



STS Congenital Remote 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). We have been contracted by the STS to conduct the STS Congenital Audit for 2018 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 the goal of CRS to provide an educational experience with feedback that will assure the integrity of collected data.

The audit process includes data abstraction performed by Cardiac Registry Support on 20 randomly sampled index operations performed between January 1, 2018 and December 31, 2018 and submitted to Duke Clinical Research Institute (DCRI). An audit will also be conducted for all mortalities related to index operations performed during this timeframe. In addition, there will be a comparison of your operating room cardiac surgery log and cases submitted to DCRI during this timeframe.

Your lead Congenital Auditor is Angela Ebel, RN, MSN. Angela – a skilled congenital abstractor with over 11 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 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: Contact your Auditor

Email your auditor at congenital@cardiacregistrysupport.com before July 1, 2019 to set up a phone call. The purpose of the phone call is to gather some preliminary information about your facility and how you abstract and enter data. The attached questions will be discussed on the phone call. Answers to the above questions will be provided to STS in a final audit summary. During our phone call, you will be provided a username and password to the CRS secure file portal.

Step 2: Upload the OR Case Log

To evaluate the comprehensiveness of the database, the auditor completes a comparison of cardiac cases performed by your surgeon(s) during 2018 to cases you submitted to DCRI in 2018.

To complete the comparison, please gather a **computer-generated operating room log** (list) of all 2018 surgical cases (bedside, OR, non-cardiac, CPB, non-CPB, ECMO, etc.) completed by your 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 https://youtu.be/qD7FEPaQH_E



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

The OR Case Log upload is due August 1, 2019. 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.

STEP A:

Go to: www.crshome.net

Click "LOGIN" in the upper right-hand corner.



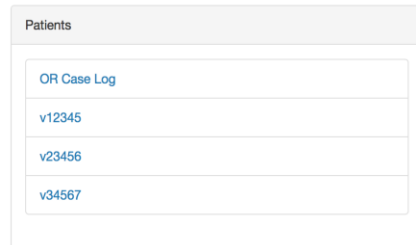
LOGIN

STEP B:

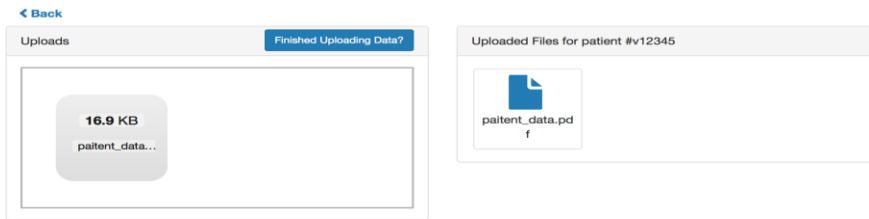
Enter your email address and the password you received on the phone call with your auditor. You will be asked to reset your password immediately. If you lose your password, email your auditor to have it reset.

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 e-mail, 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 DCRI. 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 didn't 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 DCRI/STS.
- This case was cancelled on this date but not removed for the OR schedule.
- We inadvertently entered the incorrect surgical date; will correct next harvest.
- Other: Please elaborate in next column

Step 3: Upload the Medical Records

Attached is the list of patients who will be audited, in Excel format. The tab lists the RANDOM cases to be audited and the second tab lists the MORTALILTY 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. The audit variables can be found in page five through six. 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 and/or IT department to assist with obtaining the required medical record documents. The documents must be provided in PDF format with bookmarks denoting each section. Below are sample PDF instructions to use as a guide in creating your medical records document. **For the RANDOM audit, if your Medical Record Department asks for the dates of medical records needed, an estimate is two months outpatient prior to surgical admission PLUS through inpatient admission PLUS six months postoperative outpatient care.**

Read through the below PDF instructions carefully. Each section provides guidance on specific documents to include for the audit. Work closely with your Medical Records and/or IT departments to assemble this PDF. It is critical to the success of your audit that you provide the information requested in this document.

To add bookmarks

- 1) Make sure you are on the page you would like to bookmark.
- 2) Click on the bookmark symbol. You may need to use an upgraded version of the software in order to see the bookmark symbol and complete this task.



- 3) Then name the bookmark and click enter.
- 4) Each of the following items will need to be bookmarked:

- Preop ECHO
- Preop cardiac cath (if present)
- Preop H&P (to include birth gestational age, non-cardiac congenital abnormalities, chromosomal abnormalities, syndromes and a list of previous cardiac surgeries. If not present in preop or admission H&P, provide as additional uploads)
- Admitting H&P
- Operative note
- Anesthesia record
- Perfusion record
- Extubation date/time
- Reintubation date/time (if present)
- Final extubation date/time (if present)
- post-op ICU admission note
- consult notes (this would be renal, pulmonary, ENT, infectious disease, neurology, etc)
- Post-op or pre-discharge echo
- any post-op cath reports (during the hospitalization)
- progress notes (MD notes during hospitalization)



- "All other documents" (such as lab values, RT notes and vent settings, social work, nursing notes placed all together at the end)
- Discharge summary
- Outpatient visit at or greater than 30 days postop
- If transferred to another acute care center or rehab center, provide documentation for date of discharge and any complications.

PDFs that do not include the requested information or are not bookmarked in a usable manner will be returned to you and you will be asked to re-create the PDF. Sites will have 5 business days to make the changes to the PDF files and re-upload to the portal. If documentation is missing, the site data manager will be notified and asked to upload the requested documents.

A file is attached to the email that lists the 20 random cases selected by DCRI for audit. In the event the auditor notes a case ineligible for audit, another "oversampling" case will be used. For the 20 cases, 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 DCRI.

TABLE 1: Random Case Audit Variables

Variable Name	SeqNo.	Short Name
Fundamental Diagnosis	382	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
Re-Intubated After Initial Postoperative Extubation	1071	ReIntubate
Initial Extubation Date/Time	1069	ExtubateDT
Final Extubation Date/Time	1072	FinExtubDT
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



Noncardiac Congenital Anatomic Abnormality	530	NCAA
Chromosomal Abnormality	570	ChromAb
Syndromes	610	Syndrome
Premature Birth	350	Premature
Gestational Age (if < 1 year)	370	GestAgeWeeks
Complications	4200	Complications
Discharge Location	4240	DisLoctn
Anesthesia adverse event (for participants in Anesthesia)	6380	AnesAdvEvent

In addition, attached to the email is a listing of all site mortalities for 2018 sent by DCRI. 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. **For the MORTALITY case audit, it is necessary for your Medical Record Department to upload ONLY the discharge summary and index case operative note. If the patient died outside of the organization, please provide documentation for data of death.**

TABLE 2: Mortality Case Audit Variables

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 4: Upload the Linking File

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
03/29/2018	V647	12345	110	VSD repair, Patch
04/20/2018	V653	67899	370	TOF repair, Ventriculotomy, Transanular patch
12/13/2018	V769	74878	1280	Aortic arch repair
08/22/2018	V718	67578	110	VSD repair, Patch



Step 5: Await Audit Results

Once access to your organization's medical records are obtained, the audit will begin. During this time, you may be contacted by email regarding questions (including missing information) to allow a thorough and accurate audit. It is imperative that CRS receives all records needed at the beginning of the audit. Please make sure the submitted files are complete and accurate as there will not be an opportunity for adjudication. STS will forward the final report to your Primary Data Contact and Surgeon Representative once the audit is complete.

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