

# The Impact of Integrating and Embedding a Patient and Public Research Advisory Group within a Multicentre NIHR RfPB Awarded Anaesthetic Trial – The TOPIC Study

## Abstract

Patient and public involvement (PPI) ensures that clinical research is for the benefit of patients and leads to improvements in healthcare. The TOPIC trial is a randomised controlled trial comparing the effectiveness of thoracic epidural blockade and paravertebral blockade in reducing chronic post-thoracotomy pain. The uncertainty in the original trial design promoted the implementation of a local PPI organisation, the Clinical Research Ambassador Group (CRAG). The TOPIC trial has utilised PPI from inception of the study through to dissemination of results and demonstrates the positive impact that PPI has on all aspects of the research process.

## Keywords

Patient and Public Involvement

Clinical research Ambassador Group

Advisory group

INVOLVE

## Introduction

Patient and public involvement (PPI) ensures that clinical research is for the benefit of patients and carers and leads to improvements in treatments and services<sup>1</sup>. The National Institute for Health Research (NIHR) programmes now specify that researchers must engage PPI for their proposal to be accepted by the funding programme boards<sup>2</sup>.

The TOPIC trial is a randomised controlled trial comparing the effectiveness of thoracic epidural blockade (TEB) and paravertebral blockade (PVB) in reducing chronic post-thoracotomy pain (CPTP)<sup>3</sup>. The feasibility trial has been completed and demonstrated that a full randomised controlled trial was achievable. The full study is scheduled to begin later this year. The TOPIC feasibility trial was funded by an NIHR research for patient benefit (RfPB) grant and three PPI patient ambassadors were involved in the application process. Two PPI representatives went on to become involved in the trial management group. The definitive trial has been funded by the NIHR Health Technology Assessment (HTA) programme and PPI continues to be an integral part of the study. There have been changes made to the TOPIC trial based on feedback from PPI, and both programme funding review boards commended the input of PPI. The TOPIC study demonstrates the impact of PPI on many areas of the research process.

## The Clinical Research Question and PPI

Post-surgical chronic pain is common, disabling and costly. As clinician researchers, we aim to reduce this health burden. The TOPIC research idea was initiated in a small specialty research grant application. The peer reviewers advised a review of the pain measurement tool used as the primary end point in the study. Out of three potential pain measurement tools, it was unclear which tool patients would prefer to use to express their pain. This led to the involvement of patient ambassadors to help make the decision, highlighting the crucial role of PPI even in the earliest stages of the research process.

## **Changes made to TOPIC's Study Design Following PPI Feedback**

Two patient ambassadors initially became involved in the TOPIC study design. One patient had CPTP and had experienced both interventions in the study so was able to provide valuable insight into the implications of the interventions on patients. The other PPI representative had also suffered from CPTP and had previously been involved in research, providing experience gained from involvement in other studies. The patient ambassadors offered advice on the wording of the patient information sheet and questionnaires, ensuring that the language was suitable for lay people. They were also able to offer feedback on the running of the study, and whether they felt it would be manageable for patients, especially given their first-hand experience of the surgery and the interventions.

## **Successful RfPB Grant application**

The TOPIC feasibility study proposal received £250,000 from RfPB. All PPI expenses were embedded within the grant application. Initially, there were two PPI co-applicants on the grant application. However, due to work commitments, one was unable to continue as a co-applicant, and another PPI representative took over. The co-applicants contributed to and reviewed the application to RfPB, and played active roles in the design, development and oversight of the study. The PPI co-applicants became members of the trial management group (TMG), which met regularly throughout the course of the study. The two PPI members provided feedback on study recruitment and conduct through the TMG meetings.

The TOPIC investigators were committed to fully engage PPI and so recruited the third PPI representative to join the Trial Oversight Committee (TOC). The TOC met on a regular basis, providing supervision and advice to the TMG and overseeing patient safety of randomised participants.

## **Dissemination Using PPI**

One PPI member of the TMG attended the INVOLVE conference in Birmingham in 2014 and discussed his role as a research ambassador within a clinical trial. He made a video recording of his experience, which (with his consent) has been presented at regional and national conferences and forums, such as the AAGBI annual update course on thoracic anaesthesia. The results of the feasibility study have been presented at PPI meetings and the investigators plan to utilise PPI to disseminate the results of the full study when completed.

## **HTA grant application and PPI**

Following the successful completion of the TOPIC feasibility study to time and target, the TOPIC investigators applied for funding from the NIHR HTA programme. The PPI members who were involved in the feasibility study were able to continue in their contribution to TOPIC by becoming co-applicants for the HTA grant. The application was successful, and TOPIC was awarded funds in excess of £2 million. The review board highlighted PPI as a strength of the study design:

“Excellent patient and public involvement.”

“Excellent PPI - particularly like that one of the applicants/team has undergone both TEB and PAV so is well placed to guide the development of the application and the research conduct. Also that there is involvement at all stages of the process from pre application to research, and that PPI people are to be active in the dissemination.”

The full TOPIC trial is due to start later this year, and will continue to have PPI input throughout the study.

## **Challenges of PPI**

The TOPIC investigators found it challenging to seek out an appropriate PPI representative for the study. They specifically wanted a patient ambassador with lived experience of CPTP, but initially found it challenging to find someone as existing pathways to engage PPI in research at that time were poor. The study team worked with surgical collaborators to recommend patients who had experience of CPTP. The first two PPI representatives were contacted at an early stage of the study process and were positive of the study aims and agreed to work with the research team.

The challenges of involving and engaging patients for the TOPIC trial led to the formation of a local PPI group. In 2013, the Clinical Research Ambassador Group (CRAG) was created, which provides a structured pathway for researchers to integrate with PPI at a local level<sup>4</sup>. The aim of CRAG is to provide a group of patients, carers and members of the public to support the development of good quality and meaningful research projects and grant applications. Study milestones and progress have been presented to the group on a quarterly basis and members are eager to hear updates on the TOPIC trial.

## **The impact on PPI Representatives**

Patients and the public who become involved in the research process have the opportunity to gain new knowledge and skills through their participation in PPI. One of the PPI members of the TOPIC TMG felt that he had personally benefited from his involvement:

“I now have a greater knowledge.....I do understand more now and I’ve found the [CRAG] group to be very helpful. I’ve been able to explain to other people more because of my experiences within the CRAG group” PPI TMG member for TOPIC and CRAG member.

As consequence of his involvement in the TOPIC trial, one PPI TMG member is now on the steering group of PRIORITYII - a priority setting partnership with the James Lind Alliance to explore retention of patients in clinical trials.

## **Conclusion**

The TOPIC investigators’ experience of integrating PPI as members of a research team has been positive. Including a co-applicant with experience and knowledge of PPI integration has led to continuing dialogue with PPI members and has provided a personal oversight of PPI involvement, education and financial reimbursement. This has led to an overarching positive experience from PPI members and has led to sustained momentum of engagement through the trial. In the future, PPI engagement will continue to be an integral part of the TOPIC trial, and will lead the way for further studies to involve PPI throughout all stages of the research process.

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- <sup>2</sup> NIHR. Funding and Support. Step 3 – Make a strong application. Available at <https://www.nihr.ac.uk/funding-and-support/funding-for-research-studies/how-to-apply-for-funding/make-a-strong-application.htm> (accessed 14th february 2018)
- <sup>3</sup> Yeung J, Melody T, Kerr A, Naidu B, Middleton L, Tryposkiadis K, Daniels J, Gao F on behalf of the TOPIC study investigators. Randomised controlled pilot study to investigate the effectiveness of thoracic epidural and paravertebral blockade in reducing chronic post-thoracotomy pain: TOPIC feasibility study protocol. *BMJ Open* 2016; 6: e012735.
- <sup>4</sup> Skilton E, Aslam M, Yeung J, Gao F, Melody T. Embedding patient and public involvement within research – How to set up a research patient ambassador group within an NHS trust. *JICS* 2016; 17: 234-7

# I. CPTP: a Significant Economic and Health Care Burden

- **disabling**

- 90% receive medications for pain and anxiety
- 60% disruption to daily activities
- 30% need specialist treatments
- 43% experience some level of disruption in their employment status, reduced working time, unemployment or early retirement.



*Acta Anaesthesiol Scand.* Jan 2011;55(1):60-8. *Pain.* Jan 2011;152(1):74-81.  
*Eur J Pain.* Feb 2006;10(2):127-135.