

GlobalSurg 3 National Leads online Meeting Minutes December 13th 2018

Welcome everyone to the last National Leads meeting for 2018

GlobalSurg 3 General update:

13,855 patients

7183 patients completed (decrease from number showing previously; reason to be discussed)

603 Hospitals

3000 researchers

data.globalsurg.org

Thank you to everyone - being a harder dataset to collect, GlobalSurg 3 is on track to include more patients than either of GlobalSurg 1 and 2.

The dataset is currently split as approx. 50% breast cancer, 40% colorectal cancer and 10% gastric cancer. Approx 60% of patients from high income countries; 40% from low and middle income countries These ratios are as expected based on previous studies

Missing Variable on REDCap

Ewen Harrison has emailed all National Leads this week regarding a variable that was not showing on REDCap. An error in the way the project was set up resulted in the variable for **operative approach** not being visible for some patients. This variable relates to whether the operation was performed laparoscopically or by open resection and applies to gastric and colon cancer only.

The REDCap project was tested thoroughly prior to the study start but despite this the variable remained hidden for some collaborators, although it was on the paper form.

For hospitals never performing laparoscopic surgery, it should be straightforward for collaborators to log into REDCap and simply record each patient as 'OPEN'. For those hospitals performing both open and laparoscopic surgery, the data should have been recorded on the paper forms or be available in theatre log books.

Therefore, although a large number of patients and teams have been effected, it shouldn't be too much additional work to add this data to REDCap.

Because this variable was so important for outcome in GlobalSurg 1 and 2 we feel it is worth going back to try and entering it into REDCap.

Apologies for the inconvenience – similar errors have crept in previous studies, gender for example was missing during GlobalSurg 2 and had to be added retrospectively. We are continuing to improve systems for testing data entry prior to studies opening but unfortunately errors do still occur.

Already in just a few days of asking for this data, nearly 30% of the missing data has been added to REDCap. We're really aiming to get this variable upwards of 90% complete to avoid having to exclude patients from the analysis.

We are very grateful for the support of National Leads in assisting with this task; please encourage all teams to add this data and apologise on behalf of GlobalSurg for the error.

We have identified all teams effected by this issue and they have been emailed with a notice saying 'your team has been effected please log into REDCap and add the data'. We have changed the Operation form from a green dot back to a red dot to allow teams to easily identify the effected patients.

To assist with this, we have extended the primary data entry deadline for 1 month from planned date of Monday 17th December to **10pm Monday January 21st** – this will be applied to all primary data entry and will be formally announced shortly.

Validation

We have received a lot of emails from validators asking why they have not yet been sent their REDCap account for validation?

For most cases this will be because the primary data collection team has not yet completed primary data entry.

In order to complete primary data entry, all variables must be fully completed for all of the patients in the data project in REDCap – all of the red dots must be green dots for every patient. Once the team has 5 green dots for every patient, at least 1 team must log into the authorship project and complete the form called Data Collection Completion which gives us the dates for their data collection period and confirms all patients are entered.

To recap, data entry is complete when

- a) In the Data project on REDCap, every patient has 5 green dots

AND

- b) At least 1 team member has completed the Data Collection Completion form in the Authorship project on REDCap

On the National Leads app we have now added to the curated registrations tab, columns showing whether a team has entered their data collection dates and confirmed their patients

are all entered. This allows National Leads to check whether the primary data collection is completed yet

The Validator dashboard (<https://argoshare.is.ed.ac.uk/validation/>) will also now show 'validator registered (awaiting primary data completion)' rather than 'Validator registered (awaiting confirmation)' as it previously showed.

This will allow validators who have registered to check themselves the status of the primary data entry at the hospital they are waiting to validate.

As data entry needs to be complete before validation can take place, the missing Operative approach variable does complicate when validation can begin.

There were 2 options:

- a) To go ahead with validation in the absence of the operative approach variable
- b) To wait until this variable was added before making the data of a given hospital available for validation.

After much discussion, we have elected for (b) and will wait for the operative approach to be added before releasing a period for validation.

Once the primary data collection team have completed their data entry, there is a brief further period where the dataset undergoes some quality checking by the GlobalSurg team before it is made available for validation.

On the National Leads App, in the validator tab, the column called period_confirmed that currently says Yes or No – this refers to whether the GlobalSurg team have performed their checks rather than the primary data collectors confirming their dates. We will look at improving the way this is displayed to make it easier to see whether the delay is due to the primary data team not completing their data entry or the GlobalSurg internal checks being completed.

Due to the extension in the primary data entry deadline to January 21st 2019, the period for the validation study will also be extended by a month to a date in March 2019. The final date will be announced shortly.

Authorship

Authorship for a mini team requires >90% of the data to be complete – 5 green dots for every patient. Please emphasise to your teams that they must meet this threshold to be included on the authorship list of future publications.

We are undergoing a period of checking the quality of dataset and teams who have entered data that is less than 90% complete will not be included in the final authorship list– this applies to the whole team. One of the strengths of GlobalSurg projects is the quality of the data and we're really grateful to National Leads for driving this process.

Access to Data Beyond the End of GlobalSurg 3

During GlobalSurg 3, each team has only had access to the data entered by their own team. At the end of the study we will combine all the data for each hospital together and give every collaborator at a given hospital access to the full dataset for that hospital. This will allow collaborators to perform their own hospital level analyses should they wish to.

Hospital Level Survey

The hospital level survey is in development and will be circulated in January 2019. This will be a single set of variables completed once at each hospital and will relate to infrastructure and services available at each hospital.

Data Apps

We are developing an app to allow individuals to look at their own data – similar to the GlobalSurg 2 SSI app, and a regression app which will allow countries to apply the models used in the main paper to their own data. Some of these have been sent out for testing already; if you're interested in looking at this please get in contact. There has been a request to look at all of the sub-Saharan Africa data together, including South Africa. This will be discussed with the relevant National Leads.

Happy Holidays!

Finally, thank you to everyone – 2018 has been a phenomenal year for GlobalSurg; congratulations to everyone for your many achievements throughout the year!

We've really enjoyed these National Leads online meetings, it's been a terrific forum to bring everyone together and share problems and solutions, and we appreciate your support in joining the meetings where possible.

We appreciate everyone's hard work throughout the year and hope you all manage to enjoy a break if you're celebrating the festive season! Looking forward to seeing you all online again in 2019!

Questions arising during the meeting

Q: *If collaborators have rotated from the hospital where the data was collected, as is the case in England, how can this be solved?*

A: Some hospitals will be ok as they have at least one team member remaining. National Lead for England is looking for solutions including a reciprocal arrangement whereby collaborators continuing to work in the NHS can be emailed with the data by a GlobalSurg member working in the original hospital.

Q. *If the National Lead is aware laparoscopic surgery is never performed in a particular hospital is it sufficient for the National Lead to share this information or does this still need to be added to REDCap*

A. In the first instance, it would be better for teams to add the data themselves. However, if there is no other option we can help with this on a case-by-case basis.

Q. *As the National Lead, if we know the team has moved on but we are aware there is no laparoscopic surgery at a given hospital, can we have access to every hospital so we can add the data to REDCap and set the form to complete?*

A. It is not technically possible to give National Leads access to multiple teams. The best solution is for the team to enter the data themselves, but as a last resort if the only way to get the data is by communication from the National Lead by email

The team will discuss after meeting whether it is possible to add a button to the National Leads App to allow National Leads to indicate no laparoscopic at a given hospital via the app.

Q. *If teams do not enter the data what will happen? Will their patients be excluded from analyse and the team excluded from the authorship list?*

A. We do not wish to be punitive as this is as a result of an error occurring centrally, rather than anything mistake on behalf of collaborators. However, if it helps to focus teams into action, we are comfortable with National Leads telling teams their authorship **may** be at risk if they don't add the missing data. However, we do not plan to exclude any teams on the basis of this variable being missing

Q. *Is there a way for National Leads to see which patients are missing data so we can follow up with the teams?*

A. Yes, this is possible via the National Leads app. Select the Patients tab and then a particular hospital, patients show as pink dots; incomplete patients are light pink, then they turn dark pink once complete. Hovering over the dot reveals the DAG name of the team that entered the patient. If you then switch to the curated registrations tab you can find the team associated with the DAG and find their names and email addresses.

It's not possible to seeing the missing variable for Operative approach specifically, but the dot for any patient still requiring this data will be light pink again.

When a patient has 5 green dots in REDCap, the patient turns from light pink to dark pink in the National Leads App

Q. *Can we make the registration and team changes form live again to prevent teams email National Leads with team changes.*

A. Registration and Team Changes are now closed online. Given there has been a relatively low number of emails, it's not really practical to make the forms live again for over 1000 patients. Please forward any emails relating to team still needing REDCap log ins or wishing to change their teams to enquiry@globalsurg.org and we will make any changes necessary.

Q. *If the National Leads app is showing everything is complete from the primary data collection team, why have the validators still not received their accounts.*

A. There is a brief delay between the primary data collection team completing everything they need to do and us issuing the details to validators. The process is not fully automated

and there are some internal checks performed by the GlobalSurg team before the accounts are issued

Q. *The individuals registered as the validator at some of our hospitals are moving jobs in January - will the data be available before they move?*

A. If you have validators about to move hospital, please email us and we will rush the checks and get the accounts issued as soon as possible

Q. *If there are multiple teams collecting data at a given hospital, do we need to wait until all the periods are fully completed?*

A. Technically, validation can get underway as soon as a period is fully completed by the primary data collection team and has been checked by the GlobalSurg team. However, we are also randomising the period validated at hospitals where there are multiple teams to avoid always validating the first period to be completed. Therefore in reality, we are usually waiting for several periods to be completed before randomising the period to be validated.

Q. *Are the validation dates now 21 Jan 2019 to March 2019?*

A. The validation period for any given hospital will begin once the validator has been issued with their REDCap account (which happens once the primary data entry is complete – see above discussion) and should be complete by March 2019. The validator can begin their work as soon as they receive their validators REDCap account, which may be before January 21st depending on data entry by the primary data collection team, and they should have completed their work by the validation data entry deadline which will be in March 2019.

Q. *Is there any update on the feasibility study? Should the primary data team keep collecting the data?*

A. We are undertaking a feasibility study aiming to collect oncological outcomes at 3, 6, and possibly 12 months. This is not part of primary data collection; it is not required for teams in GlobalSurg 3 but is a feasibility exercise to see if it's possible to collect these harder to obtain outcomes in our network. We'll be putting forms together in the new year to see if we can collect this data and will be in touch with collaborators in the new year.