



Quality Indicators of Outcome (QOIs) in Metastatic Bone Disease (MBD)

**Participant Information Leaflet - community**

**Please read this information carefully.**

We are asking you to take part in a study to determine outcomes after orthopaedic treatment for patients with cancer which has spread to the bone (metastatic bone disease). We want to know which outcomes are most important to patients and their carers.

Before you decide whether to take part, it is important for you to understand why the study is being done and what it will involve. Please take time to read this and talk to others about the study if you wish.

This information sheet will explain the reason for the study and what we hope to learn. It will also explain what will happen to you if you agree to take part.

Thank you for considering taking part.

**Study Overview**

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

This is a study designed to find out which outcomes after treatment (e.g. pain, function and quality of life) are most important to patients with metastatic bone disease. This will help design a set of Quality Outcome Indicators (QOIs). These will allow orthopaedic surgeons to know what is most important to their patients and how to offer the best care for patients diagnosed with metastatic bone disease. They should also help us to compare care in different regions to help standardise and improve care for all patients across the UK.

**Why have I been invited to take part?**

You have been invited to take part via one of our public adverts as you have self-identified as having been diagnosed with metastatic cancer.

**Do I have to take part?**

No, it is up to you to decide whether or not to take part. Deciding not to take part or withdrawing from the study will not affect any healthcare that you receive, or your legal rights.

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

If you choose to participate, we will ask you to complete an online questionnaire. The questionnaire will contain a number of draft outcomes (e.g. length of hospital stay after surgery, time until patient walking after surgery) which our prior research has suggested is important to patients. You will be asked to score each quality indicator on how important it is to you.

We will ask for basic details about you, such as your location, type of cancer and previous treatment. We will not be collecting any information that could personally identify you.

This data will be collected and stored in a database for analysis and development of the quality indicator outcomes, to hopefully improve future care of patients in your position.

**How long will I be in the study?**

By completing the survey, you are agreeing to take part in the study. Your participation will finish when you have completed the questionnaire. This should take 20-30 minutes, however, there is no time limit. The information from your questionnaire will be kept for at least six years after the study finishes. We will not be able to contact you at any point and we will not collect any of your personal information as part of this study.

**What will happen if I choose to proceed?**

Once you have read this information sheet and had time to think about things, you can contact the researcher if you want to ask any further questions. We are primarily interested in outcomes for patients that have metastatic bone disease, however, if you have other forms of metastatic cancer you can participate in the study.

If you choose to proceed, we will give you instructions to access the questionnaire. If you need help with this, a family member, friend or the researcher can give you some assistance.

**How will I complete the Questionnaire?**

The questionnaire is an online form, and will ask you to rank a number of potential outcome indicators based on how important they are to you. It should take around 20 to 30 minutes to complete but you can take as much time as you need. Before you complete the questionnaire, we will ask for some very general information about you, including your type of cancer and your age. If you do not have metastatic bone cancer, you can still participate but we may not include your answers in the final analysis as we need to ensure a certain number of patients with this condition are represented.

If you do not want to answer any of the questions, please just leave them blank. If you would like to speak to someone about any concerns you have as a result of any of the questions, please contact the researcher (see final page for contact details).

**What happens if I don’t want to complete the questionnaire?**

You can leave the questionnaire at any point if you wish to.

**What if I don’t want to take part anymore?**

If you change your mind after completing the questionnaire, we are unfortunately unable to remove your results from the database because we have no way of identifying your answers. We can reassure you however that this data will be completely anonymous and we will never publish any quotation that could identify you.

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

There are no direct benefits to you from taking part in this study. However, we hope that by developing the quality outcome indicators from your responses the care of future patients in your position will benefit from better care.

**What are the risks of taking part?**

Participating in this study should not cost you anything as the questionnaire is online. Some of the indicators in the questionnaire may make you anxious or sad because they deal with some aspects of cancer treatment such as surgery and end of life care. If this is the case, please get in touch with your NHS consultant or the researcher, who can arrange support or follow-up for you. You can also contact the MacMillan or Breathing Space charities, their details are at the end of this leaflet.

**What happens at the end of the study?**

The results of the study will be included in the researcher’s PhD thesis and published in a peer-reviewed medical journal. A summary of the results will be published by August 2021 on the COMET Initiative website (<http://www.comet-initiative.org/Studies/Details/1680>) but as we are not collecting your personal information, we cannot send you these directly when the study is finished.

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

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.

We will not record any person specific identifiable data, such as name, date of birth or address. All of the analyses we complete on your data will be on anonymous data.

**Who is conducting the study?**

This study is being conducted by an orthopaedic registrar in NHS Tayside who is also a PhD student with the University of Edinburgh. The study has been reviewed by specialists in orthopaedics, oncology and palliative care. The study is being supervised by Professor Simpson and Professor Sudlow of Edinburgh University.

**Who has reviewed this study?**

The study is Sponsored by the University of Edinburgh and NHS Lothian. All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from Leicester Central Research Ethics Committee. NHS Management Approval has also been given.

**What if there is a problem?**

If you have any concerns about your participation, you can talk to a researcher involved in the study. You can also talk to a doctor who is independent of the study, Mr Fraser Harrold, Consultant Orthopaedic Surgeon, NHS Tayside. Secretary: Kate McFee (01382 425718).

You also have the right to raise a formal complaint. You can make your complaint to a senior member of the research team, Professor Hamish Simpson via his secretary Kimberley Moore Ede (0131 242 6644) or to the NHS Lothian Patient Experience Team:

Waverley Gate

2 – 4 Waterloo Place

Edinburgh EH1 3EG
Telephone:  0131 536 3370
Email: feedback@nhslothian.scot.nhs.uk

**Further information**

If you would like any further information on the study, please contact the researcher Mrs Samantha Downie or Professor Hamish Simpson.

**Mrs Samantha Downie**

Chief Investigator

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**Professor Hamish Simpson**

Head of Department of Trauma & Orthopaedics

Edinburgh Royal Infirmary

Secretary Kimberley Moore Ede: 0131 242 664

If you would like to talk to someone anonymously about any of the issues raised in the questionnaires:

**MacMillan Cancer Support** 0808 808 00 00

Confidential support to people living with cancer and their loved ones

**Breathing Space** 0800 83 85 87

A confidential phoneline for anyone in Scotland feeling low, anxious or depressed

Thank you for your time.