

*Study protocol*

**Identifying Patient priorities for reseArch in global surgery through a qualitative  
exploratiON of patients' cAre experiences in low- and middle-income countries  
(PANDA)**

**Version 1.0**

17th September 2021

## **Synopsis**

### *Introduction*

Ensuring that patients' voices are heard in prioritisation of research in surgery remains challenging in low resource environments. This study aims to identify and prioritise concepts and themes for research in global surgery with patients undergoing major abdominal surgery in LMICs, and build understanding of community engagement and involvement (CEI) in surgical settings.

### *Methods*

Semi-structured interviews will be undertaken to explore experiences of perioperative care pathways amongst patients that have undergone emergency or elective midline laparotomy in low- and middle-income countries (LMICs). An interview topic guide and codebook will be co-produced in collaboration between patient representatives and researchers. Thematic content analysis will be performed to identify patients' priorities for surgical research, adopting an applied pragmatic qualitative approach. Identified themes will then be ranked by hospital inpatients and community members in a structured survey, using purposive sampling methods. A final list of ranked patient priorities will be presented from highest to lowest priority.

### *Planned impact*

This study will generate and rank research priorities for surgical care directly from patients using research methods co-produced and co-delivered by patients and researchers. These patient priorities will be used to guide future research ensuring patients' voices are the heart of the global surgery agenda.

## PANDA study steering committee

<b>SOUTH AFRICA COLLABORATING GROUP</b>	
Bruce Biccald (Anaesthesia)	Simphiwe Gumede (Research Coordinator)
Margot Flint (Chief Research Officer)	Lina Hahnle (Investigator)
<b>UK COLLABORATING GROUP</b>	
James Glasbey (Surgery)	Rupert Pearce (Critical Care)
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<b>COMMUNITY ENGAGEMENT &amp; INVOLVEMENT</b>	
Nozibele Mabel Mdayi (CEI partner, South Africa)	Gary Hickey (NIHR Global Health CEI, UK)
Mike Bahrami Hessari (CEI lead, NIHR Global Surgery Unit)	

The PANDA study steering team will evolve to include more members and sites after an initial pilot phase in Cape Town, South Africa.

## **Background**

### *Research in global surgery*

Surgery is a fundamental component of healthcare systems, with an estimated 40% of the burden of global non-communicable disease requiring surgical treatment (1-5). Global efforts over the past decade have sought to increase priority for research and policy change to underpin safe, effective and cost-effective surgical care delivery (1, 4-11). Research priorities in surgery have been identified from the perspective of policy makers, surgeons, anaesthetists and other providers involved in surgical care (9). However, the patient voice has often been missing from these processes. Without the co-production of research with patients, researchers cannot be sure that they are addressing the true needs of patients, or that the proposed methods will be acceptable. Co-prioritisation of research in global surgical care will be essential to underpin patient-driven research design, whilst developing successful models for sustainable involvement of patients and community members in future research (12, 13).

### *Community Engagement and Involvement (CEI) in Global Surgery*

Patients and members of the public are underrepresented in research conducted in low- and middle-income countries (LMICs), despite community participatory action research and service design often displaying strong evidence of co-production. Patients and public partners can be involved in all stages of the research pathway, from design to delivery and dissemination (14). However, few published trials to date have recruited patients from LMICs (15, 16), and fewer still have involved patients co-production of research (17). Whilst models of co-production in research are well established in high-income settings (for example, 'expert' patient representatives in trial steering, management, and data monitoring committees), these structures are a challenge in LMICs. Variable health literacy, access to grassroots community members, socioeconomic challenges and power imbalances all pose a challenge to traditional patient involvement models across all income settings, but can be particularly stark in lower resource settings (18). A wider understanding of CEI in LMICs is

still developing, and best practice models are still being established (12). This threatens diverse and inclusive community involvement in global health research. A key objective of the PANDA study is to identify and work with patient partners and community representatives to deliver the research protocol, and in doing so to build relationships and local capacity for CEI.

### *Justification of methodology*

PANDA seeks to use qualitative methods to understand what matters to patients in their receipt of surgical care, to prioritise these themes, and explore differences across countries and contexts. Design and delivery of PANDA will be informed by patient and community representatives, with the explicit aim of growing networks for local community involvement in LMICs. Use of qualitative methodology to explore patients experiences of surgical treatment in depth in this study will have several advantages. Firstly, it will allow deep conceptual understanding of patient's priorities during their surgical care journeys. Whilst each patient will have their own unique care story, there are likely to be commonalities to patient experience which could underpin patient-centred design for large, multi-country research studies (19-21). Secondly, working with patients and community representatives to co-produce and prioritise themes will help improve capacity and leadership for CEI in low-resource settings. Thirdly, through talking to patients about research topics in depth we will improve 'research literacy' amongst local populations, and help to identify new patient partners for research involvement in global surgery.

Through co-production of the PANDA study between patients, community members and research team members in LMICs, the key principles of sharing power, building relationships, diverse perspectives, respect and reciprocity for successful CEI will be upheld (12).

### *Justification of research topic*

Research exploring patients experiences of surgical care has predominantly focussed on the preoperative setting (i.e., access to care) (22-24). Qualitative studies of the perioperative care pathway have focussed on providers resilience to resource shortfalls (25), system level factors impacting on care delivery (26), and preoperative optimisation checklists (27). Few studies have focussed on patient priorities for their surgical care, and none in LMICs. In a study with a similar methodology in Sweden (high-income) four areas were highlighted including accessibility, reliability, caring attitudes and empowerment (28). For patients undergoing head and neck cancer surgery in an Australian hospital (high-income), psychological support for 'shocks and aftershocks' was prioritised as a key research area (29). There is an urgent need to understand patients experiences and priorities for surgical care in LMICs to inform future research planning and design.

## **Aims**

- (1) To explore and describe patients experience of perioperative care pathways in LMICs
- (2) To identify and prioritise concepts and themes for research in global surgery with patients in LMICs
- (3) To explore the feasibility of flexible, collaborative co-production of research between LMIC researchers, patients and UK researchers in global surgery.
- (4) To build capacity for CEI through identifying, training and involving patients and community members in the PANDA study.

## **Methods**

### ***Phase 1: Identifying patient priorities through semi-structured interviews***

#### *Study design*

Semi-structured interviews will be undertaken by a qualitative researcher (a trained LMIC research nurse, UK researchers or trained LMIC citizen-researcher) to explore patients' experiences of perioperative care pathways. Topic guides will be informed by a perioperative

care mapping exercise which has been completed by researchers within our network. The topic guide may be developed iteratively over time based on emerging themes and concepts (30). Interviews will be conducted in-person (on the surgical ward or in outpatient clinics) or over the telephone dependent in whichever method is practicable. This may vary depending on local community SARS-CoV-2 transmission risk, restrictions on travel and patient's preferences.

#### *Interview content and conduct*

Interview with patient-participants will explore patient experiences of their surgical care mapped to the perioperative care pathway. This may include diagnosis of a surgical condition, investigations, surgical consent and planning, admission to hospital and pre-operative care, care around the time of surgery, and their postoperative recovery. Interview probes will be used to gather data on negative and positive aspects of patient-participants' surgical care journeys, and explore the reasons for these in depth.

Interviews will be conducted using practicable methods including in-person or telephone interviews, flexible to local COVID-19 community risk, regional customs and patients' preferences. Where language barriers exist, a translator will be used to facilitate the interview. Where possible, this translator will have had specific training in language relating to medical research. Patient and community representatives will help to design the interview topic guide, schedule and setting to ensure culturally attuned conduct (18).

#### *Researchers, training and capacity building*

Flexible models of interview delivery will be adopted in the PANDA study. This will be designed to transfer research capacity to LMIC research leaders and patient partners over the duration of the study. Firstly, LMIC research nurses and citizen researchers (where applicable) will undergo targeted online training (provided by the University of Birmingham, UK) in qualitative research methods specifically related to this research design using small-

group teaching, and pilot interviews with simulated patients. This model has been previously used successfully by our team for training for randomised research (7), and communications skills in trial recruitment in LMICs (31).

Potential citizen researchers will be identified from existing CEI networks in participating centres, or where consent is given, from those participating in the qualitative interviews. LMIC research nurses will also ask participants whether they would consider becoming patient partners in research and take verbal consent for further contact. Those giving consent will be invited to join a CEI network, and contribute to ongoing data collection interpretation for example conducting further interviews, member-checking of themes, reviewing prioritisation themes, and designing patient facing research summaries. This process aims to leverage 'gatekeepers' established relationships with grassroots community members to build trust in research processes, and the concept of CEI.

### *Sampling*

Purposive sampling will be performed across selected countries within the NIHR Global Health Research Unit on Global Surgery network. Recruitment will continue until the point at which the research team judge that both the data and sample have sufficient depth and breadth (32). It is anticipated that approximately 10 to 12 interviews per country will be required in total. Purposive sampling will attempt to include a mix of interviewees of male and female gender, different age groups ( $\leq 50$ , 50 to 70,  $\geq 70$  years) living in urban and rural settings, mixed levels of education (high school level and above / below high school level), disease types (cancer / other non-communicable / trauma / infective), and operation urgency (elective / emergency). Researchers will seek a maximum-variety sample to ensure data is collected from a wide range of experiences and operation types.

### *Patient identification*

Patients will be identified using locally relevant methods in each country; these methods will balance inclusivity, breadth of patient experience and safety for the qualitative researcher. These may include patients from the inpatient ward, visiting a secondary or tertiary hospital for an outpatient visit, reaching into community hospitals, or working with community health workers or gatekeepers. Specific efforts will be made to reach marginalised and under-represented communities, and the research team will remain as flexible as possible in the setting, language and timing of interviews in order to maximise opportunity for involvement.

#### *Recruitment and consent*

PANDA eligibility will be similar to that within the Perioperative Respiratory Care and Outcomes for Patients Undergoing High Risk Abdominal Surgery (PENGUIN) trial (8). We will recruit adult patients (18 years or older) that have previously undergone an elective or emergency midline operation for any indication. Verbal consent will be taken by treating clinicians for further contact by the research team, and patients' contact details will be recorded on the PANDA patient identification log.

The qualitative interview will arrange a mutually convenient time with the patient for an in-person or telephone interview, in whichever way is safe and practicable. For patients who are able to undertake an in-person interview, written informed consent will be taken by a researcher and a PANDA Patient Information Sheet will be provided. For patients who wish to undertake a telephone interview, a researcher will take verbal consent and provide specific details about the purpose and design of PANDA as part of fully informed consent.

Patients, and citizen-researchers will be reimbursed for their time in line with NIHR guidelines (33). The amount of funding will be costed at a local or national level in collaboration with within-country partners (including patient and community representatives) to ensure a responsible, ethical application of patient payments, in line with local pay structures.

## *Analysis*

Interviews will be audio-recorded with the consent of participants, and transcribed verbatim for analysis. Where these interviews are conducted in non-English language, transcriptions will be translated by a professional translator, and appropriate translation checked and confirmed with the local LMIC researcher (language proficient). Within-country shared analysis of data will be undertaken with reference to recordings, transcriptions and field notes taken at the time of data collection or in post-interview discussion between the LMIC, UK and citizen researchers involved in data collection. Thematic analysis of content will be undertaken informed by the Framework analytical approach (34). Following initial familiarisation with the data, development of thematic frameworks and data coding will proceed in an iterative manner. Data collection and analysis will run concurrently so that emergent analytical themes can inform further data collection. Data management will be facilitated with NVivo V12 (QSR International, Victoria, Australia).

## ***Phase 2: Prioritisation of themes***

### *Study design*

In *Phase 2*, the major themes identified in *Phase 1* will be prioritised by surgical patients and the public. Themes will be listed in a single-round questionnaire format, and translated across languages as required. The design of the questionnaire will be iteratively improved in collaboration with LMIC site researchers and patient and community representatives. Use of a pragmatic, low-burden consensus method is likely to increase patient understanding and engagement with research prioritisation (35). It also reduces reliance on access and affordability of electronic voting for patients in LMIC communities in comparison to multi-round methods (e.g., Delphi consensus). Participants will be asked to rate the (1) *Importance* and (2) *Relevance* of each theme to them using a 5-level scalar measure (1= not at all important/relevant to 5=very important/relevant).

### *Sampling*

Adult patients (18 years or older) that have undergone an emergency or elective midline laparotomy for any indication will be identified on the surgical wards in participating centre. Written consent will be taken from each participant (and a short patient information sheet) by the research team. The patient will be asked to either respond to each theme as directed by a member of the research team, or self-complete the questionnaire as appropriate. The research team will seek responses from a variety of participants of different backgrounds using maximum variety sampling (at least one participant from each pre-defined characteristic). We approximate this will require a minimum of 25 participants per participating country. If possible, members of the public/community will also be sampled through community 'gatekeepers' and partners identified in *Phase 1*.

### *Analysis*

Descriptive statistics will be used to describe the order of overall importance and relevance of the themes. Differences in the median average ratings between groups (described in the sampling frame above) will be tested using the Mann Whitney test for unpaired non-parametric data.

### ***Reporting***

This study will be reported in accordance with COREQ guidelines for qualitative research. The design, planning and implementation of Community Engagement and Involvement within this study will be reported according to the GRIPP-2 framework (36).

### ***Ethical approval***

Ethical or institutional approval will be gained for each participating country and/or hospital in accordance with local regulatory frameworks. Personal data (e.g., telephone number, contact address) for participants will be held on password-protected computer held locally at the participating in-line with best data protection practice. Community Engagement and

Involvement will be conducted in line with NIHR guidelines for community engagement and involvement (37, 38), and UNICEF global best practice recommendations for community participatory research (39).

### ***Dissemination***

A workshop will be held at an NIHR Global Health Research Unit on Global Surgery meeting with citizen and qualitative researchers involved in the PANDA study, alongside a broader network of LMIC surgeons and anaesthetists. The group will review prioritised themes and share learning in global CEI methodology for future research. Further insight gained from this discussion will be used to refine and develop concepts within the final study report.

The protocol, results and methodology of PANDA will be submitted for publication in peer reviewed journals in patient involvement, global health or surgery. The results of PANDA will be co-presented by citizen-researchers and surgeon-researchers to share learning about global CEI, in selected global and in-country meetings. All publications arising from this work will be attributed to the “NIHR Global Health Research Unit on Global Surgery” and will include all contributing citizen-researchers, qualitative researchers and other contributors as equal co-authors, in alphabetical ordering.

Patient and community partners will help to co-design patient and public facing outputs including short films, graphical and lay abstracts, translated into local languages and dialects.

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