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INR point of care testing in community pharmacies – is this the future?

The international normalised ratio (INR) is used to monitor patients receiving warfarin for treatment or prevention of thrombosis and embolism. The therapeutic range of warfarin is narrow, so monitoring of INR is performed to avoid complications from both over-dosage (which increases the risk of haemorrhagic events) and under-dosage (which may result in thromboembolic events).

In New Zealand, most patients prescribed warfarin have their INR levels measured in a laboratory and receive advice from general practice on their next dose and testing frequency. Some general practices have moved away from laboratory based INR testing and have adopted surgery based INR point-of-care testing (POCT) using portable coagulometers.

In 2009 a pilot was undertaken for INR testing and warfarin management using POCT in a community pharmacy setting. It is now being followed by a larger pilot study. The future of INR monitoring could be changing with testing and management increasingly coming into the care of community pharmacies.

It is likely that there will be a mixed response to community pharmacists adopting the role of INR testing. Some GPs and practice nurses may not be overly concerned and may even be pleased by the prospect of having one less task to worry about in their already-stretched workload. Others may feel that if the task of INR monitoring is mismanaged there could be serious consequences and so may be concerned to see it delegated outside of general practice.

Community pharmacy based INR point-of-care testing pilot

New Zealand's first trial in community pharmacy-based POCT of INR took place in 2009. An anticoagulation clinic was set up at one community pharmacy using a portable coagulometer and a web-based management

support tool, which allowed a revised warfarin dose to be calculated from the INR result. Patients were shown a pictorial representation of their warfarin dose and informed when their next test was required. The process took on average less than ten minutes to complete and also provided a chance to counsel patients about their warfarin management at each appointment.

The pilot study ran from July to November 2009, and involved 40 patients with prior consent from their GP. Results have not yet been published.

Larger pilot trial currently planned

After observing the original pilot study, the Pharmaceutical Society of New Zealand supported the extension of the programme nationally and has planned a community pharmacy Anticoagulation Management Service pilot. This pilot will involve 15 pharmacies, each of which will enrol 50 patients with atrial fibrillation using warfarin. The pilot will run for one year, with an evaluation planned before the end of 2011.[1]

As with the original pilot study, the accredited pharmacists during this POCT of INR trial will:

- Check the patient's INR levels
- Input the result into a computer programme for dose recommendation
- Advise the patient of their next appropriate warfarin dose
- Notify the GP of the blood result, dose and date of next test for the patient

The pharmacists will perform these tasks under standing orders from the patient's GP, with communication protocols in place to ensure the GP remains fully informed and in charge of their patient's care. The aim is to maintain INR levels within safe parameters. Appropriate protocols will be put in place for referral back to the patient's GP, if required.[1]

INR point-of-care-testing is quick and simple to perform

POCT of INR is performed by obtaining a drop of capillary blood from a patient via fingerprick which is then processed in a portable coagulometer. An INR result is usually obtained within three minutes.

Advantages of POCT of INR include:

- INR results are obtained sooner allowing discussion of the result and any change in management at the same visit as the INR testing
- It is a more acceptable method for people who have fears of venepuncture
- It is more convenient for patients especially if they live some distance from phlebotomy services
- Possibly improved compliance with warfarin as a result of having face-to-face guidance given rather than over-the-phone

The risks of POCT are those associated with obtaining the capillary sample including: localised bleeding, bruising and vasovagal episodes. There is also a risk of needle-stick injury when obtaining the sample but this is unlikely to pose any additional risk to that associated with venepuncture for laboratory-based INR testing.

Reaction to the proposed pilot study

The pilot POCT study is an opportunity for a partnership between pharmacy and general practice and for maximisation of pharmacists skills. However, it has been suggested that trialling of POCT for INR should also be carried out in a general practice setting for a true comparison of services.

There is concern that patients undergoing anticoagulation management, who are not regularly seen in general practice, will have compromised care. Anticoagulation management is multifactorial and complex, and patients have multiple needs in addition to a check of their INR level.

On the other hand, the number of people receiving oral anticoagulation therapy, most commonly for stroke prevention in non-valvular atrial fibrillation, is growing each year, with the increasingly ageing population. Increasing demand for monitoring could stretch the resources of general practice, if it is continued to be managed there alone.[2]

The question of cost has not been fully addressed. It is unclear whether individual pharmacies will purchase the necessary equipment for POCT and in turn, what cost will be passed on to the patient, bearing in mind that current laboratory testing of INR is fully funded.

It is likely that the results of the Anticoagulation Management Service pilot will answer some of these questions and help to determine whether INR testing fits into the community pharmacy setting, both in terms of patient and clinician satisfaction and improved patient safety.

The benefits of point-of-care testing of INR

An essential aspect of improving health services in New Zealand is to encourage the provision of better and convenient access to healthcare for all patients, particularly those with chronic illnesses and those who encounter barriers to accessing services. POCT represents a way to provide a convenient service, faster results and to facilitate quicker clinical decisions.

General Practices, with a desire to provide this service and the necessary resources and capacity, are an ideal setting for POCT of INR. It is also increasingly recognised that pharmacists are well-placed to provide patient-centred services such as POCT. Similar developments involving community pharmacists are taking place in the UK, Canada and South Africa.[2] Community delivery of POCT for INR could also take place in residential aged-care facilities, led by pharmacists or general practice staff.

POCT of INR does not appear to be better than laboratory testing of INR, but it is at least as accurate and at least as effective in maintaining INR in the target range. It is also likely to be more convenient for many patients.

Is POCT of INR accepted by patients?

One study of POCT of INR by nurses in a general practice setting, found that significantly more patients preferred POCT of INR compared to usual care i.e. laboratory testing. This was due to factors such as improved capacity to make appointments, less time spent at appointments, less pain associated with the test and improved communication about medicine dose.[3]

Research in the UK, as part of a project on monitoring of diabetes and chronic heart disease using POCT, indicated that 34% of patients chose their pharmacy to monitor their condition instead of their GP. Of this 34%, almost all (97%) rated the pharmacy service better or equal to their GP. Convenience, both in terms of location and opening hours, is a key advantage of pharmacy based POCT.[2]

Is POCT of INR as accurate as laboratory testing?

In a general practice based study, calibrations of POCT and laboratory testing showed dependable INR levels from both systems.[4]

Community pharmacy-based POCT of INR has also been shown to be as accurate as laboratory INR monitoring. A study involving POCT at 16 rural pharmacies in Australia found the same results when 120 INR tests performed in the pharmacy setting were compared with laboratory tests taken within four hours.[5]

Are target INR levels achieved with POCT?

There is mixed evidence of the benefit of POCT compared to laboratory testing in maintaining INR within the target range, however POCT appears to be at least as effective.

A US-based observational study in a primary care clinic found a significant improvement in the percentage of visits in which a patient's INR result was in the target range after POCT was implemented (from 34% to 67% over one year).[6] In a more recent randomised controlled trial of POCT in general practice in Australia, there was no significant difference between the POCT and control groups (who received the usual laboratory based testing) in terms of the number of patients with results in the target range for INR (57% POCT vs 61.5% control, p=0.24).[7] Another randomised controlled trial also found that there was no significant improvement in the time spent in the INR target range, between those who received POCT in a community clinic and those who received laboratory testing.[4]

One pharmacy-based study found that more than 80% of patients receiving POCT of INR had values within their targeted range 60% or more of the time, which is comparable with values reported for anticoagulation clinics.[8]

Is POCT of INR cost-effective?

There is currently no strong evidence of the cost–effectiveness of POCT of INR in either the general practice or community pharmacy setting. New Zealand specific data is required in order to accurately estimate the cost of POCT in this country.

A large trial in a general practice setting in Australia found there was no significant difference in overall costs between POCT and laboratory testing. There was a non-significant decrease in hospital admissions for patients using POCT of INR. POCT of INR increased the number of tests that people were receiving compared to those receiving laboratory tests. Overall, it was concluded that POCT of INR was not cost-effective in the general practice setting compared to usual care.[9]

Several other studies have concluded that POCT in a general practice setting is more expensive than laboratory testing.[7, 10] However, other studies have found that POCT provided an overall saving for health care providers or from a patient perspective, through a reduction in patient visits to the GP.[6, 11–13]

A Canadian study found that both physician and pharmacist-managed anticoagulation services were associated with improved INR control, but pharmacist-managed services may be more expensive in the long-term.[14]

It is difficult to calculate cost in terms of just economic value. Costs may be offset by prolonged life or reduced hospital stays.[9]

Warfarin is underused in areas with limited access to pathology services

Research shows that warfarin may often be underused in areas in which access to pathology services for INR monitoring is limited. Patients in these areas who do use warfarin are also potentially at increased risk of under- or over-dosing events.[15] The availability of portable INR monitors in such settings would be likely to increase the level and safety of warfarin use.

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