.3 | 2.3 ± 0.2 | 20 ± 4 |
| **7** | 49.7 | 2.6 ± 0.3 | 27 ± 7 | 74 | 2.5 ± 0.2 | 16 ± 4 |
| **8** | 50.3 | 2.5 ± 0.2 | 17 ± 2 | 76.3 | 2.4 ± 0.2 | 12 ± 2 |
| **9** | 60.7 | 2.9 ± 0.2 | 11 ± 2 | 75.6 | 2.6 ± 0.2 | 13 ± 2 |
| **10** | 61.1 | 2.8 ± 0.1 | 12 ± 8 | 39.7 | 2.5 ± 0.2 | 7 ± 2 |
| **11** | 86.2 | 2.4 ± 0.2 | 13 ± 3 | 78.4 | 2.3 ± 0.2 | 13 ± 2 |
| **12** | 62.9 | 2.9 ± 0.1 | 18 ± 2 | 89 | 2.6 ± 0.2 | 16 ± 4 |
| **13** | 55.1 | 2.5 ± 0.2 | 24 ± 4 | 63.6 | 2.4 ± 0.2 | 18 ± 8 |
| **14** | 79.6 | 2.5 ± 0.2 | 17 ± 2 | 85.6 | 2.2 ± 0.2 | 18 ± 5 |
| **15** | 51.3 | 3 ± 0.3 | 19 ± 8 | 69.8 | 2.7 ± 0.2 | 12 ± 2 |
| **16** | 71.5 | 2.7 ± 0.2 | 16 ± 2 | 75.7 | 2.3 ± 0.2 | 14 ± 2 |
| **17** | 70.2 | 2.4 ± 0.2 | 23 ± 8 | 50.3 | 2.7 ± 0.3 | 9 ± 3 |
| **18** | 72.3 | 2.6 ± 0.3 | 17 ± 6 | 71.3 | 2.4 ± 0.2 | 13 ± 2 |
| **19** | 67.1 | 2.6 ± 0.2 | 28 ± 12 | 50 | 2.2 ± 0.3 | 16 ± 4 |
| **20** | 68.3 | 2.3 ± 0.2 | 26 ± 4 | 72.8 | 2.3 ± 0.3 | 29 ± 15 |
| **21** | 53.6 | 2.7 ± 0.2 | 19 ± 7 | 51.2 | 2.6 ± 0.2 | 9 ± 1 |
| **22** | 56.6 | 2.5 ± 0.2 | 41 ± 17 | 38.3 | 3 ± 0.3 | 25 ± 14 |
| **23** | 44.4 | 2.9 ± 0.2 | 18 ± 5 | 68 | 2.6 ± 0.3 | 11 ± 2 |
| **24** | 65 | 2.7 ± 0.6 | 20 ± 3 | 84.2 | 2.4 ± 0.2 | 27 ± 5 |
| **25** | 72.3 | 2.5 ± 0.2 | 12 ± 6 | 54 | 2.7 ± 0.2 | 7 ± 1 |
| **26** | 32.1 | 2.8 ± 0.5 | 6 ± 3 | 62.5 | 2.3 ± 0.2 | 10 ± 1 |
| **27** | 64.7 | 2.5 ± 0.2 | 46 ± 14 | 32.2 | 1.9 ± 0.3 | 41 ± 22 |
| **28** | 59.1 | 2.3 ± 0.2 | 17 ± 5 | 80.4 | 2.6 ± 0.3 | 20 ± 5 |
| **29** | 58.5 | 2.3 ± 0.4 | 11 ± 12 | 38.3 | 2.5 ± 0.3 | 9 ± 2 |
| **30** | 66.1 | 1.9 ± 0.4 | 8 ± 4 | 85.8 | 2.4 ± 0.2 | 18 ± 5 |
| **31** | 34.8 | 2.9 ± 0.8 | 4 ± 2 | 53.7 | 2.4 ± 0.2 | 7 ± 1 |
| **32** | 82.1 | 2.6 ± 0.3 | 14 ± 4 | 79.9 | 2.4 ± 0.3 | 11 ± 3 |
| | *Mean = 65.3%* | | *Mean = 18* | *Mean = 69.3%* | | *Mean = 17* |

*Figure 1. An example of an INR record*




## Individual mean INR

With one patient showing a rise in mean INR and another a fall and the majority showing no change, it can be concluded that the change in method did not have a significant impact on mean INR.

## Lessons and messages

Machin suggests that a reasonable standard for good control of warfarin therapy is an INR within the therapeutic range 60% of the time.[5] The British guidelines for anticoagulation control quote 50%.[6] It would appear that this standard can be achieved in my practice either by using my ad hoc approach (65.3%) or by my nurses using the 'British Columbia Health Service' standardised protocol (69.3%).

This is a study with a small number of patients in a single practice. Factors such as ethnic mix, educational status and socioeconomic status may limit the ability for these results to be generalised to other general practices in NZ.

While it is likely that most doctors would follow the same general principles, the effectiveness of an individual doctor's ad hoc approach will be unknown unless the practice data is audited. The raw data for a practice audit is easily obtained from practice management software. A Microsoft Office Excel spreadsheet could be produced easily which would allow the exercise to be reduced to a simple matter of data entry.

The switch in my practice away from the heavily doctor-intensive ad hoc system to the entirely nurse-led system was motivated by a desire to improve practice efficiency and free up doctor time. Our experience was that this was achieved. The doctor was liberated from any part in the process. The nurse's time was used more efficiently by no longer having to act as a liaison with the doctor. Patients were able to get their instructions more quickly and were able to discuss the adjustment with the nurse making the clinical decision. Nobody was more pleased by the change than our receptionist who no longer had to inform patients 'the doctor hasn't had time to look at your results yet, can you phone back later?'. This improved efficiency is likely to be even greater in a group practice where several doctors may be involved in the warfarin adjustment process.

Changing from one system to the other can be done quickly and with a minimum of planning.

While new anticoagulant drugs not requiring such rigorous monitoring are under trial elsewhere in the world, it is likely that we in NZ are still several years away from having a safe and effective alternative to using warfarin.

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**CONFLICT OF INTEREST**
None declared

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