ProMISe Newsletter

Issue 4, April 2012

Key factors for success...

After reviewing the information provided by sites regarding resources/screening and individual Screening Logs, three key factors associated with successful recruitment have been identified:

- an enthusiastic champion in/around the emergency department;
- 24/7 screening and recruitment;
- sufficient, dedicated, local resources to support the above two.

Other factors associated with successful recruitment include:

- early measurement of lactate – consider purchasing a point of care lactate monitor with your ProMISe start-up funds;
- early referral of potentially eligible patients to the local ProMISe Team – consider a dedicated ProMISe telephone number;
- easy-to-follow screening/recruitment processes.

Protocol deviations

Patients who do not receive the randomly allocated treatment (for whatever reason) must remain in the trial and continue with follow-up as per the trial protocol. They cannot be withdrawn. Everyone who is randomised is considered to be part of the trial – this is important to minimise bias.

For any patient who either does not receive the randomly allocated treatment, or does not receive all of the intervention (for patients randomised in early, goal-directed, protocolised resuscitation), please provide details of the reason in the Comments box on the Case Report Form and on the web portal.

ProMISe going forward...

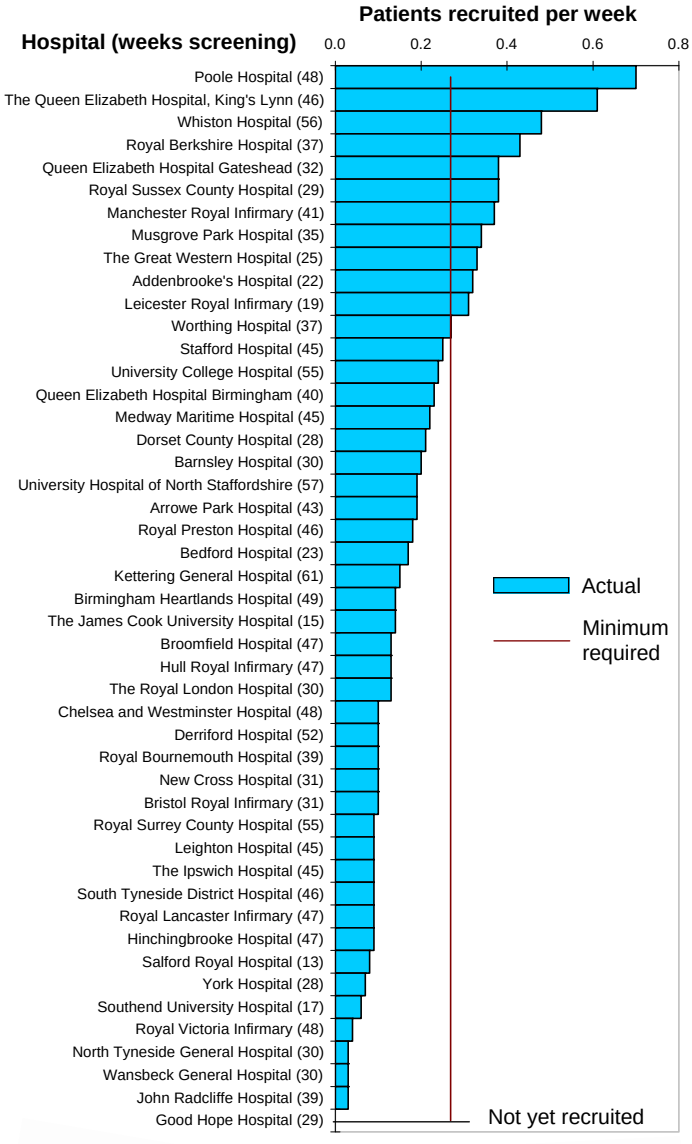
We are reaching the end of the feasibility phase of the ProMISe Trial and representatives from the NIHR Health Technology Assessment Programme, which is funding ProMISe, will be visiting the ICNARC CTU on 15 May 2012.

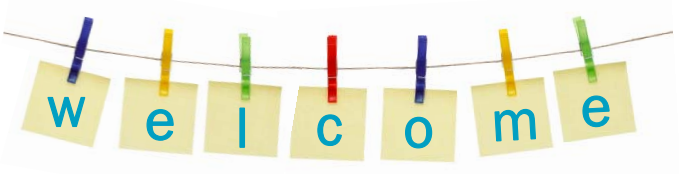
The purpose of the visit is to review progress to date and to discuss the feasibility of continuing with the ProMISe Trial.

360 patients recruited!

Congratulations to Poole Hospital who leads the way with 34 patients!

We need 1260 patients from 48 sites over two years. This equates to an average of 1.17 patients per site per month, or 0.27 patients per site per week. Congratulations to the ProMISe Teams at all those hospitals that are on or above target – thank you for all your hard work!





... to Frenchay Hospital and Salford Royal Hospital

who have recently opened to recruitment!

Patient consent

- If a patient has capacity to give informed consent, but cannot physically sign the Consent Form, the form can be signed on their behalf by a witness. The witness (ideally the next-of-kin) should be independent of the ProMISe Trial. Please ensure that a note is added to the Consent Form explaining why the patient is unable to sign and the relationship of the witness to the patient.

- When professional consultee agreement or emergency consent is used, don't forget to inform the next-of-kin, as soon as possible after randomisation, that the patient has been recruited into the ProMISe Trial. Please add a note to the Retrospective Consent page on the web portal to indicate that this has been done.

Screening Logs

Please ensure that your Screening Logs are kept up-to-date, as we will be requesting copies of these quarterly.

You should record all eligible patients (i.e. met all inclusion criteria, and no exclusion criteria) who were not randomised, and all patients who met all inclusion criteria, plus one or more of the exclusion criteria.

Data security

Please ensure that the Delegation of Trial Duties Log and Site Research Staff Contacts Form are up-to-date.

If a member of your team stops working on ProMISe, please ensure that their 'end' date is added to the Delegation of Trial Duties Log. This should then be faxed or emailed to the ICNARC ProMISe Team. It is important for data security and patient confidentiality that we restrict access to the web portal to individuals who are currently delegated to work on ProMISe.

Dates for your diary

15th Annual Meeting of the Case Mix Programme

19 April 2012
The Mermaid Conference and Events Centre, London

ProMISe Monthly Teleconference

17 May 2012, 12:30 – 13:30

UK Critical Care Research Forum (UKCCRF)

11 – 12 June 2012
Queen's University Belfast

Protocol Amendment 3

The Research Ethics Committee (REC) has approved Protocol Amendment 3. The amendment includes:

1. The addition of a short version of the Patient Information Sheet (PIS), which summarises the main points of the ProMISe Trial. This should be given to the patient or consultee along with the full version of the PIS or Consultee PIS (see SOP006, v4.0, dated 25/01/2012).

2. In cases where retrospective consent for patients with mental capacity, is not sought prior to discharge, the patient can be contacted by telephone for their retrospective consent. Please note: the REC has advised that these cases must be kept to an absolute minimum.

3. Administrative amendments to the Patient Information Sheets and Consent Forms.

Protocol Amendment 3 should now be implemented at your site.

Follow-up

A big thank you…

…for your hard work and efficiency in responding to email requests for additional patient contact information. This has facilitated an increase in the number of patients successfully followed-up at 90 days. One year follow-up has now started...

Invoicing

All invoices sent to ICNARC must quote a valid Purchase Order number. Please contact the ICNARC ProMISe Team to obtain this once a payment is due. Separate Purchase Order numbers are required for each invoice submitted.

Helplines

24/7 clinical support line
Tel: 020 7554 9775

Edwards 24/7 technical support line
Tel: 0800 756 0802