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Protocols

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Protocol for a global cohort study: Hernlas, Pathway and Planetary Outcomes for Inguinal Hernia Surgery (HIPPO)

NIHR Global Research Health Unit on Global Surgery

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Introduction

Inguinal hernia repair is one of the most common elective operations globally which was not prioritised during the pandemic. Data from the National Health Service in the United Kingdom suggests that 74,822 patients were awaiting inguinal hernia repair in June 2022. The primary aim of this study is to identify the variation in access and quality for inguinal hernia repair, using it as a tracer condition for elective healthcare.

Methods

This study will be a prospective global cohort study in which hospitals performing inguinal hernia repairs in any country are eligible to participate. Consecutive patients of all ages undergoing inguinal hernia repair will be included during 4-week periods. Both elective and emergency procedures will be included. The primary outcomes were defined as a measurement set mapped to the attributes of WHO Health System Building Blocks. Emergency rate, bowel resection rate and waiting times to elective repair will be used to evaluate access. Mesh use rate, day-case adoption rate and 30-day postoperative complications will be used to evaluate quality. These measures will be described across the four income groups as described by the World Bank classification system (high-, upper-middle, lower-middle and low-income groups). Association of postoperative complications and pre-specified variables will be tested using a multilevel logistic regression model.

Discussion

This study will provide granular data on assessment of elective healthcare. It will also identify how quality in inguinal hernia repair is varying across the world. This data will inform policymakers and governments of components in the pathway which need to be improved to reduce waiting times for inguinal hernia repair.

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Background

Inguinal hernia surgery is one of the most common elective operations globally. However, during the SARS-CoV-2 pandemic, it was significantly underprioritised, with fewer planned procedures and a likely increase in the global backlog[1]. According to the most recent data from June 2022, there were 74,822 patients waiting for inguinal hernia repair in the United Kingdom's National Health Service (NHS)[2]. In elective surgery, waiting times are highly dependent on prioritisation and patient selection, often leading to delayed surgeries for benign conditions such as inguinal hernias. The elective healthcare efficiency in turn influences waiting times for surgery overall as it underpins the patient journey[1]. Inguinal hernia repair serves as a useful tracer condition for evaluating elective healthcare due to its high prevalence, well defined diagnostic criteria with an effective treatment (surgery), supported by international guidelines[3,4]. Its patient pathway also reflects interaction between different components of the health system5,6.

All health systems faced significant stress imposed by the SARS-CoV-2 pandemic and elective care, including surgery was adversely affected[1,7]. However, data is scarce regarding the impact it had on the time that patients must wait to receive surgical care[8]. Additionally, waiting times are dependent on country-, hospital-, and patient-level factors, where the first two will affect all elective surgeries, independently of the procedure. While this issue has been the focus of discussions globally, high quality data on the current waiting times is needed to guide future strategies and identify areas of the patient pathway that require investment to improve access to elective surgery. Research on all surgical conditions that were not prioritised during the pandemic is unfeasible, however using a common condition such as inguinal hernia might allow this type of assessment in a more pragmatic way.

The primary aim of this study is to identify the variation in access and quality for inguinal hernia repair, using it as a tracer condition for elective healthcare. The secondary aims include describing surgical variation, evaluating the compliance to inguinal hernia surgery international guidelines, describing variation in anaesthetic practices, and describing the uptake of environmentally sustainable practices in operating theatres.

Methods

Summary

A prospective, multicentre, global cohort study of consecutive patients undergoing inguinal hernia repair will be delivered by the NIHR Global Health Research Unit on Global Surgery. Local teams of collaborators will identify patients and prospectively collect routine data during pre-specified 4-week periods between 30th January 2023 and 21st May 2023, with a 30-day postoperative follow-up for each patient (timeline shown in figure 1).

Centre eligibility

All hospitals performing inguinal hernia surgery as emergency or elective procedures are eligible to participate. Each hospital should ensure that all consecutive and eligible patients are included, and that data completeness is equal or greater than 95% for their site. Hospitals with more than 5% missing data will be excluded from the study, to ensure a high-quality dataset.

Patient inclusion and exclusion criteria

Consecutive patients of all ages undergoing primary inguinal hernia repair, through open groin incision, laparoscopy or robotic surgery will be included. Both planned (elective or expedited) and unplanned (emergency) procedures will be included. Cases where the inguinal hernia repair is not the main procedure, is performed through a midline incision, or where no inguinal hernia is identified during the operation will be excluded (details shown in table 1). Patients that return to theatre after primary inguinal hernia repair should be entered only once.

Outcome measures and follow-up

The measurement set was mapped to cover the four attributes from WHO Health Systems Building Blocks: access, coverage, safety, and quality[9]. The measurement set includes key performance measures and additional descriptive data. To evaluate access and coverage, emergency rate, bowel resection rate and waiting times to elective repair will be collected. To evaluate safety and quality, mesh use, day-case adoption and postoperative complications at 30 days will be collected. Further additional descriptive data to fully understand access and quality will be collected at hospital- and patient-level.

Each measure will be analysed in the relevant group of patients, as shown in figure 2. To fully evaluate surgical variation and compliance to the international guidelines on hernia management (table 2)[3,4], detailed intraoperative data will be collected, as shown in the appendix.

Postoperative follow-up at 30-days will be completed without change to the local routine practice. Where routine follow-up at 30-days is standard practice, this should be maintained and data collected at this endpoint. In centres where this is not the standard practice, patient notes, electronic systems and outpatient letters should be checked to capture if there were any complications during the 30 days after surgery.

Data points

Data will be collected from the pre-, intra- and postoperative period for each patient. Data characterising the hospital system will also be collected for each participating centre. Pre-operative variables will include demographic data, comorbidities, ASA and inguinal hernia features assessed before the operation. Intraoperative details will assess anaesthesia, surgical and environmentally sustainable practices. The case report forms and the hospital survey that will be adopted are shown in the appendix.

Data management

Data will be collected and stored online through a secure server running the Research Electronic Data Capture (REDCap) web application[10], allowing safe anonymised data storage by collaborators globally. The service is managed by the Global Surgery REDCap system hosted at the University of Birmingham, United Kingdom and is governed by the policies of the University of Birmingham. Data management and data security will abide by the requirements of the General Data Protection Regulations (GDPR) and any subsequent amendments. Collaborators will be given secure REDCap project server login details, allowing secure data storage on the REDCap system. Regular meetings with national leads, hospital leads and collaborators are planned to provide updates on progress and clarify any questions.

Statistical analysis and power calculation

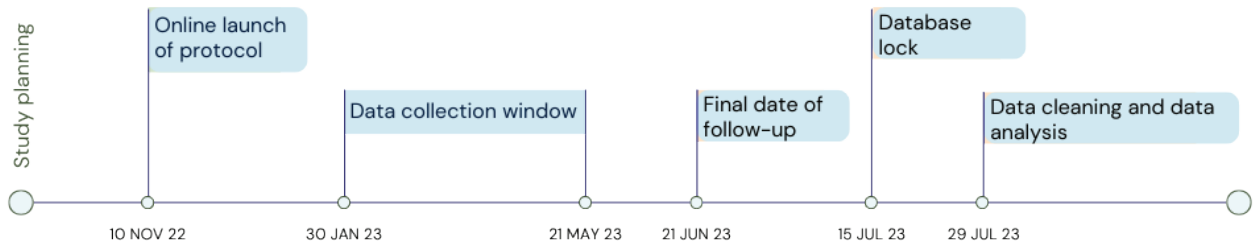
A minimum of 300 centres contributing patient-level data from 70 countries is estimated, and a sample of approximately 5,000 patients is anticipated based on previous cohort studies conducted on a similar scale (i.e. GlobalSurg, CovidSurg)[11-13].

The data will be described according to the World Bank income country classification into 4 categories[14]: low-income countries (LIC), lower-middle income countries (LMIC), upper-middle income countries (UMIC) and high-income countries (HIC). In case there are not enough patients recruited from LIC and LMIC, these two groups will be combined. Continuous variables will be presented as means and standard deviation if normally distributed, and median and interquartile range (IQR) if not normally distributed. Categorical variables will be described with frequencies and percentages. Waiting times will be calculated for each patient with time since first symptoms, date of diagnosis, date of decision to date of surgery and surgery.

A multilevel logistic regression model will explore association between postoperative complications and patient and hospital variables. Clinical plausible factors agreed by the study management group will be included as covariates. Hospitals will be included as a random effect. A p-value of <0.05 will be considered statistically significant.

Data will not be reported at an individual surgeon- or hospital-level. Country-level analyses may be conducted by national leads, but approval from all hospital leads is required.

Figure 1: Timeline of HIPPO study



Investigators

The study will follow the National Research Collaborative (NRC) authorship guidelines15. The investigators will be surgeons, nurses and/or anaesthetists around the world who are involved in the care of hernia patients. Different groups were established and will have different responsibilities. A study management group will be responsible for the study design, coordination, delivery and analysis. A data handling and management group, including statisticians, will be responsible for data chasing, cleaning, and data analysis. A dissemination committee, including national leads, will be responsible for dissemination and centre recruitment. Hospital leads, a single clinician appointed in each recruited centre, will be responsible for obtaining study approval according to local regulations, recruiting and coordinating local collaborators, and ensuring data validity and quality. Collaborators will be responsible for identifying all eligible patients and collecting the data.

Figure 2: Measurement set mapped to the relevant group of patients

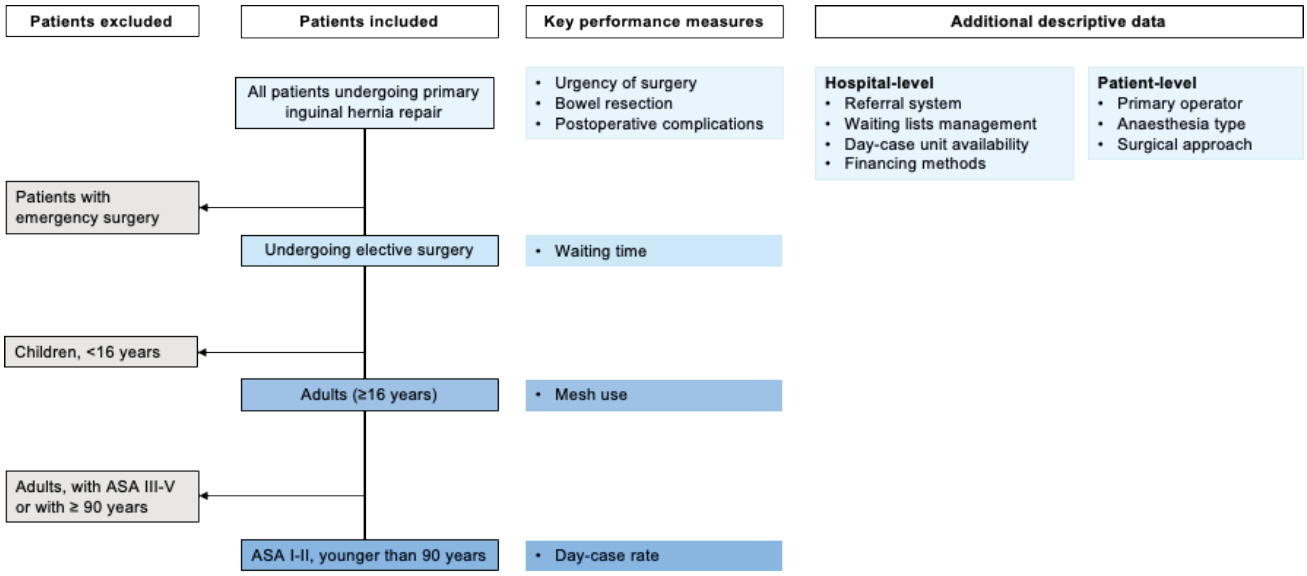


Table 1 - Inclusion and exclusion criteria

Inclusion criteria	
Age	Paediatric and adult patients
Procedure	Primary inguinal hernia repair, where this is the main procedure. For patients with bilateral inguinal hernias, data should be entered only for the larger of the two.
Approach	Open groin incision, laparoscopic, laparoscopic assisted, laparoscopic converted, robotic, robotic converted procedures.
Urgency	Elective or emergency surgery
Exclusion criteria	
Procedure	Recurrent inguinal hernias. Surgeries where inguinal hernia repair is done as an additional procedure. Patients where no inguinal hernia was identified during the procedure.
Approach	Laparoscopic or robotic that is converted to open midline.
Urgency	Elective or emergency surgery

Table 2: Intraoperative standards for inguinal hernia repair, according to the international guidelines for groin hernia management

Intraoperative standards
Anaesthesia type: Local anaesthesia is recommended for elective, open repair of reducible inguinal hernia where experience is available. Where experience is not available, general anaesthesia have benefits compared to regional anaesthesia in patients above 65 years old. Below this age, there is no clear benefit of general vs regional anaesthesia.
Mesh repair: Mesh repair is recommended as first choice, either by an open procedure or a laparo-endoscopic repair technique. Lichtenstein and laparo-endoscopic repair are best evaluated.
Non-mesh repair: If a non-mesh repair is selected, the Shouldice technique is the gold standard for open inguinal hernia repair without mesh
Laparoscopic repair: Where resources and expertise are available, laparo-endoscopic repair have faster recovery times. For the repair of primary bilateral inguinal hernia, laparo-endoscopic repair is recommended, where there is specific expertise and sufficient resources. When laparoscopic surgery is undertaken for inguinal hernia, as transabdominal preperitoneal (TAPP) and totally extraperitoneal (TEP) have comparable outcomes, the choice of technique should be based on surgeon's experience.
Day case surgery: Day surgery is recommended for the majority of groin hernia patients where adequate aftercare is organised. This includes all patients ASA I-II, or stable ASA III, with age below 90 years old.

Ethics and dissemination

All participating centres will be required to register the HIPPO study according to local regulations before the start of data collection. The study may be registered as a clinical audit, service evaluation or submitted to an ethics committee for approval, depending on local ethical body requirements. Hospital leads will be responsible for ensuring that necessary approvals are obtained prior to any data being uploaded into REDCap.

The detailed protocol and supporting documents in 9 different languages are publicly available (https://www.globalsurgeryunit.org/clinical-trials-holding-page/hippo/). The dissemination plan for HIPPO will aim to target all three key stakeholders in the delivery of surgical care: clinicians, patients, and policymakers. First, we plan to disseminate the results of this study to healthcare professionals through publication in peer-reviewed journals and international conference presentations. Patient-centric material summarising the findings will then be produced to help further translation of the study results to the general public. Finally, the key findings from the study will be summarised into an executive report to help facilitate uptake amongst government and policymakers.

Trial registration

This study is registered on clinicaltrials.gov with the identifier NCT05748886.

Discussion

This study will provide relevant information regarding access to elective healthcare, in the post-pandemic period, across the world. It will also contribute to fully understand the parts of the patients pathway that need to be optimised, which might be before diagnosis, after diagnosis or after a decision for surgery. This will allow working with the different specialties involved in the care of surgical patients, such as community healthcare workers, general practitioners, paediatricians and surgeons to improve this pathway.

This study will also provide updated data on quality and safety of inguinal hernias repair. This is relevant to identify future targets of action, such as training gaps. Evaluating mesh and surgical approach will also allow to better characterise their current availability in low-income settings, which has been perceived to be low. Evaluating postoperative complications at 30-days will allow evaluation of important gaps in safety for a simple procedure, which might be relevant to inform future trials.

Hospital level data will allow the findings from the study be put into context, accepting that different hospital types with different resources might have different findings and the main findings may not be applicable to all hospital types. This data will also be relevant from the healthcare system point, where these features are likely to have a significant role in access and quality of patient are.

The study is designed in a pragmatic way to give the opportunity to expand participation of different hospitals in global surgery observational studies. This considers the workload and the pressure in frontline teams after the pandemic and this pragmatic approach will avoid overburden while conducting high quality research. Therefore, the follow up period was defined to be 30 days and no changes in usual patient care will be done, accepting the limitations with this approach.

Ultimately, this data will be relevant to inform governments and policymakers about the improvements and investments needed to recover elective surgery to address the backlog of inguinal hernia surgery, which might be transferable to other elective procedures and care.

Writing Group

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