



## Life And Bladder Cancer

The Yorkshire Cancer Research

### Bladder Cancer Patient Reported Outcomes Survey

#### **Survey of people newly diagnosed with bladder cancer**

You are being invited to take part in a study. Before you make up your mind, it is important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully. Discuss it with relatives and friends if that would help.

If there is anything that is not clear or if you would like more information, please ask one of the local study team or telephone the Life And Bladder Cancer research office or the Life And Bladder Cancer study helpline. Contact details can be found at the end of this information sheet.

#### **What is this study about?**

Nearly 2,000 people are diagnosed with bladder cancer in Yorkshire, North Derbyshire, Humber and South Tees each year. We know quite a bit about what treatments people have and how they respond to them. However, we know less about the everyday impact of treatment on your life at home and work, your relationships, social life and emotions. We want to find out what life is like in the year following your diagnosis and treatment of bladder cancer. We will do this by asking people who have been diagnosed with bladder cancer to complete 4 questionnaires across their first year of diagnosis.

This information will help us understand what areas of care patients need and how we can improve your care. The findings of the study will be used to evaluate hospital services and to help guide future changes.

All opinions are important. We would like to hear from you whatever your age, whatever type of bladder cancer you have, whether you have symptoms or not, and regardless of other medical conditions.

#### **Why have I been invited to take part in the study?**

We are inviting you to take part as you have been diagnosed with bladder cancer in the last 3 months at one of the hospitals in Yorkshire, North Derbyshire, Humber and South Tees.

## **Can I choose whether or not to take part?**

Yes, taking part is voluntary and will not affect your medical care. Your medical team will not find out the results of your survey.

If you decide to take part, we will ask you to sign a consent form. Even if you sign the consent form, you can leave the study at any time without giving a reason. If you decide you do not wish to take part, or you leave part way through, it will not affect your rights and will not affect your current or future treatment in any way.

You do not have to make your mind up straight away. If you want longer to think it over, a member of the local study team will telephone you after 2 weeks or send a letter to ask if you have any other questions and whether you want to take part or not.

## **What will happen if I take part?**

If you decide to take part, a member of the local study team at the hospital will either send or give you a consent form. Please could you fill this in, sign it and hand it back to your local study team in person or send to the hospital in the freepost envelope provided. You will be given a copy of the consent form to keep.

Questionnaires can be filled in on paper (and posted back in the freepost envelope provided), over the phone, or via a secure online system. You will be asked how you would like to fill in the questionnaires. If you choose to fill in the questionnaires online you will be asked for your email address so that a link to the questionnaires, information about how best to access and fill in the questionnaires and a covering letter can be emailed to you.

When you have consented, the local study team will provide Public Health England's National Cancer Registration and Analysis Service (NCRAS) with your NHS number, study ID number, date of diagnosis, name, address, date of birth, gender and preferred contact option including email address for the electronic questionnaire option.

Because there are lots of hospitals taking part in this study NCRAS will pull together the details of everyone who has given their consent. This means that only people who you interact with as part of your normal care and treatment, or who have a clear basis under the law to know details about you, will have access to your personal information.

NCRAS will then send your details to the NHS approved survey provider, Quality Health Ltd, who will send out the questionnaires to you. Quality Health Limited will not use your information for any other purpose.

Over the course of the study, we will ask you to fill in questionnaires at 4 times; these are around 3 months after your diagnosis and then at 6, 9 and 12 months after your diagnosis.

Every time we plan on contacting you with a new questionnaire, we will double check that we hold your most recent address details using data from NHS Digital. Your data will be sent from Quality Health to NHS Digital to allow us to perform these checks.

In each questionnaire, you will be asked questions about your general health, your treatment, symptoms and side effects. We will also ask questions about you and your everyday life (e.g. to do with work, your marital status). Some of the questions will be asked in all 4 questionnaires, so we can track how things are changing over the year. Each questionnaire will take about 30 minutes to do, but you don't have to answer all the questions in one go. We would like you to answer as many of the questions as possible, even if you don't have any problems – as it is important for us to know this.

Completed questionnaires should be returned to the survey company, either in the freepost envelope provided, or electronically using the online system. If you contact the study helpline and complete the questionnaire over the phone, you do not need to return the questionnaire in the freepost envelope or complete online.

At the end of the study, your questionnaire answers will be sent to the University of Leeds study team for analysis. Your answers will be anonymised to remove any identifiable information before being sent to the study team.

By signing the consent form you are agreeing to all of the activities above.

If you decide to take part, please keep this information sheet and a copy of the consent form as a record of your involvement.

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

Completing the questionnaires will take up to 30 minutes. Some of the questions may be considered a little sensitive or embarrassing. These questions are included as many people with bladder cancer have problems with a number of quite personal issues. It is important we have good information about these problems to help provide better support in the future. Please be assured that **all** responses are kept completely confidential. If you do not wish to answer any questions, you can leave

these blank and only complete questions that you feel comfortable answering.

If you want to talk about any concerns you have about taking part, there is a study helpline available. We have provided details of this at the end of each questionnaire and the information sheet.

If you have any concerns about your diagnosis and treatment, please speak with your bladder cancer doctor.

If you would prefer to speak to someone who is not your doctor, you can telephone *Fight Bladder Cancer* on 01844 351621. *Fight Bladder Cancer* is a bladder cancer charity that will listen to your concerns and offer support and helpful information (Monday – Friday 9:30 – 4:30pm). You can also email them at [info@fightbladdercancer.co.uk](mailto:info@fightbladdercancer.co.uk), fill out an online contact form at <http://fightbladdercancer.co.uk/contact-us> or visit the website <http://fightbladdercancer.co.uk>.

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

There are no immediate benefits of taking part in the study. Sometimes people feel pleased to be able to take part in studies that may help others in the future.

### **What if something goes wrong?**

If you are unhappy with taking part, please telephone the study helpline.

If you would like to make a complaint, you can either telephone the study helpline, or contact your local NHS Trust's Patient Advice Liaison Service (PALS) or equivalent, who can provide an independent complaints service.

### **What if I change my mind?**

You can leave the study at any time without giving a reason. If you pull out, it will not affect your rights and will not affect your current or future treatment in any way.

We will use the information collected from you up to the time that you pull out of the study, unless you ask for your information to be removed. If you do not want us to use your information, we can remove it for up to 2 weeks following the completion of the latest questionnaire. This has to be limited to 2 weeks as some of the analysis we plan to do includes recently collected data.

If you would like to pull out of the study and for your information to not be used, please telephone the Freephone study helpline on 0800 917 1163.

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

Yes, your taking part will be kept confidential and will be handled strictly in accordance with the consent that you have given and the 1998 Data Protection Act and General Data Protection Regulation (processing is carried out under Article 6 (1)(e) and Article 9 9(2)(j) of the General Data Protection Regulation) All consent forms will be held securely by the local study team from the Trust to whom you gave consent.

Your personal details and questionnaire answers will be shared with an NHS approved survey provider, Quality Health Ltd, and with NCRAS. The survey provider will only use your personal details to send you questionnaires and reminders to complete the questionnaires. NCRAS will provide a secure environment to store and collate your personal details. Making sure your personal information is private and confidential is very important. NCRAS take great care to keep the information they hold about you confidential and, as with other medical records, strict ethical and security safeguards are in place and access is strictly controlled. You can read more information about NCRAS, including why information about you and your cancer is recorded, how this information is used, and how, if you wish, you can see your information or have it removed can be found here [www.NDRS.nhs.uk](http://www.NDRS.nhs.uk)

Your questionnaire answers will be shared with the study team in a pseudonymised format. This means that details such as your name, NHS number and address will be removed and replaced with a unique code (a study reference). Your local clinical team will complete a case report form with details about your diagnosis and treatment. This will be anonymised, using the same study reference as your questionnaires, and sent to the study team.

At no point, will the study team be able to identify you directly from any of the information provided to them.

No one will ever be able to identify you personally from anything we present or publish about the study.

The survey provider will destroy your personal details once the study has closed. The survey provider will keep completed paper and online questionnaires for 10 years after the study has closed.

The information collected will be available to other researchers to use for research and educational purposes. This will be completely anonymous and it will not be possible to identify you. Researchers wanting to use the questionnaire data will have to make a formal application to the study team.

**If you would like further information, please contact the Freephone study helpline on 0800 917 1163.**

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

When this study finishes, we'll know far more about what life is like for people in Yorkshire, North Derbyshire, Humber and South Tees who have, or who have had bladder cancer. We'll be able to understand what people say has most affected their lives after a bladder cancer diagnosis and where needs have not been met. We will share this information with healthcare professionals across Yorkshire, North Derbyshire, Humber and South Tees, so that services can be improved.

We will present the results at conferences, publish them in academic journals and write a report for the study funder, Yorkshire Cancer Research. We will publish findings on our study website, which is included at the end of this information sheet.

### **Who is organising and funding the study?**

The study is funded by *Yorkshire Cancer Research* and is being run by the University of Sheffield and the University of Leeds.

### **Who has reviewed the study?**

This study has been reviewed and approved by a group of doctors, nurses and patients and by *Yorkshire Cancer Research*. This study has been reviewed and approved by Yorkshire and The Humber – South Yorkshire Research Ethics Committee (REC reference 17/YH/0095, CAG reference 17/CAG/054).

### **Who can I contact for further information?**

#### **Life And Bladder Cancer research office:**

Telephone: 0114 215 9039 Email: [labc@sheffield.ac.uk](mailto:labc@sheffield.ac.uk)

Website: Further information about the study and the study protocol can be found by going to [www.lifeandbladdercancer.org](http://www.lifeandbladdercancer.org)

**Life And Bladder Cancer study Freephone helpline: 0800 917 1163**

**Thank you for reading this information sheet**



The  
University  
Of  
Sheffield.



UNIVERSITY OF LEEDS