Global Cohort Study: Hernias, Pathway and Planetary Outcomes for Inguinal Hernia Surgery

A global prospective cohort study on inguinal hernia surgery

Study Protocol

Partners and Sponsors:

Table of Contents

Project Timeline

Dates	Description
10th November 2022	Online launch of HIPPO Protocol
End of November 2022	Virtual conference for HIPPO Study Launch
30th January – 21st May 2023	Data collection window, any 4-week period available
30th January - 26th February 2023	Period 1
27th February - 26th March 2023	Period 2
27th March - 23th April 2023	Period 3
24th April - 21st May 2023	Period 4
21th June 2023	Final date of follow-up
15th July 2023	REDCap database locked, final data submission deadline

Collaborative Approach

This study is delivered by the management team from the NIHR Unit on Global Surgery. This team have delivered the GlobalSurg and COVIDSurg studies[1,2]. COVIDSurg identified that elective capacity, training, and environmental sustainability are priority issues for the immediate future[3-5]. HIPPO was designed to address these. The Central Management team are Aneel Bhangu, Dmitri Nepogodiev, Elizabeth Li, James Glasbey, Joana Simoes, Maria Picciochi, Sivesh Kamarajah and Virginia Ledda. The complete management and authorship groups will be published in the final paper.

Introduction

Inguinal hernia surgery is one of the most common elective operations around the world. It was significantly down-prioritised during the pandemic, with fewer planned procedures and a likely increase in a global backlog[3]. According to the most updated data, there are 74,822 patients waiting for inguinal hernia repair in the United Kingdom's National Health Service (NHS),[6] although the recommended expected waiting time should not exceed 18 weeks[7]. It is likely that other countries face the same problem, although such granular data does not exist.[8] Additionally, while waiting for an elective repair, complications of inguinal hernia might arise and an emergency surgery might be needed. Identifying the scale of the global backlog at a global level will inform policy makers on the best strategies to optimise this elective surgical pathway.

Different surgical techniques exist, with different mesh and non-mesh techniques being described. The most up-to-date international guidelines recommend Lichenstein as the gold-standard for open repair of inguinal hernias,[9] but a more tailored approach is recommended. The patient, the hernia type, and the surgeon's expertise will influence the choice of surgical technique which leads to a wide variation worldwide. Additionally, in areas where there is a deficit of surgeons, task sharing and task shifting might be implemented[10,11]. Identification of this practice across the world and the outcomes associated with it will inform future research in this area.

Finally, as inguinal hernia repair is a very common procedure, it can reflect the global uptake of environmentally sustainable measures in elective surgery[5]. Achieving a net zero health system is only possible if reducing the carbon output from operating theatres is included. Different countries might have different protocols and measures adopted to be environmentally

sustainable that could be used in different settings. Understanding the baseline point of these practices is extremely important to inform future studies in this area.

Audit Standards

Pre-operative standards
NHS UK: Inguinal Hernia Repair[7] • **Waiting times:** The maximum recommended waiting time for inguinal hernia surgery in the NHS is 18 weeks after referral from the GP

Intraoperative standards
International guidelines for groin hernia management[9] **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.
International guidelines for groin hernia management[9] **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.
International guidelines for groin hernia management[9] **Non-mesh repair: If a non-mesh repair is selected, the** Shouldice technique is the gold standard for open inguinal hernia repair without mesh
International guidelines for groin hernia management[9]: **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 TAPP and TEP have comparable outcomes, the choice of technique should be based on surgeon's experience.
International guidelines for groin hernia management[9]: **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.

Methods

1. Summary

A prospective, multicentre, cohort study will be delivered by NIHR Unit on Global Surgery globally. Mini-teams of up to five collaborators per data collection period will prospectively collect data over a continuous 28-day period at each participating centre. This will be on consecutive patients undergoing elective and/or emergency primary inguinal hernia surgery, with follow-up to 30 postoperative days.

2. Study Aims:

- ***Primary Aim:*** To identify compliance to audit standards described.
- ***Secondary Aims***
    - To understand the waiting times and access to surgery for inguinal hernia patients
    - To explore technical variation of inguinal hernia surgery
    - To explore surgical outcomes of inguinal hernia repair done by non-surgeons
    - To identify environmentally sustainable measure adopted by operating teams

3. Project Timeline:

- The suggested overall data collection periods will be Monday 30th January 2023 to 21st May 2023, with the possibility of extending for 1 more month, considering that the ethical review process might take different times in each country. Each mini-team will collect data over a 28-day, (4 weeks) consecutive period with subsequent 30-day follow-up:
    - Period 1: 00:00 30th Jan 2023 - 23:59 26th Feb 2023 (+ 30 Day Follow-up)
    - Period 2: 00:00 27th Feb 2023 - 23:59 26th Mar 2023 (+ 30 Day Follow-up)
    - Period 3: 00:00 27th Mar 2023 - 23:59 23th Apr 2023 (+ 30 Day Follow-up)
    - Period 4: 00:00 24th April 2023 - 23:59 21st May 2023 (+ 30 Day Follow-up)
- Patients should be included if their operation started (defined as ‘knife-to-skin’ time) within the time period during the data collection periods as specified above.

4. Centre Eligibility:

- HIPPO is open to any hospital globally that performs inguinal hernia surgery
- All participating centres are required to register the HIPPO study according to local regulations. In the UK, HIPPO should be registered as an audit.

- Outside of the UK, individual study investigators are responsible for ensuring the correct audit, ethical or departmental approval has been achieved prior to commencing data collection (this can be registered as an audit or service evaluation, if appropriate).
- Centres will not be allowed to upload patients' data onto REDCap until they have successful registration of the study.

5. Patient Eligibility:

Summary: Consecutive patients during the selected study period undergoing elective or emergency primary inguinal hernia repair through any operative approach.

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 are all eligible. Patients with open incisions other than groin incision (e.g. laparotomy) are excluded.
- **Urgency**: Patients undergoing planned (elective) surgery or emergency surgery

Exclusion criteria:

- **Procedures:**
    - Recurrent inguinal hernias
    - Surgeries where inguinal hernia repair is not the main procedure, but performed as an additional procedure (eg patient operated for colon cancer and undergoing inguinal hernia repair during the same operation).
    - If patients are undergoing repair of two different types of hernia they can be included if the inguinal hernia repair is the main operation. (e.g. patient undergoing both inguinal and umbilical hernia repair). However, if the inguinal hernia repair is a secondary procedure to a larger non-inguinal hernia repair, patients should be excluded (e.g patient undergoing both large incisional hernia repair and inguinal hernia repair).
    - Laparoscopic converted to open midline procedures.

- Patients undergoing surgery with intent of repair of inguinal hernia, where no hernia inguinal hernia was identified (e.g. intra-operative findings of adenopathy, femoral hernia, obturator hernia)

- **Return to theatre**:
  - Each individual patient should only be included in the study **once.** Patients returning to theatre due to complications following earlier surgery can only be included if their index procedure has not already been included in the HIPPO audit.
  - Patients with bilateral hernias undergoing repair with two separate procedures in two different times, should only be included for the first procedure.

You should collect data on consecutive patients operated at your centre during the data collection period. This means that all eligible patients should be included.

Strategies to identify consecutive eligible patients could include:

- *Daily review of elective theatre lists.*
- *Daily review of handover sheets and ward lists.*
- *Daily review of theatre logbooks (both elective).*

6. Other variables:

Data will be collected on audit standards and confounding factors for risk-adjusted analyses. These include age, sex, body mass index, American Society of Anaesthesiologists (ASA) grade, relevant comorbidities, and smoking status. Variables including inguinal hernia features assessed pre-operatively, anaesthesia type, operative approach and technique will also be collected. Without appropriately adjusting for risk factors, it is likely that any findings would be biased and unable to be appropriately analysed on a national scale. A full list of required data fields is available in **Appendix A**, and on the REDCap database.

7. Outcome Measures and Follow-up:

Primary outcome measure:

- Compliance to audit standards described

Secondary outcome measures: (see **Appendix B: Definitions of Key Outcomes**)

- 30-day follow-up
- 30-day surgical site infection rates
- 30-day reoperation rates
- 30-day readmission
- 30-day Clavien-Dindo complications

Follow-up should be performed in line with current routine practice within each hospital settings. No additional telephone, in-person or questionnaire-based follow-up is required. Source data may be acquired from hospital in-patient notes, clinical electronic systems, or outpatient letters.

8. Data Governance:

Data will be collected and stored online through a secure server running the Research Electronic Data Capture (REDCap) web application,[13,14] allowing safe anonymised data storage by collaborators across Europe. The service is managed by the Global Surgery REDCap system hosted at the University of Birmingham, United Kingdom. The security of the study database system is governed by the policies of the University of Birmingham. Data management and data security within the BiSTC REDCap 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.

No patient data will be uploaded or stored on the REDCap database without prior local permissions. All data should be handled in accordance with local data governance policies, and all paper copies of any data should be destroyed as confidential waste within the centre once uploaded to REDCap. Data collected during the HIPPO study can be used for future analyses at the Study Management Group's discretion.

9. Data Analysis & Sample Size:

Based on previous GlobalSurg-CovidSurg studies HIPPO is anticipated to include around >1000 centres globally. With recent figures provided by previous GlobalSurg-CovidSurg Week study[15], a sample of approximately 5,000 patients is anticipated. No surgeon-, hospital- or

country-specific comparisons will be performed. Further secondary analyses may be performed at the Study Management Group discretion.

10. Local Project Registration:

At any centre, if the option is available, this project may be registered as clinical audit or service evaluation. Alternatively, it may be necessary to obtain formal ethical approval. It is the responsibility of the local mini team at each site to ensure that the study is registered appropriately, according to local regulations. HIPPO should be registered in the UK and ROI as a clinical audit.

Examples of audit registration forms can be found at the online project hub. When registering HIPPO as a clinical audit you can emphasis that:

- HIPPO is a national audit, and all data collected will measure current practice.
- No changes to normal patient pathways/ treatment will be made.
- All HIPPO data will be collected and stored online through a secure server running the Research Electronic Data Capture (REDCap) web application.[14] REDCap allows collaborators to enter and store data in a secure system. Collaborators will be given secure REDCap project server login details, allowing secure data storage on the REDCap database.

Collaborators in the UK should seek their trust's Caldicott Guardian's permission to submit data to the REDCap system. **No data should be uploaded to REDCap prior to written approval from the Caldicott Guardian**. No patient identifiable information (e.g. NHS numbers) should be uploaded or stored on the REDCap database without explicit permission from the trust's Caldicott Guardian. All data should be handled in accordance with national and local data governance policies.

11. Quality assurance:

Design: This protocol was written with guidance from an expert cross-speciality advisory group.

Patient and Public Involvement: The relevance of these research topics to patients were discussed with the NIHR Global Surgy Unit Community and Engagement Involvement (CEI) lead (Michael Bahrami-Hessari) and a Patient and Public Involvement lead of ACPGBI and ESCP (Sue Blackwell). All these topics were felt to be important and relevant to patients. We

will involve patient throughout the study and will produce patient facing materials after analysing the data.

Training: HIPPO National Leads are encouraged to hold local meetings with collaborating teams to brief them on the protocol, and to feedback any local issues or questions raised.

Project team structure: At each centre, this study can be delivered and disseminated by teams of medical students, junior doctors and/or consultants. Each team should include at least one qualified doctor to provide additional local support for participating medical students.

Data completeness: Following data collection, only data sets with >95% data completeness will be accepted for pooled national analysis. To emphasise the importance of data completeness to collaborators, data collection periods with >5% missing data points will be excluded from the study and collaborators from those periods withdrawn from the published list of citable collaborators.

Validation: This collaborative methodology for has been widely validated across multiple datasets, both nationally in the UK and Ireland and internationally, demonstrating high levels of case ascertainment (typically greater than 90 to 95%) and data accuracy (greater than 96 to 98%).[16,17]

12. Authorship:

In accordance with National Research Collaborative (NRC) authorship guidelines[18], all research outputs from HIPPO will be listed under a single corporate authorship ("NIHR Unit on Global Surgery").

All collaborators will be listed as PubMed-citable collaborators in accordance with the roles defined below (so long as the minimum requirements for authorship are met).

- **Writing Group:** A group of medical students, junior doctors, consultants and external advisory board members responsible for the overall scientific content, data analysis, and preparation of research manuscripts.
- **Steering Committee**: A core group of medical students, junior doctors and consultants who have overall responsibility for protocol design, project coordination, and data handling.

- **Statistical Analysis**: A small team of dedicated statisticians who take overall responsibility for the statistical analysis plan and quality assurance of data analysis
- **National Leads**: A network of surgeons and anaesthetists established with previous GlobalSurg and CovidSurg studies. They are responsible for national coordination of the study, acting as a link between mini-teams / hospital leads, and the steering committee. Requirements for authorship on HIPPO outputs include:
    - Active engagement with dissemination of HIPPO and other NIHR Unit on Global Surgery Collaborative activities at their country.
    - Effective and responsive communication with the steering committee, and with local collaborators throughout their time as Regional Leads.
    - Recruitment of centres.
    - Representation of NIHR Unit on Global Surgery Collaborative at regional educational and research meetings.
- **Local (Hospital) Leads**: A single lead point of contact for data collection at each site who has overall responsibility for site governance registration and coordinating handover between local collaborator teams. Local Leads should be prospectively identified by Regional Leads (although remain an optional role), and these are recommended to be the junior doctor or a senior medical student within the mini-team, and only one person can fulfil this role. Minimum requirements for authorship on HIPPO outputs include:
    - Primary person responsible in obtaining local approvals for conduct of the HIPPO audit (e.g. registration of the audit, seeking Caldicott guardian permission to upload data to REDCap, submit the protocol to Ethics Commission where applicable).
    - Active involvement in a mini-team during a data collection period at the centre which meets the criteria for inclusion within the HIPPO dataset.
    - Co-ordination of handover between all local collaborator teams at the centre, and involvement in local dissemination of HIPPO.
    - Presentation of local results at their centre from the HIPPO audit (or otherwise arranges another collaborator to present on their behalf).
- **Local Collaborators (Data Collectors)**: A team of up to 5 people responsible for data collection per specialty group over a specific 4-week period at a particular centre. This should ideally be formed by an heterogeneous group with different levels of clinical training (e.g. medical students, trainees, consultants). Minimum requirements for authorship on HIPPO outputs include:

- Compliance with local audit approval processes and data governance policies.
- Active involvement in data collection over at least one data collection period at a centre which meets the criteria for inclusion within the HIPPO dataset (below).
- While assistance with other teams is encouraged, collaborator status will only be assessed based on successful completion of the allocated period.
- Collaboration with the regional / local lead to ensure that the audit results are reported back to the audit office / clinical teams.

Criteria for centre inclusion within HIPPO:

- Obtain all appropriate local approvals for conduct of the HIPPO audit.
- Successful completion of at least one data collection period at the centre (with a minimum of one eligible patient per period included). Individual data collection periods will only be included when:
  i. >95% data completeness has been achieved.
  ii. All data for the period has been uploaded within the specified deadlines.

Please note if these criteria are not met, then the contributing mini-team and/or the centre may be removed from the dataset and authorship list (please get in contact as soon as potential issues arise so we can support as many centres to be included as possible).

Appendix A: Summary of data fields (CRF)

Pre-operative Data Fields	Required data (definition / comment)
1. Patient age	**Years (months if < 1y)**
2. Patient sex	**Male / Female**
3. Height	**(cm)**
4. Weight	**(kg)**
5. Gestational age Branching logic if the patient is a child (<16y)	**(weeks)**
6. Patient ASA grade	**Grade I / Grade II / Grade III / Grade IV / Grade V**
7. Smoking status	**Never smoked / Current smoker or Ex-smoker (<6 weeks ago) / Ex-smoker (>6 weeks ago)**
8. Clinical Frailty scale*	**1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9**
9. Co-morbidities	**Ischemic heart disease / Congestive heart failure / Cerebrovascular disease / Chronic kidney disease / Diabetes Mellitus** (NIDDM / IDDM)
10. Did the patient have a test for SARS-CoV-2 in the 72h before surgery?	**Yes** (PCR / Lateral flow) / **No**
11. Did the patient have any symptoms related to inguinal hernia before surgery?	**Yes** (e.g., pain, heaviness, dull discomfort, dragging sensation) **/ No**
12. Time since first symptoms Branching logic if the patient had symptoms	**mm**
13. Date of diagnosis	**Dd / mm / yyyy / At birth (neonate 28d) / Infant (up to 1 year)**
14. Date of decision for surgery	**Dd / mm / yyyy**
15. Date of operation	**Dd/ mm / yyyy**
16. Was the patient able to do daily activities while waiting for surgery (work, school, or family duties)?	**Yes (completely) / Some, but not all / No, not at all**
17. Site of hernia	**Left / Right / Bilateral**
18. Size of inguinal hernia *Referring to the biggest one if bilateral*	**Limited to inguinal region / Limited to scrotum / Extend to mid-thigh / Extend to knee or beyond**
19. Indication for surgery	**Symptomatic / Incarcerated / Obstruction / Strangulated**

Intra-operative Data Fields	Required data (definition / comment)
1. Urgency of surgery	**Elective / Emergency** *If emergency: Was the patient already on the elective waiting list for surgery?* (Yes / No)
2. Mode of Anaesthesia *This refers to the main anaesthetic used during the operation and not as induction agents*	**Local / Regional** (spine-related / regional nerve block) **/ Sedation** (e.g., midazolam) **/ General Inhaled** (sevoflurane / halothane / desflurane / N_20 / isoflurane) **/ TIVA**
3. Was the anaesthesia given by the professional who repaired the hernia?	**Yes** (e.g., surgeon) **/ No** (anaesthetist / anaesthetic nurse / technician)
4. Was the WHO checklist used?	**Yes** / **No**
5. Prophylactic antibiotic	**Yes / No**
6. Primary Operator	**Senior surgeon** (Consultant or Attending) / **Trainee surgeon** / **Non-surgeon** (medical practitioners / non-medical practitioners) *If selected any:*

	- - How many inguinal hernias were performed prior to this? (0-50 / 51-100 / 101-200 / >201) *If selected senior surgeon:* *-What was the speciality? (general surgeon / urology / paediatric surgeon / other)*
7. Operative approach	**Open** (performed exclusively using instruments inserted in to the abdomen through a surgical incision in the groin area). **Laparoscopic** (performed exclusively using instruments inserted in to the abdomen through ports) **Laparoscopic converted to open** (surgery planned to be performed laparoscopically but for unforeseen reasons the decision was made to change to an open approach). **Robotic** (robot-assisted surgery with no conversion to either laparoscopic or open approaches). **Robotic converted to open** (surgery planned to be performed robotically but for unforeseen reasons the decision was made to change to an open approach).
8. Size of inguinal hernia	**Up to 1.5cm / Up to 3cm / >3cm / Not known**
9. Bowel resection	**Yes / No**
10. Type of hernia repair	**Primary herniotomy / Mesh** (Lichenstein / Transinguinal pre-peritoneal (TIPP) / Trans rectal pre-peritoneal (TREPP) / plug and patch / PHS (bilayer) / other) **/ Non-mesh** (Desarda / Bassini / Shouldice, other) **/ MIS** (TAPP / TEP / SILS)
11. **Mesh used**	**Yes / No** *If mesh used:* *- Country of manufacture: (Longlist, unknown)* *- Was the excess mesh re-sterilised and re-used? Yes /No* *- Type: Permanent synthetic / Absorbable synthetic / Biological / Composite* *- Suture used to fix the mesh to inguinal ligament: absorbable / non-absorbable / not fixed / glue (fibrin / histo-acryl) / tackers*
12. Operative contamination	**Clean** (Gastrointestinal (GI) and genitourinary (GU) tract not entered). **Clean-Contaminated** (GI or GU tracts entered but no gross contamination). **Contaminated** (GI or GU tracts entered with gross spillage or major break in sterile technique). **Dirty** (There is already contamination prior to operation, e.g. faeces or bile).
13. Were reusable gowns used in this procedure?	**Yes** (All scrubbed staff/ some scrubbed staff) **/ No**
14. Were reusable drapes used in this procedure?	**Yes / No**
15. Was recycling of waste performed?	**Yes, paper / Yes plastic / Yes glass / No**

Post-operative Data Fields	**Required data (definition / comment)**
1. 30-day follow-up	**Yes** (Telephone / In-person) **/ No**
2. 30-day surgical site infection	**Yes** (No readmission within 30-days / readmission within 30-days) / **No**
3. 30-day Reoperation	**Yes** (early recurrence, bleeding, injury to the vas deferens, other**) / No**
4. Post-operative length of stay	**Same day discharge** **Admitted** (If admitted, **Number** of days inpatient, considering day after surgery as day 1 to day of discharge. If the patient has not been discharged prior to the end of 30-day follow-up, enter '31').)
5. Overall Clavien-Dindo complication	**None / Grade I / Grade II / Grade IIIa / Grade IIIb / Grade IVa / Grade IVb / Grade V**

Appendix B: Definitions

A. Surgical site infections

Surgical site infection is defined at 30 days post-surgery using the Centers for Disease Control (CDC) definition of deep incisional or superficial incisional SSI as follows

1. The infection must occur within 30 days of the index operation
2. The infection must involve the skin, subcutaneous, muscular, or fascial layers of the incision
3. The patient must have at least one of the following: purulent drainage from the wound; organisms detected by wound swab; diagnosed clinically or at imaging; wound opened spontaneously or by a clinician
4. The patient has at least one of the following: pain, tenderness, localized swelling, redness, heat at the wound site, systemic fever (>38°C).

B. Clavien-Dindo Complications

Adverse post-operative events may be classified in different ways:

- **Failure of treatment** - This occurs when the original surgery fails to achieve its intended benefits; for example, persistent pain following laparoscopic cholecystectomy or tumour recurrence following cancer surgery.
- **Sequelae**: The recognised consequences of a given procedure; for example, gut malabsorption following a large small bowel resection or immune deficiency following splenectomy.
- **Complication**: Any deviation from the normal post-operative course that has an adverse effect on the patient and is not either a treatment failure or sequel.

In the Clavien-Dindo classification [35], the factor determining the severity of a complication is the treatment required. Consequently, a given complication may be graded differently depending on how it has been managed. For example, an anastomotic leak may be managed just with antibiotics if it is contained (grade II) or it may require re-operation under anaesthetic (grade IIIb).

Some other considerations:

- Intra-operative complications are not considered unless they have an adverse effect on the patient post-operatively. The only exception to this is intra-operative death; this is classified as grade V.
- All post-operative adverse events are included, even when there is no direct relationship to the surgery.
- All adverse events within the follow-up period (30 days) are included, even after following discharge.
- Diagnostic procedures are not included. For example, a diagnostic oesophagoduodenoscopy (OGD) to look for a source of bleeding without any intervention would not be considered a complication, but a therapeutic OGD with clipping of a bleeding vessel would be considered a grade IIIa complication. Since negative exploratory laparotomies are considered diagnostic procedures, they should not be recorded as complications.

Grade	Definition (examples listed in italics)
I	Any deviation from the normal postoperative course without the need for pharmacological (other than “allowed

	therapeutic regimens"), surgical, endoscopic or radiological intervention. Allowed therapeutic regimens are: selected drugs (antiemetics, antipyretics, analgesics, diuretics and electrolyte replacement), physiotherapy and wound infections opened at the bedside but not treated with antibiotics. ***Examples**: Ileus (deviation from the norm); hypokalaemia treated with K; nausea treated with cyclizine; acute kidney injury treated with intravenous fluids.*
II	Requiring pharmacological treatment with drugs beyond those allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included. ***Examples**: Surgical site infection treated with antibiotics; myocardial infarction treated medically; deep venous thrombosis treated with enoxaparin; pneumonia or urinary tract infection treated with antibiotics; blood transfusion for anaemia.*
IIIa	Requiring surgical, endoscopic or radiological intervention, not under general Anaesthetic (GA). ***Examples**: Therapeutic endoscopic therapy (do not include diagnostic procedures); interventional radiology procedures.*
IIIb	Requiring surgical, endoscopic or radiological intervention, under GA. ***Examples**: Return to theatre for any reason.*
IVa	Life-threatening complications requiring critical care management with single organ dysfunction, or neurological complications including brain haemorrhage and ischemic stroke (excluding TIA). ***Examples**: Single organ dysfunction requiring critical care management, e.g. pneumonia with ventilator support, renal failure with filtration; SAH; stroke*
IVb	Life-threatening complications requiring critical care management with multi-organ dysfunction.

C. Clinical Frailty Score

Clinical Frailty Scale

1 Very Fit – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.

2 Well – People who have no active disease symptoms but are less fit than category 1. Often, they exercise or are very active occasionally, e.g. seasonally.

3 Managing Well – People whose medical problems are well controlled, but are not regularly active beyond routine walking.

4 Vulnerable – While not dependent on others for daily help, often symptoms limit activities. A common complaint is being "slowed up", and/or being tired during the day.

5 Mildly Frail – These people often have more evident slowing, and need help in high order IADLs (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.

6 Moderately Frail – People need help with all outside activities and with keeping house. Inside, they often have problems with stairs and need help with bathing and might need minimal assistance (cuing, standby) with dressing.

7 Severely Frail – Completely dependent for personal care, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).

8 Very Severely Frail – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.

9 Terminally Ill – Approaching the end of life. This category applies to people with a life expectancy <6 months, who are not otherwise evidently frail.

Scoring frailty in people with dementia

The degree of frailty corresponds to the degree of dementia. Common **symptoms in mild dementia** include forgetting the details of a recent event, though still remembering the event itself, repeating the same question/story and social withdrawal.

In **moderate dementia,** recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting.

In **severe dementia,** they cannot do personal care without help.

Appendix C: Steps for successful inclusion of your centre

1. Contact your hospital lead about participation in the HIPPO study to register a mini-team.

2. Form a mini-team of up to five collaborators, that can either be medical students, junior doctors, trainees or consultants.

3. Each team can cover as many periods as they want to, working together to deliver 30-day follow-up. Discuss with your regional lead to establish a 28-day consecutive data collection period from below to suit your availability:

    - Period 1: 00:00 30th Jan 2023 - 23:59 26th Feb 2023 (+ 30 Day Follow-up)
    - Period 2: 00:00 27th Feb 2023 - 23:59 26th Mar 2023 (+ 30 Day Follow-up)
    - Period 3: 00:00 27th Mar 2023 - 23:59 23th Apr 2023 (+ 30 Day Follow-up)

4. Ensure that you secure formal audit approval from your hospital's clinical audit department prior to commencing data collection. This may seem daunting at first but is in fact quite straight forward. Every hospital has an audit department and it is a simple case of approaching them with the information we have prepared in this protocol and applying this to the local audit registration form. You will need a local consultant to support you and sign the hospital's audit form (this should be the same consultant which is supervising the mini-teams). Ensure that the audit department knows that this is part of a national project and that you will enter data on REDCap.

*It is essential that you begin this process **immediately**; approval can take up to a month or more. You may have to contact or even visit the hospital before your placement starts to ensure that you will be ready. If you have any difficulties contact your hospital lead, national lead or the steering committee.*

5. Contact your hospital's Caldicott Guardian (often the medical director - the audit department can help you find out who this is) to request permission to submit data to REDCap. You need additional permission from the Caldicott Guardian to store any patient numbers on REDCap.

6. Agree with your audit office and Caldicott Guardian on how you will facilitate 30-day follow-

up. You will require the hospital number for each patient to undertake follow-up, and so this needs to be stored in a safe and secure manner until accessed for 30-day follow-up, in line with local and national data governance guidance. This can be within the hospital site (paper or computer), or on REDCap (if permission from the Caldicott Guardian has been obtained).

7. Once the audit is registered and you have Caldicott Guardian approval, please forward evidence of this to your regional lead. REDCap accounts will not be issued until proof of audit registration AND Caldicott approval has been received.

8. Arrange to meet with the other members of your mini-team, including the junior doctor and, if possible, supervising consultant. If possible, it is also highly recommended to meet with the preceding mini-team at your centre:
    - They will have a lot of helpful advice regarding what worked well. In your mini-team, agree in advance who will be responsible for each stage of the project (e.g. identifying patients, collecting baseline data, completing follow-up, data entry to REDCap).
    - Talk through how you will identify patients and collect required data.

9. Identify all patients fitting the inclusion criteria within your specified four-week window. Contact your regional lead with any questions or issues that may arise over your data collection period.

10. Regularly follow-up for information on complications over the 30-day post-operative period. This study is prospective, so you should not wait until the end of the post-operative period to follow-up patients (this would be retrospective). Discuss the best way to follow up patients with the hospital lead, because this might vary from centre to centre.

Be proactive in identifying post-operative adverse events, as this will prevent under-estimation of true complication rates. Remember that in this audit no changes to normal patient follow-up should be made.

Strategies for identifying complications in the follow-up period include:

- *Regularly reviewing patient notes to identify in-hospital complications.*
- *Reviewing clinic notes and clinic letters, if seen in clinic by 30 days.*

- *Checking electronic systems and handover lists for re-admissions.*
- *Checking for A&E re-attendances.*

If case notes are reviewed shortly prior to discharge they do not be need to be requested/retrieved again for follow-up at 30-days, but do check electronic records for discharge letters, clinic letters, re-admissions.

11. Ensure all data has been uploaded to the REDCap system by the data collection deadline, and you have completed all fields, avoiding missing data points. If more than 5% of patients at your centre have missing data, your centre cannot be included in the HIPPO dataset and your name will be withdrawn from the author list.

12. It is a condition of participation in HIPPO that following completion of the audit at your centre you must ensure that your local results are presented to your hospital's surgical department and/or reported back to the audit department. You may also like to return to present again at a later date, when the final national results of HIPPO become available

Appendix D: References

1. GlobalSurg Collaborative. Mortality of emergency abdominal surgery in high-, middle- and low-income countries. *Br J Surg* 2016; **103**: 971– 988.
2. GlobalSurg Collaborative. Surgical site infection after gastrointestinal surgery in high-income, middle-income, and low-income countries: a prospective, international, multicentre cohort study. *Lancet Infect Dis* 2018; **18**: 516– 525.
3. COVIDSurg Collaborative. Elective surgery cancellations due to the COVID-19 pandemic: global predictive modelling to inform surgical recovery plans. Br J Surg. 2020 Oct;107(11):1440-1449.
4. COVIDSurg Collaborative. Resilience of elective cancer surgery systems during COVID-19 lockdowns: an international, multicentre, prospective cohort study. *Lancet* 2021; 398(Suppl 2): S11
5. Bhangu A, Frankling C, Glasbey JC et al. Net zero surgery: proof of concept and uncertainties. *The Bulletin*. 2022 Oct: 104, 7
6. Nepogodiev D, Acharya R, Chaudhry D, et al. Forecasting waiting lists for elective procedures and surgery in England: a modelling study. medRXiv. 2022.
7. Report by the Comptroller and Auditor General. NHS waiting times for elective and cancer treatment. 22 March 2019.
8. Gomez D, Nantais J, Telesnicki T, de Mestral C, Wilton AS, Stukel TA, Urbach DR, Baxter NN. A Population-based Analysis of the COVID-19 Generated Surgical Backlog and Associated Emergency Department Presentations for Inguinal Hernias and Gallstone Disease. Ann Surg. 2022 May 1;275(5):836-841.
9. HerniaSurge Group. International guidelines for groin hernia management. Hernia. 2018 Feb;22(1):1-165.
10. Beard JH, Ohene-Yeboah M, Tabiri S, Amoako JKA, Abantanga FA, Sims CA, Nordin P, Wladis A, Harris HW, Löfgren J. Outcomes After Inguinal Hernia Repair With Mesh Performed by Medical Doctors and Surgeons in Ghana. JAMA Surg. 2019 Sep 1;154(9):853-859.
11. Schroeder AD, Tubre DJ, Voigt C, Filipi CJ. The State of Surgical Task Sharing for Inguinal Hernia Repair in Limited-Resource Countries. World J Surg. 2020 Jun;44(6):1719-1726.
12. Guidance on the use of laparoscopic surgery for inguinal hernia (Technology Appraisal Guidance no.18), National Institute for Clinical Excellence, January 2001).
13. Harris PA, Taylor R, Minor BL, et al. The REDCap consortium: Building an international community of software platform partners. *J Biomed Inform*. Jul 2019;95:103208. doi:10.1016/j.jbi.2019.103208
14. Harris P, Taylor R, Thielke R, Payne J, Gonzalez N, Conde NJ. Research electronic data capture (REDCap) – A metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform*. 2009;42(2):377-81.
15. GlobalSurg-CovidSurg Collaborative. Timing of surgery following SARS-CoV-2 infection: an international prospective cohort study. Anaesthesia 2021; 76: 731–5.
16. Collaborative S. Impact of postoperative non-steroidal anti-inflammatory drugs on adverse events after gastrointestinal surgery. *Br J Surg*. Oct 2014;101(11):1413-23. doi:10.1002/bjs.9614
17. Collaborative S. Prognostic model to predict postoperative acute kidney injury in patients undergoing major gastrointestinal surgery based on a national prospective observational cohort study. Original Article. *BJS Open*. 27/07/2018 2018.
18. National Research Collaborative & Association of Surgeons in Training Collaborative Consensus Group. Recognising contributions to work in research collaboratives: Guidelines for standardising reporting of authorship in collaborative research. *Int J Surg*. 2017;52:355-360. doi:10.1016/j.ijsu.2017.12.019