STUDY TITLE: Stomas and IBD: how do people make decisions about surgery and does reality match anticipation?

STOMAS AND IBD

We would like to invite you to take part in this original study being carried out by a team of researchers at King's College London, St Mark's Hospital, and Guy's & St Thomas' Hospitals. The study is funded by Crohn's & Colitis UK. The team, led by Dr Lesley Dibley at King's, aims to explore the issues which influence decision-making about stoma-forming surgery for people with IBD, and whether the reality of living with a stoma matches pre-surgery anticipations of the experience. The study also aims to explore clinician perceptions of stoma-forming surgery, understand the issues facing clinicians when they introduce the possibility of stoma-forming surgery to patients, and how clinicians decide to recommend stoma-forming or stoma-sparing surgery.

You should only take part if you want to; choosing not to take part will not disadvantage you in any way. Before you decide if you want to take part, it is important that you understand why the research is being done and what you would be asked to do. 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. You can contact us using the details on the final page.

What does the research aim to do and what are the benefits?

We have seen, when doing other IBD studies, that some people with IBD tolerate a very poor quality of life due to symptoms of urgency (having only a few moments to get to the toilet before passing stool), frequency (having to open their bowels many times a day), pain and incontinence. People often seem to put up with these symptoms because they do not want to have a stoma. There is evidence that in other patients with chronic conditions affecting bowel function, such as those with a spinal cord injury, results are often better than expected. Many patients tell us that they wish they had made the decision to have this surgery sooner, as it has dramatically improved their quality of life. Our clinical colleagues tell us that they witness a similar resistance to stoma-forming surgery in their patients, even when this is recommended for clinical reasons other than the symptoms described above. There is very little information, particularly from those who have had the experience, which addresses the emotional, psychological and social aspects of having a stoma. This makes it difficult for people to make an informed decision about stoma-forming surgery. It may mean that they avoid thinking about the possibility of having a stoma when they are well, and so they are not emotionally prepared when, in an acute or emergency situation, a stoma may be required. Emotional distress about stoma surgery may have a negative effect on post-surgery recovery.

There are no published reports on the views that clinicians (IBD specialist doctors, colorectal surgeons, IBD and stoma nurses) have about recommending stoma-forming or stoma-sparing surgery, or what they think patients think about stomas. We would like to ask you to help us address these issues. This work may be very useful for helping patients understand the factors which guide your decision-making, and enable them to make decisions about stoma-forming surgery before their health status becomes critical, thus potentially improving outcomes. It will also help identify any differences in perceptions of stomas between clinicians and patients, which can inform the way that the possibility of stoma-forming surgery is introduced to patients.

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How will the research be done? The research is being carried out in three phases:

In Phase 1: we will conduct four separate focus groups with people who either have A) a current temporary stoma; B) a permanent stoma; C) a recently–reversed stoma; and D) never had a stoma but very concerned about the possibility of having to have one. Participants in each group will be asked to share their experiences of anticipating or living with a stoma for IBD.

In Phase 2: we will conduct individual interviews with people in each of the categories (A, B, C & D) to gather more detailed information about issues which arise from the focus groups.

In Phase 3: we will interview clinicians (IBD specialist doctors, colorectal surgeons, IBD and stoma nurses) about their views of recommending stoma-forming surgery, and what they think patients think about stomas.
We are inviting you to take part in Phase 3 (clinician interviews).

Who can take part? You can take part if you work anywhere within the UK and you hold a current position as an IBD specialist physician, as a colorectal surgeon or as a nurse in IBD, colorectal or stoma care; you must have worked in this field for at least three years, and see a minimum of 20 IBD cases yearly. You must be fluent in English.

What will happen if I agree to take part? We will conduct 20 interviews (5 per professional group) with IBD specialist physicians, colorectal surgeons, IBD nurses and stoma nurses. You do not have to live in London to take part as interviews will be conducted by Skype, by telephone, or face to face according to your preference, at a time, date and place (if face to face) to suit you.

One of the team will interview you. They will check that you are eligible for the study, and ask you to confirm your age, gender, clinical role and number of years working in the field of IBD. They will remind you about the study and give you the chance to ask questions. If you request a Skype or telephone interview, you will be asked to confirm verbally that you consent to participate, and this will be recorded on a digital audio device.

If you request a face to face interview, you will be asked to sign a consent form stating that you agree to being interviewed for this study. You will be asked some prepared questions about your decision-making regarding stoma-forming surgery, and how you think patients' perceive this possibility. You will also be asked some questions arising from what you say in the interview. You will only be asked questions about your clinical experiences that are relevant to the study.

At the end of the session, the interviewer will recap the main points addressed during the interview. You will be asked to confirm that your experiences and opinions have been understood, and you will be able explain further if you need to. We are sorry, but we cannot give you anything for taking part in a one to one interview. When the interview is finished, you will not be asked to do anything else for this study.

How will you record the focus groups and interviews? We will use a digital audio voice recorder. This device is about the size of a mobile phone, and will be placed centrally between you and the interviewer if your interview is face to face. It makes no noise and you will soon forget it is there. If your interview is via Skype or telephone, we will use the same equipment, plus a telephone ear-piece, to record your interview.

Are there any risks to me in taking part? We cannot identify any risks to you of taking part in this study.

What about confidentiality and anonymity?

Your personal details (name, age, contact details) will remain confidential, will not be shared with anyone who is not on the research team, and will only be used to contact you about this study. Personal data will be stored in line with the Data Protection Act.

Your identity will be known to the researchers who conduct the interviews. If you choose a face to face interview, your address will be known to one other member of the research team at our offices. It is good research practice to make sure that someone else on the team knows where researchers are when they are working on location. A copy of the interview schedule and route will be kept securely and destroyed as soon as the interviews have been completed. It will not be shared with the rest of the research team.

The digital audio file of your interview, captured and stored on the recording device, will be sent securely via the electronic file transfer service at King's to a professional transcriber (Dawn Evans) who has worked with us several times before. Dawn adheres to a professional code of conduct which respects confidentiality. Her copy of the audio file and the final transcription will be deleted once the transcription has been returned to us. Digital transcripts and audio files will be kept securely on the University's central server. Paper transcripts will be stored in a locked filing cabinet in our research office at King's.

Some members of Crohn's & Colitis UK are also working on the study with us as part of our team and will be helping us to analyse the interviews. Involving people who have had the experience that is being researched makes the data analysis better. Before your interview transcript is shared with any other team member, or with the charity members, anything which might identify you, such as names, where you live, or the hospital you work in, will be removed. We will use numbers or pseudonyms to identify the transcripts instead.

What are the possible benefits? If you take part, what you tell us will enable us to appreciate the issues which inform clinician decision-making about stoma-forming surgery, and whether clinician perspectives of this treatment option differ from the perspectives of patients. This information may inform the methods by which clinical staff introduce the notion of stoma-forming surgery in the future. It has the potential to increase patient understanding, and help them make more informed decisions earlier in their care pathway, perhaps also improving post-operative outcomes. We will send you a summary of the report findings when the study is finished, unless you tell us you do not want to receive this.

What will you do with the results of the study? We plan to publish two academic papers arising from this study, and to present our findings at a range of medical and nursing conferences. All uses of the data, for example in academic papers or conference presentations, will be anonymous. You will not be able to be identified. We will also make a report of the study findings available via the website and newsletter of Crohn's & Colitis UK, and offer a report to the Ileostomy Association.

Who is funding the study? The study is funded by Crohn's & Colitis UK through the 'Living with IBD' funding stream. The grant reference number is SP2014 / 2.

Who is doing the study? Dr Lesley Dibley leads the study team. She, Professor Christine Norton and Wladzia Czuber-Dochan have worked together at King's for many years on a number of projects looking at different aspects of living with IBD, including bowel incontinence, stigma and fatigue. All are qualified nurses. Julie Duncan is IBD Nurse Specialist at Guy's & St Thomas' Hospital; Jennie Burch (Enhanced Recovery / Stoma Nurse), and Janindra Warusavitarne (colorectal surgeon) are at St Mark's Hospital.

Three members of the funding body will also help us with this study. It is good research practice to help patients and public become involved in the process of research - not as people who take part in the study in

the way we are asking you to - but who have the same illness and use their experience to help shape the way the study is run, to analyse the data and to write and present the results.

Do I have to take part? It is up to you to decide whether to take part in this study or not. Even if you decide to take part, you are still free to withdraw from the study at any time up until 30th September 2016. After then, data from your interview will have been analysed and combined with all other data. You do not have to give a reason for withdrawing.

What happens now? You should spend at least 24 hours deciding if you want to take part or not. We will contact you in a few days' time, using the details you provided when we either gave you this information leaflet in your workplace or sent it to you in response to our request for participants via the Association of Coloproctology of Great Britain and Ireland, the Association of Stoma Care Nurses UK. When we contact you, we will ask if you have had a chance to read this leaflet, if you fully understand what the study involves, and if you would like to take part. If you ***do not*** want to take part, we will respect your decision, and will not contact you again. If you ***do*** want to take part, we will ask you which type of interview you would prefer, and will arrange a date and time with you for the interview to take place.

What if I need to know more, before I can decide? For information and independent guidance about taking part in medical research, please visit: http://www.nihr.ac.uk/get-involved/take-part-in-research.htm

If you have require more information about this study, or need this leaflet in a larger font size, please contact either Lesley or Wladzia:

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What if there is a problem? If you have a concern about any aspect of this study, please contact Dr Lesley Dibley using the details above. Lesley will do her best to answer your questions.

This study is sponsored by King's College London (KCL). The sponsor will at all times maintain adequate insurance in relation to the study independently. KCL, through its own professional indemnity and no fault compensation, and the Trusts, have a duty of care to patients via NHS indemnity cover, in respect of any claims arising as a result of clinical negligence by its employees, brought by or on behalf of a study patient.

Thank you very much for taking the time to read this information leaflet