

### Validation of matrix-assisted laser desorption/ionisation-time of flight mass spectrometry (MALDI-TOF MS) for the bloodstream infection focus on outcomes trial

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**Objectives:** Around 90-100,000 Blood Stream Infections (BSI) occur per annum in the UK at a cost of £6,200 per episode, with mortality up to 40%. Lack of BSI research leads to deficiency of information on outcomes/ risk factors for poor outcome. Patient factors related to underlying disease, site and severity of infection impact adversely on outcome whilst timely appropriate antimicrobial chemotherapy and removal of infected prosthetic materials are beneficial. Rapid laboratory based Diagnosis (RD) has beneficial effects on antibiotic use in infected patients and may reduce mortality. This multicentre trial aims to develop a programme of linked research studies aimed at improving management of BSI, reducing patient mortality. The RD technology chosen is Matrix Assisted Laser Desorption/Ionisation-Time of Flight Mass Spectrometry (MALDI-TOF MS). Validation of the MALDI-TOF Mass Spectrometry (MS) was required for bacterial identification from culture plates and direct from positive blood cultures. **Methods:** 853 previously identified BSI isolates including *S. aureus*, Enterobacteriaceae, Streptococci, & *Candida* were identified using MS with manufacturer's "from culture plate" method. 333 positive blood cultures (316 single organism (SO), 17 polymicrobial cultures (PM)) were processed using 3 programmes (Standard (SP), Blood Culture (BCP) & Blood Culture minus mixed culture feature (BCnomixP)) with manufacturer's Sepsityper kit, alongside conventional bacteriology. Any discrepancies were confirmed using 16S. **Results:** Of 853 isolates from culture plates, MS accurately identified 98.9%, with 98.4% accurately identified on the first occasion. 9 out of 23 Alpha Haemolytic Streptococci (AHS) mis-identified as *S. pneumoniae*. Variations in *Acinetobacter* species were noted but were not considered significant. Of the 316 SO blood cultures 93.4% were accurately identified using the SP, with the majority of failures exhibiting "no reliable ID". The BCP and BCnomixP gave accurate IDs in 92.1% and 97.8% respectively. The majority of inaccuracies using the BCP were due to false mixes. 35.3% of PM cultures were accurately identified using BCP. In all other PM cultures one of the species was accurately identified. **Conclusions:** MS performed well for identification of bacterial BSI isolates from culture plates. AHS and anaerobes were problematic. For direct identity from blood cultures the MS performed better using the blood culture programme minus the mixed culture feature.

<b>SINGLE ORGANISM CULTURES</b>			
<b>TOTAL NON-MIXED samples</b>	<b>No of samples exhibiting confirmed result by STANDARD analysis</b>	<b>No of samples exhibiting confirmed results by BLOOD CULTURE analysis</b>	<b>No of samples exhibiting confirmed result by new BLOOD CULTURE (NO MIX) analysis</b>
<b>316</b>	<b>295 (93.4%)</b>	<b>291 (92.1%)</b>	<b>309 (97.8%)</b>
<b>SINGLE ORGANISM CULTURES - failures</b>			
<b>Non Ids</b>	<b>STANDARD analysis</b>	<b>BLOOD CULTURE analysis</b>	<b>BLOOD CULTURE (NO MIX) analysis</b>
<b>No reliable ID</b>	<b>21 (6.7%)</b>	<b>5 (1.6%)</b>	<b>5 (1.6%)</b>
<b>False mixes</b>	<b>0</b>	<b>18 (5.7%)</b>	<b>0</b>
<b>No peaks</b>	<b>1 (0.3%)</b>	<b>2 (0.6%)</b>	<b>2 (0.6%)</b>