



## PATIENT INFORMATION SHEET

### 1. INTRODUCTION TO THE STUDY

You are invited to take part in a research Study that is researching patients who are attending Emergency Departments suffering with a head injury, and who are regularly prescribed medications or tablets known as “anticoagulants”. The Study is organised by the Emergency and Immediate Care Group at the University of Sheffield and will be undertaken at your local hospital.

Please take the time to read the following information carefully and discuss it with others if you wish. Before you decide, it is important for you to understand why the Study is being done and what it will involve. Please contact the AHEAD Study team if there is anything that is not clear or if you would like additional information.

### 2. WHAT IS THE PURPOSE OF THE STUDY?

The Study aims to evaluate the care that you received in hospital. We would like to look at how your head injury was managed including use of any tests and investigations, and we would also like to collect information regarding any complications that you might have suffered as a result of your injury. The same information will be collected at hospitals across the country and for up to 3,000 patients who have been admitted to hospital with a similar problem. We are also interested in your views and experiences with the care that you received on your admission to hospital. We would like to know if and how this might be improved in the future, and how you feel now about your head injury.

Our aim is to produce information with your help which can be used in the future as guidance for emergency healthcare staff who will be caring for patients attending with head injuries whilst taking anticoagulant medications.

### 3. WHY HAVE I BEEN CHOSEN?

According to hospital records you have attended hospital recently with a head injury, and you are also prescribed one of a group of medications known as “anticoagulants” such as warfarin tablets.

### 4. DO I HAVE TO TAKE PART?

No. Your participation is voluntary and you are free to withdraw from the Study at any time without giving any reason, without your medical care or legal rights being affected. You can do so by contacting the Research Nurse on any of the contact details shown on the accompanying letter.

If you do decide to take part, please read through and keep this information sheet for future reference and then sign the enclosed consent form.

### 5. WHAT WILL HAPPEN TO ME IF I TAKE PART? WHAT AM I BEING ASKED TO DO?

We would like to collect anonymised information of those patients like yourself attending hospital with a head injury – no personal details such as name, address or date of birth will be used. This data will be entered by a Research Nurse based in your Emergency Department to a hospital computer

onto a secure database. The database is managed by the AHEAD Study team at the University of Sheffield. If you do not want your anonymised information to be included in the Study, please contact the Research Nurse (details with the accompanying letter) within a month of receiving this letter and he/ she will ensure that it is not viewed or used. This will not affect your hospital care at any point in the future.

We will also ask you to complete a questionnaire at home with questions about how you feel after your head injury, your views regarding your care in hospital and for any ideas on how you feel things could be improved. The Questionnaire is enclosed along with the consent form.

***Your views are valued and important to us, and we hope that with your help we can improve the treatment of other patients attending hospital with head injuries in the future.***

#### **6. WHAT ARE THE POSSIBLE BENEFITS, DISADVANTAGES, AND RISKS OF TAKING PART?**

We do not expect that there will be any disadvantages or risks for you in taking part in this Study. However, please be assured that if you raise any problems the AHEAD Study team will respond to all issues and views sensitively, as well as confidentially. If you would prefer that the Research Nurse does not access any information about your recent hospital visit with a head injury, please let us know by contacting the Research Nurse (details with the accompanying letter). This will not affect your treatment, care, or hospital records in any way.

#### **7. WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL? WHAT WILL HAPPEN TO THE RESULTS OF THE AHEAD STUDY?**

All information which is collected about you during the course of the Study will be anonymised (name, address and date of birth removed) and kept strictly confidential. You will not be identified in any reports or publications. We will present and share the results at conferences and in specialist research journals where the information will be of interest to doctors, scientists, hospital managers and policy makers throughout the UK and also internationally.

#### **8. WHO IS ORGANISING AND FUNDING THE STUDY?**

The Study is organised by the University of Sheffield, and funded by the NHS National Institute for Health Research (NIHR) for Patient Benefit Programme.

#### **9. WHO HAS REVIEWED THE STUDY?**

The Study has been given a favourable ethical opinion for conduct in the NHS by the Sheffield Research Ethics Committee.

#### **CONTACT DETAILS**

If you would like further information about the AHEAD Study, please contact:-

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*AHEAD Study Manager*

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University of Sheffield, 30 Regent Street, Sheffield S1 4DA**

**THANK YOU FOR TAKING THE TIME TO READ THIS LEAFLET**