

BIVDA response to the UK Health Security Agency consultation on UK SMI S 12: sepsis and other systemic and disseminated infections

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British In Vitro Diagnostics Association (BIVDA)

5. Are you happy to have your comments included in the RUCs?*

Yes

6. Select option (happy with document, no further comment / I would like to provide comment)*

I would like to provide comment

7. Section for comments

References

8. Comments / evidence

Generally, the references used to evidence scientific data on sepsis and other disseminated infections were historical, with most of the references being over 10 years old. Many more recently publications are available on this area, and we would welcome more up to date scientific evidence.

The conclusions go on to state that there is insufficient data in this area, which is not accurate.

9. Section for comments

Full document

10. Comments / evidence

The document is very minimal on patient/host response on infection. We would encourage this to be included in the scope of the document. This is key area of the management of infections and is a newly evolving area for diagnosis to identify outcomes.

11. Section for comments

Full document

12. Comments / evidence

This sector of diagnostics is rapidly evolving, with new innovations being introduced to the market regularly. There is no mention within this document of innovative products and the benefits they could bring to patients. Inclusion of reference to innovative technologies would bring this document in line with other government publications which encourage innovation for diagnostics in the UK.

13. Section for comments

Full document

14. Comments / evidence

BIVDA would encourage this document to include point of care IVDs within the scope. Point of care products allow for rapid diagnosis (in some cases as quickly as within an hour), meaning patients can be treated faster and have a better prognosis. Lab-based diagnostics are a crucial part of patient management and so should also remain included within the scope.

15. Section for comments

Full document

16. Comments / evidence

In a number of places throughout the document, blood is referred to as a sample type. Samples may be from whole blood or from blood cultures, so further differentiation within the document may be beneficial to clarify this.

17. Section for comments

18. Comments / evidence

19. Please upload supporting references if available

20. Are there any potential organisational and financial barriers in applying the recommendations or conflict of interest?*

Funding pathways into the NHS should be taken into account for organisations to ensure appropriate resource within health institutions. For example, the appropriateness of which organisations are applicable for efficient and optimal patient management.

21. Are you aware of any health benefits, side effects and risks that might affect the development of this UK SMI?*

Early diagnosis is the main benefit of such standards. This includes the use of point of care products, and other products which span the whole cycle of patient management from initial presentation to treatment.

22. Are you aware of any interested parties we should consider consulting with on the development of this document?

BIVDA would be keen to contribute to any further conversations on this topic as the trade association for in vitro diagnostic organisations.

23. Where did you hear about this consultation? (Standards Unit email bulletin / Internet search / Twitter / From a professional body website / From a patient/public website or organisation / Word of Mouth / Other, please specify)

Standards Unit email bulletin

24. Suggestions on:

a. any gaps in the UK SMI repository that you would like filled?

This document and consultation do not adequately reflect the research and development ongoing in the industry at the minute, such as other relevant products available on the market. This is also the case when consideration innovative products and the future of the sector.

b. how UK SMIs can be improved?

UK SMIs need to ensure that host response is considered, as well as the scope of products involved.

25. In general, how satisfied are you with the UK SMI service? (Satisfied / Neutral / Dissatisfied)

Neutral