



Global PaedSurg Study

Frequently asked Questions:

1) Accessing REDCap

I haven't received a REDCap login – what shall I do?

All collaborators with study approval have been sent two emails with REDCap login details. The first is to register for REDCap. The second is to register for the study within REDCap.

If you have not received the email it is likely because it has gone to your **junk mail**. Unfortunately many of the REDCap emails go straight to junk.

Hence, please check your junk mail for an email from 'medstats'. Please then select '**not junk**' at the top of the email to move the email to your inbox. Of note, the **link to set your password** for REDCap will only appear if the email is in your inbox.

If you have not yet received REDCap login details please kindly add medstats@kcl.ac.uk and MedStats_ServiceAccount@emckclac.onmicrosoft.com to your contacts list to prevent the emails going to junk.

I have received a REDCap email but I have not received a password – what shall I do?

REDCap will not set your password. Within the email there should be a link for you to set your own password. If the link is not visible in your email it could be because either the email needs to be moved from junk mail to your inbox (as discussed above) or it is because the link is being blocked by your hospital computer.

Hence, please try accessing the email from a home or different device.

When will REDCap login details be sent to me?

REDCap login details will be sent to you before you are due to start data collection or upon receipt of your study approval.

You will be able to commence data collection from the 1st day of the month following the date on your study approval. For example, if you have a study approval from the 5th November then you can collect data from 1st December.

I have tried all of the above and still haven't received REDCap login details – what shall I do?

Please email us on Global.PaedSurg5@gmail.com and one of the organising committee members will investigate. We will check that the REDCap team have the correct email address for you.

If you have an alternative email address that we can use please send that. We have had a few problems with institutional email addresses receiving REDCap login emails hence a personal email may work in this instance.

2) Questions regarding the study protocol

The study started in October, can I still participate or is it too late?

Yes. You are only required to contribute a minimum of 1-month of data. Data collection is open until the end of April 2019. You require local study approval to participate in the study. Hence, the latest you can provide study approval is the 1st April to participate in the study.

What if a patient presents with more than one of the study conditions?

Only conditions presenting acutely during the data collection period should be included as a study condition. For example, if a patient has previously had a duodenal atresia repair as a neonate and then presents acutely with Hirschsprung's disease at a few months of age during the study period, only Hirschsprung's Disease should be included in the study within the following section:

What study condition does this patient have? *Oesophageal atresia, Congenital diaphragmatic hernia, Intestinal atresia, Gastroschisis, Exomphalos/ Omphalocele, Anorectal malformation, Hirschsprung's Disease*

Within the 'demographics' section of the data collection form there is a space to detail other congenital anomalies:

5. Does the patient have another anomaly in addition to the study condition?

Yes, Cardiovascular, Yes, Respiratory, Yes: Gastrointestinal, Yes: Neurological, Yes: Genito-urinary, Yes: Musculoskeletal, Yes: Down syndrome, Yes: Beckwith-Wiedemann syndrome, Yes: Cystic fibrosis, Yes: Chromosomal, Yes: Other, No

Hence, in the case described here full details would be provided for Hirschsprung's disease (not duodenal atresia) as a study condition, but the patient should be noted to have an associated congenital anomaly of the gastrointestinal tract.

If a patient presents with two or more anomalies such as oesophageal atresia and anorectal malformation at birth then both should be included as a study condition in full. This can be done on the same data collection form by selecting both study conditions on REDCap.

What is meant by primary intervention?

Primary intervention for each of the study conditions is defined as follows:

- **Oesophageal atresia:** surgery, either temporising or definitive, to manage the oesophageal atresia and/ or tracheo-oesophageal fistula.
- **Congenital diaphragmatic hernia:** surgery to reduce the hernia and close the defect.
- **Intestinal atresia:** surgery, either temporising or definitive, to manage the obstruction including stoma formation and primary anastomosis.
- **Gastroschisis:** any procedure to either cover or reduce the bowel and/ or close the defect. This includes application of a silo (regardless of whether or not they go on to require surgery). It excludes initial covering of the bowel in a plastic covering (bag or cling film) prior to intervention.
- **Exomphalos:** surgery or application of topical treatment to the sac in patients managed conservatively (regardless of whether or not they go on to require surgery).
- **Hirschsprung's disease:** surgery, either temporising or definitive, or rectal/ distal bowel irrigation,

laxatives or digital stimulation in patients managed conservatively. This does not include pre-operative washouts.

- Anorectal malformation: surgery, either temporising or definitive, or anal/ fistula dilatation in patients with a low anorectal malformation managed conservatively.

Primary intervention excludes: Surgical procedures not directly related to the temporizing or definitive management of the congenital anomaly. For example, it excludes chest drain placement, abdominal drain placement and central line placement.

Please include surgical interventions regardless of whether an anaesthetic was used or not and regardless of the location – the intervention does not have to have occurred in the operating theatre to be included.

Should a patient be included if they did not receive a primary intervention?

Yes. Patients presenting primarily with one of the study conditions who receive surgery, routine care (conservative generic ward care only), palliative care or no care must be included to reflect true outcomes.

What is the age range of the patients to be included?

Any neonate, infant or child under the age of 16-years (birth - 16 years).

Who can participate in the study?

Any healthcare professional caring for neonates and children presenting with one of the study conditions can participate as a collaborator in the study. This includes surgeons, anaesthetists, paediatricians, neonatologists, nurses and allied health professionals. Collaborators can range from medical student to consultant level. Students and junior doctors, nurses and allied health professionals should gain permission from the senior surgeon or physician who oversees the care of the children to be included in the study in order to participate. This senior healthcare professional should be included as a collaborator within the team and will hold the responsibility of ensuring data collected is accurate, complete and without duplicates.

Is my hospital eligible to participate if we undertake very few cases?

Any hospital dealing with these congenital anomalies is eligible to participate, regardless of size, location, specialisation or funding sources. Government, private, missionary and other hospitals can participate. In order to participate, you must submit ALL consecutive eligible cases that are undertaken within your chosen data collection period. Each study mini-team covering a month of data collection must include at least one patient in the study to be eligible for co-authorship.

How should we deal with cases who are referred? For example, if one centre sends most complicated cases to another centre after diagnosis and initial management has been done do we collect data from the hospital where definitive surgery is done or from the hospital where the diagnosis and temporary management is done?

Patients should be included in the study from the centre where they received their primary intervention (see definitions above).

Patients can only be included in the study if they are presenting for the first time with their congenital anomaly and hence receiving primary treatment. Patient's coming to a hospital for subsequent elective

surgery, treatment or follow-up must not be included in the study at all. Children who have received basic resuscitative and supportive care for their condition at a different healthcare facility and then been transferred to the study centre for their primary intervention can be included. These patients should be included from the receiving centre where the primary intervention took place, NOT the referring centre. The study is not designed to capture data on patients being referred out and this could also result in a duplication of patients in the study.

Can we participate in the study if we don't undertake neonatal or paediatric surgery at our centre?

Yes, but you can only include patients who either die at your centre or who receive conservative treatment and are sent home. You must not include patients who you have resuscitated and referred to a paediatric surgery centre. Of note, all patients to be included must be patients presenting for the first time with the study conditions – patients presenting for follow-up or further management must not be included.

What is the team structure?

There can be up to three collaborators in a team per month of data collection. Data collection can be undertaken by just one team for up to seven months duration (1st October 2018 to the 30th April 2019) or by multiple teams (of up to three collaborators per team) each collecting data over a different one-month period. This allows for more than three collaborators to participate from an institution. The maximum number of collaborators participating from one institution is twenty-one. The minimum length of data collection for participation in the study is one-month.

Who will be included in the final authorship list?

Publishing journal(s) will be asked to make all collaborators PubMed citable co-authors. The authorship on the front page of the article will read 'Global PaedSurg Research Collaboration' with all authors' names listed in full at the end of the article. This methodology is based on an equal partnership model previously described in The Lancet and utilised by a number of national and international collaboratives. Similarly, all collaborators will have their names listed as an author on all resulting oral international conference presentations. On international poster presentations 'Global PaedSurg Research Collaboration' will be utilised to encompass all collaborators due to space restrictions. In publication(s), authors will be listed according to their role in the study with details of what was involved: Local collaborators, Continent, regional and country leads, Lead investigators, Lead organizers, and Steering committee. Each individual collaborator can participate in more than one role in the study and this will be represented in the authorship list accordingly.

How should I apply for study approval?

According to King's College London Research Ethics Committee guidelines, this study is classified as an audit and hence does not require ethical approval.

The study fulfills the audit criteria as follows:

- All data collected measures current practice. The study does not involve any changes to normal patient management.
- Current practice and outcomes in low, middle and high-income countries will be compared to published standards in the literature. Table 2 in the study protocol details the current mortality standards for each of the seven study conditions in high-income countries.
- All the study data is routinely collected information which should be known to the study team without asking any additional questions to the patient/ parents.
- All data to be entered into REDCap is entirely anonymous, with no patient identifiable information.
- No individual collaborator, institution or country will be independently identifiable in the study results.

- All data will be stored securely and will be governed by a regularly updated and regulated data protection plan by King's College London data protection team.

Additional advice has been sought from King's College Hospital Research Ethics Department with respect to NHS patients. Confirmation has been provided that since the study is classified as an audit it does not require ethical approval. Local audit approval must be sought accordingly.

You are required to gain local approval for the study at your institution according to your local regulations. In some centres the study may be deemed an audit, however in others full ethical approval may be required. Evidence of local study approval, sent via email to the principal investigator, will be required to gain login access to the REDCap data collection tool.

If no formal ethics or audit committee exists, collaborators must seek approval from the Director of the Hospital or Head of the Surgery, Paediatric or Neonatology Unit in order to participate. In these circumstances please email a signed letter confirming the latter to the principal investigator.

Do patients relatives need to provide consent?

For clinical audits collecting routine, anonymous, de-identified data, patient consent may not be required. However, regulations vary from centre to centre and in countries around the world and hence you should check your local regulations regarding this and follow them accordingly.

Will I have ongoing access to the data which I submit from my own institution?

Throughout the data collection period, collaborators will be able to access the data they submit from their own institution, via the REDCap system. Access will end automatically shortly after the data collection period closes. However, access will be reinstated at any time on request and collaborators can download their own data to analyse as they wish.

What if my institution has lots of complications during the short data collection period? Is there a possibility that I could cause embarrassment to my hospital or country?

It will not be possible to identify individual surgeons, institutions or countries within the final published results. You should submit your data regardless of how well or poorly you think you have performed, or how results may have been affected by external circumstances. Our study intends to describe management as it actually happens in real life.

Is any financial support available for participants?

Funding has been provided by the Wellcome Trust to cover the costs of the REDCap data collection tool and supporting REDCap administration team and data protection team (£4032) and the website design, development and maintenance (£850).

In line with other continent-wide and global collaborative, prospective, observational cohort studies such as this, funding is not available for individual ethical applications and payments will not be made to collaborators participating in the study.

Collaborators will collect anonymous data regarding their own patients, they will maintain ownership of their data throughout the study and will be able to download and analyse the data for local audit and improvement purposes. All collaborators will be a co-author on resulting publications and the study will provide additional

opportunities and benefits to the collaborator, team and future patients as highlighted on page 4 of the protocol. In many institutions, audit and/ or ethical approval does not incur a fee. In sites where this is required, ethical review boards may consider this to be a locally driven collaborative project rather than a formal international study for fee purposes.

Funding is not available for patient follow-up. Please follow-up patients to 30-days post primary intervention as best you can within the capacity of your current service. There is an option to document when follow-up is not possible on the data collection form.

The Wellcome Trust has had no input into the content of the study protocol other than to recommend open-access publication of the results in a peer-reviewed journal and to make the full anonymised dataset publicly available following publication.

What about publication of the study?

The study protocol has been registered on ClinicalTrials.gov and the study protocol will be submitted for peer-reviewed publication. Following completion of the study, one or more teleconferences will be held to share and discuss the data analysis undertaken and the study results amongst collaborators. The final manuscript will be shared with all collaborators for approval prior to submission. The main results paper will be submitted for open access publication in a peer reviewed journal. We shall request that all collaborators are listed as PubMed citable co-authors.

Can I publish the local data of my country in a separate paper?

Yes. Collaborators will have the opportunity to undertake sub-analyses of the data for their country (if all collaborators from that country agree), region or continent. All local collaborators providing data for that region, the country/ regional/ continent leads for that region, the lead investigators, lead organisers and steering committee will be listed as co-authors. Submission of sub-analyses for publication cannot occur until the main study has been published.