

Participant Information Sheet

GASTROS eDelphi Survey

Standardising Outcome Reporting in Gastric Cancer Surgery Research

We would like to invite you to take part in a research study. Before you decide if you wish to participate, you need to understand why the research is being done and what it would involve for you. Ask us if there is anything that is not clear or if you would like more information.

What is the study for?

Gastric cancer (also known as stomach cancer) is the fifth commonest cancer in the world. The main treatment is surgery to remove all or part of the stomach, however we know that surgery can cause short and long-term side-effects that impact on patients in many ways. Research studies (trials) of new surgical treatments need to be able to measure how well a treatment works in treating the cancer, but also what side effects it may have and how they may affect patients. Researchers do this by measuring 'outcomes'. Examples of outcomes might include 'overall quality of life' and 'complications' of the treatment given.

Identifying the best surgical treatments for gastric cancer involves comparing and combining results from different trials. At the moment, this is difficult to do because most trials measure different outcomes and use different tests to measure each outcome.

We are developing a 'core outcome set' (COS) for surgical trials in gastric cancer. This is a list of outcomes that all surgical trials for gastric cancer should measure and report as a minimum. Having a core outcome set will help to make sure that the results from all trials can be combined to achieve a better understanding of which surgical treatments are best for patients. It is important that the outcomes included in a core outcome set are relevant to both healthcare professionals and patients.

As part of our research so far, we have identified outcomes which may be important to both researchers and patients by examining scientific journals over the last 20 years and undertaking interviews with patients. We would now like you to score the importance of these outcomes to you, by taking part in an online survey. The most important outcomes for the whole group (surgeons, cancer nurses and patients) will form the 'core outcome set', to be used in the design of future trials.

Why have I been contacted?

You have been contacted because you are one of the following:

1. A patient who has undergone surgery or is about to undergo surgery for gastric cancer
2. An Oncology Nurse who deals with gastric cancer patients
3. A Consultant Surgeon who performs gastric cancer surgery

Do I have to take part in the study?

No. It is up to you whether you decide to take part or not. Not taking part will have no effect on the treatment you receive now, or in the future. If you decide to take part then later change your mind, you can withdraw at any time without giving your reasons by contacting the research team on the details below.

What will I have to do if I take part?

If you agree to take part, we would like you to visit the online survey which can be found by visiting the following internet address <http://survey.gastrosstudy.org>. You will be asked to agree to take part in the study by registering your details and answering some simple questions. You will then be presented with a list of outcomes and we would like to ask you to score each one.

In addition, if you feel that an important outcome has not been included in the survey, you will have the opportunity to enter it during the survey.

In total, there will be two surveys to complete. After the first survey, the research team will analyse the scores for each outcome, present you with the results and then ask you to score them again. The first survey may take up to 30 minutes to complete; the second may take up to an hour. We will contact you by email when the second survey is ready to complete and will send weekly emails to people who have not responded. The two surveys will take place over the course of approximately 6 months.

What information will I need to provide?

Before you begin the survey, we will ask you to provide the following information:

- Age
- Gender
- The country you live in

If you are a patient, you will also be asked the following questions:

- Who you live with
- How long ago your surgery was (if applicable)
- What type of surgery you had (open or laparoscopic/minimally invasive/keyhole surgery)
- How much of your stomach was removed
- Whether you underwent any other treatments

If you are an oncology nurse, you will also be asked:

- How long you have cared for gastric cancer patients

If you are a surgeon, you will also be asked:

- Your professional title
- How long you have worked as a gastric cancer surgeon
- How many gastrectomies you have undertaken in your career to date
- How many gastrectomies you perform each year

This information may help the research team understand the answers given by participants in the survey.

Will my data be confidential?

Yes. All information collected about you will be kept confidential. Information you submit during the registration process will be kept securely, so that only the researchers and those who monitor the study can see it. We will keep your data for 15 years according to the guidelines set out by Manchester University NHS Foundation Trust. Any data we share when we present our results will be anonymised.

Who will cover my expenses?

As this survey will take place online, there should be no expenses to cover.

What are the possible benefits of taking part?

There are no direct benefits to you taking part, but your views may help to benefit patients in the future.

What are the possible disadvantages of taking part?

If you are a patient, you might find it upsetting to score some of the outcomes in the survey. If you are a patient, you may have had an upsetting complication during your treatment which we are asking you to consider. If you do not wish to answer some questions, that is alright. You can withdraw from the survey at any point. If you become distressed and wish to speak to somebody, you can call a specialist cancer nurse on + 44 (0) 161 701 0147.

What if I want to make a complaint?

If you have a complaint about any aspect of the study, please contact a member of the research team via telephone or email:

Research Team Contact Details:

Aleksandra Metryka, Study Coordinator

Email: gastros@mft.nhs.uk

Tel: +44 (0)161 701 3543

If you are not satisfied, you can contact the Patient Advice Liaison Service at Manchester University NHS Foundation Trust on +44 (0)161 276 8686 or pals@mft.nhs.uk.

Who can I speak to about the study independent of the research team?

You can contact the contact the Patient Advice Liaison Service at Manchester University NHS Foundation Trust on +44 (0)161 276 8686 or pals@mft.nhs.uk.

What will happen to the results of the survey?

The results will be presented to a meeting of patients, nurses and surgeons to finalise a core outcome set for use in gastric cancer surgery trials, aimed at deciding how effective a type of surgical treatment is. We may contact you to take part in this meeting which is entirely voluntary. More information can be found on our website (www.gastrosstudy.org) and by contacting the research team. The results will be published in scientific and medical journals and presented at national and international conferences. In addition, we will send the results of the study to you. You will not be identifiable from the published or presented results.

Who is funding and organising the study?

The study is funded by the UK's National Institute for Health Research (NIHR) Doctoral Research Fellowship programme and is a collaboration between the University of Manchester and Manchester University NHS Foundation Trust (United Kingdom). The research is supported by the European Gastric Cancer Association, The Medical Research Council's Hubs for Trials Methodology Research and is organised by the University of Manchester.

Who has reviewed the study?

The North West - Greater Manchester East Research Ethics Committee, which has responsibility for scrutinising all proposals for research on humans, has examined the proposal and has raised no objections from the point of view of research ethics. It is a requirement that your records in this research, together with any relevant medical records (if you are a patient), be made available for scrutiny by monitors from Manchester University NHS Foundation Trust, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

What do I need to do next?

If you agree to take part, please visit <http://survey.gastrosstudy.org> and:

1. Click on which language version of the survey you wish to complete.
2. Read the consent statements on the first page and register your details
3. Begin the survey.

Further Information:

If you wish to find out more about the study, then please visit our website at www.GASTROSSStudy.org. The research team will be pleased to answer any questions and can be contacted via the details shown below:

Research Team Contact Details:

Aleksandra Metryka, Study Coordinator

Bilal Alkhaffaf, Consultant Surgeon & Chief Investigator

Email: gastros@mft.nhs.uk

+44 (0)161 701 3543