Reviewer’s report

Title: Development of a clinical prediction rule for sepsis in primary care: protocol for the TeSDIT study

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Reviewer: Michael Power

Reviewer's report:

My comments, with much better formatting, are also in the Word file that has been emailed separately to the editorial office.

Review of TeSD-IT study

LINE   TEXT   COMMENTS
2       protocol of the TeSD-IT study  Prepositions are almost arbitrary, but "protocol for" is easier on my ear. Google finds 3 times as many "protocol for"-s.
34      We will …  Tenses go backwards and forwards rather randomly.
Consider using the future, present, or past tense consistently.
34      The following candidate predictors are prospectively recorded  It is a pity that GP's did not record the most likely site of infection and their confidence in their guess.

Perhaps the discussion section could explain why this was not done?
35-36   1) age; 2) body temperature; 3) systolic blood pressure; 4) heart rate; 5) respiratory rate; 6)
36       peripheral oxygen saturation; 7) altered mental status; 8) rigors and 9) rapid illness progression.
Items 1 - 6 are parameters
Items 7 - 9 are values of parameters

For precision and consistency, for 7 - 9 consider mental status, history of rigors, rate of progression
50      samples will be retrieved  samples will be obtained?
52      validation is needed  validation will be needed
69-70   but patients’ early stages of sepsis are often presented
70      in primary care. But patients often present in primary care in the early stages of sepsis
72      patients can be treated at home or have to be referred to a hospital  A patient can safely be treated at home or should be referred to a hospital
84-85   Besides the white blood count, the SIRS parameters are heart rate &lt;90/min,
85       respiratory rate &gt;20/min, and a body temperature &lt;36°C or &gt;38°C.  In this sentence, and in the subsequent text, the meanings of parameter and criterion are confused. A parameter is a variable that can take a range of values. A criterion is a specified value of a parameter, and it is used as a threshold for some decision about classification or action.
In this example, "heart rate" is a parameter, while "heart rate &lt;90/min" is a criterion used in the definition of SIRS.
So, this sentence should be: "…the SIRS criteria are …"
90      The parameters used in the qSOFA  As above: The criteria used in the qSOFA
94      have all shown to increase  have all been shown to increase
Both signs and symptoms as well as additional biomarkers like CRP, lactate and PCT are however not evaluated for early detection of sepsis in primary care. Do you mean to say "No study has (to our knowledge) assessed the contribution to the accurate early detection of sepsis in primary care of factors such as symptoms, signs, and biomarkers potentially available as point of care tests such as CRP, lactate, and PCT"?

The name of the study implies that CRP, lactate, and PCT are available as point of care tests, but this is not stated explicitly anywhere. This is a good place to do so.

Candidate predictors were selected if there was evidence to suggest that they might usefully contribute to the diagnosis of sepsis, and if they can be easily and objectively measured by GPs.

The NICE sepsis guideline specifically recommends to further evaluate PCT in sepsis research. The NICE sepsis guideline recommends research to further evaluate the use of PCT point of care tests for diagnosing serious bacterial infection and initiating antibiotic therapy.

This is a wider brief than sepsis research.

In this consensus definition, sepsis is defined by an increase of two SOFA-points. The operational definition of sepsis is the presence of infection and a SOFA score of at least two above the baseline (which can be assumed to be zero in patients not known to have preexisting organ dysfunction).

Or, if brevity is important, and most patients triaged by GPs have baseline SOFA scores of zero:

The operational definition of sepsis is the presence of infection and a SOFA score of at least two.

Patients will continue to be recruited.

End of follow-up is 30 days after inclusion of the last patient. Does "follow-up" mean that patients were seen for the study up to 30 days after the inclusion of the last patient?

Maybe discuss this in the discussion section?

Sepsis were published, which we try to implement are as good as possible. Sepsis were published (which we try to implement) are as good as possible.

(increase of ≥2 points from baseline due to infection)
Imputation of SOFA points:

Peripheral oxygen saturation (SpO2) and supplemented oxygen are used to estimate respectively the pO2 and FiO2 for calculation of the pO2/FiO2 ratio. Results from blood gas analyses are (outside the ICU) are not taken into account as the amount of oxygen supplied at the time of blood collection is unknown. For the estimation of the pO2 and FiO2, the following conversion tables are used: Replace pO2 by the conventional abbreviation, PaO2.

The table uses PaO2 as the column header.

SOFA points are adopted from the electronic medical records from the ICU SOFA points are obtained from …

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