

Supplemental Digital Content (SDC) 2

Barriers and facilitators of laparoscopic surgical training in rural north-east India:

A qualitative study

E Wilkinson, N Aruparayil et al

Information Sheet and Consent Form



UNIVERSITY OF LEEDS

Faculty of Medicine and Health, School of Medicine,

Leeds Institute for Health Sciences

20 May 2019

My name is Ellen Wilkinson and I am a BSc student in International Health at the University of Leeds, working in association with NIHR Global Health Research Group – Surgical Technologies (GHRG-ST). I am carrying out a research study into the training experiences of rural surgeons in laparoscopic surgery, to establish recommendations for the inclusion of laparoscopic training in the DNB – Rural Surgery curriculum. I am inviting you to participate in this qualitative study, which is being carried out as part of my university studies, with fieldwork taking place 20 May – 25 May 2019.

The study has been granted ethical approval by the Nuffield Centre for Internal Health and Development Ethics committee, University of Leeds (Approval No: FMHREC-18-2.4), and in India from Maulana Azad Medical College, New Delhi (Approval No: F.1/IEC/MAMC/67/02/2019/No101).

This information sheet will tell you more about the project, and what you will be asked to do if you take part. Please read this sheet in full and take some time to consider whether you would like to be involved. Thank you.

Background

Laparoscopic surgery has some widely recognized advantages over open surgery, such as reduced infection, blood loss, postoperative pain and hospital stay. These are particularly significant in LMICs such as India, especially in rural and remote areas, where resources may be scarce and sanitation and clean water lacking. The DNB – Rural Surgery was developed to produce ‘rural doctors with advanced training in rural generalist surgical skills’, yet despite the benefits such as those outlined above, laparoscopic surgery is not part of its curriculum.

Why have you been chosen?

You have been chosen because you have experience in training and practice in laparoscopic surgery in rural India, and I would like to explore your views and experiences, positive and negative, to establish the importance of laparoscopic surgery in such an environment. I would like to understand your perspective on the relevance and importance of a structured laparoscopic training programme for health professionals in India like yourself, and what the components of this may be.

Do you have to take part in the study?

There is no obligation to take part, you may decline without reason. You may withdraw at any time up until 01 July 2019 and your data will be securely disposed of. To do so, get in touch with me at your convenience using the contact details below.

What will you be asked to do in the study?

If you chose to, you will take part in a one-on-one interview of up to around 60 minutes long, using open-ended questions to explore your views and experiences. The interview will take place at a mutually convenient time between 9am-5pm working hours, between XX and XX May 2019, at the health facility XXXX.

Who will be present during the interview?

The interview will be conducted by myself, the lead researcher. No other persons will be present.

Will the interview be recorded?

With your permission, the interview will be audio-recorded and then transcribed. Audio-recording is important in order to ensure accuracy of data and to allow for analysis. The audio recording will be transcribed as soon as possible and then immediately destroyed. All electronic data will be kept confidential until 01 July 2019 when it will be pseudonymized, before it may be used in a publication.

You may decline for the interview to be recorded, in which case I will take word processed notes on your responses throughout the duration of the interview.

What are the risks of being involved in the study?

There are no anticipated risks of taking part in this study.

What are the benefits of taking part in the study?

There are no direct benefits to yourself of taking part in the study, however, your interview responses may help to shape the future of laparoscopic training in India for rural surgeons such as yourself.

What will happen to the research results?

A report will be submitted to the University of Leeds for marking as a for-credit dissertation for my BSc International Health.

Publication will be sought in a peer-reviewed journal, and anonymized results may be presented elsewhere such as at a conference, or to stakeholders in organizations such as the Association of Rural Surgeons of India.

Will your information be kept confidential?

All consent forms and hard-copies of notes will be secured in locked cupboard and scanned and uploaded to the encrypted University of Leeds drive as soon as possible, before being securely destroyed. Electronic data will be stored on my password protected laptop before also being uploaded to the University of Leeds drive as soon as possible, as recommended by the University of Leeds Information Protection Policy. This way, your data will be kept fully confidential until 01 July 2019, when it will be pseudonymized for anonymization purposes. After this, it may be shared with other members of the GHRG-ST research team, and confidentiality broken for publishing or presentation purposes of anonymized results. No identifiable personal information that can be traced to you will be accessed by anybody other than myself, the lead researcher.

Pseudonymisation:

Direct identifiers will be replaced with pseudonyms. Names will be replaced with a number, for example, 'Participant 1'. Other direct identifiers will be replaced with generalized terms, for example, 'Crofts Memorial Hospital' will be replaced with 'North-East Indian hospital'. Other identifiers such as age will be used with wide ranges, if deemed necessary to include in the results, such as 'surgeon in his 50s' rather than '59 years old'. Some direct identifiers such as sex may be randomly switched, or not included in the presentation of results at all unless absolutely necessary.

What should you do next if you want to be involved in the study?

Please contact me, the lead researcher, and you will be asked to fill out a consent form, before an interview will be conducted at a time convenient to you.

Contact information

Lead Researcher: Ellen Wilkinson

Email address: ellenwilkinson@gmail.com

Phone number: XXXXXXXXXXXX

Supervisor, University of Leeds:

Dr Amrit Virk

a.virk@leeds.ac.uk

Supervisor in-country:

Mr Noel Aruparayil

n.k.aruparayil@leeds.ac.uk

Thank you for taking the time to read this information sheet.

	Add your initials next to the statement if you agree
<p>I confirm that I have read and understand the information sheet dated 20 May 2019 explaining the above research project, and I have had the opportunity to ask questions about the project.</p>	
<p>I understand that my participation is voluntary and that I am free to withdraw at any time up until 01 July 2019 without giving any reason and without there being any negative consequences. In addition, should I not wish to answer any particular question or questions, I am free to decline.</p> <p>I understand that if I decide to withdraw from the study, any data relating to me that I have already provided will be securely destroyed by 01 July 2019.</p>	
<p>I give permission for members of the GHRG-ST research team to have access to my anonymized responses. I understand that my name will not be linked with the research materials, and I will not be identified or directly identifiable in the report or reports that result from the research.</p> <p>I understand that my responses will be kept strictly confidential until pseudonymized, when direct identifiers will be replaced with numbers or general terms, or simply omitted. After pseudonymization, I understand that my responses may be used for publication.</p>	
<p>I agree for the data collected from me to be stored and used in relevant future publications in an anonymized form, for a period of up to 2 years after anonymization</p>	
<p>I understand that only the lead researcher will have access to the data until it is pseudonymized.</p>	
<p>I understand that other researchers may use my words in publications, reports, web pages, and other research outputs, only if they agree to preserve the confidentiality of the information as requested in this form.</p>	
<p>I understand that relevant sections of the data collected during the study, may be looked at by auditors from the University of Leeds where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.</p>	
<p>I agree to take part in the above research project and will inform the lead researcher should my contact details change during the project and, if necessary, afterwards.</p>	

Lead Researcher: Ellen Wilkinson Email: ellenwilkinson@gmail.com Telephone XXXXXXXXXXXX	
---	--

Name of participant	
Participant's signature	
Date	
Name of lead researcher	Ellen Wilkinson
Signature	
Date*	

*To be signed and dated in the presence of the participant.

Once this has been signed by all parties the participant should receive a copy of the signed and dated participant consent form, the letter/ pre-written script/ information sheet and any other written information provided to the participants. A copy of the signed and dated consent form should be kept with the project's main documents which must be kept in a secure location.