STS Congenital Audit Instructions

Thank you for participating in The Society of Thoracic Surgeons (STS) Congenital Heart Surgery Database audit. The purpose of the audit is to evaluate consistency in data collection processes and validate the data contained in the database.

Our company is Cardiac Registry Support (CRS). The STS has contracted us to conduct the STS Congenital Audit for 2019/2020 cases. CRS has been abstracting and auditing data across various registries since 2009. By adhering to the STS Training Manual and Data Specification Manual, it is CRS's goal to provide an educational experience with feedback that will assure the integrity of collected data.

The audit process includes data abstraction performed on 20 randomly sampled index operations performed between July 1, 2019, and June 30, 2020, and submitted to IQVIA. An audit will also be conducted for all mortalities related to an index operations performed during this timeframe. In addition, there will be a comparison of your site's operating room cardiac surgery log and cases submitted to IQVIA during this timeframe.

Your lead congenital auditor is Angela Ebel, RN, MSN. Angela – a skilled congenital abstractor with over 12 years of experience – has worked with CRS since 2014. She regularly attends the annual STS Advances in Quality and Outcomes (AQO). One of two congenital heart surgeon auditors will also participate in the audit process.

Below you will find the steps required to complete the audit process. If at any time you have questions or concerns, please contact us at congenital@cardiacregistrysupport.com. Please include your STS Participant ID in all communication with CRS.

Step 1: Select an Audit Date (Due)

All audits are conducted by webinar on a specific date you select. The auditing surgeon and CRS will review the previously provided medical records on this date. The audit team will meet with you the morning of the audit date and provide your site summary results later that same day.

The below dates are available for the auditing surgeons to assist with the auditing process. Please select an audit date as soon as possible to get the date best for your site. The dates are first-come-first-served to all sites being audited, so please select and email CRS with an audit date as soon as possible.

Date	Time	Surgeon Auditor
	8am – 6pm	
	8am – 6pm	
	8am – 6pm	
	8am – 6pm	
	8am – 6pm	
	8am – 6pm	
	8am – 6pm	

Step 2: Upload the OR Case Log (<mark>Due</mark>)

To evaluate the completeness and comprehensiveness of the database, the auditor completes a comparison of cardiac cases performed by your surgeon(s) during 2019 and 2020 to cases you submitted to IQVIA. To complete the comparison, please assemble a **computer-generated operating room log** (list) of all July 1, 2019 – June 30, 2020 surgical cases (bedside, OR, non-cardiac, CPB, non-CPB, ECMO, etc.) completed by your STS surgeons. The file must be in Excel format and include only the date of procedure, procedure description, surgeon's name, and patient's medical record number. To learn more about the congenital OR Case Log, go to: http://www.youtube.com/watch?v=D4aFd1VuvRg

SurgDt	ProcDesc	Surgeon	MRN
02/07/2018	VSD repair	Smith	45678
02/14/2018	ASD repair	Jones	23456
02/23/2018	Coarctation Repair	Roberts	12345

Your uploaded file is maintained in designated access control locations that employ encryption to protect data at rest. All access to the designated locations is audited and monitored. Transmission of the data is conducted using compliant encryption algorithms and verified certificates meeting Health Insurance Portability and Accountability Act of 1996 (HIPAA) standards. Cardiac Registry Support's File transfer portal secures connection and transmissions with Transport Layer Security (TLS).

STEP A:
Go to: www.crshome.net
Click "LOGIN" in the upper right-hand corner.

                                          LOGIN

STEP B:
Enter your email address and the password provided in a separate email by your auditor. You will be asked to reset your password immediately. If you lose your password, email your auditor to have it reset.
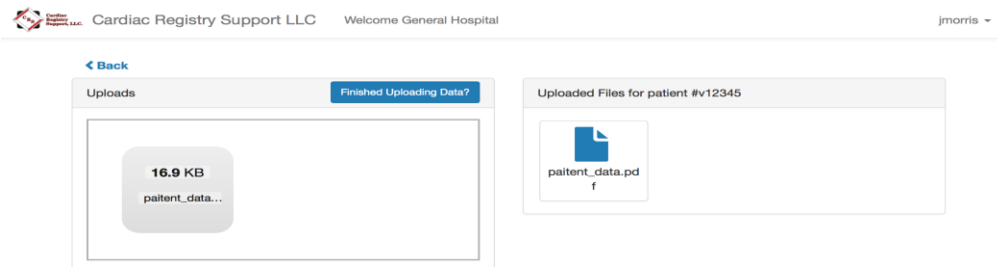
STEP C:
After you reset your password, login again with your new password. On the main page, click on the OR Case Log folder.

Drag the OR Case Log file from your computer to the upload area. You will see the file names you uploaded on the right-hand side.

STEP D: Once you are finished uploading your OR Case Log, click the "Finished Uploading Data?" button to close uploads and inform us that you are done uploading.
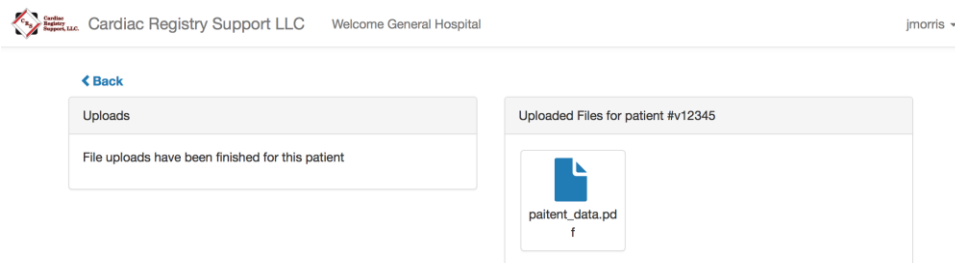
Notify CRS, via email, at congenital@cardiacregistrysupport.com when the file has been uploaded and is ready for audit. Be sure to include your Participant ID in the subject of the email.
Once we receive your computer-generated OR case log, CRS will begin to match your OR list to the list submitted to IQVIA. Once we match each case, we will send you a secure email highlighted with cases we have questions about. We then ask you to mark each unmatched case with the case type, mortality/non-mortality, and the reason why the case does not match. You will be able to select the reason from one of the following choices:

- Our site inadvertently missed this case and did not submit it at harvest time. We will submit this case next harvest.
- Our site does not enter this type of case.
- We abstracted the case but do not submit this case type to IQVIA//STS.
- This case was canceled on this date but not removed for the OR schedule.
- We inadvertently entered the incorrect surgical date; will correct the next harvest.
- Other: Please elaborate in next column

Step 3: Upload the 20 Random Audit Medical Records (Due)

A file is attached to the email that lists the 20 random cases selected by IQVIA for audit. The first tab lists the RANDOM cases to be audited and the second tab lists the MORTALITY cases for audit. Each case is listed by Operation ID, which is a de-identified number that links the case to the STS Database and

corresponds to a field in your vendor software. For the 20 cases selected, the below variables in Table 1 will be re-abstracted by the auditor and compared to the patients' medical records and the data submitted to IQVIA. To learn more about the Random Case Audit, go to:
http://www.youtube.com/watch?v=D4aFd1VuvRg

In the event the auditor notes a case ineligible for audit, another "oversampling" case will be used. Do not include oversampling cases in the upload. You may wish to prepare and save the first two cases on the oversampling list at your site.

Contact your Medical Records to assist with obtaining the required 20 cases medical record documents. Each case needs to be provided in a separate document, PDF format, with specific bookmarks denoting areas of the audit. If your Medical Records department automatically adds standard bookmarking (standard bookmarking is not preferred by the auditing surgeon), it will still be necessary for your site to add the specific bookmarks. Below are the specific required bookmarks requested by your auditing surgeon. It is critical to the success of your audit that the bookmarks requested be available in each document.

Required Bookmarks for Random 20 Cases:
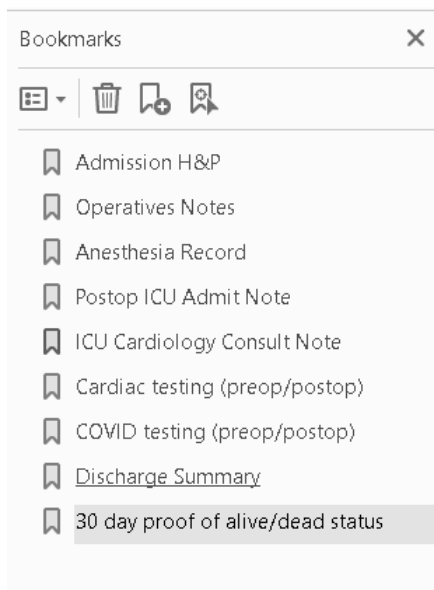
To add bookmarks:
Make sure you are on the page you would like to bookmark. Open the left arrow in your pdf to view the Bookmarks area.

Click on the bookmark symbol with the (+) sign. Then name the bookmark and click enter.
You may need to use an upgraded version of the pdf software to see the bookmark symbol and complete this task.

PDFs that do not include the requested information or are not bookmarked in a usable manner will be returned and you will be asked to re-create the PDF. If documentation is missing, the site data manager will be notified and asked to upload the requested documents.

Random Audit Case Data Elements		
Variable Name	SeqNo.	Short Name
Fundamental Diagnosis	374	FundDiagnosis
Preoperative Factors	850	PreOpFactor
Primary Diagnosis	900	PrimDiag
Diagnosis	890	Diagnosis
Operation Type	1056	OpType
Primary Procedure	940	PrimProc
Procedure	930	Procedure
Complications	4200	Complication
Date of Birth	310	DOB
Age at time of surgery	820	AgeDays
Date of Admission	780	AdmitDt
Date of Surgery	790	SurgDt
Date of Hospital Discharge	4220	HospDischDt
Weight	810	WeightKg
Height	800	HeightCm
Date of Database Discharge	4250	DBDischDt
Mortality Status at Hospital Discharge	4230	MtHospDisStat
Mortality Status at Database Discharge	4260	MtDBDisStat
Mortality-30-day Status	4300	Mt30Stat
Number of Cardiothoracic operations	1090	PrvCtOpN
Gender	340	Gender
Premature Birth (if <1 year)	350	Premature
Noncardiac Congenital Anatomic Abnormality	530	NCAA
Chromosomal Abnormality	570	ChromAb
Syndromes	610	Syndrome

|		
Gestational Age (if < 1 year)	370	GestAgeWeeks
Location from which Patient was Admitted	781	AdmitFromLog
Discharge Location	4240	DisLoctn
Anesthesia adverse event (for participants in Anesthesia)	6380	AnesAdvEvent
COVID – Diagnosis	6724	TempCode
COVID – Date	6723	TempDt

Step 4: Upload All Mortality Audit Medical Records (<mark>Due</mark>)

In addition, attached to the email is a listing of all site mortalities for data period July 1, 2019, and June 30, 2020, sent by IQVIA. For all site mortalities, the below variables in Table 2 will be re-abstracted by the auditor and compared to the patients' medical records and the data you submitted to DCRI.

Contact your Medical Records to assist with obtaining all mortality cases medical record documents. Each case needs to be provided in a separate document, PDF format, with specific bookmarks denoting areas of the audit. If your Medical Records department automatically adds standard bookmarking (standard bookmarking is not preferred by the auditing surgeon), it will still be necessary for your site to add the specific bookmarks. Below are the specific required bookmarks requested by your auditing surgeon for the mortality audit. It is critical to the success of your audit that the bookmarks requested be available in each document. To learn more about the Mortality Case Audit, go to: http://www.youtube.com/watch?v=D4aFd1VuvRg

Required Bookmarks for All Mortality Cases:
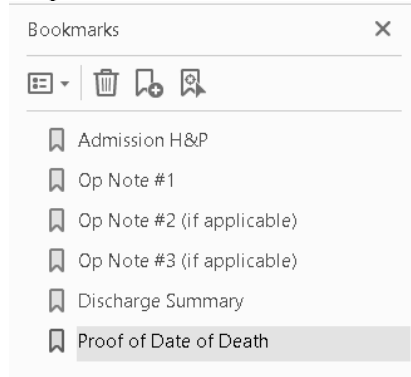
Mortality Audit Case Date Elements		
Variable Name	**SeqNo.**	**Short Name**
Date of Surgery	790	SurgDt
Date of Admission	780	AdmitDT
Date of Hospital Discharge	4220	HospDischDt
Date of Birth	310	DOB
Age at time of surgery	820	AgeDays
Gender	340	Gender

Operation Type	1056	OpType
Date of Database Discharge	4250	DBDischDt
Mortality Status at Hospital Discharge	4230	MtHospDisStat
Mortality Status at Database Discharge	4260	MtDBDisStat
Mortality-30-day Status	4300	Mt30Stat
Mortality Date	490	MtDate

Step 5: Upload the Linking File (Due)

Prior to the start of the audit, it will be necessary to provide auditors with a file that links the patient medical record number to the STS Operation ID. To provide this, insert each patient's medical record number into the case list attached in the indicated column provided for both random and mortality cases. Upload this file through the CRS portal.

SurgDt	OperationID	MRN	PrimProc	ProcedureDesc
03/29/2020	V647	12345	110	VSD repair, Patch
04/20/2020	V653	67899	370	TOF repair, Ventriculotomy, Transannular patch
12/13/2019	V769	74878	1280	Aortic arch repair
08/22/2019	V718	67578	110	VSD repair, Patch

Step 6: Await Audit Date

Once access to your organization's medical records is obtained, the initial review of medical records will begin. During this time, you may be contacted by email regarding questions (including missing information) to allow a thorough and accurate audit.

You will receive a reminder email of your upcoming audit seven days prior to the date.

It is possible that the auditing surgeon could be called into the OR at their site. In the event this occurs, the auditing surgeon contacts CRS, and CRS will email you immediately regarding the cancellation and rescheduling. We understand that your site surgeon may get called into the OR last minute also. If you need to cancel and reschedule, please email us as soon as you know, even if over the weekend.

Step 7: Day of Audit

On the day of your audit, the following agenda will be followed:

8am - 9am
- Site team and audit team on meet by webinar
- Introductions
- Audit team reviews purpose of audit, components of audit
- Site data manager presents site's data abstraction process to STS audit team.
- STS audit team reviews site's OR Case Log results.
- Dismissal, site data manager remains on-call for questions.

- Webinar locked once site personnel exit webinar.

9am - 1pm
- Auditing Surgeon and CRS working on Random Case Audit
- If auditing team is unable to locate a needed piece of information, CRS contacts site data manager by email or text.
  - CRS will unlock the webinar.
  - Site Data Manager enters webinar.
  - Site Data Manager logs into their EMR to provide needed information.
  - Site Data Manager exits webinar.
  - CRS locks webinar.

1pm - 2pm
- Auditing Surgeon and CRS break for lunch

2pm - 4pm
- Auditing Surgeon and CRS working on Mortality Case Audit
- If auditing team is unable to locate a needed piece of information, CRS contacts site data manager by email or text.
  - CRS will unlock the webinar.
  - Site Data Manager enters webinar,
  - Site Data Manager logs into their EMR to provide needed information.
  - Site Data Manager exits webinar.
  - CRS locks webinar.

4pm
- If ready, CRS sends draft audit results to the site data manager by email.

5pm - 6pm Summary Conference
- The site surgeon, site data manager, auditing surgeon, and CRS meet by webinar.
- The site may also invite other members of their team to the Summary Conference.
- The webinar is unlocked.
- The audit team will again reviews the purpose of the audit.
- The audit team will review:
  - 20 case audit results
  - major complications audit results
  - mortality case reviews results
  - summary and recommendations

At the conclusion of the summary conference, your site will be provided five working days to adjudicate any discrepancies noted in the draft audit report. Pleas provide explanations or documentation to congenital@cardiacregistrysupport.com. If your site offers no feedback by the end of the fifth working day, results will be emailed to STS. Afterward, STS will then provide your site the final audit results.

Thank you for your participation in the ongoing independent audit of the STS Congenital Heart Surgery Database. We look forward to working with you.