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Participant Information Sheet (PIS) for participants **[PIS-A]**

**Defining Sepsis on the Wards: point of prevalence study (DESEPTiW)**

We would like to involve you in a clinical study we are conducting. The study is entirely voluntary, and you are free to withdraw from the study at any time.

**Introduction**

Before you decide, it is important that you understand why the study is being done and what it involves. One of our team will go through the study with you and answer any questions you may have. Please feel free to talk to others and please ask us if there is anything that is unclear**.**

**Background**

Sepsis is a condition that arises when the body’s response to an infection injures its own tissues and organs. Sepsis may lead to serious illness especially if not recognized early and treated promptly.
Sepsis can be caused by a huge variety of different bugs, most cases being caused by common bacteria, which we all come into contact with every day without them making us ill. Sometimes, though, the body responds abnormally to these infections, and causes sepsis.

Prior to this study, we have investigated how many patients have sepsis in the Welsh hospitals, using a certain definition. With the advance in medical knowledge, this definition has changed and we would like to see if this has any effect on the number of patients suffering from the condition. Moreover, we hope to compare the numbers in Wales and England, by extending the study to other hospitals.

**Why have I been asked to take part in the trial?**

The clinical team treating you suspects that you might have sepsis and you are having or have had treatment for this, and have spent some time in the Emergency Department or on a hospital ward. We’re one centre of many across the UK, enrolling such patients into this clinical study.

**Do I have to take part?**

No. Once you have read this information sheet, if you agree to take part, we will ask you to sign a consent form. You are free to withdraw at any time, without giving a reason, and this will not affect the care you receive*.*

**What will happen to me if I take part?**

You will receive exactly the same treatment as if you did not participate but we will collect routine clinical data about you, your infection and your recovery. We will also invite you to participate in short, 5-question quality of life questionnaire 6 months after you will be discharged from the hospital following this episode. This will be conducted via a 3-5 minute telephone interview.

In the unlikely event of your death – we will continue to collect relevant information from your medical records, if required.

**What information is collected?**

For all patients included, we will record a few details such as name, age, hospital number, NHS number and telephone contact number and details about the care required to treat sepsis.

**How is this information used?**

The information collected about you will be stored on a secure database. We will only use identifiable information so we can follow-up your recovery and can contact you for the quality of life questionnaire. This will only be accessible to the study clinicians and nobody else. In order to look at how well you recover over a longer period of time we will use the information collected in UK hospitals and link it with existing healthcare records held by the Health and Social Care Information Centre (HSCIC) in England or the Secure Anonymised Information Linkage Databank (SAIL) in Wales. SAIL is an approved privacy protecting research system where information is anonymised before being linked to hospital and GP records. No identifying information such as names, addresses or dates of birth are held on the SAIL system. The statisticians analysing the data cannot identify them. The study statisticians will analyse the information to assess the difference between the two definitions and the variability of care delivery.

**How secure is this information?**

The information is held on a secure computer system in the NHS and further anonymised information on the SAIL databank and the study has been approved under the Data Protection Act by the lead site, Aneurin Bevan University Health Board.

**What are the possible disadvantages and risks of taking part?**

There are no disadvantages and no risks.

**What are the possible benefits of taking part?**

Participation in the trial will not benefit you during their hospital stay. The information we get from this study will improve our understanding of sepsis and may improve care of patients with this problem across the UK and the world.

**What if something goes wrong?**

If you wish to ask further questions, or complain about any aspect of the trial, please contact any of the trial organisers, or PALS (the Patient Advice and Liaison Service at the hospital) for further information. The telephone number is ***[Insert Local contact details]*.**

**Will my taking part in this trial be kept confidential?**

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. All information that is collected about you during the course of the trial will be kept strictly confidential. Procedures for handling, processing, storing and destroying data are compliant with the Data Protection Act 1998.

**What will happen to the results of the trial?**

The trial is estimated to take less than one year to undertake, and it is hoped to publish the results during 2017. If you would like a copy of the published results, please contact your local principle investigator ***[Insert Local contact details]*.**

**If you feel uncomfortable or distressed after reading this information sheet and would like to have more information about your clinical condition, your treating clinical team will be more than happy to offer further explanation and support.**

**Thank you for taking the time to read this information.**

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| Local Co-ordinator for  | ***[Insert Local contact details]*** |
| Head investigator &Co-ordinating centre | Dr Tamas SzakmanyAnaesthetic DepartmentAneurin Bevan University Health BoardRoyal Gwent HospitalNewportNP20 5UBSzakmanyt1@cardiff.ac.uk |