

Welcome to the third issue of our participant newsletter for CIPHER. We hope you find it interesting and informative.

We hope you and your loved ones are well and are managing through these unusual and difficult times. First of all, we wanted to say thank you so much for continuing to complete your follow up questionnaires.

Thank you!

How are we doing?

We recruited a total of **2498** participants to the study.

Number of questionnaires completed in the study so far:



- 1852** 6-week questionnaires
- 1667** 6-month questionnaires
- 1442** 12-month questionnaires
- 1229** 18-month questionnaires
- 838** 24-month questionnaires
- 380** 30-month questionnaires
- 117** 36-month questionnaires
- 17** 42-month questionnaires

[Data as of 01/11/21]

Update on recruitment and study follow up

Recruitment to CIPHER has been slower than expected because of the COVID-19 pandemic and a decision had to be made in June about the best way forward. The NIHR (NHS research branch) who funds the study, independent steering committee (which includes patient representatives) and the CIPHER study researchers all agreed that it made most sense to stop recruiting, despite not reaching the target of 4,000. The decision was taken to focus on continuing to follow participants to find out if they develop a parastomal hernia (PSH).

There were four main reasons for choosing this way forward:

1. Continuing follow up is unlikely to be affected by any future waves of the COVID-19 pandemic because questionnaires are sent by the research team for participants to complete.
2. It will provide evidence about risk factors for PSH most quickly. This was considered to be particularly important by patient representatives. The existing number of participants (over 2,000) is sufficient to identify important patient and surgical factors associated with developing a PSH.
3. Several objectives of the study were about using mesh to reinforce the stoma. However, surgeons have used mesh so rarely for participants that these objectives would not be answered even if recruitment continued.
4. It will allow us to move on to the next stage in this research area sooner. This is likely to involve formally assessing surgical and patient risk factors associated with PSH in a randomised controlled trial.

We have another 9 months left of follow up data collection. During this time, we would be grateful if you could continue to complete all your questionnaires as best as you can. CT scan appointments and the Stoma questionnaire are especially important. Your continued participation is crucial in providing high quality data for our research. We appreciate your commitment and continued support.

Online Questionnaires

If you currently receive your questionnaires by post and you want to receive them online, please email us at cipher-study@bristol.ac.uk or speak to your local study team and ask them to update your preferences.

Next step—assessing PSH using CT scans

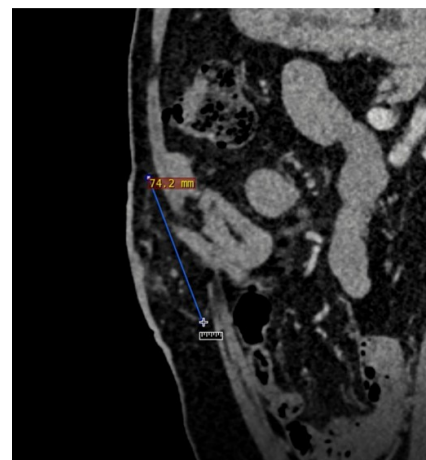


CIPHER aims to evaluate the relationship between patients' symptoms and radiology in confirming that a PSH has developed.

In order to obtain the objective radiological data, all CT scans will be assessed by surgical trainees nationwide.

Dr Niroshini Rajaretnam

Niroshini Rajaretnam, a Senior Colorectal Research Registrar on the study team will be leading a training programme for the trainees which includes completing a training curriculum and passing an exam in order to become CIPHER CT scan assessors. The assessment will include taking precise PSH measurements in different views as seen in this Figure. A database for the training programme and CIPHER scan assessments is being finalised. The training programme will start in the new year.



Publications

Two reports about CIPHER have been published this year. Both are freely available using the links below. The first one described the protocol for the study, setting out the aims, design and methods [1]. It is important to ensure that the protocol is publicly available before doing any analyses of the results so that, subsequently, people reading the results can check that the data are analysed as planned. The paper was published before deciding to stop recruitment and justifying this decision will be important in future publications.

The second report described the relative cost-effectiveness of using a mesh implant or not to reinforce the stoma at the time of formation [2]. Information from the questionnaires completed by participants was key to quantifying how PSH impacts on quality of life, in turn informing estimation of the 'cost per quality of life adjusted year' of using mesh or not. The effectiveness of mesh in preventing a PSH developing was based on 13 previous randomised studies. The analysis showed that using mesh is a cost-effective strategy when forming a stoma. However, mesh is not widely used in the NHS, as reflected in CIPHER. Due to uncertainty about whether the results of the randomised studies can be applied in the UK, this analysis raises the priority of a large UK randomised study of mesh versus no mesh.

1. Tabusa H, Blazeby JM, Blencowe N, et al. Protocol for the UK cohort study to investigate the prevention of parastomal hernia (the CIPHER study). *Colorectal Dis.* 2021;23:1900–1908.

<https://doi.org/10.1111/codi.15621>

2. Mohiuddin S, Reeves BC, Smart NJ, Hollingworth W; the CIPHER study group. A semi-Markov model comparing the lifetime cost-effectiveness of mesh prophylaxis to prevent parastomal hernia in patients undergoing end colostomy creation for rectal cancer. *Colorectal Dis.* 2021;00:1–13.

<https://doi.org/10.1111/codi.15848>



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CONTACT THE CIPHER TEAM

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Still working from home with occasional days in the office, please email if you would like to arrange a time to speak to us on the phone

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