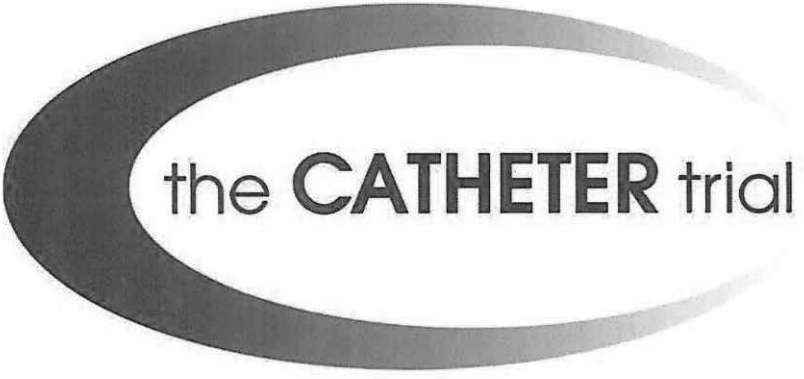

INVITATION TO HELP WITH RESEARCH

PATIENT INFORMATION SHEET

Version 4 121007

1. Introduction

We would like to invite you to take part in a research study. This leaflet tells you why the research is being done and what it will involve. We hope you will find this information helpful.

2. What is the purpose of the study?

A significant proportion of patients in hospital require a urethral catheter for one reason or another. A possible side effect of having a catheter is a urinary tract infection.

This study is designed to investigate whether certain types of urethral catheters can reduce these infections. Such infections have implications not just for patients but also for their families, doctors, the hospital and the NHS as a whole.

Recently it has been shown that catheters containing antibiotics or antiseptics such as silver may lessen the risk of infections. But these catheters are expensive and at present, there is not enough evidence to support widespread use. This research is being conducted in order to produce the evidence that is needed.

3. Why are you inviting me?

You are being invited because the doctors looking after you have decided you need a urethral catheter. Only

patients who require catheters for a short period are eligible to take part, which means your catheter is likely to stay in for less than 14 days.

4. Do I have to take part?

No, you do not have to take part if you do not want to. Taking part in this study is entirely voluntary, and it is up to you to decide whether or not to take part.

You do not have to give a reason not to take part. And if you decide to take part but later change your mind, you can withdraw at any time without giving a reason.

A decision not to take part or a decision to withdraw at any time will not affect the healthcare you receive, and will not alter the treatment your doctors have already planned. For instance, a urethral catheter will still be inserted into your bladder, because the decision to catheterise you has nothing to do with the study. The only difference is the type of catheter you might be receiving.

5. What do I have to do if I decide to take part?

If you decide to take part, you will be given this information sheet to keep. Once you understand all that the study involves and you are happy to take part we will ask you to sign a consent form. A copy of the information sheet and the signed consent form will be retained in your hospital case notes.

6. What will happen to me if I take part?

Your details - including name, date of birth, contact address, hospital number and your GP contact details - will be recorded onto a confidential database at the Health Services Research Unit in Aberdeen.

A computer will randomly assign the type of catheter to be inserted: either a standard catheter or one coated with either an antibiotic or antiseptic. The member of staff looking after you will insert the catheter as normal. The doctors looking after you will decide how long your catheter will stay in. Taking part in the study will not affect this decision.

After that a number of urine samples will be collected at specific intervals and analysed to check for infections. A sample will be collected at the time of catheterisation or just before the catheter is inserted and a second sample will be collected 3 days after your catheter is removed. The only other time a urine sample might be collected is if your doctor thinks it is necessary, such as if a urine infection is suspected. During the period when the catheter is in place, the trial Nurse will look at your hospital notes to check for infections.

We will also ask you to complete a number of short questionnaires about your health and about your experience of having a catheter. One questionnaire will be while the catheter is in place, the next three days after its removal, a Diary to be completed at 1 and 2 weeks after catheter removal and a final questionnaire will be sent out to you approximately 6 weeks after you joined the study. Once you have gone home, a member of the Trial Office team in Aberdeen may telephone you

to remind you to send back the questionnaires. We will inform your GP about your participation in the study, and after you leave hospital, we may contact your GP for further information to determine if you have any related problems that require his or her attention.

7. What are the risks and benefits for me if I take part?

We believe that this study has no risks for your health. The evidence from earlier studies suggests that the risk of problems associated with the use of coated catheters are no higher than they are for standard catheters. As mentioned earlier, apart from the type of catheter that will be inserted, the study will not affect any aspect of your hospital care.

As with most clinical trials, the benefits to individuals taking part are likely to be small, but it is hoped that the results of this study will guide catheter usage nationally in the future and in this way benefit patients, doctors and the NHS as a whole.

8. What if something goes wrong?

We do not believe that taking part in this study increases the risk of something going wrong with your care. If you are harmed by taking part in this research project, there are no special compensation arrangements. But if you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the

course of this study, the normal NHS complaints mechanisms are available to you.

9. Will the information I give be kept confidential?

Yes it will. All information which is collected about you during the course of the study will be kept strictly confidential. Your name will not be written on the questionnaire. The data you give will be kept secure on the database using password-protection and will be stored using a Study Identity Number to maintain confidentiality. Any information you provide will be seen by the research team only.

When the results of the study are published, individuals who have participated will not be identified in any way.

10. How will the information I provide be used?

Once the results of the study have been gathered and analysed, we hope to publish the results in medical journals so that others can read about and learn from them. This kind of research helps us to plan more efficient and effective use of catheters in the future.

11. Who is organising and funding the research?

The research is organised by a team of researchers based in the University of Aberdeen and is funded by NHS Health Technology Assessment Programme. The researchers in this study conduct research on a full-

time basis and are paid a fixed salary which is independent of whether you participate in the study or not.

12. Who has reviewed and approved the study?

The study has been reviewed and approved by the Grampian Multicentre Research Ethics Committee.

Thank you very much for reading this.

Please discuss this information with your family, friends or GP If you wish.

13. How do I get in touch with the research team if I want any further information about the study?

If you have any questions, concerns or complaints about the study, please contact the research team at the following contact numbers and addresses:

Local Recruitment Officer:

XXXXXXX
XXXXXXXXXXXXXXXXXXXXX
XXXXXXXXXXX
XXXXXX
XXXXXXX
XXXXXX

Tel: +44 (0) xxxx xxxxxx
Fax: +44 (0) xxxx xxxxxx
Email: xxxxxx@xxxxxxxxx

Central Trial Office:

CATHETER Study Office Academic Urology Department/HSRU Health Sciences Building
University of Aberdeen
Foresterhill
Aberdeen
AB25 2ZD

Tel: +44 (0) 1224 559043
Fax: +44 (0) 1224 554580
Email: catheter@abdn.ac.uk

If you decide to take part, please ensure you keep a copy of this information sheet.