

<b>Title:</b>	<b>The use of INR point-of-care testing in general practice, 2005</b>
<b>Agency:</b>	Medical Services Advisory Committee (MSAC) Australian Government Department of Health and Ageing GPO Box 9848 Canberra ACT 2601 Australia <a href="http://www.msac.gov.au">http://www.msac.gov.au</a>
<b>Reference:</b>	<b>MSAC Application 1071. Assessment report ISBN 0 642 82736 2</b>

### **Aim**

To assess the safety, effectiveness and cost effectiveness of INR point-of care testing (POCT) in general practice and the circumstances under which public funding should be supported for it.

### **Conclusions and results**

#### *Safety.*

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

#### *Effectiveness*

Two studies were identified that met the eligibility criteria for the assessment of diagnostic performance of INR POCT in general practice compared with INR laboratory-based testing. One was a randomised cross-over trial (level II evidence) and the other was a case series (level IV evidence). Overall, there was no significant difference in diagnostic performance between POCT and laboratory testing in the two studies. However, in the cross-over trial, at high INR levels, the POCT levels were higher than those obtained using laboratory testing. The key outcome measures were time in the therapeutic range in the cross-over trial and mean INR level in the case series. The cross-over trial was limited by a small sample size, resulting in low study power.

If a diagnostic test is to be effective it needs to be accurate, management needs to change as a result of the test, and that change in management needs to be effective. There was support for change in management in response to abnormal INR levels. When the INR level is low there is an increased risk of thromboembolism and when it is high there is an increased risk of bleeding. Given the use of time in the therapeutic range as an intermediate outcome measure in the cross-over trial, the results can be linked to the risk of haemorrhagic or clinical events. Patient management was changed in this trial according to specific INR levels. However, overall there was little data on the use of INR POCT in general practice, with only two studies identified that fulfilled the eligibility criteria, and there was uncertainty about the diagnostic performance of POCT at high INR levels.

#### *Cost-effectiveness*

The economic analysis of INR POCT in general practice as a substitute for INR testing through laboratories in patients receiving warfarin therapy was limited to direct costs, due to the uncertainty surrounding the effectiveness of INR POCT in general practice. The limited analysis found that the incremental direct cost per test of INR POCT would be \$16.20. This estimate was based on expert opinion.

### **Recommendations**

MSAC recommended that after consideration of safety, effectiveness and cost-effectiveness, there is insufficient evidence to support the use of INR point-of-care testing in general practice at this stage.

### **Method**

A systematic review of INR POCT in general practice was conducted. The literature was searched up to October 2004 using Medline, Embase, Current Contents, Science Citation Index, Cochrane Library, DARE, and various website sources. Study selection criteria were stipulated and standard checklists were used to appraise study quality.

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