Human Research Ethics Application

Application Management Information
Application ID: 2023/ETH01055
Created date: 17/05/2023
Originating Application ID:
**This is the earliest application from which this application (2023/ETH01055) was copied.*
Parent Application ID:
**This is the immediate predecessor from which this application (2023/ETH01055) was copied.*
Version Number: 1
Application submitted to: Hunter New England Local Health District; Hunter New England Human Research Ethics Committee.

The applicant has requested that this ethics application be considered under the Greater than low risk review pathway.

Section 1 – Core Information

Pre-application conditions

The applicant/s have acknowledged that:

1. The HREA has been designed for ethics review of human research, as defined in the National Statement.
2. Adequate resources must be available to conduct this research project.
3. All relevant institutional polices pertaining to the conduct of this research project should be considered and adhered to.
4. Research activities must not commence until ethics approval (and site authorisation, if appropriate) has been provided.

Project Overview

Q1.1 Project Title:

Global Evaluation of Cholecystectomy Knowledge and Outcomes (GECKO)

Q1.2 Summary of the research project:

GECKO is a prospective multi-site international observational study on emergency and elective cholecystectomies. Coordinated by the NIHR Unit on Global Surgery, who delivered the HIPPO and COVIDSurg studies (2019-2023), it will involve similar data collection in over 90 countries with a trainee-led collaborative model. COVIDsurg and our patient engagement team confirmed elective capacity and training as priorities.
Cholecystectomy is performed for a range of gallstone pathologies and is a common operation globally. GECKO will allow contemporaneous snapshot audit of real world practice
The Primary Aim of this study is to define the global variation in compliance to pre-, intra-, and postoperative audit standards.
Secondary Aims will evaluate the complex interaction of factors which define safe cholecystectomy and patient care.
- surgical technique

- adverse outcomes
- unsuspected gallbladder cancer
- training variations
- environmental sustainable measures

There will be eight data collection periods (14 days plus 30 day and 1 year follow up)

Q1.3 Which category/ies of research best describes the project?

Clinical Sciences - 1103, Other Medical and Health Sciences - 1199, Public Health and Health Services - 1117

Q1.4 In what environments will the research be conducted?

Hospital(s)

Q1.5 What organisation/entity has overall responsibility for this project?

Sponsor type: Collaborative group
Sponsor name: The NIHR Global Health Research Unit on Global Surgery in conjunction with the Surgical Trainee Organisation for Research Central Coast

Q1.6 Describe how this research project is currently, or will be, funded.

No funding required
Human volunteer resources
in kind support

Q1.7 Anticipated starting date of the research project:

As soon as ethics and any other relevant approvals have been provided.

Q1.8 Anticipated duration of the research project:

18 Months

Disclosure of interests

Q1.10 Do any members of the research team (including persons not listed in this application), have any financial or non-financial interests related to this research?

No

Restrictions

Q1.11 Are there any restrictions or limits on publication of data or dissemination of research outcomes of this project?

No

Evaluations

Q1.12 Has the scientific or academic merit of the research project been evaluated?

No

Q1.13 Has this research project had prior ethics review?

No

Q1.14 Will any further or additional specialised review of this application be sought?

No

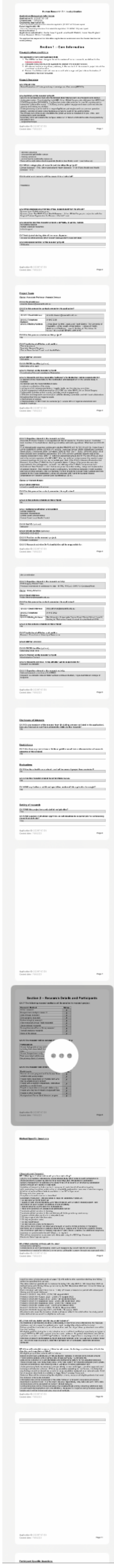
Setting of research

Q1.15 Will this project be conducted at multiple sites?

Yes

Q1.16 Will separate institutional approvals or authorisations be required prior to commencing research at each site?

Yes



Section 2 – Research Details and Participants

Q1.17 The following research methods will be used in the research project:

Research Method	Status
Action research	✗
Biospecimen analysis research	✗
Data linkage research	✗
Ethnographic research	✗
Epidemiological research	✗
Interventional/Clinical Trials research	✗
Observational research	✓
Survey/Interview/Focus Group research	✗
Textual analysis research	✗
None of the above	✗

Q1.18 The research will be conducted with the following:

Participation	Status
Human beings (via active participation), including their associated biospecimens and/or data.	✓
Human biospecimens only	✗
Data associated with human beings only (i.e. as the primary object of research)	✗

Q1.19 The research will involve the following participants:

Participants	Status
Women who are pregnant and the human fetus	✗
Children and young people	✗
People highly dependent on medical care who may be unable to give consent	✗
People with a cognitive impairment, intellectual disability or mental illness	✗
People in dependent or unequal relationships	✗
People who may be involved in illegal activities	✗
People in other countries	✗
Aboriginal and Torres Strait Islander peoples	✗

Method Specific Questions

Observational Research

M7.1 What type of observation will you be conducting?

GECKO is a multisite international observational study which aims to audit compliance to cholecystectomy surgery guidelines for preoperative and intraoperative gallbladder surgery management for patients who present for either elective or emergency gallbladder surgery through any operative approach.
Variables of interest include standard demographic and clinical information together with evaluating the global uptake of environmentally sustainable measures in elective surgery.
A full list of required data fields is available in the GECKO protocol.
Primary outcome measure:
Compliance to audit standards described
Secondary measures: (protocol page 8, page 18, appendix A page 25)
? 30 day and 12 month follow up
? quality of safe cholecystectomy with rates of critical view of safety cholangiogram and conversion to open surgery or subtotal cholecystectomy
? assess adverse events and their management
? rates and outcomes of unsuspected gallbladder cancer
? evaluate global variation in training
? evaluate global variation in the availabllaity of cholecystectomy services up
? assess sustainable practice in cholecystectomy
? 30 day surgical site infection rates
? 30 day reoperation rates
? 30 day readmission
? 30 day Clavien-Dindo complications
This will be done through an observational audit of routine clinical practice of managing and follow up of consecutive patients presenting to hospital and meeting the eligibility criteria.
The information gathered is routinely captured in daily clinical practice. No additional telephone, in-person or questionnaire-based follow-up is required.
This will be recorded on a purpose build database using the REDCap (Research Electronic Data Capture) system.

M7.2 What sampling strategy will you use?

Convenience sampling
Collaborators at each participating centre will prospectively collect data for all patients presenting to hospital for elective or emergency gallbladder surgery through any approach who

meet the entry criteria (see protocol page 12) with knife to skin. operation starting time falling within the specified time periods.
The data collection periods will be between Monday 31st July 2023 to 19th November 2023 as

Collaborators at each participating centre will prospectively collect data for all patients presenting to hospital for elective or emergency gallbladder surgery through any approach who

meet the entry criteria (see protocol page 12) with knife to skin. operation starting time falling within the specified time periods.
The data collection periods will be between Monday 31st July 2023 to 19th November 2023 as defined below with 30 day follow up concluding by 19th December 2023 and 12 month follow up by 19th December 2024.
Each mini-team will collect data over a 14 day, (2 weeks) consecutive period with subsequent 30-day and 12 month follow-up:
Period 1: 00:00 31 July 2023 - 23:59 13th August 2023
Period 2: 00:00 14th August 2023 - 23:59 27th August 2023
Period 3: 00:00 28th August 2023 - 23:59 10th September2023
Period 4: 00:00 11th September 2023 - 23:59 24th September 2023
Period 5: 00:00 25th September 2023 - 23:59 8th IOctober 2023
Period 6: 00:00 9th October 2023 - 23:59 22nd October 2023
Period 7: 00:00 23rd October 2023 - 23:59 5th November 2023
Period 8: 00:00 6th November 2023 - 23:59 19th November 2023
All patients who meet the inclusion criteria and are admitted to hospital within the study period dates defined above would be eligible for inclusion.

M7.3 How will you match and follow up participants?

No matching of participants as data is irrevocably de-identified once entered into the REDCap database, and all prospective patients who meet the eligibility criteria will be included.
Follow up will be conducted as part of the routine post discharge follow up standard care within the clinic setting.
All eligible patients during the study inclusion periods will be identified prospectively and given a unique ?REDCap ID? when entered into the study database. No patient identifiable data will be uploaded or stored on the REDCap Database. Local site hospital leads may keep a local cross-reference of patient identification numbers (hospital numbers) and REDCap IDs to enable follow up. This will be kept in a secure, encrypted spreadsheet on a hospital, password-protected computer.

M7.4 How will potential sources of bias be addressed, including consideration of both the direction and magnitude of bias?

All eligible prospective patients will be included.
Based on previous GlobalSurg-CovidSurg studies, GECKO is anticipated to include around >1000 centres globally with a sample size of approximately 10,000 patients.
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 gallbladder and cholecystectomy 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 Hippo Data Summary Document.
Selection Bias will be minimised by the eligibility criteria, because all eligible patients that meet the inclusion criteria are included
Information bias will be minimised by the data validation and quality assurance processes described in section 9 and 11 of the study protocol. Specifically, only data sets with >95% data completeness will be accepted for pooled national analysis.
Confounding bias will be minimised using statistical methods and by collecting additional data on participant demographics and comorbidities, preoperative diagnosis and procedure-specific details and it will be minimised using statistical methods.

Recruitment Questions

Q2.1.1 Indicate how you will identify and recruit participants for your research, referencing any relevant sections of your Project Description/Protocol as appropriate.

All patients who meet the inclusion criteria and are admitted to hospital for cholecystectomy within the defined study period dates will be included in the GECKO Study.
Inclusion criteria:
Age: adults greater than or including 18 years of age
Procedure: Primary cholecystectomy where this is the main procedure.
Approach: Open, laparoscopic, laparoscopic assisted, laparoscopic converted, robotic, robotic converted procedures, gasless laparoscopy are all eligible. Patients having a cholecystectomy as part of anther procedure are excluded.
Urgency: Patients undergoing planned (elective) surgery or delayed or emergency surgery
Exclusion criteria:
Mirizzi syndrome
Surgeries where cholecystectomy is not the main procedure, but performed including return to theatre
known gallbladder malignancy

All eligible patients during the study inclusion periods will be included prospectively, as identified from daily review of theatre lists, handover lists, new inpatient referrals etc. As this is an observational audit of usual practice, patient consent is not required.
We will include people with disabilities and people from culturally and linguistically diverse backgrounds, although these groups will not be specifically targeted.

Q2.1.2 How will your recruitment strategy take account of the ethical considerations relevant to the specific people you are recruiting?

This is an international audit and no changes to usual practice (including normal patient pathways/ management) will take place. All data collected will measure current practice.

(Observational specific question)
Q2.1.M7.1 How will you distinguish between participants and non-participants in your research, and how will you manage that distinction?

Participants will be identified from lists produced using hospital systems with data collectors encouraged to undertake daily review of relevant theatre lists, handover meetings/sheets and ward lists, theatre logbooks, inpatient referrals to the surgical team, and multidisciplinary team meetings. This will be used to identify participants admitted to hospital and meeting the inclusion criteria. Once identified as being eligible for the GECKO Study, the site data collection team will record the patient on the hardcopy patient identification log (which is stored in a secure location at each site). The only purpose of the log is to manage the data entry process at the site level. The patient identification log will not be uploaded or transferred electronically

(Observational specific question)
Q2.1.M7.2 How will you determine whether it is appropriate to obtain consent from the people whom you are observing?

This audit requires data associated with human beings only, collected prospectively with no active participation from participants.
This study is requesting a waiver of consent, therefore, no formal recording of consent process would be obtained. The participant will not be aware that their data has been reviewed and will not be able to withdraw from the study. Eligible patients will have no change to standard

medical care, no interventions and access to their medical record for the purpose of this study will be limited to the collection of data relevant to this observational study (as outlined in the Study Protocol). All data required for this study will be available in the medical record as standard data recorded during the treatment of the patient. All data collected for this project will be entered into the study database in an irrevocably de-identified format, and reported in an aggregate format.

Consent Questions

Q2.2.1 Indicate by reference the relevant section/s of your Project Description/Protocol that address/es consent.

Page 22 of the protocol identifies that the study is an audit of practice with no requirement for any change to normal patient management. Individual study investigators are responsible for ensuring the correct approvals have been achieved prior to commencing data collection. We consider it is appropriate for this study to have a waiver of consent given its nature as an observational audit which audits routinely collected data which will be de-identified and aggregated.
This study evaluates the process of care particularly within the pre-operative setting and complicance to international guidelines. Duration of symptoms prior to accessing primary care, surgical referral and surgical intervention. These delays are a barometer of a health system in crisis and auditing of this information is beneficial to inform policy makers of strategies to optimise care.
There will be no change to the care that a patient will receive whether they were/were not included in the audit.
Specifically, with regards to the National Statement of Ethical Conduct on Human Research:
a) involvement in the research carries no more than low risk (see paragraphs 2.1.6 and 2.1.7) to participants
This is an international audit and no changes to usual practice (including normal patient pathways/ management) will take place. All data collected will measure current practice. There is no need to contact the patient directly for any information. There will be no change to standard treatment.
b) the benefits from the research justify any risks of harm associated with not seeking consent
This is an observational audit which audits routinely collected data which will be de-identified and aggregated where identifying the scale of the global backlog of gallbladder surgery at a global level that has occurred due to de-prioiritisation of this common operation during the COVID-19 pandemic will inform policy makers on the best strategies to optimise this elective surgical pathway.
c) it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records)
Based on previous GlobalSurg-CovidSurg studies, GECKO is anticipated to include around >1000 centres globally. With recent figures provided by previous GlobalSurg-CovidSurg Week study, a sample of approximately 10,000 patients is anticipated.
d) there is no known or likely reason for thinking that participants would not have consented if they had been asked
GECKO is a national audit, and all data collected will measure current practice, with no changes to normal patient pathways/ treatment.
The relevance of these research topics to patients were discussed with the NIHR Global Surgery Unit Community and Engagement Involvement Team) and a Patient and Public

Involvement lead . 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.
e) there is sufficient protection of their privacy
All data will be irrevocably de-identified, no dates are recorded eg age (years) number of days since diagnosis. refer to the Data Summary Document.
f) there is an adequate plan to protect the confidentiality of data
Data will be collected and stored online via the Research Electronic Data Capture (REDCap) web application, hosted and managed by the NIHR Unit on Global Surgery REDCap system hosted at the University of Birmingham, United Kingdom. No patient identifiable data will be uploaded or stored on the REDCap database.
Specifically:
De-identified study data will be collected and stored online through a secure server running the Research Electronic Data Capture (REDCap)web application, 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 therequirements 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.
A hardcopy patient identification log will be maintained at each site and stored in a secure location. The only purpose of the log is to manage the data entry process at the site level. The patient identification log will not be uploaded or transferred electronically. 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 data by the NIHR Unit on Global Surgery.
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 GECKO study can be used for future analyses at the Study Management Group's discretion.
g)in case the results have significance for the participants? welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media)
At the end of the study, regarding dissemination as the patient data is irrevocably de-identified we will be unable to feed back to individual patients.
However, at a local level, all local research teams will include at least one general surgical trainee/consultant, who will be able to appropriately follow up any secondary or incidental findings noted during the course of the data collection period.
At a hospital level, audit results may be used to inform site-specific reports for service evaluation purposes at the hospital level and with local stakeholders.
However as national lead my responsibilities include dissemination to the media and to present at medical meetings to educate/inform fellow doctors. As an Australian colead for the covidsurg

study my responsibilities included media management/spokesperson. As part of this process we released a press statement via the media team at both the Royal Australasian College of Surgeons and the University of Newcastle. This led to national news coverage in both written press (the Australian), television, channel 9 news and local radio including ABC in Newcastle. In this way I would plan to provide information back to not only the local but also the national community. I?m happy to provide a copy outlining the degree of coverage we received for the previous project. With regards to medical meetings I have already presented to the Royal Australasian College of Surgeons Annual Research Meeting and thus far 30 Australian sites in all states and territories have expressed their interest to participate.
h) the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled Results will be shared at conference presentations and submitted for peer review publication. Research output presented in non-technical language including visual abstracts will be shared on social media and through the NIHR Global Unit on Surgery.
Publications are submitted under an open access policy.

Q2.2.2 Will you be obtaining consent from some or all participants to participate in the research?

Not for any participants

Q2.2.3 Are family members, authorised representatives or any others involved in the participants' decision to participate in the research?

No

Q2.2.4 Will there be an opportunity to confirm or re-negotiate consent during the research project?

No

Q2.2.6 Describe any ethical considerations related to the approach to consent that you will be seeking and your strategies for addressing and managing these issues.

We consider that this study poses negligible risk to participants and the benefits justify any potential risk of harm. This study is a prospective observational audit of usual practice: there will be no changes to usual practice for participants and all data collected is routinely collected data. Data will be de-identified and appropriately stored and analysed to ensure patient confidentiality
using secure systems.

Q2.2.7 Are you proposing to use an opt-out approach with respect to some or all of the participants?

No

Q2.2.8 Are you requesting a waiver of the requirement for consent with respect to some or all participants?

Yes

Yes

Q2.2.8.1 How will you ensure that the research satisfies the guidance for waiving consent as listed in National Statement 2.3.10?

We consider that this study poses negligible risk to participants and the benefits justify any potential risk of harm. This study is a prospective observational audit of usual practice: there will be no changes to usual practice for participants and all data collected is routinely collected data.

Data will be de-identified and appropriately stored and analysed to ensure patient confidentiality using secure systems.

Risk Questions

Q 2.3.1 Describe the risks and burdens associated with your research, referencing any relevant sections of your Project Description as appropriate.

This project is designed to audit international practice and outcomes. As a prospective observational study, this protocol is considered by the investigation team to pose negligible risk to patients. No changes to standard practice will be applied and no patient data beyond routinely collected data will be audited. All data transferred to a central dataset will be irrevocably de-
identified. Although no identifiable data will be transferred centrally, in the process of auditing clinical records data collectors will have access to patient records.

Q 2.3.2 Describe how these risks will be mitigated and managed.

All data collected for this project will be de-identified. All dates are just reported as number of days only (eg days since diagnosis) which means that the data is irrevoccably de-identified. Any data categories that have small sample sizes will not be reported or published to avoid any possible risk of re-identification of patients or clinicians, and no hospital-level sub analyses will be conducted by the NIHR Unit on Global Surgery. Data collectors will be provided with appropriate training on maintaining patient confidentiality, appropriate access of medical records, and comply with site-specific guidelines and regulations. Study supervisors will be available at all times to provide overarching supervision to the project, and provide support and advice to data collectors about ethical conduct. This study may improve service provision in relation to the management of elective and emergency presentations for gallbladder surgery.

Benefit Questions

Benefit Questions

Q2.4.1 Describe the benefits associated with your research, referencing any relevant sections of your Project Description as appropriate.

Patients with various gallstone pathologies such as biliary colic, cholecystitis and gallstone pancreatitis present for both elective and emergency cholecystectomy surgery. Elective surgery was significantly de-prioritised during the pandemic which has resulted in a significant global backlog. Whist waiting for elective surgery there is a risk of acute compications of gallstones which will necessitate emergency surgery.

Compliance to existing international guidelines on the optimal management of cholecystectomy is not clear, especially during the current increase in waiting times secondary to the COVID-19 pandemic. In patients who are fit for surgery, cholecystectomy may be performed as an emergency operation at the index admission, elective surgery with no previous admissions or as a delayed operation following an emergency admission to hospital. The burden on healthcare systems is primarily due to patient readmissions and complications arising from the operation rather than perioperative morbidity or mortality. As a result, surgical societies have shifted their focus towards creating a culture of safety which is a complex process that relies not only on the operation itself, but also factors such as promoting adequate training, improved hospital infrastructure and enhancing peri-operative care. There remains a paucity of evidence around variations of safe provision of cholecystectomy globally and GECKO was designed to allow contemporaneous data collection to bridge this knowledge gap.

Different surgical techniques exist which determine the quality of safe provision of cholecystectomy. The most up-to-date international guidelines recommend laparoscopy with different bail out options for difficult procedures including subtotal cholecystectomy and conversion to open surgery. Obtaining a critical view of safety and a cholangiogram are the gold- standard for preventing bile duct injury. The patient, the gallstone pathology 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. Identification of this practice across the world and the outcomes associated with it will inform future research in this area.

Finally, as cholecystectomy is a very common procedure, it can reflect the global uptake of environmentally sustainable measures in elective surgery. 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.

This study will capture prospective outcome data and describe the variation in management of acutely and electively presenting gallsone pathologies requiring surgery worldwide. This could be useful to externally validate ongoing trials, and identify new research gaps to power new trials. Additionally, this study aims to inform policy makers on the best strategy to optimise this elective cholecystectomy surgical pathway. This could improve understanding of risks of emergency surgery in this cohort and guide management recommendations.

Q2.4.2 Explain how benefits of this research justify any risks or burdens associated with the research.

There will be no changes to usual clinical care in this study, and risks to patients are minimal.

Improving the timely [redacted] together with optimisation of the

Improving the timely elective management of cholecystectomy together with optimisation of the elective surgery pathway is important for patients affected by the disease and will help to minimise the risk of emergency cholecystectomy.
The patient, the type of gallstone pathology 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. Identification of this practice across the world and the outcomes associated with it will inform future research in this area.
Finally, as cholecystectomy is a very common procedure, it can reflect the global uptake of environmentally sustainable measures in elective surgery. 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.
The potential benefits of this research may have flow on effects by adding to the literature and informing recommendations and guidelines. Unit level data for comparison will be fed back to collaborators to support local service improvement upon request.

Q2.4.3 How will you manage participants' expectations of the perceived benefit of participating in the research?

Patient consent will not be required for the audit, and therefore there should be no expectation of perceived benefit from patients who are included in the study.
Data collectors will make it clear that the potential benefits of the service evaluation for the hospital are dependent on what the results of the audit find, which may be compared to the international dataset after conclusion of the study.

Section 3 – Data and Privacy

Data Characteristics

Q3.1 Indicate the type of information/data you will be collecting for this project.

Personal information

Health information

Q3.2 Indicate the type of information/data you will be using in this project:

Personal information

Health information

Q3.3 Indicate the degree of identifiability of information/data you will be collecting for this project.

Re-identifiable (coded) information

Q3.4 Indicate the degree of identifiability of information/data you will be using in this project.

Non-identifiable information

Q3.5 Describe any ethical considerations relating to the collection and/or use of the information/data in this project.

Data will be maintained in a purpose build database using the REDCap (Research Electronic Data Capture) system. REDCap is the industry standard secure clinical research database. Irrevocably de-identified study data will be collected and stored online through a secure server running the Research Electronic Data Capture (REDCap)web application, 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. Each collaborator will have their own unique login which will only give them access to the participant data for which they are responsible. No participant identifiable data will be entered into the main database. Each site will maintain records of which participant is recruited into the study and their unique REDCap identifier through the use of a local cross-reference of hospital numbers and REDCap IDs. This should be kept in a secure, encrypted spreadsheet on a hospital, password-protected computer.

Q3.6 Identify the source/s of the information/data that you will be collecting and/or using in this project.

Medical/health/mental health record

Q3.7 Describe any ethical considerations relating to the source of information/data as indicated in the response to the previous question.

None

Q3.8 Was the information/data that you are using previously collected for a purpose other than research?

Yes

Q3.8.1 Provide a rationale for your use of information/data for a purpose other than that for which it was originally collected.

Data was previously collected routinely for health care related reasons in the medical record. This record will be accessed to find information such as demographic information, procedure-specific information, and complications

Activities Planned for/with Data

Q3.9 Do you plan to disclose any personal information/data in this project to a third party?

No

Q3.10 How will you protect the privacy of participants and non-participants in any notes and/or publications arising from your research?

Data will only be presented at an amalgamated level of participants. The study is expected to include more than 5000 participants internationally so no individual patient will be identifiable from the published records.

Q3.11 Are there any restrictions on your ability to assure the confidentiality of participants?

No

Q3.12 Do you plan to share any individual research results obtained during this research to the participants?

No

Q3.13 Describe how you will handle any secondary or incidental findings that arise from the analysis of personal information/data.

Any secondary or incidental findings will be discussed with the local site principal investigators, and appropriate members of the local research team. All local research teams will include at least one general surgical trainee, who will be able to appropriately follow up any secondary or incidental findings.

Q3.14 Describe how the information/data will be stored, accessed, archived and/or destroyed.

Data will be collected [redacted] Electronic Data Capture (REDCap)

Data will be collected and stored online via the Research Electronic Data Capture (REDCap) web application, hosted and managed by the Global Surgery REDCap system hosted at the University of Birmingham, United Kingdom. . No patient identifiable data will be uploaded or stored on the REDCap database.

Q3.15 Describe any ethical considerations relating to the storage of, access to or destruction of information/data in this project.

None

Q3.16 Will the outcomes of this project be disseminated to the participants?

No

Q3.16.2.1 Justify why the outcomes of this project will not be disseminated to the participants.

The participants will be irrevocably de-identified, and given a waiver of consent is requested, it will not be practical to relay information directly to participants.
However the responsibilities of the national lead (section 12, page 14) include
o Active media engagement with dissemination of HIPPO and other NIHR Unit on Global Surgery Collaborative activities at their country. As national co-lead for previous Covidsurg and Globalsurg projects the media campaign targeted national newspapers, radio and television including Channel 9 News, The Australian and ABC radio which enables broad distribution of study findings to the broader community.
o Representation of NIHR Unit on GlobalSurgery Collaborative at regional educational and research meetings which will influence the education of health practioners. This project has already been presented at the Annual Surgical Research Conference of the Royal Australasian College of Surgeons, and the presentation is available online.

Q3.17 Describe any foreseeable future activities for which information/data collected and/or used in this project may be made available.

It is possible that this study will generate research questions from the data gathered and analysed. Other researchers, including collaborators in this project, can approach the study management group for access to the data if, and only if, they have prior approval for their study from a properly constituted Human Research Ethics Committee.

Q3.18 Describe any ethical considerations relating to the planned or possible future use of information/data in this project.

The study management group, the NIHR Unit on Global Surgery will be the steward of the data collected. They will consider making the data available to any collaborator who has an appropriate study that depends upon the data as long as, and only, that study has received prior approval by a properly constituted Human Research Ethics Committee.