**Hill, Maddy**

**From:** adaptsepsistrial, Resource
**Sent:** 24 September 2019 11:28
**Cc:** adaptsepsistrial, Resource
**Subject:** ADAPT-Sepsis September Newsletter

# ADAPT-Sepsis September Newsletter

Biomarker-guided antibiotic duration for sepsis

@AdaptSepsis Trial Website Trial Email

**Welcome to the new email format of the ADAPT-Sepsis newsletter! Please let us know if you have any suggestions for improvements or information you would like to see included on a monthly basis.**

**Please click on the headers below which will take you to the different sections.**



# Trial Update

Hello all, we hope you are feeling revitalised after the summer break. Over August we have had 53 patients recruited to the trial! Thank you all for your hard work, especially during times of staff annual leave and absence.

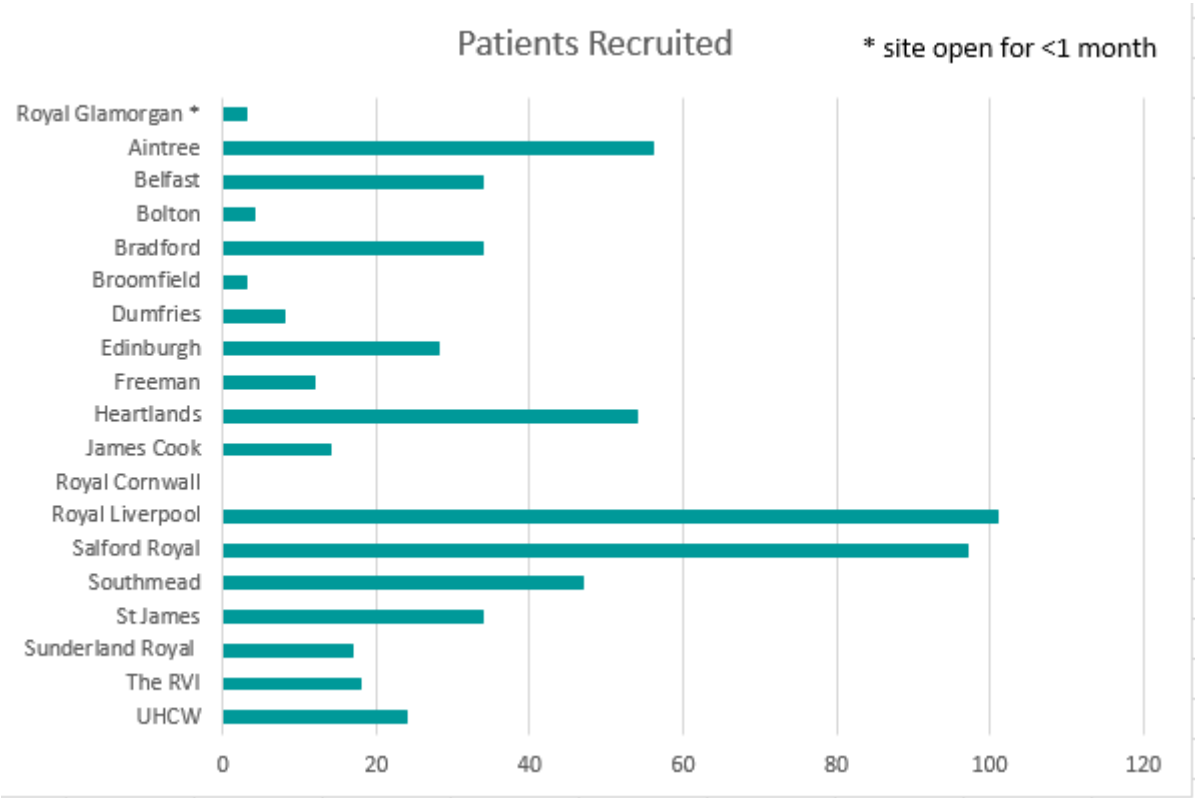
Since our last update we have welcomed Lancaster Royal Infirmary and Royal Glamorgan to the study, a thanks to the teams at both sites for your hard work getting ready for the green light! We have a number of sites still in setup so look forward to progressing over the next few weeks.

## Trial Milestones

**627** patients recruited so far

**20** sites open to recruitment

**7** further sites initiated to date




# Training Materials

We have developed some training slides for non-GCP trained staff both on and off ICU, who are delegated to receive/disseminate the antibiotic protocol stoppage advice. The slides highlight both the trial intervention, and key GCP principles relevant to their role. The PowerPoint is available on request - please let us know if you would like a copy.

We also have an ADAPT-Sepsis trial poster suitable for staff areas, which aimed towards screening and identification of patients suitable for enrolment. Again, please get in touch with the trial team if you would like a copy.

# Sepsis Evidence Update

ADAPT-Sepsis is important and timely for the NHS, as the early and potentially prolonged use of broad-spectrum antibiotics is increasing. The recommended duration of antibiotic therapy for sepsis is based on evidence of low quality that may lead to an overuse of antibiotics, contributing to the development of antimicrobial resistance, which is both a national and global priority. An internal re-review has been undertaken by NICE of their Diagnostic Guidance 18, and no new evidence sources have been identified to add to the already low quality evidence based that has resulted in the commissioning of the ADAPT-Sepsis trial. Therefore, ADAPT-Sepsis remains crucial nationally and internationally to help progress a definitive answer to the use of PCT and CRP biomarkers in helping to determine the duration of antibiotic treatment for sepsis.

---

# Data Update

A big thank you to all staff involved in data entry who have contributed to the big improvement in the antibiotic data entered onto the ADAPT-Sepsis database. We have seen a big reduction in the proportion of missing data over the last month, thank you very much for your time and effort inputting this. Please do continue to ensure that you **return to input antibiotic stop dates** for your patients, particularly if they are discharged still on systemic antibiotics for sepsis, as this is a major component of our primary outcome.

A reminder that as we are only collecting antibiotic data relevant to suspected sepsis, and therefore only require start dates for antibiotics administered for the sepsis episode.

---

# Learning Points

## Non-trial PCT

Please remember that routine or non-trial PCT should not be performed in ADAPT-Sepsis participants from the time of randomisation until Day 28. If a PCT test is performed, please complete a protocol deviation form to document the occurrence.

## Transcription of Antibiotic Stoppage Advice

We are delighted by the methods adopted by our trial sites to pass on the antibiotic stoppage advice to treating teams, and we thank you for your continuing hard work in this space. If you are transcribing the stoppage advice onto an electronic patient record, please do ensure the advice is copied ***verbatim***, as this is essential for the delivery of the intervention.

## Fixed Term Antibiotics

For the purposes of ADAPT-Sepsis, a long-term course of antibiotics has been defined as 21 days or more. As per the exclusion criteria for the trial, patients who are placed on courses of 21 days are not eligible to be randomised, and any patients already on the intervention should be withdrawn to follow up only. For trial patients who are placed on antibiotics for courses under 21 days, we ask that you allow the patients to remain on the trial intervention. This was originally decided based on peer review from the NIHR and guidance from the NHS, who are keen that this population of patients is included in the trial, and contribute towars the data and evidence, given the acknowledged low quality evidence for patients deemed to require courses of antibiotics less than 21 days (e.g. uncomplicated bacteraemia). We appreciate that there are varying practices across NHS Trusts relating to courses of antibiotics of 1 or 2 weeks, however it's important that we are able to add to the evidence base surrounding these courses of antibiotics, by including these patients in the trial intervention. We appreciate your support, and as always, if you have any questions please do not hesitate to get in touch.

## Eligibility Clarifications

The 24 hour clock for antibiotic treatment starts when a patient is administered

antibiotics specifically for sepsis, regardless of if they have received antibiotic treatment for an infection leading up to the sepsis episode.

## News

As part of our continuing engagement with the scientific community, look out for our article in the October issue of the IBMS Monthly Magazine, where we describe the importance of ADAPT-Sepsis, and acknowledge the role of biomedical scientists in delivering the trial!

## Co-enrolment

Below is our current list of approved co-enrolling trials with more in progress.

A2B, A-STOP, BIT (Immune biomarkers and clinical outcome in trauma patients), BLING III, GenOMICC, ILoNIS, ILTIS, INTACT, PQIP, REALIST, RESORP, REST, SNAP-IT, STARRT-AKI, STRESS-L, The 65 Trial, SQUEEZE, Understanding stroke-induced B cell changes and their relationships with stroke-associated infection and VACIRiSS.

Co-enrolment with observational studies is a fast tracked process. Where co-enrolment with observational studies will take place, please forward the relevant trial protocols for our records and approval.

For interventional studies, we will conduct a thorough review process with the

respective coordinating teams. Please inform us of any current or upcoming interventional studies to prioritise.