A guide to navigating your ethics committee or review board

Introduction:

Welcome to the Global Tracheostomy Collaborative (GTC)! We are excited to welcome you to an exciting new quality improvement collaborative to help improve the care for children and adults with tracheostomy. The following is a guide to help you navigate the ethics committee or institutional review board at your institution.

In the spirit of quality improvement, the data collected as part of the GTC's Quality Improvement Database is intended to inform member institutions about their clinical practices and assist them in improving patient safety and quality. However, we recognize that participation in the GTC Quality Improvement Database, involves accessing a patient's medical record, abstracting sensitive and protected health information, and sharing this de-identified data with the collaborative. Thus, we anticipate that different jurisdictions will have different approaches towards participation (e.g. data abstraction and data sharing) in this multi-institutional quality collaborative. Some jurisdictions may consider this a quality improvement initiative and require no formal approval or review by the ethics committee or institutional review board; while other jurisdictions may consider this clinical research and require a full formal application to the ethics committee or institutional review board.

Each new member of the GTC Quality Improvement Database is required to notify the collaborative, upon joining, that their data collection efforts are within the scope of their local ethics committee or institutional review board. Thus to help assist you in the process of reviewing your participation in the GTC Quality Improvement Database with your ethics committee or institutional review board we have provided the following guide.

Please feel free to copy and paste the text from this document directly into your correspondences with institutional ethics or institutional review board.

This guide contains 4 sections:

- **A. Applying to the ethics committee or institutional review board**
- **B. Data Collection**
- **C. Data Access and Data Storage**
- **D. REDCAP Database Security**

A. Overview of Institutional Review Board/ Ethics Committee Application

Should I notify my institutional review board /ethics committee about my hospital's participation in the GTC Quality Improvement Database?

Yes. You should discuss your hospital's participation in the GTC Quality Improvement Database with your institutional ethics committee or institutional review board representative. Each new member site is required to notify the collaborative, upon joining, that their data collection efforts are in compliance with the requirements of their institutional ethics committee or institutional review board. Please inquire with your institutional ethics committee or institutional review board about whether a formal application will be necessary, or whether on the grounds of quality improvement your participation is exempt. If, for example, your institutional ethics committee or institutional review board's representative(s) determine that your involvement constitutes quality improvement efforts, and at your institution this does not require a formal review, then likely there is no further action necessary before your site may begin to collect and submit clinical data to the GTC Quality Improvement Database. In some jurisdictions it is necessary to obtain approval from an institutional ethics committee or institutional review board for the transfer of data across jurisdictional borders. Discussing these issues with your local ethics committee or institutional review board will assist in determining what approach may be necessary.

Below, you will find supporting documentation about the quality improvement collaborative, data collection elements, and data security aspects of the GTC quality improvement database.

Please also feel free to directly copy elements from this document into your institutional ethics committee or institutional review board application, if necessary.

Does the GTC consider participation in the Quality Improvement Database to be a Quality Improvement Initiative?

Yes. The leadership of the GTC considers participation in the GTC Quality Improvement Database a quality improvement or quality assurance initiative. The goal of data collection and analysis is to assist your hospital, and other member hospitals, in making data-driven decisions to improve the quality of tracheostomy care. We anticipate that member sites will gain insights from their data, and the data of peer institutions, and translate this data into clinical improvement and patient safety initiatives. While the database may be accessed to research queries -- any individuals wishing to access the GTC database for research purposes must first submit a request to the GTC leadership committee and any data disseminated for scholastic purposes will be de-identified of identifying patient information.

What if my institution's review committee considers participation in the GTC Quality Improvement Database a clinical research endeavor, what type of institutional review board/ethics committee application(s) should I file?

For instances where participation in the GTC quality improvement database is considered by clinical research your institutional ethics committee or institutional review board, we anticipate you will be eligible to apply as an "*exempted*" activity involving "*existing patient data or patient health information*". In situations where you are requested by your institutional ethics committee or institutional review board to submit a formal review, we would recommend selecting "*request for exemption*" or classification as '*low or negligible risk research*' as appropriate.

How does participation in the Quality Improvement Database count as an "exempted" study involving "existing patient data or patient health information"?

While varying from institution to institution, there are generally several main categories of study exemption. An exempted study traditionally means that the potential for harm as a result of participation in a study is very minimal. Typically for a study to be considered an exempted study, the study must meet one of the following criterions:

1. Research conducted in established educational settings;
2. Research involving the use of educational tests, surveys, or interviews;
3. Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens;
4. Research conducted by a government agency.

Participation in the GTC Quality Improvement Database likely fits into option #3: *Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens*.

The GTC Quality Improvement Database does not involve collection of biological samples, clinical trial enrollment, or distribution of pharmaceuticals. The GTC Quality Improvement Database is retrospective, meaning that all data captured contains previously collected patient health information. The results are obtained from medical record abstraction and there is no new data generated or collected as a result of participation in the database. While information obtained through participation in the GTC Quality Improvement Database may be used to drive clinical decisions (e.g., implement a safety bundle targeted towards a specific adverse event) this would be intended to improve patient care.

What should I record for "Funding Sources" and "Disclosures"?

Access to the GTC Quality Improvement Database is available to sites as a result of their membership in the GTC. GTC member sites do not receive financial compensation for participation in the study, or funding for staff member time to record data into the database. Thus, sites will likely record that this project is "internally sponsored." Please record the appropriate financial disclosures for key members of your project team. Some member sites may have project team members who are on the steering committee of the GTC leadership group and we encourage this disclosure, albeit not as a financial relationship.

My institution is in Europe. Are there special considerations I should include in my application?

The European law currently only allows participation in the GTC database if all data exported to the GTC is de-identified, without any 'protected health information'. The law does not allow 'protected health information' to exit Europe. The database design allows European sites to select to enter only de-identified data GTC. Sites store protected health information that corresponds to record IDs in our database for their own use, but this protected health information should not be entered into our database and will not be available to the GTC. In this case, you do not need to apply for ethics committee approval to participate since you are only participating in the GTC for quality improvement purposes. However, we do advise that you inform your hospital's data protection supervisor (e.g. Caldicott guardian in the UK National Health Service) or institutional review board representative. If you wish to use your data for research or publication purposes later on, you will need to obtain ethics approval to do so as per your usual protocol.

The GTC has aspects of audit and service evaluation. If you wish to conduct specific audit projects using your GTC data, you should also check with the clinical governance office for your organisation, what other review arrangements or sources of advice apply to the project. For example, there may be standard guidelines on the conduct of clinical audit.

B. Data Collection

How are patients identified in the Quality Improvement Database?

Each subject that is entered into the GTC Quality Improvement Database will be assigned a unique identification that is automatically generated by REDCAP in a sequential manner (e.g., 1 followed by 2).

Are hospital medical record numbers used in the Quality Improvement Database?

No. The automatically generated REDCAP ID is the only identifier of patients in the database. Member sites are encouraged (so long as this is approved by their institutional ethics or institutional review board) to maintain a separate linkage between the GTC Quality Improvement Database record identification number and the patient's hospital medical record number. This is so sites can ensure that they have not made duplicate entries and so that they can conduct internal patient reviews. However, all member sites must maintain this linkage independently and should specially discuss this with their institutional review board representative. Member sites will be unable to enter unique identifier (e.g., government identification number, hospital medical record) into any part of the GTC Quality Improvement Database identification number.

What protected health information will be used in the Quality Improvement Database?

The mandatory section of the GTC Quality Improvement Database contains the following fields, which are traditionally referred to as 'protected patient health information':

- Date of Birth
- Date of Hospital Admission
- Date of Tracheostomy Tube Insertion
- Date of Hospital Discharge
- Date of Decannulation
- Date of Death

The GTC Quality Improvement Database is customizable, so that if your site's institutional review board /ethics committee prohibits you from collecting these variables, we can remove them from your site's dataset.

For a listing of all of the data variables included in the GTC Quality Improvement Database.

C. Data Access and Data Storage

How do I access the database?

The Global Tracheostomy Collaborative Quality Improvement Database is accessed via a secure web URL (redcap.vanderbilt.edu). Upon joining the Global Tracheostomy Collaborative Quality Improvement Database, each site member will receive their own unique username and password. Each user will have defined user privileges assigned to them by the GTC data management group. These privileges will be set so each member is granted the rights to view, enter, import, and export ("download") only the data entered by their site and will not have access to data from other sites.

Who else will have access to the data entered for each site?

Data entered by members of your site is visible only to you, other members of your site and to the GTC database management group. No other site will have access to your site's data. The database management group maintains access to your data for the sole purposes of data integrity, validation, and analysis. The GTC will send out data reports, however, sites will only get their own data plus comparative data, which does not allow identification or inference about the identity of other sites

How can I download the data I have entered for each site?

Each site is granted the rights to export ("download") only the data entered by their site and will not have access to the dataset entered from other sites. This ensures that no member site will have access to enter, review, or export ("download") data from other sites. The GTC will send out data reports to all participating sites. In this report sites will receive their own data plus de-identified comparative data, which does not allow identification or inference about the identity of other sites. Member sites agree not to enter any unique institutional or patient records (e.g., government identification number, hospital medical record) in any part of the GTC Quality Improvement Database. Sites should keep an internal Study ID log to link the GTC identification number with any identifying information.

How is my data stored securely in the collaborative quality improvement database?

Vanderbilt University Medical Center ("VUMC") will host the web application for managing the registry using its Research Electronic Data Capture ("REDCap") software. VUMC will establish unique user accounts, passwords and authentication for individuals authorized by GTC to submit data using REDCap. (See: www.project-redcap.org and below REDCap security summary).

D. REDCAP Data Security

What is REDCap?

The Global Tracheostomy Collaborative (GTC) quality improvement collaborative uses software from the global REDCap (Research Electronic Data Capture) consortium for data collection and management. The global consortium is composed of over 900 active institutional partners in 75 countries. The consortium supports a secure, password-protected, web-based application (REDCap) designed exclusively to support data capture for research studies. The REDCap application provides: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and, 4) procedures for importing data from external sources.

How will the GTC use REDCap?

The GTC has created a secure, password-protected, web-based database for collection of patient-level tracheostomy related outcomes. The database is accessible on any Internet connection worldwide using the secure web URL (redcap.vanderbilt.edu). Users will log into the website and submit data into pre-designed fields. There are no programs or applications ("software") to download.

What types of access will each site have to the data?

When an institution joins the GTC Quality Improvement Database, each member from that site will receive their own unique site username and password for login from the GTC database management group. Each username will have user privileges assigned to it by the GTC data management group. These privileges are set so that site users will be granted the rights to export ("download") the original data entered by their site and will not have access to datasets from other sites. This ensures that no member site will have access to enter, review, or export ("download") data from other sites. The GTC will send out data reports to all participating sites. In this report, sites will receive their own data plus de-identified comparative data, which does not allow identification or inference about the identity of other sites.

How will the Global Tracheostomy Collaborative reporting protect data privacy?

Data entered by each site is visible only to that member site and to the Global Tracheostomy Collaborative database management group. No other site will have access to another site's dataset. The database management group maintains access to the full dataset for the purposes of data integrity, validation, analysis and reporting. The GTC will send out data reports to all participating sites, which will include de-identified comparative data, which does not allow identification or inference about the identity of other sites.

How is data stored securely in the GTC Quality Improvement database?

- Technical Attributes: REDCap stores its data and all system and project information in various relational database tables (i.e. utilizing foreign keys and indexes) within a single MySQL database. This data is stored in an unencrypted form, and resides at Vanderbilt University Medical Center. Vanderbilt University conducts daily (or twice daily) backup of these relational tables, to ensure proper and complete saving of inputted data The front end of REDCap is written in PHP, which is a widely used, robust, open source scripting language for web applications. This front-end web server is redcap.vanderbilt.edu, which can be accessed through any internet connection because it is protected by an SSL certificate.

- Data Monitoring: REDCap has a built-in audit trail that automatically logs all user activity and logs all pages edited by every user, including contextual information (e.g. the project or record being accessed). The data management committee of the GTC will run regular data quality assessment reports to ensure that data has been entered correctly. If sites have entered erroneous data they will receive notification from the data management committee with reference to the erroneous data field and patient identification. The GTC will assign each member of a site his or her own unique username. Using data access group associations, the GTC will restrict each site's access to their own site's data. Please refer to the video on "data exporting" on the member section of the GTC website.

- Data Exporting: The Data Export Tool has advanced export features that allow one to implement data de-identification methods, such as being able to automatically remove free-form text fields, remove dates, perform date shifting, and remove fields tagged as identifiers (e.g. PHI) from the data file being exported by the user. Your site will only be able to export data which you have entered and will not have access to data from other sites. You are responsible for securely storing data you export from REDCAP as per your hospital data storage guidelines.

- Data Security: To help protect and secure data stored in REDCap's database, the software application employs various methods to protect against malicious users who may attempt to identify and exploit any security vulnerabilities in the system (for a full description, please visit: www.project-redcap.org)

Additional Information:

For further information about the REDCAP system please visit (project-redcap.org). Please also refer to the following publication of the REDCAP system:

Paul A. Harris, Robert Taylor, Robert Thielke, Jonathon Payne, Nathaniel Gonzalez, Jose G. Conde, Research electronic data capture (REDCap) - A metadata-driven methodology and workflow process for providing translational research informatics support, J Biomed Inform. 2009 Apr;42(2):377-81.