GECKO

GlobalSurg 4: Global Evaluation of Cholecystectomy Knowledge and Outcomes

A global prospective cohort study on cholecystectomy

HOSPITAL LEAD INFORMATION PACK

Protocol: click here.

CRF: click here.

Data Dictionary: click here.

Site Survey: click here.

Patient Information Sheet: click here.

Patient Consent Form: click here.

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About This Pack

In this booklet, we present a summary of the study protocol and project timeline, outline the steps you need to take before the study launch as hospital lead, and provide general tips and tricks for managing this project.

Contents

Protocol Summary

Background

There remains a paucity of evidence around the variations of safe provision of laparoscopic surgery for gallbladder disease internationally, including low- and middle-income countries. To bridge this knowledge gap, GECKO will allow contemporaneous data collection on the quality of cholecystectomies using measures covering infrastructure, care processes and outcomes.

Aim

To establish global variation in practice and outcomes of cholecystectomy, considering pre-, intra-, and post-operative parameters.

Inclusion Criteria
- Any hospital in the world performing cholecystectomy
- Patient inclusion criteria:
    - **Age:** adult only (≥18 years of age).
    - **Procedure:** Primary cholecystectomy, where this is the main procedure.
    - **Approach:** Open, laparoscopic (including gasless), laparoscopic converted, robotic, and robotic converted procedures are all eligible.
    - **Urgency:** All settings (elective, delayed, and acute).

Data collection
- Eight 2-week periods between August and November 2023, with 30-day and one-year follow-ups.
- Collected using an online web application (REDCap), a widely used and secure data capture service.

Outcomes
- **Primary outcome:** the compliance to pre-, intra-, and post-operative audit standards.
- **Secondary outcomes:**
    30-day and 1-year textbook outcomes for cholecystectomy including:
    - Postoperative complications (Clavien-Dindo classification)
    - Intraoperative complications (including bile duct and vascular injuries)
    - Length of stay
    - Readmission rates
    - Mortality rates
    - Postoperative imaging or intervention

    Unsuspected gallbladder cancer rates, and their 30-day and one-year outcome rates including:
    - Complication rates (Clavien-Dindo classification)
    - Time-to-recurrence rates (time from surgery to recurrence)
    - Revisional surgery rates (liver resection, bile duct resection and/or lymph node dissection).

GECKO Protocol Online Launch — 8th May 2023

Virtual Conference for GECKO Launch — 30st June 2023

Data Collection Period 1
31st July 23' – 13th Aug 23'

Data Collection Period 2
14th Aug 23' - 27th Aug 23'

Data Collection Period 3
28th Aug 23' – 10th Sep 23'

Data Collection Period 4
11th Sep 23' – 24th Sep 23'

Data Collection Period 5
25th Sep 23' – 8th Oct 23'

Data Collection Period 6
9th Oct 23' – 22nd Oct 23'

Data Collection Period 7
23nd Oct 23' – 5th Nov 23'

Data Collection Period 8
6th Nov 23' – 19th Nov 23'

Data Collection Periods from 31st July 2023 – 19th November 2023

REDCap Data Lock — 31st January 2024

Data Validation and Analysis

Short-term Outcomes Presented and Disseminated

One-year follow up period — 31st July – 19th November 2024

Long-term Outcomes Presented and Disseminated

Before Study

Register GECKO locally

GECKO should be registered according to local clinical governance or research and ethical guidelines. It is the responsibility of **you as the hospital lead** to ensure GECKO is registered appropriately, according to local regulations. Where the project may be registered as a **clinical audit or service evaluation**, all participating centres must do so. Formal ethical approval may be necessary in some centres.

We advise that you begin this process early as it may take several months to obtain necessary approvals for the study.

When registering GECKO, ideally as a clinical audit, you should emphasise that:
- GECKO is an international audit, and all data collected will measure current practice.
- No changes to normal patient pathways/treatment will be made.

All **GECKO** data will be collected and stored online through a secure server running the Research Electronic Data Capture (REDCap) web application. 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.

No data should be uploaded to REDCap prior to written approval from the Caldicott Guardian or ethical board.

We have also made patient information sheets and consent forms (*see cover page*), for centres that require those documents, which will also be made available on the online GECKO hub.

Before Study

Publicise GECKO and recruit collaborators

Any medical professional is eligible to be part of the mini-team, including allied health professionals and medical students.

Advertise the GECKO study as soon as possible; gaining interest and momentum of the study early on will ensure maximum participation from medical students, trainees and consultants/attendings.

<u>**Recommended approaches**</u> to publicise the project and recruit collaborators include:
- **Public announcements** - handover, grand rounds and events held by your local hospital focusing on surgical interests
- **Posters** - social areas/break rooms/changing rooms
- **Social media** - such as creating a Facebook group or Twitter page or posting on already existing Facebook and other social media groups
- **Posts** - in departmental/hospital bulletins
- **Emails** - local surgical departments, individuals, societies and associations who may be interested in the project

When collecting information about the expression of interest, ensure that you collect all the necessary details to contact members (**full name, emails, ORCID IDs (needed for REDCap registration) and phone numbers for local Whatsapp groups**), as well as their availability with regards to which data collection periods that would be able to take part in and in which centres they would be placed at the time. This will allow you to create mini-teams effectively.

Before Study

Organise mini-teams and data collection

You will be responsible for mini-teams of up to 5 people per data collection period. It is essential you organise these early and arrange to meet the members of these mini-teams to ensure each collaborator understands the study and their role.

Meetings could include discussion of the following:

- A strategy on how they will carry out their data collection**. Identification of consecutive patients is key for the successful running of GECKO**.

- Strategies to identify consecutive eligible patients are:

  - Daily review of elective theatre lists.

  - Daily review of handover sheets/ emergency admission and ward lists.

  - Daily review of theatre logbooks (both elective and emergency).

You will need to maintain communication over each 2-week period over WhatsApp (or another social media platform of choice), ensuring you are available and approachable.

- 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).

- Mini-teams should get in touch with their hospital lead in case of any problems

Note: Each mini-team is not limited to a single data collection period, and can collect data in multiple periods. It is your job as the hospital lead to ensure that data periods are covered by mini-teams.

Before Study
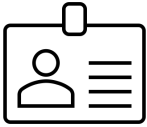
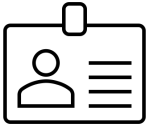## Create an ORCID-iD for REDCap registration

Study data will be collected and stored online via the Research Electronic Data Capture (REDCap) web application. **To register on REDCap, all members of each mini-team are required to have an ORCID-iD.** The ORCID-iD is a unique, open digital identifier that distinguishes members from every other researcher with the same or a similar name to them.

The ID is structured as a 16-digit number (e.g. 1234-1234-1234-1234). **Please instruct your mini-team to register for this and send their 16-digit number to your hospital lead as soon as possible** (https://orcid.org/register). Some ORCID-iDs can contain an X among the 16-digits. This is normal.

Make sure that each member of the mini-team sets their ORCID-iD visibility setting to "Everyone". This is done by going under profile and clicking "Account Settings"→"Visibility" →"Everyone". **Data cannot be accessed if ORCID-iD visibility is not set to "Everyone".** .

Register mini-teams on REDCap

Please ensure that all members of each mini-team are registered on REDCap. Login details for mini-team registrations will be sent to the email of the hospital lead filled in the Hospital Lead Expression of Interest Form. This will be in the first week of June.

In order to describe local processes and resources, each hospital site will be asked to complete an online site survey questionnaire to delineate the variation of cholecystectomy services and training amongst included hospitals. **Please do not fill the site survey on paper.** The site survey is available online on REDCap to complete. This is to allow for monitoring of responses.

Completion of site survey online on REDCap is mandatory. REDCap login details will not be sent to mini-teams if site survey is not filled.

During Study
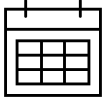
Conduct a 'mock' data collection day

We advise running a 'mock' data collection day before your period starts to get you prepared for when the study starts.

This will give your mini-team time to find where to access all the necessary day on the first day of your data collection period.

Any issues highlighted during this 'mock' day should be discussed with you (the hospital lead) and fed back to **subsequent mini-teams**.

Handover to next mini-team

We strongly recommend meeting with the preceding mini-team at your centre prior to the start of your collection period. This is not available to teams in Period 1, which is why we recommend the 'mock' data collection exercise outlined above.

Learning from the previous mini-team before will allow your team to gain helpful advice regarding what worked well and what did not.

Lastly, at the end of a 2-week period please reach out to the incoming mini-team and ensure you provide a similar level of help and guidance enabling them to hit the ground running as well.

During Study

REDCap ID – Hospital Patient ID Key

When a patient is identified for inclusion, collaborators can collect data through several options:

- Upload data straight into REDCap via a trust computer
- Data collection forms (paper CRF) and upload data later

Regardless of method of data collection, please store the Patient Identification Number and the corresponding REDCap ID on a hospital computer.

This is important as it will allow you to return to each patient record on REDCap to complete the 30-day follow up and address any missing data.

No patient identifiable information is to be stored on REDCap to preserve data anonymity as per the audit and ethical guidelines.

This record key should be always kept in a secure and safe place within your trust until after GECKO is completed. Patient identifiable material should NOT leave the hospital at any point during GECKO.

Ensure data accuracy & 30-day follow up

It is your job as the hospital lead to ensure that the inputted data is accurate. Ensure that each mini-team has an accurate understanding of cholecystectomy to allow for accurate data input into REDCap.

Follow-up at 30-day of the postoperative period is important. Be proactive in identifying post-operative adverse events, as this will prevent underestimation of true complication rates.

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.

Ensure all data has been uploaded to the REDCap system by the data collection deadline, avoiding missing data points.

Aim to have complete data for all patients.

- If more than 5% of a patient's record is missing on REDCap, that record ID will be excluded from the GECKO dataset, and it will not count towards your authorship.

During Study

Patient-Data for 1-year follow-up

Our study will also investigate 1-year follow up outcomes of patients with bile duct injury or gallbladder cancer. To ensure a successful 1-year follow-up, please do the following:

- **Keep a list of all patient ID and corresponding RedCap ID in a safe, secure computer system to allow identification of these patients at a later date.** This should be in the form of an encrypted spreadsheet held securely on the local hospital computer network by a member of the data collection team (a hospital lead, supervising consultant/attending, or audit officer).
- **Where it is anticipated that a hospital lead will rotate to another hospital, then the supervising consultant should facilitate the secure storage of patient ID and corresponding RedCap ID**.
- Ensure the audit office / local governing bodies are clear this will be a follow-up study.
- In high-volume centres where achieving high data completeness may be burdensome, involvement additional team members to provide support will be permitted.

After Study
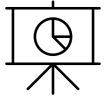
Presenting results locally

The hospital leads will have the opportunity to present he local results of the study at their centres following the completion of the study. The presentation template and local data will be made available after data analysis is completed.

Authorship

All authors will be credited in accordance with National Research Collaborative Authorship guidelines, and research outputs from GECKO will be listed under a single corporate authorship:

GECKO Study Group, NIHR Global Surgery Unit

All collaborators will be listed as PubMed citable collaborators, with the roles defined in the protocol, provided that minimum requirements for authorship are achieved.

Hospital Lead Tips & Tricks

- Make sure to **emphasise to team member their roles** and responsibilities upon signing up.

- Ensure **clear communication throughout**, including being welcome to questions being asked.
  - Collaborators should feel comfortable asking you anything regarding data collection.

- If the interest is greater than the maximum number of collaborators you can assign, you can **consider keeping a 'reserve' list**, should any of the collaborators be unable to participate due to an illness or other change in circumstance.

- **Ensure handover between data collection is completed.**
  - This is critical for sharing any lessons learnt from period 1 into subsequent periods.

- **Frequently check in on collaborators** to open up discussion around any issues and look to encourage them to ask questions frequently on group chats to share information.

- Be organised and be prepared well in advance.
  - **Make sure deadlines are adhered to.**
  - **Keep track of collaborators and hospital leads,** their data collection periods and which hospital sites they're responsible for.

Checklist Summary

Pre-Study

Completed?

1. Register GECKO as an audit at your site

2. Recruit collaborators and publicise the study

3. Form mini-teams within your hospital for each data collection period

4. Ensure each mini-team member has an ORCID-iD

5. Register mini-teams on REDCap

During Study

1. Conduct mock data collection day

2. Handover to next mini-team

3. Data uploaded to RedCAP

4. Ensure data is complete with 30-day follow up

5. Patient data is securely stored for 1-year follow-up

Contact Details

GECKO Hub – https://www.globalsurgeryunit.org/clinical-trials-holding-page/project-gecko/

Central emails – geckostudy@gmail.com

Dedicated REDCap email – geckoredcap@gmail.com