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**PATIENT INFORMATION SHEET**

Building a High-Fidelity Pacing Simulator and Automatic Alerting Algorithm (PACESIM)

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Dr Alexander Tindale

**Introduction and Invitation:**

We would like to invite you to take part the PACESIM project, where we aim to **build a simulator** to teach doctors how to better manage temporary pacemakers.

Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve for you.

Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

**What is the purpose of the study?**

The purpose of the study is to build an accurate pacing simulator in order to train future generations of doctors. To do this we need to record data from temporary pacemakers used after cardiac surgery.

**What is a temporary pacemaker?**

Almost every patient who undergoes an open-heart operation has a temporary pacemaker fitted at the time of the operation. This device (see image 1) involves two wires attached to the top and bottom chambers of the heart (the right atrium and right ventricle) which are then attached to a temporary pacemaker box that can supply electricity to the heart (Image 1).

This device stimulates the heart to beat if the heart’s own electrical system is not working properly. 85 out of every 100 patients require the temporary pacemaker at some stage after open-heart surgery. In the vast majority of patients, the electrical system recovers by itself and the temporary pacemaker is removed before hospital discharge.



Image 1: Diagram showing a Temporary Pacemaker circuit

**Why is it important to build a pacing simulator?**

Temporary pacing management can be complicated because certain parameters change quickly and failure to program the pacemaker settings accordingly can result in lower blood pressures or dangerous heart rhythms.

Therefore, temporary pacemakers require daily checks to ensure they are performing safely and well. Teaching these skills traditionally occurs at the patient’s bedside.

However, there is limited standardised training in temporary pacemaker management in the UK and no simulator training.

We want to create an accurate simulator so that learners can practice adjustments on the simulator rather than a real patient’s pacemaker settings. The model for this is airline simulators, where learners and experienced pilots have regular simulator sessions to learn new skills and practice old ones.

As part of the same project to build a simulator, we will also create an alarm system that can automatically detect when a pacemaker is not working well. This system will then alert doctors and give clear instructions on how to adjust the pacemaker.

**Why have I been invited?**

You are being asked to participate in this research study because you are undergoing cardiac surgery at Harefield Hospital that will require a temporary pacemaker to be fitted.

**Do I have to take part?**

No - It is up to you to decide whether or not to be involved. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form to show you have agreed to be part of the study.

You may choose not to participate in this study, or you may leave the study at any time without giving a reason. This would not affect the standard of care you receive.

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

The research will be conducted at Harefield hospital. When you are admitted for your cardiac surgery, a trial investigator will come and talk to you to answer any further questions you may have. At this point we will talk through the consent form and gain written consent.

Being in this trial will require **no additional procedures / surgery.** The only difference in care will be the length of time it takes to perform the first pacing check. During the pacemaker check we will record extra data that will lengthen the time taken to perform an initial check and an echocardiogram during this data collection.

**The type of study**

This is a data collection study. Therefore, there is no additional invasive procedure for patients in the trial.

**Details of the study:**

1. On the day of your admission to Harefield a study investigator will talk through the study again. At this point you can ask any questions you may have before signing the study consent form
2. Your surgery will proceed as usual, with a temporary pacemaker system inserted as part of standard care
3. After surgery you will be taken to the Intensive Care Unit (ICU) as usual:

- Outside of this study, a temporary pacemaker system is checked daily. This usually takes about 15 minutes per patient

- In this study, **a single pacemaker check** within 72 hours of surgery will be longer (it will take **one to two hours rather than fifteen minutes**)

- After the basic (usual) safety checks have been performed, the study doctors and physiologists will change certain parameters of the pacemaker (mainly the delay between the top and bottom chambers of the heart being stimulated). This will involve a more extensive set of checks to maximise your blood pressure and to record data

- The data recorded will include the ECG (electrocardiogram that records electrical data from your heart) and blood pressure measurements

- In addition, at several points in the recording we will take echocardiographic data: this is an ultrasound scan of your heart

- There is no additional risk to you, as the patient, from taking part in this study

- all further pacemaker checks will performed as usual i.e taking roughly fifteen minutes and involving only the usual safety checks.

In summary, this intervention is not designed to have any positive or negative effect on your clinical course, but rather to record data using different pacemaker settings that we can later analyse and use to build the pacing simulator.

From a patient’s perspective, the only difference to standard care will be that a single pacemaker check within 72 hours of surgery will require **between one to two hours to perform rather than the usual fifteen minutes**, but all subsequent checks will be of the usual duration. Data will be collected at your bedside in the ward. In certain circumstances, such as space constraints, we may have to move you to the cardiac catheter lab for the data collection. However, this is unlikely, and we have built a mobile testing station so that the checks can be performed with minimal imposition upon enrolled patients.

Once we have collected this data from this first pacemaker check, you are unlikely to have any further involvement in the trial. In some circumstances it may be beneficial to the study to return and record further data (for example if your heart rhythm changes after surgery). As with all parts of the study2, you can withdraw your consent for further extensive pacemaker checks (over and above the basic safety checks) at any time.

**What is the drug, device or procedure that is being tested?**

We are not testing any new drugs or devices in this trial.

**What are the alternatives for diagnosis or treatment?**

If you do not take part in this trial you will receive the usual care after cardiac surgery including the usual daily pacemaker checks,

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

The only disadvantage is the time commitment during the data collection of one to two hours rather than the usual 15 minutes for a temporary pacemaker check. During the check we will also use the echocardiogram machine which uses ultrasound to take images of the heart from outside the chest wall.

**What are the side effects of any treatment received when taking part?**

There will not be any side effects over and above the usual risks after cardiac surgery

**What happens when the research study stops?**

At the end of the research, your care will continue as usual under your normal doctor.

**What if I do not want to carry on with the study?**

If you do not want to take part in this study, you will receive standard care as determined by your doctor. Your participation in this study is voluntary and you may withdraw from the study at any time without prejudice to your future medical care. Should you decide to withdraw from the study for any reason, you are asked to contact Dr Alexander Tindale

immediately.

Should your participation in the study be terminated, regardless of the reason, you will not suffer any penalties or loss of benefits to which you are otherwise entitled.

**What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (Call Harefield hospital on 01895 82373 and ask to speak to Dr Alexander Tindale). There is also a dedicated telephone number set up that can be contacted at any time – 07942 316334.

If you remain unhappy and wish to speak to a third party with regards to any queries that you have with any problems or complain formally, you can do this through the NHS Complaints Procedure through the PALS office. *(PALS:* 0207 349 7715 *or email: pals@rbht.nhs.uk).*

**Harm**

If the event that something does go wrong and you are harmed during the research and this is due to someone’s negligence then you may have grounds for legal action for compensation against the Royal Brompton and Harefield hospitals but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you. NHS indemnity does not offer no-fault compensation i.e. for non-negligent harm, and NHS bodies are unable to agree in advance to pay compensation for non-negligent harm.

**Will my taking part in the study be kept confidential?**

All information collected about you during the course of the research will be kept strictly confidential. Any information about you that leaves the hospital will have your name, address and personal details removed so that you cannot be recognised from it.

**How will we use information about you?**

We will need to use information from you for this research project.

This information will include your name, NHS number, date of birth and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

**What are your choices about how your information is used?**

* You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
* We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.
* If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

**Where can you find out more about how your information is used?**

You can find out more about how we use your information

* at [www.hra.nhs.uk/information-about-patients/](https://www.hra.nhs.uk/information-about-patients/)
* our leaflet available from <https://www.rbht.nhs.uk/patients-visitors/patients/patient-support-services/your-personal-information>
* by asking one of the research team
* by sending an email to ig@rbht.nhs.uk, or
* by ringing us on 0207 352 8121 ext. 2610.

Additional information on the use of patient data in research in line with the General Data Protection Regulation (GDPR) is also provided [here](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/).

**Will my General Practitioner / Family doctor (GP) be informed of my involvement?**

Yes, unless you specify otherwise.

**What will happen to the results of the research study?**

The anonymized data will be analysed in conjunction with collaborators from the Department of Bioengineering at Brunel University London and the National Heart and Lung Institute at Imperial College London. This numerical data will be used to build a pacing simulator and algorithms for recognizing suboptimal pacing settings, and these will improve the care of future cohorts of patients.

The results of the trial will be published but your identity will not be revealed. Most results will be published in the medical press and if you are interested in knowing the results of the study please contact Dr Alexander Tindale about this who can keep you informed of study developments. Additionally, you are entitled to see any results or information about you under the Freedom of Information Act.

The results will also be made available to the project sponsors (Boston Scientific and the British Heart Foundation) in the form of anonymized data.

Finally, your medical records will be made available for review by the study investigators and regulatory authorities (who periodically check that the studies are being carried out correctly). The information in these records will be kept confidential but on rare occasions the law may require disclosure to third parties.

**Who is organising and funding the research?**

The Royal Brompton and Harefield Hospitals (RBHH) part of Guy’s and St Thomas’ NHS Foundation Trust (GSTFT) is sponsoring the research. The study is being funded by external grants awarded by the British Heart Foundation (a charity that funds cardiovascular research in the UK) and Boston Scientific (a commercial company that makes a number of medical devices). The doctors conducting the research are not being paid for including you in the study.

**Who has reviewed the study?**

All research in the NHS is looked at by an Independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by the local Research Ethics Committee. In addition, approval has been gained from local Research & Development Offices*.*

**Contact for Further Information**

If you would like any further information about the study, either now or at time during the course of the study, please ask phone Harefield Hospital on 01895 823737 or 07942 316334 and ask to speak to Dr Alexander Tindale.

Thank you for taking the time to consider this study. If you do choose to participate, you will be given a copy of this information sheet to keep and also a copy of the consent form that you will be asked to sign.

We hope that the results of this study will allow us to build an accurate temporary pacing simulator in order to better train future cohorts of doctor and cardiac physiologists.