

ProMISe Newsletter

Issue 2, August 2011

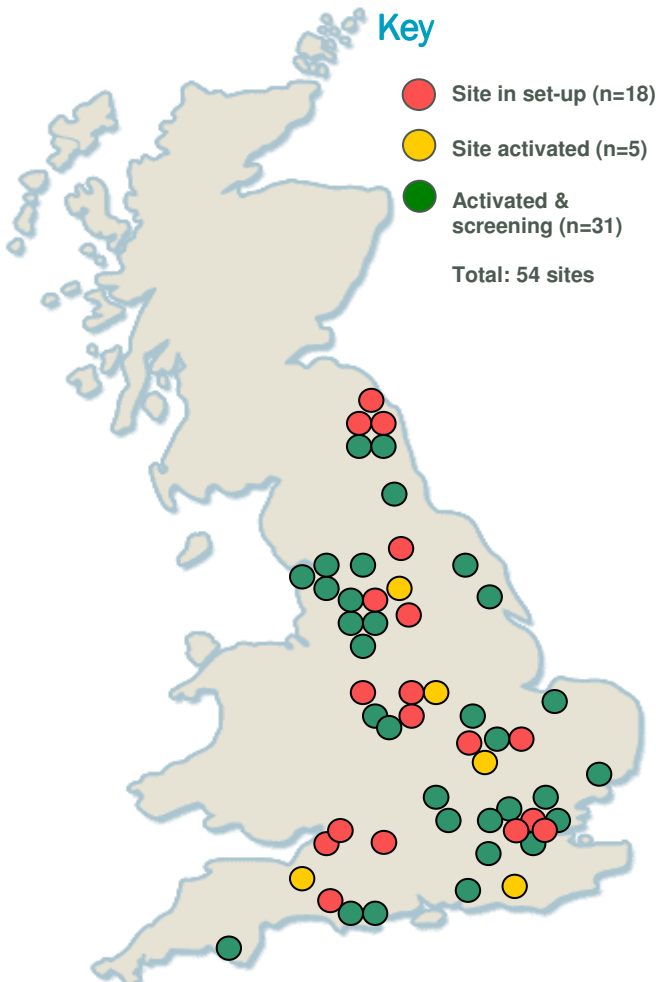
Aim and rationale

Initial resuscitation of patients with severe sepsis may result in stabilisation of vital signs such as heart rate, systolic blood pressure, mean arterial pressure etc, but does not always relieve tissue hypoxia, which may persist despite the patient "looking good". Additional therapy to restore adequate systemic oxygenation and perfusion by correcting low ScvO₂ and/or elevated blood lactate may be required to improve the care and outcome of these patients. The aim of ProMISe is to evaluate whether resuscitating to standard guidelines, including targeting ScvO₂, improves outcomes in patients with severe sepsis.



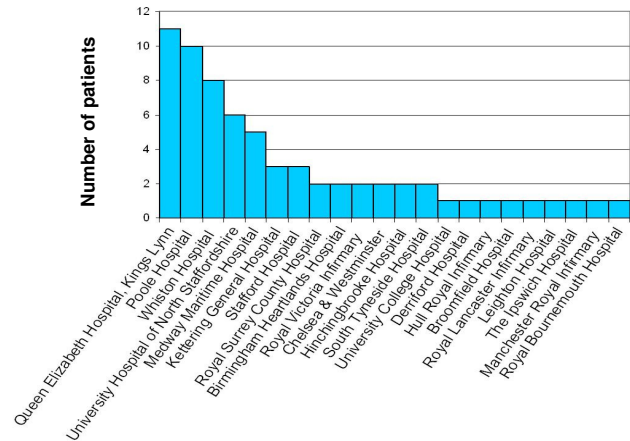
36 sites activated

Of the 36 sites activated, 31 are actively screening for patients.

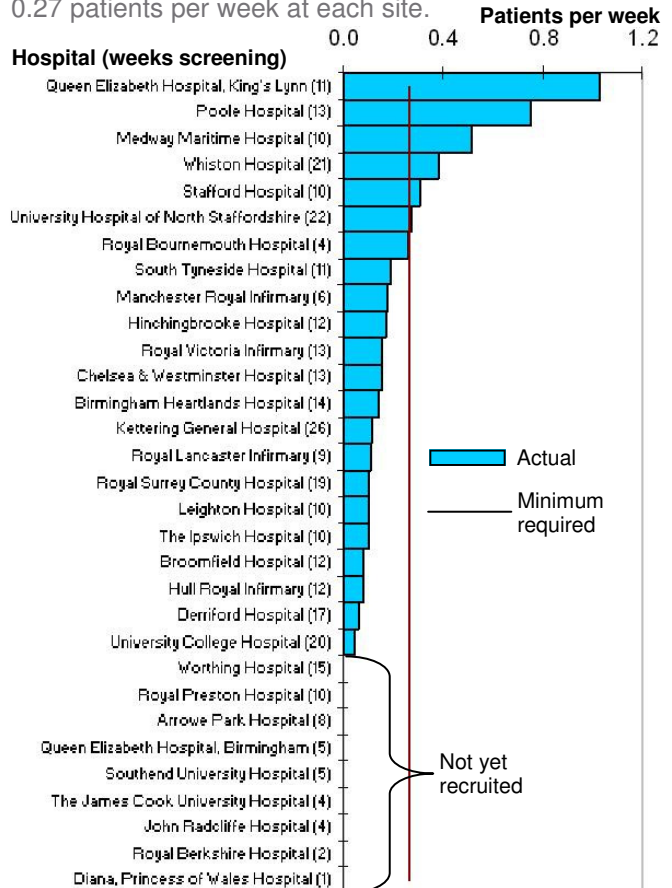


67 patients recruited

Queen Elizabeth Hospital (King's Lynn) lead the way with 11 patients:



We need 1260 patients from 48 sites over two years. This equates to an average of 1.17 patients per month or 0.27 patients per week at each site.



Congratulations to the ProMISe Teams at:

Queen Elizabeth Hospital (King's Lynn), Poole Hospital, Medway Maritime Hospital, Whiston Hospital and Stafford Hospital who are all currently above target! If you are having issues recruiting then please do not hesitate to contact us and do join the monthly teleconference (see next page) to discuss with the ProMISe Team and other sites.

Screening Logs

Please ensure your Screening Logs are kept up-to-date, as we will request copies of these periodically.

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



CLRN resources

We hope you are managing to obtain the agreed resources for ProMISe through your CLRN.

Please contact us if you are having any problems.

"ProMISe is a key project on the critical care portfolio – as a stand alone trial it is highly likely to strongly influence critical and emergency care in the UK"

Professor Tim Walsh
Chair NIHR CCRN Critical Care Specialty Group

ProMISe teleconferences

The ProMISe teleconferences provide an opportunity for you to ask questions and/or discuss any aspect of the ProMISe Trial with the ICNARC Team and to share experiences with other participating sites.

The second ProMISe teleconference was held on 18 July 2011 and was attended by 20 people from 13 sites - thank you to all who participated!

"ProMISe has been very well received in the Emergency Department here in Poole. The whole team is enjoying being part of a national research study and it has really boosted morale in our Department. We have got nurses and doctors of all grades actively seeking ProMISe patients – and there's real excitement when we find one. ProMISe has proved to be just the springboard we needed to get our research team going – we now have five research nurses making up one whole-time equivalent and we are about to start our second and third studies!"

Dr Nick Jenkins
Principal Investigator
Poole Hospital



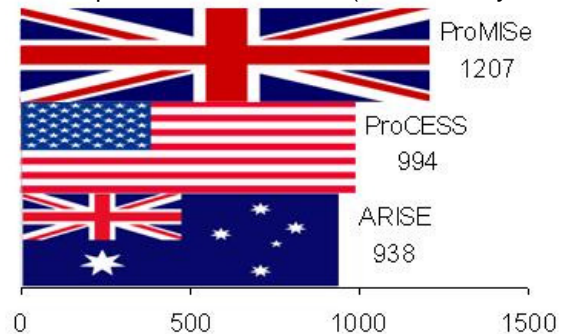
International trials update

There are two other ongoing trials with similar aims to ProMISe.

ProCESS: Protocolised Care for Emerging Septic Shock
1950 patients/40 sites

ARISE: Australasian Resuscitation in Sepsis Evaluation
1600 patients/45 sites

Number of patients left to recruit (as of 31 July 2011)



We may have started later but we are still in with a chance of beating our former colonies!

We randomised more patients than ProCESS in July. Keep this up and we may get to the chequered flag first!

FAQs

Clinical

Q. Do I need to give a one-litre fluid challenge to confirm the hypoperfusion inclusion criterion (lactate >4mmol)?

A. No - a fluid challenge is only needed to confirm refractory-hypotension and not hypoperfusion.

Trial Management

Q. Can another member of our ProMISe Team receive notification of randomisation emails?

A. Yes - please contact us, with the relevant details, and this will be set-up.

Q. Can the patient be consented and randomised outside of the ED?

A. Yes - patients must meet all eligibility criteria in the ED, however consent and randomisation can occur outside the ED.

Important contacts



ICNARC ProMISe Team, general enquiries

Email: promise@icnarc.org

Tel: 020 7554 9784

Fax: 020 7388 3759

ProMISe 24/7 clinical support line

Tel: 020 7554 9775

Edwards 24/7 technical support line

Tel: 0800 756 0802

SAE reporting to ICNARC

Fax: 020 7388 3759

