



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



A global prospective cohort study on inguinal hernia surgery

### Study Protocol

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## Project Timeline

Dates	Description
<b>10<sup>th</sup> November 2022</b>	Online launch of HIPPO Protocol
<b>End of November 2022</b>	Virtual conference for HIPPO Study Launch
<b>30<sup>th</sup> January – 21<sup>st</sup> May 2023</b>	Data collection window, any 4-week period available
<b>30<sup>th</sup> January - 26<sup>th</sup> February 2023</b>	Period 1
<b>27<sup>th</sup> February - 26<sup>th</sup> March 2023</b>	Period 2
<b>27<sup>th</sup> March - 23<sup>th</sup> April 2023</b>	Period 3
<b>24<sup>th</sup> April - 21<sup>st</sup> May 2023</b>	Period 4
<b>21<sup>th</sup> June 2023</b>	Final date of follow-up for NIHR Unit on Global Surgery to request sites to submit data
<b>15<sup>th</sup> July 2023</b>	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<sup>1,2</sup>. COVIDSurg identified that elective capacity, training, and environmental sustainability are priority issues for the immediate future<sup>3-5</sup>. 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. In Australia, Amanda Dawson will perform the role of National Lead. 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<sup>3</sup>. 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),<sup>6</sup> although the recommended expected waiting time should not exceed 18 weeks<sup>7</sup>. It is likely that other countries face the same problem, although such granular data does not exist.<sup>8</sup> 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,<sup>9</sup> 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<sup>10,11</sup>. 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<sup>5</sup>. 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<sup>7</sup>

- **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<sup>9</sup>

**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<sup>9</sup>

**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<sup>9</sup>:

**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.

## 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 impact of waiting times in 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 30<sup>th</sup> January 2023 to 21<sup>st</sup> 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 30<sup>th</sup> Jan 2023 - 23:59 26<sup>th</sup> Feb 2023 (+ 30 Day Follow-up)
  - Period 2: 00:00 27<sup>th</sup> Feb 2023 - 23:59 26<sup>th</sup> Mar 2023 (+ 30 Day Follow-up)
  - Period 3: 00:00 27<sup>th</sup> Mar 2023 - 23:59 23<sup>th</sup> Apr 2023 (+ 30 Day Follow-up)
  - Period 4: 00:00 24<sup>th</sup> April 2023 - 23:59 21<sup>st</sup> 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.

## 6. Patient identification:

*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 to avoid selection bias.*

*Strategies to identify consecutive eligible patients could include:*

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

## 7. 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 the Data Summary Document, and on the REDCap database.

## 8. Outcome Measures and Follow-up:

### Primary outcome measure:

Compliance to audit standards described

### Secondary outcome measures: (see [Appendix A:](#))

- 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.

## 9. Data collection processes and governance:

This project will involve the formation of mini-teams of 1 – 5 collaborators. Mini-teams will include a specialist consultant at each site. These teams will prospectively collect data in up to 4 continuous 28-day periods on all eligible patients undergoing inguinal hernia surgery. To ensure data is collected on all consecutive eligible patients these teams will review elective theatre lists, handover sheets/emergency admission and ward lists, and theatre logbooks (both elective and emergency) on a daily basis.

Following the identification of an eligible patient undergoing inguinal hernia surgery within a study data collection time period, the patient will be added to a Patient Identification Log. This log will be a way to link the patient Medical Record Number (MRN) with the study Research Electronic Data Capture (REDCap) Database to facilitate data entry and missing data requests. This is a site-specific document, that will include the patient MRN and a unique REDCap ID (only). The hardcopy Patient Identification Log must be stored in a secure location at each site. The patient identification log will not be uploaded or transferred electronically or provided to any member of the research team outside of each hospital site.

All study data (as outlined in the Data Summary Document) will be recorded directly into the REDCap study database and will not be recorded in paper format. All data recorded in the

REDCap database will be de-identified, with all direct and indirect identifiers irrevocably removed by each site, with no way to re-identify the data by the NIHR Unit on Global Surgery.

The Principal Investigator at each site must ensure that the study team observe local data governance and national privacy regulations. A start-up meeting will be conducted in Australia prior to the collection of study data to overview the protocol, local procedures, and Australian data privacy regulations.

Since the HIPPO study is a prospective study, the study team will be required to continue to review the medical record of each participant for a period of 30 days following the date of surgery. Individual sites will create their own system to manage this process that is best suited to their site and team requirements. The process will be facilitated by The Patient Identification Log. This log will be confidentially destroyed by each participating site immediately following the completion of the data collection phase of the study (15<sup>th</sup> July, 2023).

De-identified study data will be collected and stored online through a secure server running the Research Electronic Data Capture (REDCap) web application,<sup>13,14</sup> allowing safe anonymised data storage by collaborators internationally. 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. These include appropriate best practices such as network firewalls, system and security monitoring and two factor authentication. REDCap access privileges will be managed and maintained by the NIHR Unit on Global Surgery to ensure that users can only access data relevant to their site. That is, each site user will only have access to their site's data.

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.

All study data will be collected through patient information systems including accessing both written and electronic hospital records. These records will include patient charts, medication charts, investigation results, theatre notes, discharge summaries, relevant letters from outpatient clinics and surgeons' rooms. Refer to the Data Summary Document for details of all de-identified datafields to be entered in the REDCap Database.



**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 study documents should be destroyed as confidential waste within the site at the completion of the study, or according to the local governance requirements. Data collected during the HIPPO study can be used for future analyses at the Study Management Group's discretion.

#### **10. 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<sup>15</sup>, 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.

## 11. Local Project Registration:

This project may be registered as clinical audit or service evaluation. Alternatively, it may be necessary to obtain formal ethical approval. In Australia, a National Mutual Acceptance Ethics Application will be submitted by the national lead. It is the responsibility of the local mini team at each site to ensure that the study is authorised appropriately by the site's Research and Governance Office (RGO), 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.<sup>14</sup> 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.** In Australia, no data should be uploaded to REDCap prior to written local governance authorisation. No patient identifiable information (e.g. NHS numbers) will be uploaded or stored on the REDCap database. All data should be handled in accordance with national and local data governance policies.

## 12. Quality assurance:

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

**Patient and Public Involvement:** The relevance of these research topics to patients were discussed with the NIHR Global Surgery 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 specialist consultant 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%).<sup>16,17</sup>

### 13. Authorship:

In accordance with National Research Collaborative (NRC) authorship guidelines<sup>18</sup>, 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 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. A responsibility of the local (hospital lead) is to ensure that each mini-team is assigned a specialist consultant as supervisor.

Minimum requirements for authorship on HIPPO outputs include:

- Primary person responsible in obtaining local approvals for conduct of the HIPPO audit (e.g. obtaining local governance authorisation, adding the site to the HREC approval).
  - 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).
- **Supervising Specialist Consultant:** A supervising specialist consultant will be assigned for each mini team. The responsibilities of this role are to ensure that local guidelines are adhered to by all members of the mini-team and to ensure that any incidental findings made during the course of the data collection process are communicated to the treating inguinal hernia surgeon, according to local hospital policy.

- **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 a 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: 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 ( $>38^{\circ}\text{C}$ ).

## 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 <sup>35</sup>, 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	<p>Any deviation from the normal postoperative course without the need for pharmacological (other than "allowed therapeutic regimens"), surgical, endoscopic or radiological intervention.</p> <p>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.</p> <p><b><i>Examples:</i></b> <i>Ileus (deviation from the norm); hypokalaemia treated with K; nausea treated with cyclizine; acute kidney injury treated with intravenous fluids.</i></p>
II	<p>Requiring pharmacological treatment with drugs beyond those allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.</p> <p><b><i>Examples:</i></b> <i>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.</i></p>
IIIa	<p>Requiring surgical, endoscopic or radiological intervention, not under general Anaesthetic (GA).</p> <p><b><i>Examples:</i></b> <i>Therapeutic endoscopic therapy (do not include diagnostic procedures); interventional radiology procedures.</i></p>
IIIb	<p>Requiring surgical, endoscopic or radiological intervention, under GA.</p> <p><b><i>Examples:</i></b> <i>Return to theatre for any reason.</i></p>
IVa	<p>Life-threatening complications requiring critical care management with single organ dysfunction, or neurological complications including brain haemorrhage and ischemic stroke (excluding TIA).</p> <p><b><i>Examples:</i></b> <i>Single organ dysfunction requiring critical care management, e.g. pneumonia with ventilator support, renal failure with filtration; SAH; stroke</i></p>
IVb	<p>Life-threatening complications requiring critical care management with multi-organ dysfunction.</p>

## 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.



**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).



**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.



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



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



**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.



**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.

#### 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 B: 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 30<sup>th</sup> Jan 2023 - 23:59 26<sup>th</sup> Feb 2023 (+ 30 Day Follow-up)
  - Period 2: 00:00 27<sup>th</sup> Feb 2023 - 23:59 26<sup>th</sup> Mar 2023 (+ 30 Day Follow-up)
  - Period 3: 00:00 27<sup>th</sup> Mar 2023 - 23:59 23<sup>th</sup> Apr 2023 (+ 30 Day Follow-up)
  - Period 4: 00:00 24<sup>th</sup> April 2023 - 23:59 21<sup>st</sup> May 2023 (+ 30 Day Follow-up)
4. Ensure that you secure authorisation from your hospital's Research Governance Office (RGO) prior to commencing data collection. This may seem daunting at first but is in fact quite straight forward. Every hospital has a RGO and it is a simple case of approaching them with the information we have prepared in this protocol and applying for authorisation . You will need a local consultant to support you and sign the application 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 RGO to request permission to submit data to REDCap.
6. Agree with your RGO 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.

7. Once the study is authorised and you have Human Research Ethics Approval (HREC), please forward evidence of this to your regional lead. REDCap accounts will not be issued until proof of RGO authorisation AND HREC 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 C: References

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