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From: adaptsepsistrial, Resource
Sent: 24 April 2019 16:17
To: adaptsepsistrial, Resource
Subject: ADAPT-Sepsis April Newsletter & Investigator Meeting Feedback

ADAPT-Sepsis April Newsletter

Investigator Meeting Special

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 Easter break. Once again we have had another record breaking month: **61** patients were recruited in March! Thank you all for your hard work.

Since our last update we have welcomed Dumfries to the study who are eager to get going! We have a number of further SIVs planned for the coming weeks so look forward to progressing set up at further sites.

Thanks for everyone who came to our Investigator Meeting on 09th April. Please see below to learn more and for a summary of our main discussion points.

We will soon attend the **ACB Focus** and **UKCCRG** Conferences so please see below if

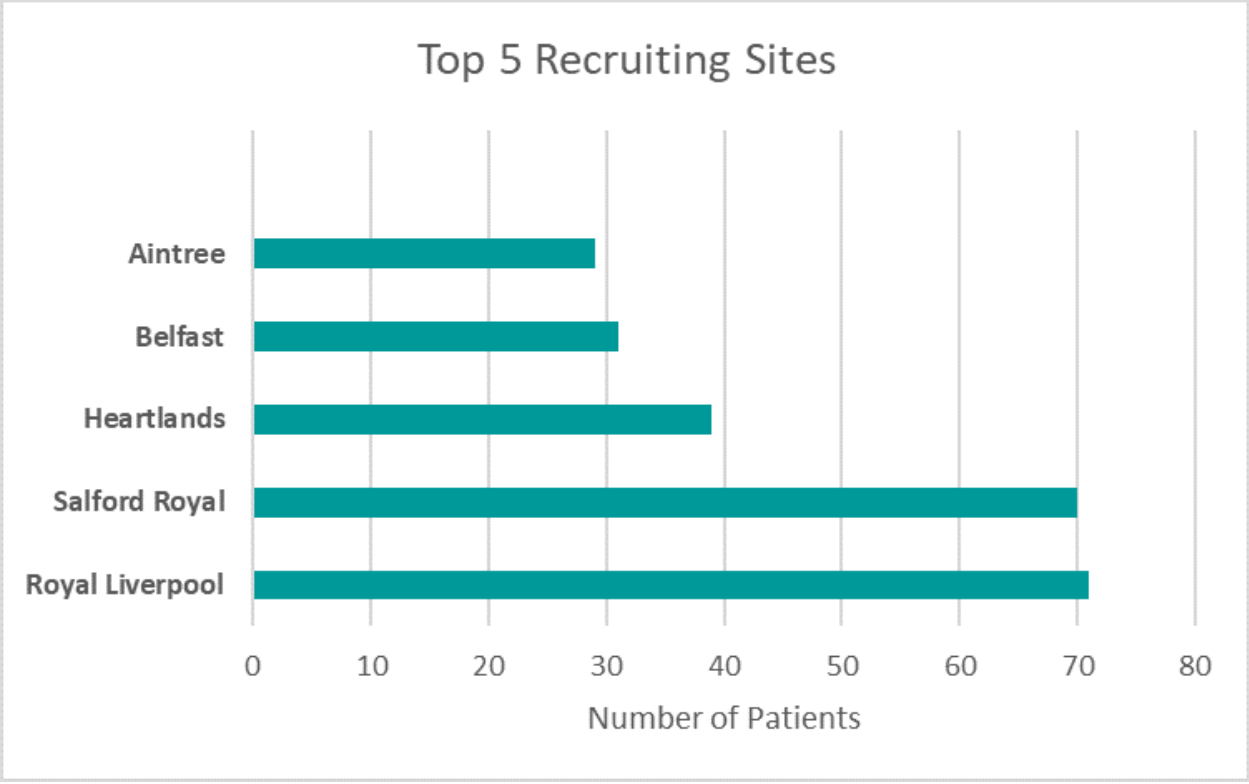
you are interested in attending.

Trial Milestones

368 patients recruited so far

15 sites open to recruitment

17 sites initiated to date

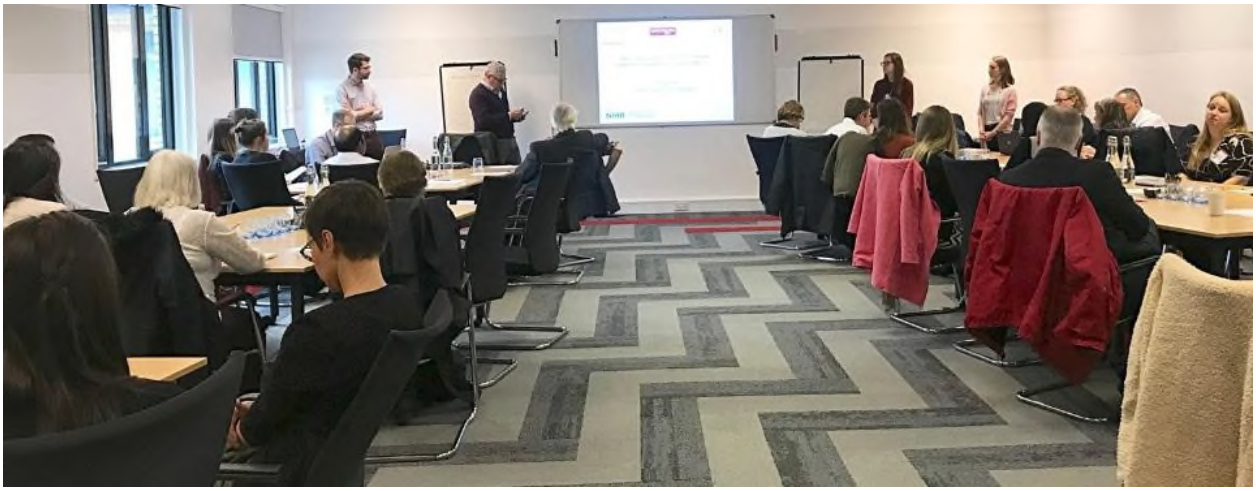


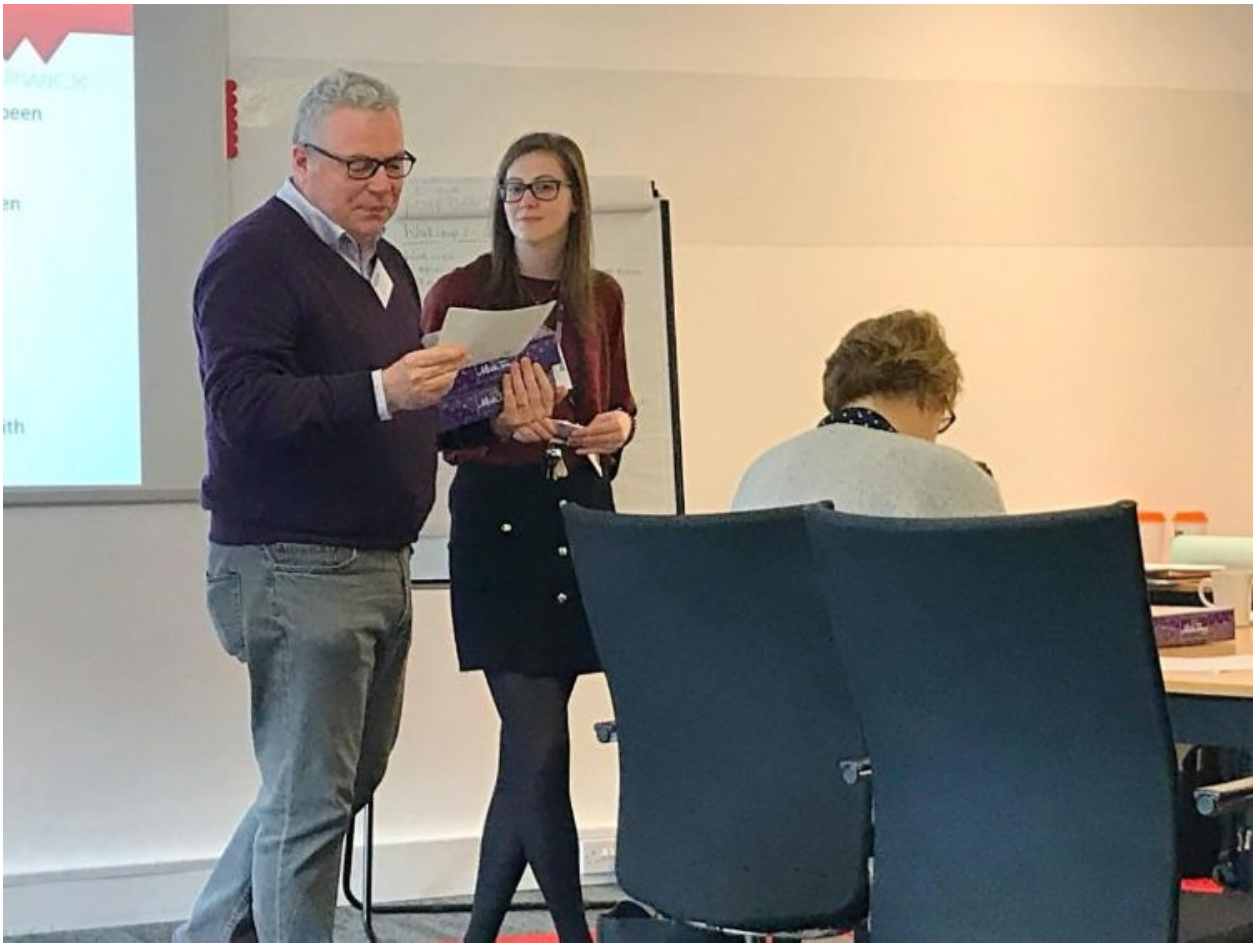
Investigator Meeting April 2019

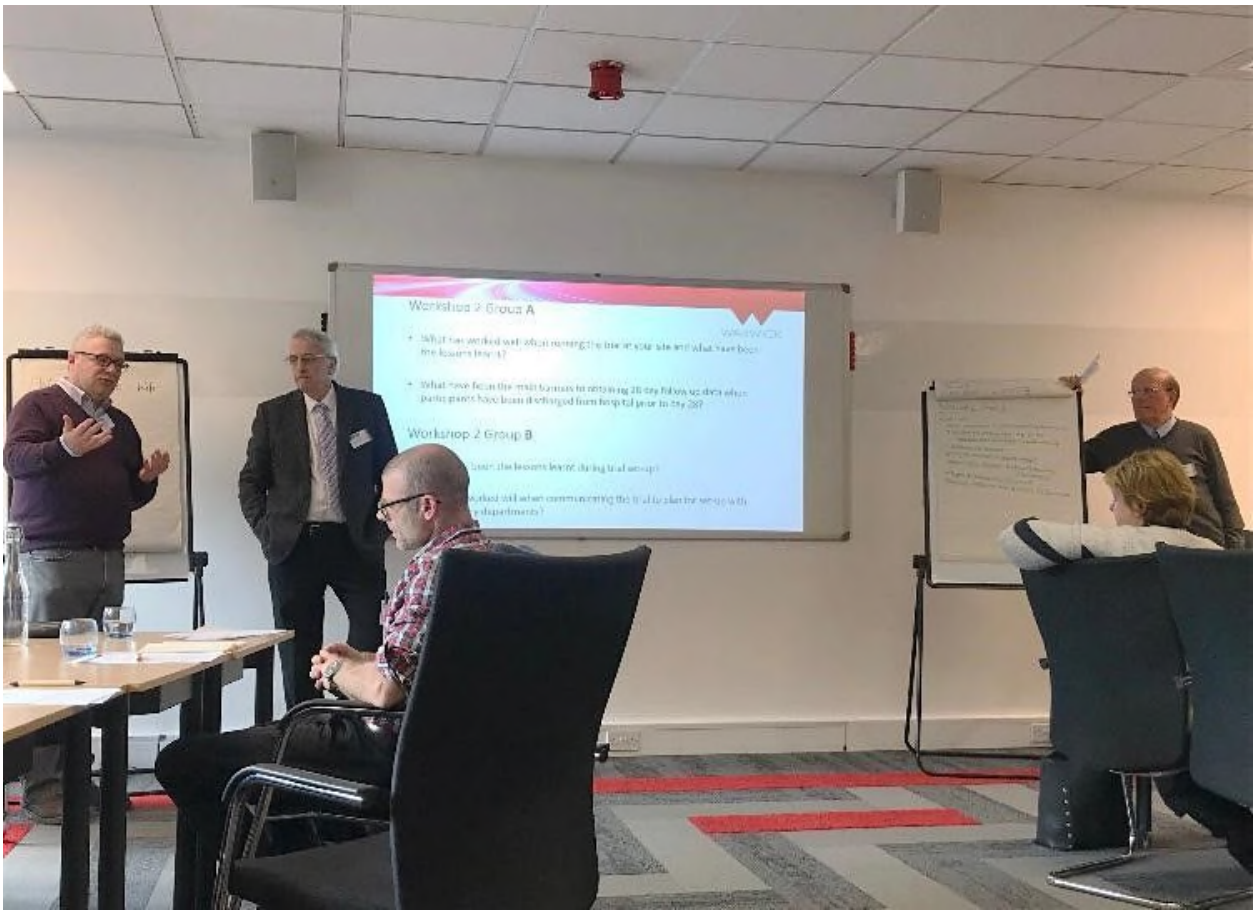
Thank you to all who attended our investigator meeting here at Warwick on 09th April. We had a great day and really valued the opportunity to catch up with you all face to face. Congratulations to anyone who won a prize for their hard work on the study, which is hugely appreciated. Well done also to Jo Gresty for winning the ADAPT-Sepsis quiz!

A special thanks go to our PPI representatives Keith Young and Gordon Sturmey, who provided an insightful talk on the patient experience and their involvement in supporting clinical trials, and to Ruth Poole who offered early insight into the PRE-ADAPT process evaluation trial which you will hear more about over the coming months.

The bulk of the day was devoted to our group workshop sessions which allowed attendees to share their individual experiences of the study, best practise tips and methods for tackling challenges. Thank you for engaging with these discussions and for helping to share your broad knowledge. Please see below for a summary of these discussions.







Investigator meeting feedback

Workshop 1

How have you successfully identified and recruited patients within the 24 hour window?

- Twice daily screening minimises the number of potential patients who are missed.
- Outreach teams can help to identify patients that are due to be transferred to ICU, saving time in the 24 hour window.
- Embedding research in clinical practise; consultants, junior doctors, ward nurses and more can help to identify patients for recruitment on presentation to ICU and throughout their stay. Familiarising staff in the studies your unit is participating in can be invaluable. Informal coffee mornings are a great way to

spread the word!

WCTU Action: To assist with training and engagement of wider teams.

What have you implemented to improve patient participation?

- Seeking consent from relatives via telephone has been beneficial (currently approved for England, Wales and Northern Ireland).
- Use of electronic systems to flag up potential patients to be screened. It is sometimes possible to filter for specific study eligibility criteria to aid this process further.
- The term 'sepsis' is often misused and it is important to challenge how patients have been labelled prior to ICU admission. Although a patient could have been described as septic whilst on another ward, this might not be a true reflection. Discussion with clinical colleagues and examination of a patient's antibiotic treatment can help to reveal when an accurate sepsis diagnosis was given and when the 24 hour window commenced for a patient.
- Seeking consent using the short patient information sheet initially before providing the more detailed information sheet on recovery can help to avoid overwhelming patients with capacity and allow them to more easily assess whether they would like to take part in the study.

How to facilitate trial research blood sampling after patients are discharged from ICU.

- Early communication is key – if a patient is on the study and receiving the intervention on a Thursday or Friday, a clear plan should be made with the ward staff to identify arrangements to cover the weekend. A point of contact should be identified who will be available over the weekend.
- A variety of methods to flag up a patient's involvement in the study is helpful. Handover documents can be issued to the receiving team when a patient is discharged from ICU and placed in the patient's medical notes. Stickers can also

be placed in the patient paper notes or messages added to electronic systems and even screensavers can be used to flag up participation. Please let us know if you have any further ideas!

- Outreach teams can be utilised to facilitate sample collection in the days following ICU discharge.
- Input from phlebotomy teams can be a great help in maximising successful trial blood sampling. Discussions with the phlebotomy manager and the nurse in charge can assist with the coordination of research sample collection with any routine bloods to reduce patient burden.
- Where possible, a physical presence of ICU research staff on the wards when obtaining blood samples can help to foster relationships and assist with later communication of trial treatment advice.

WCTU Action: To explore what further materials and training we can provide to assist with this process. Videos are being prepared which will explain to ward staff what the trial is, how the sampling will take place and what the treatment advice will mean.

How have you successfully delivered trial antibiotic treatment advice to care teams?

- Enthusiasm when handing advice over to ward teams makes a big difference! Using the trial handover tools provided by WCTU, and local team innovations to try and help disseminate information.
- Sending messages via the Trust intranet or in Whatsapp groups can help to highlight the trial advice.
- It can be helpful to involve the wider teams when patients have been discharged to the ward, ie. informing microbiology teams before discharge that patient remains on ADAPT-Sepsis intervention, or adding an ADAPT-Sepsis tag onto the antibiotic prescription, with phone number for research team.

WCTU Action: To develop trial videos highlighting trial information that can be sent to wider teams and ward staff. To look into the possibility of having ADAPT-Sepsis wrist

bands for patients still on intervention, with a QR code linking to the trial videos.

Workshop 2

What are the major lessons learnt from trial set up?

- Communication and engagement with the wider biochemistry team throughout the set up process is vital. Whilst the lab leads take responsibility for the trial duties, often the biomedical scientists are the ones who will be performing the day to day tasks. Involving these staff in the set up process, including attendance at SIVs, will assist with training and facilitate a smooth sampling process.
- Holding internal training events and grand rounds aimed at microbiology and biochemistry teams can support engagement. WCTU training slides can assist with this.
- The creation of local SOPs can be used alongside trial materials to explain exactly how the sampling procedure will be conducted locally by the biochemistry teams

What has worked well when running the trial at your site?

- Having the microbiology team involvement from the beginning works well eg. passing on advice during micro ward round.
- Having a flexible working team helps follow patients onto wards.
- Making sure all the consultants are on board and engaged in the trial is really important.
- It has been helpful for some sites to ensure that VPN access/static IP address can be provided to one or two members of the research team to be able to access the database from home. **Note** - the upcoming database amendment will alleviate this point.
- Having a research nurse presence on the unit can encourage other staff to be involved in the trial.

WCTU Action: To involve the wider biochemistry teams, microbiology teams and ICU pharmacy teams in our site set up discussions and support the creation of local SOPs.

UKCCRG & ACB Focus 2019

The UK Critical Care Research Group are hosting their Twelfth national forum for clinical research in critical care, emergency medicine and acute medicine on:

Thursday 6 - Friday 7 June 2019 in Leeds

The ADAPT-Sepsis Team will attend this year's meeting and will host a drop-in Q&A session for all current and upcoming recruitment sites at **13:00 - 13:00 on Thursday 06th June**. Please let the trial team know if you plan on attending this event to help us with planning.

Wednesday 1 - Friday 3 May 2019 in Glasgow

The trials team will be attending The Association for Clinical Biochemistry and Laboratory Medicine national meeting: Focus 2019. This will be a great chance for any biochemistry team members at potential future sites to discuss how the study could be run at your centre and for our current teams to feedback on your experiences so far.

Our laboratory lead from St James, Helena Baker, will be sharing her experiences of the trial during our talk at **09:55 on Thursday 02nd May** and we will be staffing a research stand throughout the event. Please feel free to drop by to discuss how you can get involved at your site.

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.

Telephone Consent

Just to emphasise a change in our last protocol amendment (V2.0) - it is now permitted to gain verbal telephone consent from personal consultees, friends or relatives prior to obtaining written informed consent. We hope this will assist with gaining consent within our tight inclusion window.

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. We have included a couple of examples to help illustrate this:

Scenario 1:

64y male patient arrives at A&E with signs and symptoms of a lower respiratory tract infection (pneumonia) of low severity, with no clear signs of sepsis. It is not thought safe to discharge the patient home due to complex social circumstances and the fact he has not been drinking very well and has a persistent fever. He is treated in the Emergency Assessment Unit (EAU) overnight with a single first line iv community acquired antibiotic based on local hospital guidance and iv fluids. The following day, 36 hours after admission, his condition is worsening with a low blood pressure - not improving with iv fluids - his oxygen saturation is falling despite mask supplementary oxygen, his urine output is falling and he has become confused. He is reviewed urgently by the EAU team, his iv antibiotics are escalated to dual therapy appropriate for severe community acquired pneumonia and sepsis, and he is referred to critical care.

Overall, he has received 36 hours of iv antibiotics since admission but has only just received iv antibiotics for a severe infection/sepsis – he is therefore eligible for consideration for recruitment into the ADAPT-Sepsis study assuming the senior treating clinician agrees.

Scenario 2:

A 64y female patient is day 3 after large bowel resection surgery for a tumour. She is making good progress and starting to take oral fluids. An old iv cannula site is looking red, feels hot to touch and she has a mild fever. Her treating surgical team decide that she may have a cellulitis and treat her with iv flucloxacillin through another iv canula having already removed the old canula. The following day, 36 hours after commencing iv flucloxacillin, she becomes very unwell with clear signs of septic shock. Her iv antibiotics are escalated to broad spectrum – including two agents – and she is referred to critical care.

Although she has received at least 36 hours of iv antibiotics, the iv antibiotics for septic shock have only just been commenced and she is eligible for consideration for recruitment to ADAPT-Sepsis assuming the senior treating clinician agrees.

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, STRESS-L, The 65 Trial, Understanding stroke-induced B cell changes and their relationships with stroke-associated infection

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.