STS Congenital On-Site 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 for the period of the audit.

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 be attending the site visit and assisting 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 **August 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.

Please note we will provide you with three potential dates for the STS Congenital Cardiac Surgeon and CRS Auditor to set up the site visit.   Please confirm with your surgeon which of the dates is acceptable for a site visit.

Step 2: Facilitate Auditor Access to Medical Records

During the site visit, it will be necessary to have access to your electronic medical records system for each of the 20 case audits and all mortality cases. For our visit we will require access to **two department computers** and our own EMR usernames and passwords. We will be bringing our own

laptops to enter data into audit software. If it is necessary to complete site HIPPA forms, please email them as soon as possible to congenital@cardiacregistrysupport.com.

A file is attached that lists the 20 random cases selected by DCRI for audit. The first tab includes cases RANDOM cases to be audited and the second tab includes MORTALITY cases to be audited. In the event the auditor notes a case that becomes 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 you 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 Events (if participating in Anesthesia Module)	6380	AnesAdvEvent

Also 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.

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 3: 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 for 2018.

To complete the comparison, please gather a **computer-generated operating room case 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 ONLY include the surgical date, 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

After receiving your login and password for the CRS secure portal, upload the OR Case Log by 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 password you received on the phone from 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 in again with your new password.
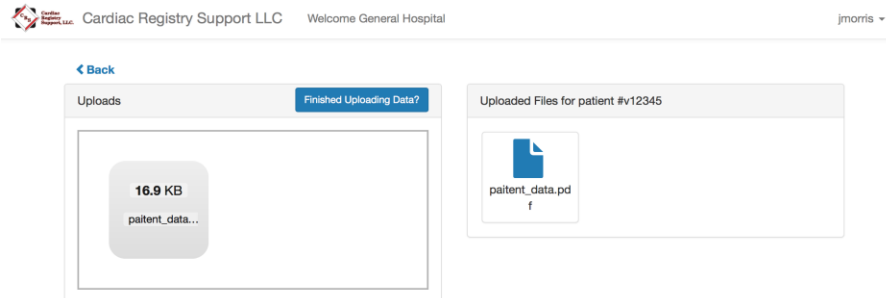On the main page, click on the OR Case Log folder.
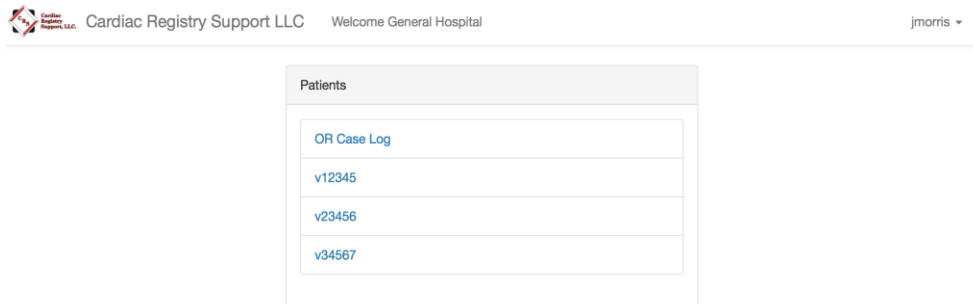
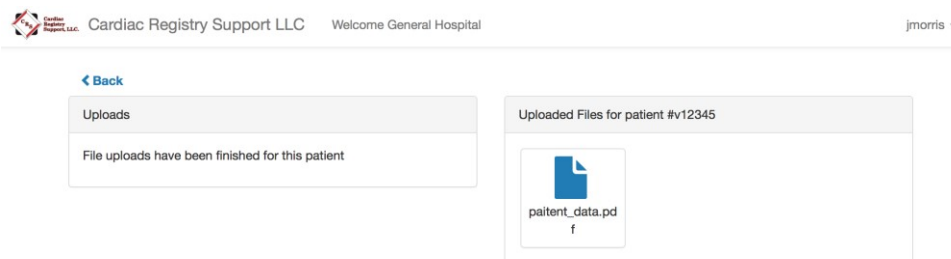Drag the OR Case Log file from your computer to the upload area.
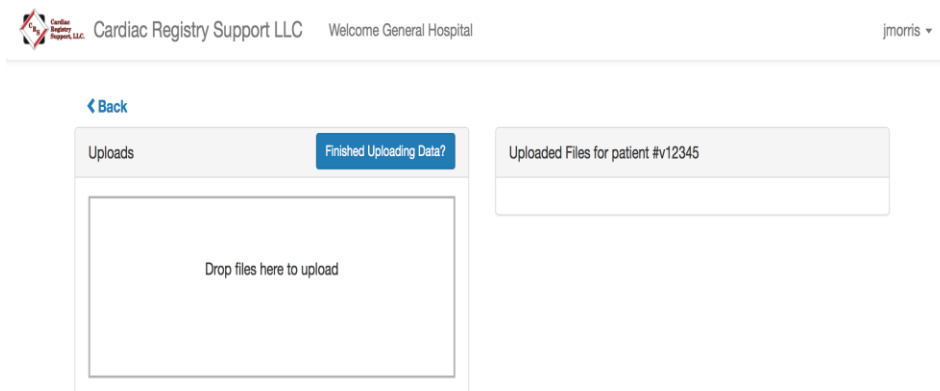
You will see the file names you uploaded on the right-hand side.

STEP D:

Once you are finished uploading the 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 any 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 scheduling software.
- We inadvertently entered the incorrect surgical date; will correct next harvest.
- Other: Please elaborate in next column

Step 4: Upload Mortality Documents

For each mortality (Patient ID) listed on attached Excel document, upload the following documents through the CRS Portal in the folder provided:
- The surgeon's operative note associated with the index operation, even if the operation occurred in the previous calendar year.
- The final discharge or death summary.
- If the death occurred outside of your facility, provide documentation for date of death.

Step 5: Upload the Linking File

Prior to the audit visit, it will be necessary to provide auditors with a file that crossmatches 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 to 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 6: Day of Audit

It will be helpful during our site visit to have the data manager available to assist with finding data points in the medical record. The below tentative schedule will be followed:

Day 1:
0800   STS Congenital Auditing Surgeon and CRS auditor to meet with Data Manager and Surgeon to discuss process, questions, and schedule for the day
0900   Auditors begin medical records case review of random case audits
1200   Lunch
1300   Auditors continue medical records review of random case audit
1630   Stop for the day

Day 2:
0800   Auditors begin medical records case review of site's mortalities
1000   Auditors compile report for summary conference
1200   STS Congenital Auditing Surgeon and CRS auditor conduct summary conference with Data Manager and Surgeon. Please feel free to invite additional Surgeons, Anesthesia, Perfusion, Cardiac Surgery PA/NP staff. We will require a room to accommodate the attendees expected.
1330   Auditors leave

Upon audit completion, a Congenital Summary and Mortality Summary Report (with data completeness rates, data accuracy, and Operation IDs with any mismatches) will be completed and sent to the STS. Please make sure your EMR 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.