

ProMISe Newsletter

Issue 3, December 2011

47 sites open... 167 patients recruited!

Rationale for ProMISe

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. ProMISe will evaluate whether resuscitating to standard guidelines, including targeting ScvO₂, improves outcomes in patients with severe sepsis.

This winter, think ProMISe

Data from the Case Mix Programme Database indicate that **admissions with severe sepsis** to critical care from the emergency department (ED) increased by over **60%** during winter 2010/11 compared with the previous summer. As we expect more patients with severe sepsis to present at the ED during the coming months, please be vigilant this winter and **don't forget ProMISe!**

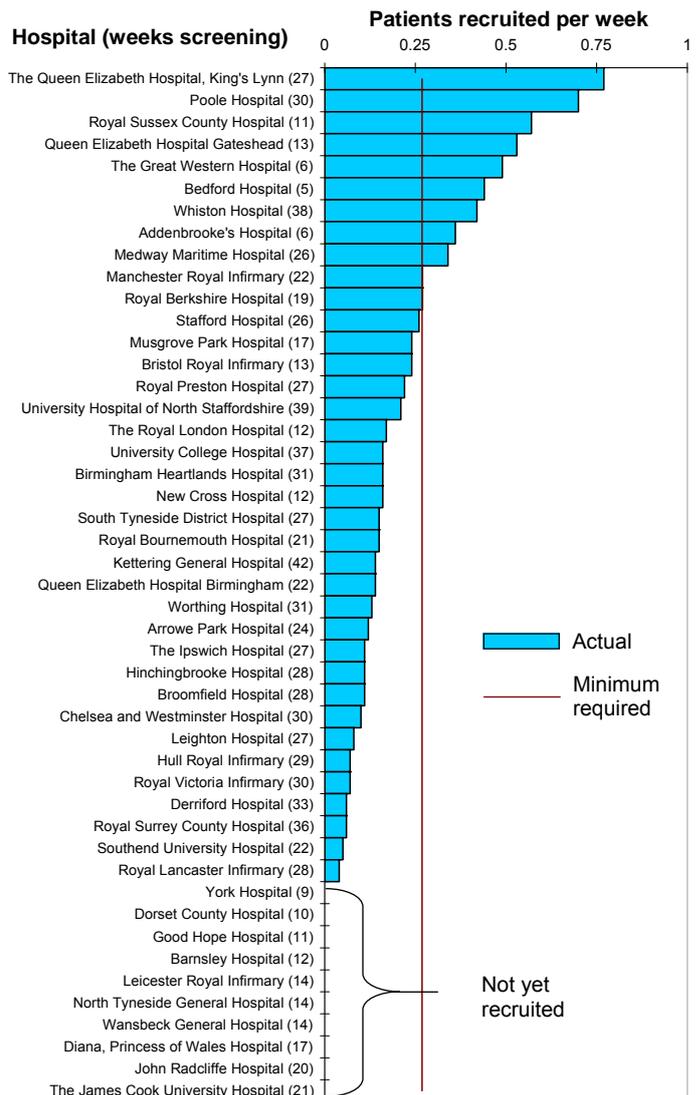


Top tips for recruitment

- Dedicated ProMISe Research Nurse – apply to your local CLRN
- Good communication links between team members in emergency medicine, acute medicine and critical care medicine
- Display ProMISe posters prominently in the ED and give ProMISe pocket cards (with inclusion criteria) to all ED staff
- Early lactate measurement
- Screen 'out of hours' – evenings and weekends (see overleaf)

Congratulations to **Queen Elizabeth Hospital (King's Lynn)** and **Poole Hospital** who lead the way with 21 patients each!

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.



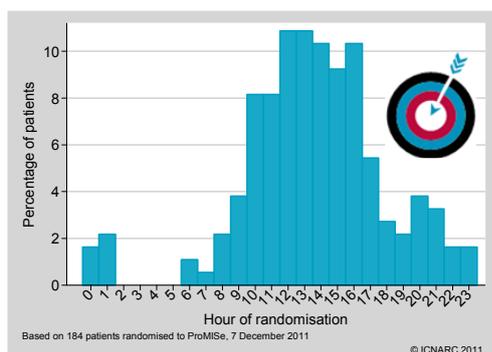
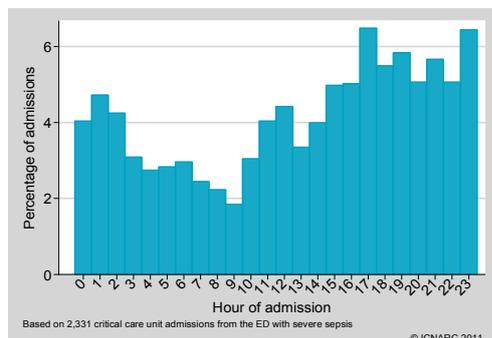
Congratulations to the ProMISe Teams at all those hospitals that are on or above target – thank you for all your hard work!

If you are having problems with recruitment, don't forget we have a teleconference every month to share experiences and ideas for best practice (see overleaf).



Target screening

Data from the Case Mix Programme Database indicate that most admissions to critical care from the ED with severe sepsis occur in the evening (17.00 to 00.00). Targeting screening to later in the day may help to increase recruitment rates.



Eligibility for ProMISe

One of the inclusion criteria for ProMISe is: refractory hypotension or hypoperfusion.

Refractory hypotension is defined as a systolic BP \leq 90mmHg or a MAP $<$ 65mmHg which persists following a one-litre fluid challenge.

Hypoperfusion is defined as a blood (venous or arterial) lactate of \geq 4mmol l⁻¹. It does not need to be confirmed by a one-litre fluid challenge.

The exclusion criterion, '*Immunosuppressive agents for uncured cancer or immunosuppression for organ transplantation or from systemic disease*', has been removed. Please ensure that all staff are aware of this change and that the new 'Randomisation – Eligibility' Case Report Form (version 2.0, dated 3/10/11) is now in use at your site.

Dates for your diary

Next Teleconference

Thursday 19 January 2012, 12:30 – 13:30

The Intensive Care Society State of the Art Meeting

12 – 14 December 2011

ICNARC will have a stand in the exhibition
– please come and visit us!

Delivery of the intervention

The protocol for early, goal-directed therapy does not have to be delivered by local ProMISe research staff. It can be delivered by bedside clinical staff with relevant staff available on the telephone for advice and guidance as required. Don't forget, there is also a ProMISe Investigator available for advice and support 24/7 via the ProMISe clinical support line.

Timely data entry

Please ensure that data are entered onto the ProMISe Web Portal as soon as possible. The 'Baseline – Contact details' page should be completed soon after randomisation as we need to inform the patient's GP of their participation in the ProMISe Trial within a week of randomisation.



Retrospective consent

Retrospective consent should be obtained from the patient as soon as possible after they regain mental capacity, while the patient is still in hospital. Please inform the ProMISe Team at ICNARC if a patient regains mental capacity and is discharged from hospital before retrospective consent could be obtained.

24/7 clinical support line

A ProMISe Investigator is available 24/7 for advice and support. If you don't get an answer when you call, please leave a message, including your name and telephone number. Your call will be returned as soon as possible.

Important contacts

General enquiries

Email: promise@icnarc.org

Tel: 020 7554 9784

Fax: 020 7388 3759

24/7 clinical support line

Tel: 020 7554 9775

SAE reporting

Fax: 020 7388 3759

Edwards 24/7 technical support line

Tel: 0800 756 0802

