The size of sepsis in Wales: point prevalence study of sepsis in the acute hospital

Project Protocol
Version 3.1
Table of contents:

1. Study co-ordination and management
   1.1 Chief Investigators
   1.2 Steering Committee
   1.3 Hospital coordinators

2. Background

3. Study aims and objectives
   3.1 Rationale

4. Methods
   4.1 Inclusion criteria
   4.2 Exclusion criteria
   4.3 Centres
   4.4 Ethical considerations

5. Data management
   5.1 Data collection and data sources
   5.2 Standardisation of data collection
   5.3 Data handling
   5.4 Data analysis
   5.5 Sample size analysis
   5.6 Data management and ownership

6. Organisation

7. Dissemination of results

8. References
1. Study co-ordination and management

1.1 Chief Investigator

Tamas Szakmany
Gemma Ellis

1.2 Steering Committee

Judith Hall
Robert Lundin
Ben Sharif
Ilaria Pignatelli
Chris Hancock
Paul Morgan
Terence Canning
Gemma Ellis
Tamas Szakmany

1.3 Hospital coordinators
TBC
2. Background

Sepsis is a systemic response to infection, which causes a potentially damaging inflammatory response. Severe sepsis is defined as sepsis leading to the dysfunction of one or more organ systems. Successful management of sepsis requires prompt recognition and immediate response with appropriate escalation of care to Critical Care if required (1).

In the UK sepsis is estimated to be responsible for the deaths of 37,000 people every year and to cost the NHS £2.5 billion and for Wales this could equate to a figure of 1800 deaths and a cost of £125 million (2). However, accurate data collection in the non Critical Care setting is still under development in Wales and it is thought that the real number will be far higher. A patient with sepsis is five times more likely to die than a patient who has suffered a heart attack or stroke (1,3).

Through participation in the 1000 Lives Plus RRAILS/Sepsis Wales Programme, all Welsh healthcare organisations have reached consensus on use of the Sepsis 6 as the optimum treatment protocol with the aim of all elements being delivered within 1 hour of the patient having been identified as having sepsis (4). The Sepsis 6 is a bundle of 6 interventions:

1. Give high-flow oxygen via non-rebreathe bag
2. Take blood cultures and consider source control
3. Give IV antibiotics according to local protocol
4. Start IV fluid resuscitation Hartmann’s or equivalent
5. Check lactate
6. Monitor hourly urine output consider catheterisation

Sepsis is a major cause of avoidable mortality and it is imperative that we understand the size of the problem within Wales so that we can improve the quality of care our patients receive. An initial point prevalence feasibility study was carried out on June 18th 2014 across 2 University Health Boards in Wales, comprising of 4 acute hospitals. The results indicated that out of 2716 in-patients in the four hospitals during the study period, 312 patients had NEWS ≥3 with 84 of these fulfilling 2 or more SIRS criteria. Out of these 51 had signs of infection, classified as sepsis, and 21 had infection and organ dysfunction. Out of the 51 patients with sepsis, critical care clinicians saw only seven, and two patients were admitted to the ICU. Three patients received the full Sepsis 6 bundle within 1 hour (5).

It is proposed that we look at the prevalence for the whole country by repeating this study across the 15 acute hospitals in Wales.
2.1. Rationale
Several methods are under development in NHS Wales for measuring sepsis and The Sepsis 6 compliance in response to the elevation of sepsis to a Tier 1 priority. It is felt that although these methods are becoming more reliable, there is a need to establish an accurate prevalence figure against which future progress can be evaluated.

3. Study aims and objectives
   • Establish an estimate of the burden of sepsis by determining the prevalence of sepsis presenting to all 15 acute hospitals in Wales.
   • Assess practice gaps in care of patients with sepsis by measuring compliance with the Sepsis 6 bundle.
   • To evaluate the impact of sepsis on patient outcome.

4. Methods
A prospective, observational, quality improvement project of the prevalence of adult patients (≥ 18 years old) scoring 3 or above on the NEWS chart who were admitted due to sepsis or who develop sepsis as an in-patient and who are acutely unwell with sepsis in the acute hospitals. Compliance with sepsis 6 will also be assessed.

4.1 Inclusion criteria
For the study day (08:00 to 07:59), consecutive patients presenting to the emergency department (ED), acute hospital wards and critical care areas with sepsis related admission and patients presenting to the emergency department (ED), acute hospital wards and critical care areas with acute ongoing sepsis will be enrolled. To be eligible patients must have all of the following:
   1. Must be admitted or transferred to either the ED or hospital ward or critical care area.
   2. Have a NEWS score of 3 or above
   3. Have a high clinical suspicion of an infection
   4. Have sepsis as defined by
      a. An infection together with two or more SIRS criteria

4.2 Exclusion criteria
The following patients will be excluded:
   1. Patients less than 18 years of age
4.3 Centres
The project aims to involve all acute hospitals in Wales – 15 in total:

• Bronglais General Hospital
• Glan Clwyd Hospital
• Glangwili General Hospital
• Morriston Hospital
• Nevill Hall Hospital
• Prince Charles Hospital
• Prince Philip Hospital
• Princess of Wales Hospital
• Royal Glamorgan Hospital
• Royal Gwent Hospital
• University Hospital Llandough
• University Hospital of Wales
• Withybush Hospital
• Wrexham Maelor Hospital
• Ysbyty Gwynedd

4.4 Ethical considerations
The study involves collection of non-patient identifiable information resulting from standard care provided and does not involve any interventions. The project will be registered at the R&D Departments of the participating Health Boards. The patient’s hospital identification will be kept in the site files only and not shared with the study team. This will enable the local investigators to contact the patients identified as having sepsis 6 months after hospital discharge to request them, with their consent, to complete a Quality of Life SF-36 questionnaire.

5. Data management

5.1 Data collection and data sources
Data will be collected by medical students across all the hospitals via a secure open-source web-based toolkit. Data will be collected from patient NEWS charts, medical notes and electronic records as appropriate. The data will be entered automatically in an electronic database designed to handle the information. Data security will be maintained using industry level encryption and by ensuring that data servers are protected by the Cardiff University firewalls. The devices used by the data collectors will have individual identifiers and the technology enables the study team to monitor the process in real time and if necessary erase all the data from the device remotely.
5.2 Standardisation of data collection
A standardised electronic case report form (CRF) will be used to guide data collection. This will contain definitions and explanations for each of the fields. We will conduct a survey amongst the survivors of the study who were diagnosed with sepsis and regained capacity, to assess their health related quality of life using the SF-36 questionnaire. This short questionnaire will be sent to all survivors after 6 months of hospital discharge to be filled and returned by the participants with their consent.

5.3 Data handling
An electronic database will be stored on a password-protected computer. Only investigators involved in the study will have access to the database.

5.4 Data analysis
The data to be collected are all collected as part of routine clinical care. Categorical variables will be described as proportions and will be compared using chi-square or Fisher’s exact test. Continuous variable will be described as mean and standard deviation if normally distributed or median and inter-quartile range if not normally distributed. Comparisons of continuous variables will be performed using one-way ANOVA or Mann-Whitney test as appropriate. A logistic regression model will be performed to assess independent association between prognostic factors and outcomes. Significance will be set at $p<0.05$. A single final analysis is planned at the end of the study.

5.5 Sample size analysis
For this prospective study we would aim to enrol as many patients as possible within the 24-hour study period.

5.6 Data management and ownership
On behalf of the Trial Steering Committee (TSC), Cardiff University will act as custodian of the data. The TSC will take responsibility for the content and integrity of any data. The TSC will retain the right to use all pooled data for scientific and other purposes. Only summary data will be presented publicly.
6. Organisation

The project will be led by a TSC which will be responsible for project completion. The duties of this team will include administration of all project tasks, communication between project partners (including funders, steering committee members, national and local co-ordinators, etc), data collation and management. The TSC is responsible for the scientific conduct and consistency of the project. The TSC will ensure communication between the study management team and co-ordinators as necessary.

7. Dissemination of results

Data will be presented and disseminated in a timely manner. The TSC will appoint a writing committee to draft the scientific report(s) of this project. All participating centres will have their efforts recognized by each investigator being labelled as a ‘collaborator’ in the authorship of the paper and thus listed in PubMed.

8. References:


