**Reviewer's report**

**Title:** Clinical benefit of point-of-care testing for acute coronary syndromes, heart failure and thromboembolic events in primary care: a cluster-randomised controlled trial.

**Version:** 1  **Date:** 1 June 2010

**Reviewer:** Caroline Laurence

**Reviewer's report:**

This paper reports on the use of three PoC tests for better diagnoses of acute coronary syndromes, heart failure and thromboembolic events in primary care. The focus is on determining if the PoCT assists the GP to make a correct diagnosis of these conditions.

The authors acknowledge that correct diagnoses in primary care is difficult and the potential adverse outcomes if correct diagnosis is delayed.

However, this paper requires some major revision, particularly the methodology, to clarify the study results and allow a better assessment of conclusions reached.

• **Major Compulsory Revisions**

A major problem with this paper is the inadequate description of the methods. This in turns makes it difficult to assess the validity of conclusions drawn and the results. Specifically the methods do not describe adequately:

• What is the conventional diagnosis employing best clinical practice? It was not clear what the process was for the control group and a brief description of what this is would help.

• Why were practices only included if they were some distance from a laboratory with specialised diagnostic systems?

• When PoCT was undertaken in the practice? For the intervention group was this done at the first visit of the patient and did the control group have a laboratory test undertaken. Who undertook the test? Was venous blood used? Was there standardisation in procedures between practices? (training of staff in devices, QA program etc)

• Where the intervention GPs provided with information on the interpretation of the results?

• It is not clear how the confirmed diagnosis was reached. Who determined the confirmed diagnosis? Was it an independent physician or local hospital? What evidence did they use for this? Is the confirmed diagnosis then used to determine if the working diagnosis was correct?

• The baseline data collected from the patient is not mentioned in the methods, but reported in the results.
The aim of the study did not match the methods and result. The hypothesis was that PoCT testing for cTnT, NT-proBNP and/or D-dimer in venous whole blood would provide simple, rapid and accurate diagnosis of ACS, HF and TE. Nowhere does the paper report on the how the process is simple or rapid. It is only dealing with the accurate diagnosis. The hypothesis needs to be refined to reflect what is reported. Additionally, it should include what its accuracy is compared to or is the aim improving the accuracy of GP diagnosis through the use of PoC tests? Is accuracy being defined as the correct diagnosis by GP (and confirmed) as well as accuracy of the specific tests in identifying the condition? Or both?

Some interpretations of the results are inaccurate and misleading and need to be revised. In results, para 1 the authors state there was a significantly higher LDL value in the controls. There is no evidence of a statistical test being undertaken and so the term significance needs to be removed. Moreover, if the LDL is an example where the intervention and control differ, why is not glucose included as the difference is the same as for LDL (0.4 mmol/L)?

In the results para 3, the authors state that the groups differed in rates of acute chest pain and calf pain. For calf pain the difference between the groups was 4%. If this determines a difference then why was not Oedema also included with a 4% difference? Similarly in Table 3/results para 4, the authors state that only the proportion of patients with previously diagnosed HF differed substantially between groups. In reviewing the results in Table 3, a greater difference was found between the treatment groups for hypertension (7% difference) and diabetes was 6% the same as HF.

Table 4: I am not clear about what is presented with this table. Is it showing the accuracy of the working diagnosis based on the confirmed diagnosis for each the treatment groups? If it is, this needs to be made clear in the heading and the text.

I am not sure if the conclusion regarding the greater diagnostic accuracy in the PoCT group (results para 8) are correct. For three of the conditions the NPV was almost the same 100% vs 99%. It was only with the MS and other conditions where there seemed to be some difference between GPs using PoCT for their diagnosis and those who did not. However, this small difference may be clinically important and so needs to be interpreted in this context.

Some clarity about the biomarker performance is needed (results para 9). This only relates to the intervention group of results and if so, this needs to be stated in the text. I am unclear as to why the working diagnosis and confirmed diagnoses are included. If the aim is to test the accuracy of the three tests to identify correctly the diagnosis then it should be compared to the confirmed (correct) diagnosis. The inclusion of the working diagnosis results seem to indicate that the GP may not have been interpreting the test results correctly when making his/her working diagnosis and so it is not an issue of the accuracy of the test, but the use of the test in making a clinical decision. This is a different question entirely and an important one to discuss.
Discussion – overall the discussion is long and some of the conclusions drawn are overstated based on the result provided. This is made more difficult by the lack of information provided in the methods, which makes interpretation of the results very difficult.

The conclusion need reworking as the study did not report on the simplicity or speed of the PoCT devices an only looked at the role in accurately determining the diagnosis.

Minor Essential Revisions

Table 3 title and headings need to be changes as all items listed are not pre-existing diagnoses.

If the focus of the paper is a comparison between groups (intervention and control) it is not clear why in the results presents the frequency of diagnoses within each group (results para 5) While it is of interest, it does not contribute to the paper.

Results para 7. It is not clear in this paragraph which is the intervention and control group results. It would help is this was included in the text and also the frequencies included.

Not clear what ** means in presentation of p values.

Discussion (para 2) – incorrect result presented in last sentence it should be 78% of controls not 80% of controls.

Figures 1 and 2. These graphs may be easier to interpret if the intervention and control results are adjacent to each other, rather than in two separate graphs.

Discretionary Revisions

None

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

I declare that I have no competing interests.