

# PedCath IMPACT User's Guide

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## Overview

### IMPACT Overview

The American College of Cardiology Foundation's NCDR developed a new, national clinical data registry. The IMPACT Registry™ (**IM**proving **P**ediatric and **A**dult **C**ongenital **T**reatment) that assesses the prevalence, demographics, management and outcomes of pediatric and adult patients with congenital heart disease who are undergoing diagnostic catheterizations and catheter-based interventions. The collection and analysis of this data will facilitate performance measurement, benchmarking, and quality improvement initiatives. The IMPACT Registry will provide significant contributions to the knowledge base and outcomes associated with congenital heart disease. To date, no single registry has collected sufficient national quality-focused data on the management and real-world outcomes of quality-focused data of patients who undergo diagnostic and interventional catheterizations.

### PedCath IMPACT Registry Module

PedCath's IMPACT module will allow you to collect and submit patient demographic, admission, and procedural data to the IMPACT Registry.

The PedCath IMPACT Registry module is for the most part, a self-contained component that contains all of the data collected for the IMPACT Registry. The IMPACT module leverages much of the data already entered for the PedCath cath report, so that it will not have to be entered multiple times. (Any data that is shared will either not be editable within the IMPACT module, or synchronized between both locations.)

Ten procedure types are currently collected:

- Diagnostic Cath
- ASD Closure
- Coarctation Procedure
- Aortic Valvuloplasty
- Pulmonary Valvuloplasty
- PDA Closure
- Proximal PA Stenting Procedure
- Electrophysiology Cath
- Electrophysiology Ablation Procedure (EAP)
- Transcatheter Pulmonary Valve Replacement (TPVR)

Genetic/Congenital Conditions	History & Risk Factors	Arrhythmias	Research Studies
22q11 Deletion (DiGeorge Syndrome): <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	Noonan Syndrome: <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	Rubella: <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	
Alagille Syndrome: <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	Trisomy-13: <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	Trisomy-18: <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	
Congenital Diaphragmatic Hernia: <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	Down Syndrome: <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	Turner Syndrome: <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	
Down Syndrome: <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	Heterotaxy: <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	Williams-Beuren Syndrome: <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	
Heterotaxy: <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	Marfan Syndrome: <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes		
Marfan Syndrome: <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes			

The Episode of Care information (admission/discharge, insurance, patient history, etc.), adds a new hierarchy level to PedCath between the Patient and Cath levels. The Episode of Care data will need to be entered only once for a patient's hospital visit, regardless of the number of cath procedures performed

during that visit. When adding a second IMPACT cath record within a hospital visit you will be prompted to use the existing Episode of Care.

Even though there is an added hierarchy level, the main PedCath interface remains largely unchanged (the arrival and discharge dates are now shown underneath the cath grid on the Browse screen). This was done to allow PedCath users to create cath reports as they normally do and give them the choice to either work on the IMPACT data themselves, or ignore the IMPACT module and have other staff members fill in the data to break up the work.

The IMPACT administrative module will allow you to create submission files (one per quarter), create a number of CSV extract files, or import IMPACT cases from another vendor.

### More on Work Flow

A PedCath report must exist before adding an IMPACT report to it. It does not have to be completed or signed to fill in the IMPACT data. It is recommended to add your PedCath personnel to the cath report prior to working on the IMPACT Case Data section, so that the operator may be specified for that case.

You can however fill in the Episode of Care data before the PedCath report is started, if desired.

**Note on Cath Locking:** IMPACT data may be edited after the PedCath cath report has been signed. However any data within the IMPACT module that is shared between IMPACT and the PedCath report will not be editable after the PedCath report has been locked.

### Case Complete Checkoff

PedCath also gives you the option to specify if the IMPACT forms for a case have been filled out to completion and reviewed. This is an optional feature that can be turned on/off for your institution in the IMPACT administrative options.

If the feature is enabled, a **Case Complete** check box will appear on the IMPACT form and a check icon will be shown in the cath grid on the Browse screen indicating what cases have been checked off (A blank form icon will be shown next to cases where the IMPACT forms have been started but not checked off).

The data panels will still be editable after the Case Complete box is checked for a case. This feature can be used to facilitate data entry work flow and is ignored by the submission module (only cases with a discharge date set will be submitted to IMPACT.)

## PedCath Cath Report/IMPACT Shared Data

Much of the data on the PedCath Edit screen will be submitted to IMPACT. Once entered on the PedCath Edit screen the data will show up within the IMPACT Registry module and will not have to be re-entered.

### Case Data

The following table shows cath-level data from the PedCath report that are shared with IMPACT.

Field	Editable in IMPACT Module	Sync Details
Cath Date	No	
Procedure Start Time	Yes if missing	One-way sync from cath report if the value is set. If entered in the IMPACT module it doesn't sync back to cath report.
Procedure End Date		
Procedure End Time		
Weight	No	
Height	No	
Vein/Artery (Site and Largest Sheath Size)	Yes	Two-way sync
Closure Methods	Yes	Two-way sync
Fluoro time (min)	No	
Contrast Total (cc)	No	
Rad Dose	No	
Total DAP	No	
Case Operator	Yes	Two-way sync
Diagnoses/Procedures	Yes	Two-way sync IMPACT coding can be used on the PedCath report with a global setting.

### Hemodynamics

PedCath will send select measurements from your first set of hemodynamics to IMPACT (or the one selected as the IMPACT set with baseline measurements). Fields with green bars indicate the data going to IMPACT (there are some with blue bars that are submitted as well).

The following table shows hemodynamic data collected by IMPACT and the source PedCath fields.

IMPACT Data Collected	PedCath Field
Systemic Artery Saturation	dAO sat, or SA sat override if specified
Mixed Venous Saturation	SVC sat, or MV sat override if specified
Systemic Ventricular Systolic/End Diastolic	If systemic ventricle is LV: LV Systolic, LV End Diastolic  If systemic ventricle is RV: RV Systolic, RV End Diastolic

Systemic Blood Pressure (Systolic, Diastolic, Mean)	dAO systolic, diastolic, mean (or Systemic mean override if specified)
PA Pressure (Systolic and Mean)	PA systolic and mean (or PA mean override)
Pulmonary Ventricular Systolic Pressure	If pulmonary ventricle is RV: RV Systolic  If pulmonary ventricle is LV: LV Systolic
Pulmonary Vascular Resistance Index	Rp (calculated)
Cardiac Index	Qs (calculated)
Qp/Qs ratio	Qp/Qs (calculated)

If any hemodynamics are missing or incorrect on the IMPACT forms they can be updated on the PedCath Edit screen (click Edit Cath from the main Browse screen). It's recommended to coordinate changing any data with the attending physician for the case since any data changed there will affect the cath report. It's recommended to enter the values into the Calculation Overrides section rather than the main site pressures when you can, as to not incorrectly indicate a value was taken during the case when it wasn't. For instance if the dAO pressure was not taken during the case, but instead a non-invasive systemic blood pressure was taken (which is acceptable by IMPACT) it's recommended to enter it into the calculation overrides systemic pressure boxes.

The screenshot shows the IMPACT software interface for editing a catheter report. The main window displays patient information, case information, and hemodynamic data. A 'Calculation Override' dialog box is open, allowing users to override specific values. The dialog box has a 'Systemic' section with input fields for 'Sys', 'Dias', and 'dAO'. A green arrow points from a callout box labeled 'Click here' to the 'Calculation Override' button in the main interface.

PO2	Site	O2%	Default	Mean	Default Mean
0	MV	67	67 SVC	6	6 RA
0	PA	89	89 PA	25	25 PA
0	PV	97	97 LA	9	9 Avg
0	SA	97	97 dAO	61	61 dAO

Site	Sys/A	Dias/V	Mean
SVC			
RA			6
RV	50		P
PA	37		25
RPA			
LPA	37	12	22

Site	Sys/A	Dias/V	Mean
LA			8
LV	95	10	S
aAO	95	39	57
dAO	97	40	61

## Systemic/Pulmonary Ventricle Designations

IMPACT is interested in collecting the systemic and pulmonary ventricle pressures. Since PedCath does not collect data in this way, PedCath8 now allows you to designate which ventricle is the systemic ventricle and which is the pulmonary. You will need to change the designation from the defaults whenever a patient is double outlet, has transposition of the great arteries, or other configuration where the LV is not the systemic ventricle and/or RV is not the pulmonary ventricle.

To change the ventricles designations click the S or P next to either the RV or LV pressures in the hemodynamics grid.

If the patient is single ventricle, please specify so within the Episode of Care History and Risk Factors section. If this is the case you will be able to set the systemic ventricle designation but not the pulmonary.

The screenshot displays the 'Edit Cath Report' window with the following sections:

- Patient Information:** First Name: Iggv, Middle Name: K, Last Name: Impack, Medical Record Number: Other123, Date of Birth: 08/15/1965, Gender: Male.
- Case Information:** Cath Date: 05/24/2016, Cath Number: 873665, Weight (kg): 170.0, Height (cm): 80.0, Account Number: 93756.
- Personnel:** Operator: Allen D. Everett, MD, Role: Attending.
- Hemodynamic Sets:** Set 1 of 1: Example cath, IMPACT Set checked.
- Calculations:** BSA = 1.53 m<sup>2</sup>, Qp = 18.47 L/min, Qs = 4.92 L/min, Rp = 0.87 units, Rs = 11.17 units, Qp/Qs = 3.75 : 1, Rp/Rs = 0.08.
- Hemodynamics Grid:** A table with columns for O2%, Site, Sys/A, Dias/V, and Mean. The PA (89) site has a 'P' designation in the Mean column.


The 'Specify Systemic/Pulmonary Ventricles' dialog box contains the following options:

- Systemic Ventricle:**  Left Ventricle,  Right Ventricle
- Pulmonary Ventricle:**  Right Ventricle,  Left Ventricle,  None

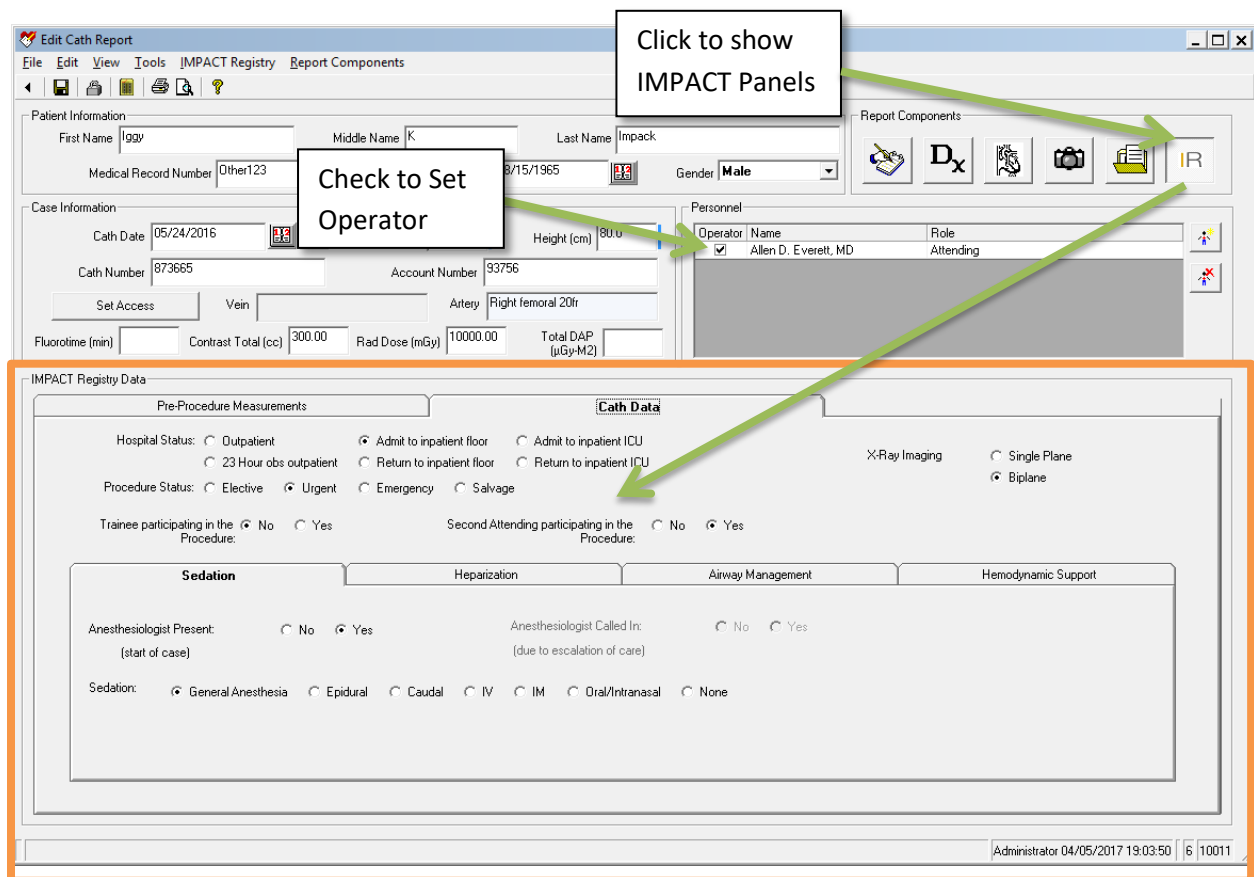
A callout box labeled 'Click here' points to the 'P' designation in the hemodynamic grid.

## Access IMPACT Data on Edit Screen

As of version 8.1, PedCath will allow you to access and edit additional IMPACT data directly from the PedCath Edit Screen. You will be able to edit any of the IMPACT pre-procedure and cath level measurements.

To view the IMPACT panels, simply click the  toggle button in the Report Components group, and the IMPACT data will be displayed where the Hemodynamics normally are, on the lower half of the screen.

The case operator may be set as well, by checking off the appropriate staff member in the Personnel grid.



The screenshot displays the 'Edit Cath Report' application window. The top menu includes 'File', 'Edit', 'View', 'Tools', 'IMPACT Registry', and 'Report Components'. The main area is divided into several sections:

- Patient Information:** Fields for First Name (I99V), Middle Name (K), Last Name (Impack), Medical Record Number (Dther123), Birth Date (8/15/1965), and Gender (Male).
- Case Information:** Fields for Cath Date (05/24/2016), Cath Number (873665), Account Number (93756), and Artery (Right femoral 20fr).
- Personnel:** A table with columns for Operator Name and Role. The entry 'Allen D. Everett, MD' is checked under the Operator Name column.
- Report Components:** A group of icons including 'Dx', 'IR', and others. A callout box labeled 'Click to show IMPACT Panels' points to the 'IR' icon.
- IMPACT Registry Data:** A large panel outlined in orange, containing various measurement options. A callout box labeled 'Check to Set Operator' points to the 'Operator' checkbox in the 'Cath Data' section.

The 'IMPACT Registry Data' panel includes the following sections:

- Pre-Procedure Measurements:** Radio buttons for Hospital Status (Outpatient, Admit to inpatient floor, Admit to inpatient ICU, 23 Hour obs outpatient, Return to inpatient floor, Return to inpatient ICU), Procedure Status (Elective, Urgent, Emergency, Salvage), and Trainee/Second Attending participation.
- Cath Data:** Radio buttons for X-Ray Imaging (Single Plane, Biplane).
- Sedation:** Radio buttons for Anesthesiologist Present (No, Yes) and Sedation type (General Anesthesia, Epidural, Caudal, IV, IM, Oral/Intranasal, None).

The bottom right corner of the window shows the text 'Administrator 04/05/2017 19:03:50 | 6 | 10011'.



## IMPACT Registry Module

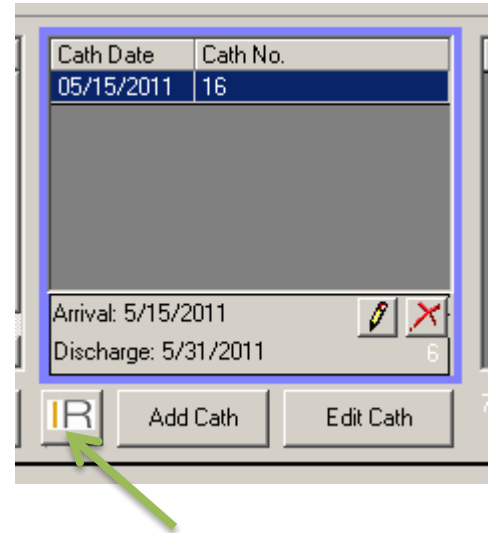
To load the IMPACT Registry Module, simply highlight a cath report and click the “IR” button. This will start a new IMPACT episode of care and case record if they have not been started yet; otherwise it will allow you to view or edit the existing data.

The module is split up into multiple data panels. You can access each panel by clicking the navigation links on the left side of the screen. The Procedure-Specific Data panel links are not shown until the performed procedures are specified.

When you select any field on any of the data panels, the field number and coding instructions will be shown at the bottom of the screen. Click the question mark button for more information about this field.

Pick lists are available for the Pre-Procedure Diagnosis, Specific Procedures performed, and Events. The interface for those lists works in the same way as the Dx section in PedCath, and is not detailed here.

The Episode of Care panel is selected by default when you enter the registry module. The next sections will detail the data panels that make up the IMPACT Registry module.



Print / Validate / Save

Navigation Links

Data Entry Panel

Coding Instructions

## IMPACT Module Data Panels

### Demographics

The patient demographic information should already be filled out from the PedCath patient record (there are some fields PedCath does not require that may be missing – those should be filled in for IMPACT if known). Changing the information here will change the patient record in PedCath.

In addition to the main elements there are two auxiliary fields (Aux1 and Aux2). You may be instructed by NCDR to fill in these fields for certain patients. There is also an option to exclude demographic information from the submission file for this patient. These options are available only within the IMPACT module and not on the main PedCath Patient Edit form.

The screenshot displays the 'PedCath - IMPACT Registry v2.0' application window. At the top, a yellow banner shows patient information: 'Patient: Impack, Iggy K', 'Cath Date: 5/24/2016', and 'Cath #: 873665'. A green arrow points to the 'Demographics' tab in the left-hand navigation menu. The main content area is filled with demographic data entry fields:

- First Name:
- Middle:
- Last Name:
- MRN:
- Date of Birth:  (with a calendar icon)
- Gender:  (dropdown menu)
- SSN:    (with a checkbox for 'SSN Not Available')
- Auxiliary 1:
- Auxiliary 2:
- Other ID:
- Checkboxes for 'Exclude identifying fields from submission'
- Race section: 'Race: (check all that apply)' with options for White, Black/African American, American Indian/Alaskan Native, Asian (Asian Indian, Chinese, Filipino, Japanese, Korean, Vietnamese, Other), and Native Hawaiian/Pacific Islander (Native Hawaiian, Guamanian or Chamorro, Samoan, Other Island).
- Hispanic or Latino Ethnicity: Radio buttons for 'No' (selected) and 'Yes', with sub-options for Mexican, Mexican-American, Chicano, Puerto Rican, Cuban, and Other Hispanic, Latino or Spanish Origin.

At the bottom left, a 'Case Complete' checkbox is checked. A bottom status bar contains a help icon, a message box with '[2010. FirstName] Coding Instructions: Indicate the patient's first name.' and 'Target Value: The value on arrival at this facility', and 'Save & Close' and 'Close' buttons.

## Episode of Care

An episode of care stores data related to a patient's hospital visit. This includes arrival/discharge information, insurance information, prior caths and surgeries, genetic conditions and risk factors.

An episode of care may be associated with one or more cath procedures.

PedCath - IMPACT Registry v2.0

Patient: Impack, Iggy K Cath Date: 5/24/2016 Cath #: 873665

IMPACT Registry™

Demographics

Episode of Care

Case

Pre-Procedure Clinical Evaluation

Cath Data

Hemodynamics

Procedures Performed

ASD Closure

Coarctation Procedure

Aortic Valvuloplasty

Pulmonary Valvuloplasty

PDA Closure

Proximal PA Stenting Procedure

Electrophysiology Ablation Procedure

TPVR

Events

Discharge

✓ Case Complete

Arrival Date: 05/10/2016 Patient Zip Code: Zip Code N/A

Insurance Payers: (check all that apply)

Private Health Insurance  Medicare  Medicaid  Military Health Care

State-specific Plan (non-Medicare)  Indian Health Service  Non-US Insurance  None

HIC: 55555000312

Premature Birth (if < 1 yr old):  No  Yes

Birth Weight (if < 30 days old): kg

Gestational Age (if < 1 yr old): weeks

Fundamental Diagnosis Code:

Prior Cardiac Catheterization:  No  Yes

Number of Prior Cardiac Catheterizations: 3

Date of Last Catheterization: 10/02/2010

Most Recent Procedures(s):

420. Conduit: RA to RV (Device implantation)

410. Conduit: RA to PA (Device implantation)

400. Conduit: LV to PA (Device implantation)

Prior Cardiac Surgery:  No  Yes

Number of Prior Cardiac Surgeries: 6

Date of Last Surgery:

Most Recent Surgery(s):

30. ASD Repair: Patch

40. ASD Repair: Device

20. ASD Repair: Primary closure

Genetic/Congenital Conditions History & Risk Factors Arrhythmia Research Studies

22q11Deletion (DiGeorge Syndrome):  No  Yes Noonan Syndrome:  No  Yes

Alagille Syndrome:  No  Yes Rubella:  No  Yes

Congenital Diaphragmatic Hernia:  No  Yes Trisomy-13:  No  Yes

Down Syndrome:  No  Yes Trisomy-18:  No  Yes

Heterotaxy:  No  Yes Turner Syndrome:  No  Yes

Marfan Syndrome:  No  Yes Williams-Beuren Syndrome:  No  Yes

No To All

Patient Restriction Auxiliary 3: Auxiliary 4:

[3000. ArrivalDate] Coding Instructions: Indicate the date the patient arrived at your facility. Target Value: N/A

Save & Close Close



The Prior Cath Catherization import will look at your cath database and tell you how many prior caths, date of the last cath, and the most recent procedures performed. You can use the information returned in the wizard to fill in those fields on the Episode of Care panel.

The discharge information is part of the Episode of Care record, but is stored on the Discharge panel, described in a later section.

Two auxiliary values (3 and 4) can be entered on this form if instructed to do so by NCDR.

Prior Caths

The following information was found in the PedCath database:

Cases Found: 2

Last Cath Date: 6/3/2011

Most Recent Procedures

115. Pulmonary artery: Central (Proximal left and/or pro:

Use Cancel

See the **Managing Episodes of Care** section for information on managing the episode of care records outside of the main IMPACT module.

### Pre-Procedure Clinical Evaluation

In the Pre-Procedure Clinical Evaluation section you will enter some pre-procedure lab measurements, medications, rhythms, as well as select the pre-procedure diagnosis codes. Height and Weight are taken from the PedCath report. The pre-procedure diagnosis codes are chosen from a hierarchical list similarly to the Dx section of PedCath.

PedCath - IMPACT Registry v2.0

Patient: Impack, Iggy K Cath Date: 5/24/2016 Cath #: 873665

IMPACT Registry™

**Case**

- Demographics
- Episode of Care
- Pre-Procedure Clinical Evaluation**
- Cath Data
- Hemodynamics
- Procedures Performed
  - ASD Closure
  - Coarctation Procedure
  - Aortic Valvuloplasty
  - Pulmonary Valvuloplasty
  - PDA Closure
  - Proximal PA Stenting Procedure
  - Electrophysiology Ablation Procedure
  - TPVR
- Events
- Discharge

Case Complete

Pre-Procedure Diagnosis Code(s):  
800. Single ventricle: DIRV  
850. Single ventricle: Other  
900. TGA: VSD  
Height: 80 cm  
Weight: 170 kg  
[Edit]

Pre-Procedure Labs:  
Hemoglobin: 15 g/dL Creatinine: 8 mg/mL O2 Sat: 80 %  
 Not Drawn  Not Drawn

Pre-Procedure Conditions:  
Single Ventricle:  No  Yes Sepsis:  No  Yes  
Necrotizing Enterocolitis:  No  Yes (if < 30 days old) Pregnant:  No  Yes

Pre-Procedure Medications:  
(check all that apply)  
 Antiarrhythmics  Anticoagulants  Antihypertensives  Antiplatelets  
 Beta Blockers  Diuretics  Prostaglandins  Vasodilators

Pre-Procedure Rhythms:  
(check all that apply)  
 Sinus Rhythm  Atrial Ectopic Tachycardia (AET)  Supraventricular Tachycardia (SVT)  
 Afib/Flutter  Junctional Rhythm  Idioventricular Rhythm  
 Second Degree AV Block  Third Degree AV Block  Paced

[3000. ArrivalDate] Coding Instructions: Indicate the date the patient arrived at your facility.  
Target Value: N/A

Save & Close Close

## Cath Data

The Cath Data section will allow you to enter data pertaining to the case such as the cath arrival/departure time, catheter access and closure methods, sedation, heparinization, airway management, and hemodynamic support (Inotrope, ECMO and LVAD use).

The Operator drop down list will allow you to choose the operator for the case from staff members involved in the case. You must add staff members to the PedCath report before they will show up in the operator list. If the staff member does not have an NPI number associated with them, it should be specified on the staff edit screen before submission to the registry.

The Cath Lab Arrival Date will be set automatically from the cath date on the PedCath report. The arrival time is required for IMPACT submission.

Fluoro Time/Dose and Contrast are taken from the PedCath report and cannot be changed on the IMPACT forms. An indexed dosage value may be specified on the IMPACT form (only one fluoro time/dose value need be specified).

Two auxiliary values (5 and 6), can be entered on this form if instructed to do so by NCDR.

PedCath - IMPACT Registry v2.0

Patient: Impack, Iggy K Cath Date: 5/24/2016 Cath #: 873665

IMPACT Registry

Demographics

Episode of Care

Case

Pre-Procedure Clinical Evaluation

**Cath Data**

Hemodynamics

Procedures Performed

- ASD Closure
- Coarctation Procedure
- Aortic Valvuloplasty
- Pulmonary Valvuloplasty
- PDA Closure
- Proximal PA Stenting Procedure
- Electrophysiology Ablation Procedure
- TPVR

Events

Discharge

Case Complete

Procedure Start Date/Time: 05/24/2016 10:00 Procedure End Date/Time: 05/24/2016 13:30

Operator: Allen D. Everett, MD (NPI=) Trainee participating in the Procedure: No Yes Second Attending participating in the Procedure: No Yes

Hospital Status: Outpatient Admit to inpatient floor Admit to inpatient ICU  
23 Hour obs outpatient Return to inpatient floor Return to inpatient ICU

Procedure Status: Elective Urgent Emergency Salvage

Access Location: Venous Arterial Both

**Venous Access**

Venous Access Site: Left brachial Right brachial Left femoral Right femoral Left jugular Right jugular Left subclavian Right subclavian Hepatic Transthoracic Umbilical Other

Venous Sheath Size: French (largest)

Venous Closure Methods: Add Remove

Method not documented

**Fluoroscopy** Sedation Heparization Airway Management Hemodynamic Support

X-Ray Imaging: Single Plane Biplane

Contrast Volume: 300 mL Cumulative Air Kerma: 10000 mGy

Fluoro Time: minutes Dose Area Product: µGy-M2

Auxiliary 5: Auxiliary 6:

[5048: ProcStartTime] **Coding Instructions:** Indicate the time the procedure started, to the nearest minute. The time of the procedure is the time that the skin incision, vascular access, or its equivalent, was made in order to start the procedure.

**Notes:** Indicate the time (hours:minutes) using the military 24-hour clock, beginning at midnight (0000 hours).

Save & Close Close

## Hemodynamics

The hemodynamics data on this form is all read-only and taken from the PedCath report. Please refer to the prior Hemodynamics section (page five) regarding PedCath/IMPACT shared data for information on entering the hemodynamic data on the PedCath Edit screen.

PedCath - IMPACT Registry v2.0

Patient: Impack, Iggy K Cath Date: 5/24/2016 Cath #: 873665

IMPACT Registry™

**Demographics**

**Episode of Care**

**Case**

Pre-Procedure Clinical Evaluation

Cath Data

**Hemodynamics**

Procedures Performed

- ASD Closure
- Coarctation Procedure
- Aortic Valvuloplasty
- Pulmonary Valvuloplasty
- PDA Closure
- Proximal PA Stenting Procedure
- Electrophysiology Ablation Procedure
- TPVR

Events

Discharge

Case Complete

Baseline Hemodynamics

Systemic Arterial Saturation:  %  Not Assessed

Mixed Venous Saturation:  %  Not Assessed

Systemic Ventricular Pressure:

(Systolic)  mmHg  Not Assessed

(End Diastolic)  mmHg  Not Assessed

PA Pressure:

(Systolic)  mmHg  Not Assessed

(Mean)  mmHg  Not Assessed

Systemic Blood Pressure:

(Systolic)  mmHg  Not Assessed

(Diastolic)  mmHg  Not Assessed

(Mean)  mmHg  Not Assessed

Pulmonary Ventricular Systolic Pressure:  mmHg  Not Assessed

Pulmonary Vascular Resistance Index:  Wood Units\*m2  Not Assessed

Cardiac Index:  L/min/m2  Not Assessed

Qp/Qs ratio:   Not Assessed

Choose Baseline Set **(Data Entered on PedCath Edit Screen)**

Set **LV is Systemic Ventricle**

**RV is Pulmonary Ventricle**

**[6000. SystemicArtSat] Coding Instructions:** Indicate the systemic arterial saturation obtained during the procedure in %.

**Notes:** The systemic arterial saturation can be obtained by invasive or non-invasive means. Pulse oximetry saturation may be used if the arterial saturation was not measured with an arterial blood sample. If the value obtained is outside of the valid range, code the highest or lowest number possible.

Save & Close Close

## Procedures Performed

In the Procedures Performed section, check off all of the procedures that were performed for the case.

All of the procedures except for Diagnostic Cath will require additional procedure-specific data to be entered.

After checking a procedure, a data panel link will be shown on the left side of the screen within the Procedure-Specific Data group.

You can also specify any additional specific procedures by choosing them from a pick-list.

The screenshot shows the 'PedCath - IMPACT Registry v2.0' application window. The patient information at the top is 'Patient: Impact, Iggy K', 'Cath Date: 5/24/2016', and 'Cath #: 873665'. The left sidebar contains a navigation menu with the following items: Demographics, Episode of Care, Case (Pre-Procedure, Clinical Evaluation, Cath Data, Hemodynamics), Procedures Performed (highlighted with a green arrow), Events, and Discharge. Under 'Procedures Performed', several sub-items are listed, some with checkboxes: ASD Closure, Coarctation Procedure, Aortic Valvuloplasty, Pulmonary Valvuloplasty, PDA Closure, Proximal PA Stenting Procedure, Electrophysiology Ablation Procedure, and TPVR. The main content area shows a list of checked procedures: Diagnostic Cath, ASD Closure, Coarctation Procedure, Aortic Valvuloplasty, Pulmonary Valvuloplasty, PDA Closure, Proximal PA Stenting, Electrophysiology Cath, Electrophysiology Ablation Procedure, and Transcatheter Pulmonary Valve Replacement (TPVR). Below this is a text box for 'Specific Procedure(s):' containing the text: '260. Conduit: LV to aorta (Coil implantation)', '150. Pulmonary vein: Lingula (Lingular pulmonary vein) (Balloon dilation)', and '400. Conduit: LV to PA (Device implantation)'. An 'Edit' button is located to the right of this text box. A callout box with a bracket points to the 'Procedures Performed' link in the sidebar, containing the text: 'Procedure-Specific Data Panel links show here'. At the bottom of the window, there is a 'Coding Instructions' section with a 'Target Value: N/A' and 'Save & Close' and 'Close' buttons.

## ASD Closure

The ASD Closure section will be available if ASD Closure is checked under the Procedures Performed section. It is required to have at least one defect.

To add more than one defect, click the Add Defect button. Clicking the Remove Defect button will remove the currently active defect tab.

## Managing Devices

To add any devices, you must mark one or more defects as treated.

To add a device, type in the device id within the device id column or click the icon within that column to bring up the device list.

To remove a device, either delete the Device ID number, or right-click the number within the Num column and choose Delete Device.

To designate the defects that are treated by a particular device, type the defect numbers within the Associated Defect(s) column, separated by commas if more than one. So for instance if the device should be associated with Defect 1 and Defect 3, type "1, 3" in the grid cell.

Patient: Impack, Iggy K Cath Date: 5/24/2016 Cath #: 873665

Primary Procedure Indication:  Right ventricular volume overload  Chronic lung disease  Failure to thrive  
 Recurrent respiratory infections  Ventilator dependent  Cyanosis  
 Stroke prevention  Migraines  Pulmonary hypertension

Total Septal Length: 2 mm Atrial Septal Aneurysm Present:  No  Yes  
 Not Assessed

Add Defect Remove Defect

**Defect 1** Defect 2 Defect 3

ASD Multi-Fenestrated:  No  Yes Rim Measurement Performed:  No  Yes

ASD Size: 15 mm IVC Rim Length: mm  
Balloon Sizing Performed:  No  Yes Aortic Rim Length: mm  
Stretched Diameter Performed:  No  Yes Posterior Rim Length: mm  
Size: 20 mm  
Stop Flow Technique Performed:  No  Yes Residual Shunt Size:  
Size: 20 mm  None to trivial (<3 mm)  
 Significant (>=3 mm)

Devices

Num	Device ID	Associated Defect(s)	Outcome of Device
1	902	1, 3	Implanted, not released Occluder - AMPLATZER Multi-Fenestrated Septal Occluder-Cribriform 35 mm [AGA Medical]
2	895	3	Implanted, released Occluder - AMPLATZER Duct Occluder 12/10 mm x 8 mm [AGA Medical]
3	900	1, 3	Implanted, released and retrieved Occluder - AMPLATZER Multi-Fenestrated Septal Occluder-Cribriform 25 mm [AGA Medical]

[7000. ASDProclnd] Coding Instructions: Indicate the primary reason the atrial septal defect (ASD) procedure is being performed.  
Target Value: The value on current procedure

Save & Close Close



## Coarctation Procedure

The Coarctation Procedure section will be available if Coarctation Procedure is checked under the Procedures Performed section.

If the Device ID is known it can be directly typed in the box, otherwise you can look it up in the device list by clicking the “...” button.

To add more than one device, click the Add Device button. Clicking the Remove Device button will remove the currently active device tab.

PedCath - IMPACT Registry v2.0

Patient: Impack. Iggy K Cath Date: 5/24/2016 Cath #: 873665

IMPACT Registry™

**Demographics**

**Episode of Care**

Case

**Pre-Procedure Clinical Evaluation**

**Cath Data**

**Hemodynamics**

**Procedures Performed**

- ASD Closure
- Coarctation Procedure**
- Aortic Valvuloplasty
- Pulmonary Valvuloplasty
- PDA Closure
- Proximal PA Stenting Procedure
- Electrophysiology Ablation Procedure
- TPVR

**Events**

**Discharge**

Case Complete

Primary Procedure:  Abnormal ventricular function  Congestive heart failure  Exercise hypertension  Systemic hypertension

Indication:  High resting gradient  Angiographic appearance  Pseudoaneurysm

Nature of simple discrete coarctation (One site of intervention):  Native  Post Treatment

Most Recent Prior Treatment:  Surgical Repair  Catheter-based Intervention

Pre-Procedure Minimal Diameter: [ ] mm  Not Assessed

Pre-Procedure Peak Systolic Gradient: [ ] mmHg  Not Assessed

Post-Procedure Minimal Diameter: [ ] mm  Not Assessed

Post-Procedure Peak Systolic Gradient: 12 mmHg  Not Assessed

Coarctation with Additional Associated Aortic Obstruction:  No  Yes

Additional Intervention on Aortic Arch:  No  Yes

Pre-Procedure Total Ascending to Descending Aortic Systolic Gradient: [ ] mmHg

Post-Procedure Total Ascending to Descending Aortic Systolic Gradient: [ ] mmHg

Add Device Remove Device

**Device 1** Device 2 Device 3

Device ID: 12 [ ... ] Balloon - HIGHSAIL Coronary Dilatation Catheter 2.75 mm x 8 mm [Abbott Vascular]

Device Type:  Balloon  Stent

Purpose:  Compliance testing  Stent redilation  Angioplasty  Stent implantation

Outcome:  Implanted intended site  Implanted other location  Not deployed

Max Inflation Pressure: 10 atm(s) In Stent Minimal Diameter Assessed:  No  Yes

Outcome:  Inflated with rupture  Inflated without rupture

In Stent Minimal Diameter: [ ] mm

[7100. CoarcProclnd] Coding Instructions: Indicate the primary reason the Coarctation procedure is being performed.

Target Value: The value on current procedure

Save & Close Close

## Aortic Valvuloplasty

The Aortic Valvuloplasty section will be available if Aortic Valvuloplasty is checked under the Procedures Performed section.

For each inflation you must specify if the balloon technique was Single or Double, and fill out device information for each balloon. If the Device ID is known it can be directly typed in the box, otherwise you can look it up in the device list by clicking the “...” button.

To add additional inflations, click the Add Inflation button. Clicking the Remove Inflation button will remove the currently active inflation tab.

PedCath - IMPACT Registry v2.0

Patient: Impack, Iggy K Cath Date: 5/24/2016 Cath #: 873665

IMPACT Registry™

Demographics

Episode of Care

Case

Pre-Procedure Clinical Evaluation

Cath Data

Hemodynamics

Procedures Performed

- ASD Closure
- Coarctation Procedure
- Aortic Valvuloplasty**
- Pulmonary Valvuloplasty
- PDA Closure
- Proximal PA Stenting Procedure
- Electrophysiology Ablation Procedure
- TPVR

Events

Discharge

Case Complete

Primary Procedure Indication:  Aortic stenosis gradient  Abnormal stress test/EKG  LV dysfunction  Symptoms

Valve Morphology:  Unicuspid  Bicuspid  Tricuspid  Quadricuspid  Uncertain

Pre-Procedure Aortic Valve Insufficiency:  None  1+ (mild)  2+ (moderate)  3+ (moderately severe)  4+ (severe)

Aortic Valve Diameter:  mm Pre-Procedure Peak Systolic Gradient:  mmHg

Add Balloon Remove Balloon

Balloon 1 Balloon 2

Balloon Technique:  Single  Double

Device ID Balloon 1:  ... Device ID Balloon 2:  ...

Balloon - HIGHSAIL Coronary Dilatation Catheter 3.25 mm x 18 mm [Abbott Vascular]

Balloon Stabilization:  No  Yes Post Dilatation Systolic Gradient:  mmHg

Max Inflation Pressure:  atm(s) Post Dilatation Regurgitation:  None  1+ (mild)  2+ (moderate)  3+ (moderately severe)  4+ (severe)

Balloon Outcome:  Inflated with rupture  Inflated without rupture

[7200. AVProclnd] Coding Instructions: Indicate the primary reason the aortic valvuloplasty (AV) procedure is being performed.

Target Value: The value on current procedure

Selections:

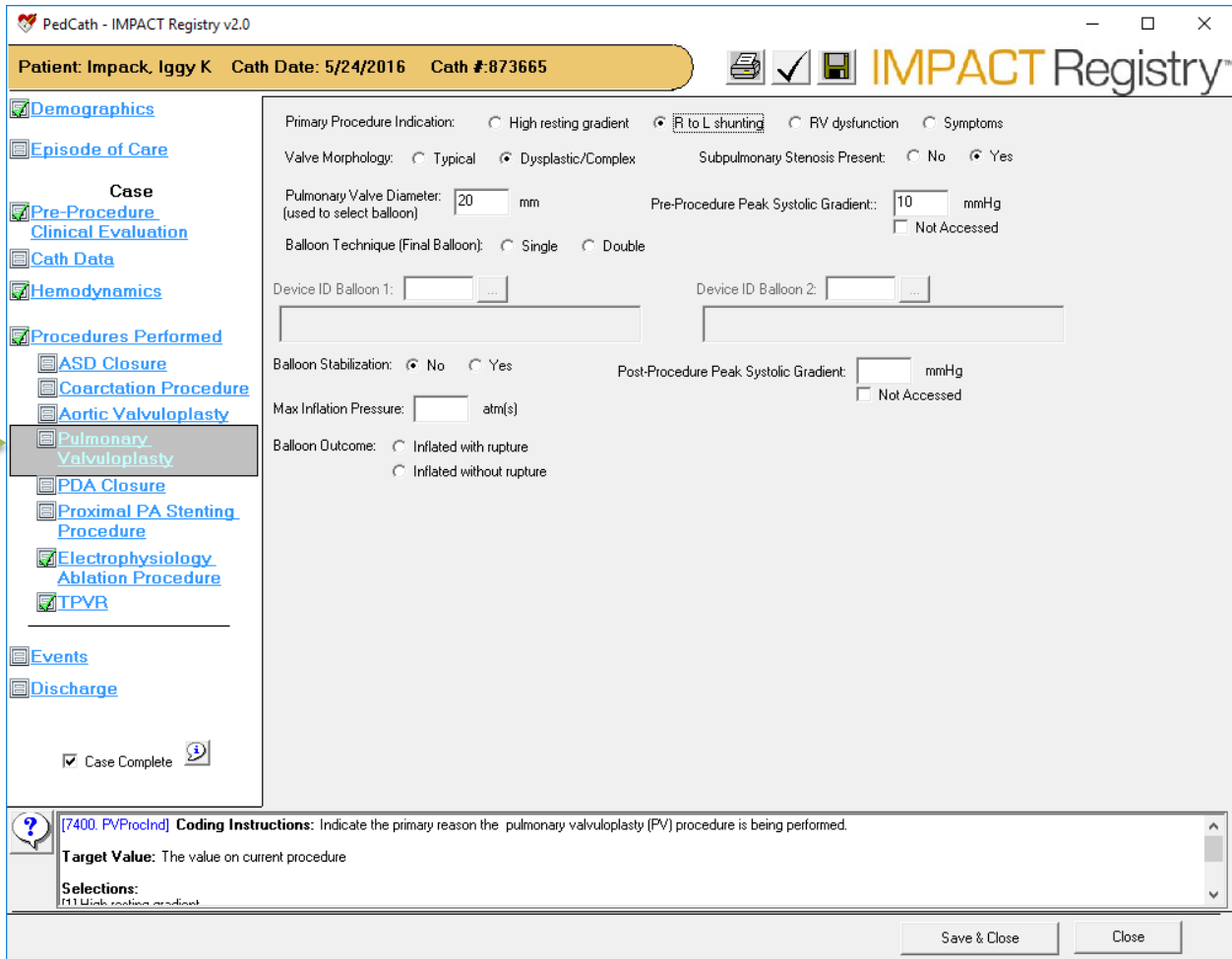
- [1] Aortic stenosis gradient

Save & Close Close

## Pulmonary Valvuloplasty

The Pulmonary Valvuloplasty section will be available if Pulmonary Valvuloplasty is checked under the Procedures Performed section.

This section is arranged similarly to the Aortic Valvuloplasty panel. Please refer to page 18 for more information.



PedCath - IMPACT Registry v2.0

Patient: Impack, Iggy K Cath Date: 5/24/2016 Cath #: 873665

IMPACT Registry™

**Demographics**

**Episode of Care**

**Case**

Pre-Procedure Clinical Evaluation

Cath Data

Hemodynamics

**Procedures Performed**

- ASD Closure
- Coarctation Procedure
- Aortic Valvuloplasty
- Pulmonary Valvuloplasty**
- PDA Closure
- Proximal PA Stenting Procedure
- Electrophysiology Ablation Procedure
- TPVR

Events

Discharge

Case Complete

Primary Procedure Indication:  High resting gradient  R to L shunting  RV dysfunction  Symptoms

Valve Morphology:  Typical  Dysplastic/Complex Subpulmonary Stenosis Present:  No  Yes

Pulmonary Valve Diameter:  mm Pre-Procedure Peak Systolic Gradient:  mmHg  
(used to select balloon)  Not Accessed

Balloon Technique (Final Balloon):  Single  Double

Device ID Balloon 1:  Device ID Balloon 2:

Balloon Stabilization:  No  Yes Post-Procedure Peak Systolic Gradient:  mmHg  
 Not Accessed

Max Inflation Pressure:  atm(s)

Balloon Outcome:  Inflated with rupture  Inflated without rupture

[7400. PVProcInd] **Coding Instructions:** Indicate the primary reason the pulmonary valvuloplasty (PV) procedure is being performed.

**Target Value:** The value on current procedure

**Selections:**  
[1] Link to main procedure

Save & Close Close

## PDA Closure

The PDA Closure section will be available if PDA Closure is checked under the Procedures Performed section.

### Managing Devices

To add a device, type in the device id within the Device ID column or click the icon within that column to bring up the device list.

To remove a device, either delete the Device ID number, or right-click the number within the Num column and choose Delete Device.

Patient: Impact, Iggy K Cath Date: 5/24/2016 Cath #: 873665

Primary Procedure Indication:  SBE prevention  Left ventricular volume overload  Pulmonary hypertension

PDA Diameter Aortic Side:  mm PDA Minimum Lumenal Diameter:  mm PDA Length:  mm

PDA Classification:  Type A (conical)  Type B (window)  Type C (tubular)  Type D (complex)  Type E (elongated)

PA Obstruction:  No  Yes Aortic Obstruction:  No  Yes Residual Shunt Size:  None to trivial (immed after device placement)  Significant (caused by implant)  Not Assessed  Not Assessed

Devices

Num	Device ID	Outcome of Device
1	910	Implanted, not released Occluder - AMPLATZER Muscular VSD Occluder 8 mm x 7 mm [AGA Medical]
2	920	Implanted, released Occluder - AMPLATZER Septal Occluder 19 mm [AGA Medical]
3	940	Implanted, released and retrieved Occluder - AMPLATZER Septal Occluder 4 mm [AGA Medical]

[7600. PDAProclnd] Coding Instructions: Indicate the primary reason the patent ductus arteriosus (PDA) procedure is being performed.  
Target Value: The value on current procedure

Save & Close Close

## Proximal Pulmonary Artery Stenting Procedure

The Proximal Pulmonary Artery Stenting Procedure section will be available if Proximal PA Stenting Procedure is checked under the Procedures Performed section.

To add more than one defect, click the Add Defect button. Clicking the Remove button will remove the currently active defect tab.

There are some pre and post procedure hemodynamics and measurements collected for this procedure.

Make sure to specify whether or not the patient is Single Ventricle within the Episode of Care panel so that all of the appropriate measurements are shown.

## Managing Devices

To add a device, type in the device id within the Device ID column or click the icon within that column to bring up the device list.

To remove a device, either delete the Device ID number, or right-click the number within the Num column and choose Delete Device. To designate the defects that are treated by a particular device, type the defect numbers within the Associated Defect(s) column, separated by commas if more than one. So for instance if the device should be associated with Defect 2 and Defect 3, type "2, 3" in the grid cell.

PedCath - IMPACT Registry v2.0

Patient: Impack, Iggy K Cath Date: 5/24/2016 Cath #: 873665

Primary Procedure Indication:  PA gradient  RV hypertension/dysfunction  Pulmonary insufficiency  
 PA flow discrepancy  Angiographic narrowing

Add Defect Remove Defect

Defect 1 Defect 2 Defect 3

Defect Location:  Right proximal PA  Left proximal PA

Distal Obstruction Present:  No  Yes

Sidebranch Jailing:  No  Yes

Intended:  No  Yes

Artery:  Proximal Artery  Lobar Artery

Decreased Flow:  No  Yes

Pre-Procedure Post-Procedure

Proximal Systolic Pressure:  mmHg  
Distal Systolic Pressure:  mmHg  
Proximal Diameter:  mm  
Distal Diameter:  mm  
PA Vessel Diameter Minimum:  mm

Devices

Num	Device ID	Associated Defect(s)	Outcome of Device
1	1290	1, 2, 3	Stent - MULTI-LINK RX ULTRA Coronary Stent System 4.0 mm x 38 mm [Abbott Vascular]
2	1330	1, 2, 3	Stent - MULTI-LINK VISION DTW Coronary Stent System 2.75 mm x 12 mm [Abbott Vascular]
3	1460	1, 3	Stent - Protege EverFlex Self-Expanding Biliary Stent 8 mm x 20 mm [ev3]

[7700.PASProclnd] Coding Instructions: Indicate the primary reason the pulmonary artery (PA) stenting procedure is being performed.  
Target Value: The value on current procedure

Save & Close Close

## EP Cath / EP Ablation Procedure

The Electrophysiology Ablation Procedure section will be available if either the EP Cath or EP Ablation Procedure are checked under the Procedures Performed section.

If only EP Cath is checked then only the first three tabs of the data panel will show. When EP Ablation is checked the Targets and Ablation Catheters should also be filled out as well.

PedCath - IMPACT Registry v2.0

Patient: Impack, Iggy K Cath Date: 5/24/2016 Cath #: 973665

IMPACT Registry™

Demographics

Episode of Care

Case

Pre-Procedure Clinical Evaluation

Cath Data

Hemodynamics

Procedures Performed

- ASD Closure
- Coarctation Procedure
- Aortic Valvuloplasty
- Pulmonary Valvuloplasty
- PDA Closure
- Proximal PA Stenting Procedure
- Electrophysiology Ablation Procedure**
- TPVR

Events

Discharge

Case Complete

Main

Pre-Procedure Symptom Severity Survey

Ablation Procedure

Targets

Ablation Catheter(s)

Primary Procedure Indication

- Evaluation of specific arrhythmia
- Evaluation of event or symptoms suggesting arrhythmia
- Evaluation of prior antiarrhythmic treatment
- Evaluation of risk for ventricular tachyarrhythmia
- Preoperative evaluation

History of Congenital Heart Disease

- No structural heart disease or trivial, unoperated congenital heart disease
- Repaired functionally two-ventricle congenital heart disease
- Repaired tetralogy of Fallot and tetralogy-like variants
- Transposition of the great arteries following atrial-level (Mustard or Senning) palliation
- Fontan palliation of functionally univentricular heart
- Pre-Fontan palliation of functionally univentricular heart
- Unoperated acyanotic congenital heart disease
- Unoperated cyanotic congenital heart disease

Previous EP Therapy Attempted

- No
- Yes

Catheter Ablation  Pharmacologic Therapy  Chemical cardioversion  DC cardioversion

Pacemaker insertion  ICD insertion  Arrhythmia surgery

Number of Prior Catheter Ablation procedures: 1

[10000, EPPImagIInd] Coding Instructions: Indicate the primary reason the procedure is being performed.

Target Value: The value on current procedure

Save & Close Close

## Transcatheter Pulmonary Valve Replacement (TPVR)

The TPVR section will be available if Transcatheter Pulmonary Valve Replacement (TPVR) is checked under the Procedures Performed section.

To add a device, type in the device id within the Device ID column or click the icon within that column to bring up the device list.

To remove a device, either delete the Device ID number, or right-click the number within the Num column and choose Delete Device.

PedCath - IMPACT Registry v2.0

Patient: Impack, Iggy K Cath Date: 5/24/2016 Cath #: 873665

IMPACT Registry™

**Demographics**

**Episode of Care**

**Case**

**Pre-Procedure Clinical Evaluation**

**Cath Data**

**Hemodynamics**

**Procedures Performed**

- ASD Closure
- Coarctation Procedure
- Aortic Valvuloplasty
- Pulmonary Valvuloplasty
- PDA Closure
- Proximal PA Stenting Procedure
- Electrophysiology Ablation Procedure
- TPVR

**Events**

**Discharge**

Case Complete

Clinical Indication:  Symptomatic  Prevention of symptoms in asymptomatic patient  Declining ventricular function

Worsening arrhythmias  Other

Hemodynamic Indication:  Predominant valve/conduit Obstruction  Predominant valve/conduit Regurgitation  Mixed obstruction /regurgitation

Underlying anatomic reason for Right Ventricular Outflow Tract (RVOT) dysfunction:

Congenital Heart Disease repaired using RVOT valve/conduit  s/p Ross Procedure with repair using RVOT valve/conduit

No Congenital Heart Disease with RVOT valve/conduit  Native RVOT dysfunction secondary to surgical intervention

Native RVOT dysfunction secondary to transcatheter intervention  Native RVOT dysfunction with no prior interventions

**Pre-Procedure Testing** | RVOT Anatomy and Function | Coronary Artery Assessment | Conduit Preparation | Post-Procedure Testing

Echocardiogram:  No  Yes MRI:  No  Yes

Mean gradient across valve/conduit: 100 mmHg RVEF: 100 %

Maximum gradient across valve/conduit: 200 mmHg LVEF: 200 %

Pulmonary Valve Regurgitation Severity:

None  1+ (mild)  2+ (moderate)

3+ (moderately severe)  4+ (severe)

LVEF: 99 % PR Fraction: 100 %

RVEDV Index: 300 RVESV Index: 200

Tricuspid Regurgitation Severity:

None  1+ (mild)  2+ (moderate)

3+ (moderately severe)  4+ (severe)

LVEDV Index: 400 LVESV Index: 300

**Devices**

Num	Device ID	Outcome of Device

**[11000. TPVRClinInd] Coding Instructions:** Indicate the primary clinical reason for the procedure.

**Target Value:** The value on current procedure

Save & Close Close

## Events

The Events section will allow you to enter complications that arose during the procedure, as well as post-procedure treatments. You can also specify events from a more comprehensive list in the Other Events section.

PedCath - IMPACT Registry v2.0

Patient: Impack, Iggy K Cath Date: 5/24/2016 Cath #: 873665

IMPACT Registry™

**Demographics**

**Episode of Care**

**Case**

Pre-Procedure Clinical Evaluation

Cath Data

Hemodynamics

Procedures Performed

- ASD Closure
- Coarctation Procedure
- Aortic Valvuloplasty
- Pulmonary Valvuloplasty
- PDA Closure
- Proximal PA Stenting Procedure
- Electrophysiology Ablation Procedure
- TPVR

**Events**

Cardiac Arrest	<input checked="" type="radio"/> No	<input type="radio"/> Yes
Arrhythmia	<input checked="" type="radio"/> No	<input type="radio"/> Yes
AV Block	<input type="radio"/> No	<input type="radio"/> Yes
Spontaneously Resolved	<input type="radio"/> No	<input type="radio"/> Yes
Antiarrhythmic Medication	<input type="radio"/> No	<input type="radio"/> Yes
Cardioversion	<input type="radio"/> No	<input type="radio"/> Yes
Temporary Pacemaker	<input type="radio"/> No	<input type="radio"/> Yes
Permanent Pacemaker	<input type="radio"/> No	<input type="radio"/> Yes
New Heart Valve Regurgitation	<input checked="" type="radio"/> No	<input type="radio"/> Yes
Tamponade (Requiring pericardial drainage)	<input checked="" type="radio"/> No	<input type="radio"/> Yes
Air Embolus	<input checked="" type="radio"/> No	<input type="radio"/> Yes
Embolic Stroke	<input checked="" type="radio"/> No	<input type="radio"/> Yes
Device Malposition or Thrombus	<input checked="" type="radio"/> No	<input type="radio"/> Yes
Retrieved via Catheterization	<input type="radio"/> No	<input type="radio"/> Yes
Retrieved via Surgery	<input type="radio"/> No	<input type="radio"/> Yes
Device Embolization (Requiring device retrieval)	<input checked="" type="radio"/> No	<input type="radio"/> Yes
Retrieved via Catheterization	<input type="radio"/> No	<input type="radio"/> Yes
Retrieved via Surgery	<input type="radio"/> No	<input type="radio"/> Yes
New Requirement for Dialysis	<input type="radio"/> No	<input checked="" type="radio"/> Yes
Coronary Artery Compression	<input type="radio"/> No	<input type="radio"/> Yes
Erosion	<input type="radio"/> No	<input type="radio"/> Yes
Esophageal Fistula	<input type="radio"/> No	<input type="radio"/> Yes
Left Bundle Branch Block (LBBB)	<input type="radio"/> No	<input type="radio"/> Yes
Right Bundle Branch Block (RBBB)	<input type="radio"/> No	<input type="radio"/> Yes
Airway Event Requiring Escalation of Care	<input type="radio"/> No	<input checked="" type="radio"/> Yes

No To All

**Other Events and Post-Procedure Treatments**

Event Requiring ECMO	<input checked="" type="radio"/> No	<input type="radio"/> Yes
Event Requiring LVAD	<input checked="" type="radio"/> No	<input type="radio"/> Yes
Bleeding Event	<input type="radio"/> No	<input checked="" type="radio"/> Yes
Bleeding Event at Access Site	<input type="radio"/> No	<input checked="" type="radio"/> Yes
Hematoma at Access Site	<input type="radio"/> No	<input checked="" type="radio"/> Yes
Retroperitoneal Bleeding	<input type="radio"/> No	<input checked="" type="radio"/> Yes
Gastrointestinal Bleeding	<input type="radio"/> No	<input checked="" type="radio"/> Yes
Genitourinary Bleeding	<input type="radio"/> No	<input checked="" type="radio"/> Yes
Other Bleeding	<input type="radio"/> No	<input checked="" type="radio"/> Yes
RBC Transfusion	<input type="radio"/> No	<input checked="" type="radio"/> Yes
Drop in Hgb	<input type="radio"/> No	<input checked="" type="radio"/> Yes
Anemia prior to Cath Procedure	<input checked="" type="radio"/> No	<input type="radio"/> Yes
Post-operative Blood Loss	<input checked="" type="radio"/> No	<input type="radio"/> Yes
ECMO Blood Replacement	<input checked="" type="radio"/> No	<input type="radio"/> Yes
Peripheral Nerve Injury	<input checked="" type="radio"/> No	<input type="radio"/> Yes
Phrenic Nerve Paralysis	<input checked="" type="radio"/> No	<input type="radio"/> Yes
Pneumothorax	<input type="radio"/> No	<input checked="" type="radio"/> Yes
Pulmonary Embolism	<input checked="" type="radio"/> No	<input type="radio"/> Yes
Pulmonary Vein Stenosis	<input checked="" type="radio"/> No	<input type="radio"/> Yes
Radiation Burn to Skin	<input checked="" type="radio"/> No	<input type="radio"/> Yes
Deep Vein Thrombosis	<input checked="" type="radio"/> No	<input type="radio"/> Yes
Conduit Tear	<input type="radio"/> No	<input checked="" type="radio"/> Yes
Location	<input checked="" type="radio"/> Confined or therapeutic tear without hemodynamic change	
	<input type="radio"/> Rupture into pericardial or pleural space	
	<input type="radio"/> Rupture into bronchus, cardiac chamber, aorta, or other vessel	
Treatment	Pericardial or pleural drain; Covered with TPV; Other ...	

[11000, TPVRClinInd] Coding Instructions: Indicate the primary clinical reason for the procedure.

Target Value: The value on current procedure

Save & Close Close



## Events Continued

PedCath - IMPACT Registry v2.0

Patient: Impack. Iggy K Cath Date: 5/24/2016 Cath #: 873665

IMPACT Registry™

**Demographics**

**Episode of Care**

**Case**

Pre-Procedure  
 Clinical Evaluation

Cath Data

Hemodynamics

**Procedures Performed**

ASD Closure

Coarctation Procedure

Aortic Valvuloplasty

Pulmonary Valvuloplasty

PDA Closure


Proximal PA Stenting Procedure

Electrophysiology Ablation Procedure

TPVR

**Events**

**Discharge**

Case Complete 

**Events** | **Other Events and Post-Procedure Treatments**

Other Vascular Complications Req Rx  No  Yes

Other Events:  No  Yes

Choose...

**Post-Procedure Treatments**

Planned Cardiac Surgery:	<input type="radio"/> No <input checked="" type="radio"/> Yes	Unplanned Other Surgery:	<input type="radio"/> No <input checked="" type="radio"/> Yes
Unplanned Cardiac Surgery: (due to cath complication)	<input type="radio"/> No <input checked="" type="radio"/> Yes	Due to Cath Complication:	<input type="radio"/> No <input checked="" type="radio"/> Yes
Unplanned Vascular Surgery: (due to cath complication)	<input type="radio"/> No <input checked="" type="radio"/> Yes	Subsequent Cardiac Cath: (due to cath complication)	<input type="radio"/> No <input checked="" type="radio"/> Yes

**[11000. TPVRClinInd] Coding Instructions:** Indicate the primary clinical reason for the procedure.

**Target Value:** The value on current procedure

Save & Close Close

## Discharge



The Discharge section will allow you to enter the discharge date and status. Any cases without a discharge date will not be submitted to IMPACT.

Cardiac Surgery dates and times performed during the episode of care may also be entered here.

Entering follow-up data can also be done here. (Refer to the Follow-ups section in the manual).

The screenshot displays the IMPACT Registry software interface for patient management. The window title is "PedCath - IMPACT Registry v2.0". The patient information bar shows "Patient: Impack, Iggy K", "Cath Date: 5/24/2016", and "Cath #: 873665". The left sidebar contains a navigation menu with categories: Demographics, Episode of Care, Case, Pre-Procedure Clinical Evaluation, Cath Data, Hemodynamics, Procedures Performed, Events, and Discharge. The "Discharge" option is highlighted with a green arrow. The main content area is divided into several sections: "Discharge Date" (05/28/2016), "Discharge Status" (Alive/Deceased), "Death in Lab" (No/Yes), "Primary Cause of Death" (a list of medical conditions with radio buttons), "Cardiac Surgery during this admission" (No/Yes), and "Cardiac Surgery Date(s) / Times(s)" (5/24/2016). A "Follow-ups" button is located at the bottom of the main area. The bottom status bar includes a help icon, a question mark, and text: "[9000.DCDate] Coding Instructions: Indicate the date on which the patient was discharged from your facility. Target Value: The value on discharge". At the very bottom, there are "Save & Close" and "Close" buttons.

## Error/Completeness checking

PedCath will display a check icon (  ) next to the navigation links for data panels that have been fully filled out. If any panels have been started but have missing fields, a form icon (  ) will be displayed instead, and any panels that haven't been started will not have an icon.

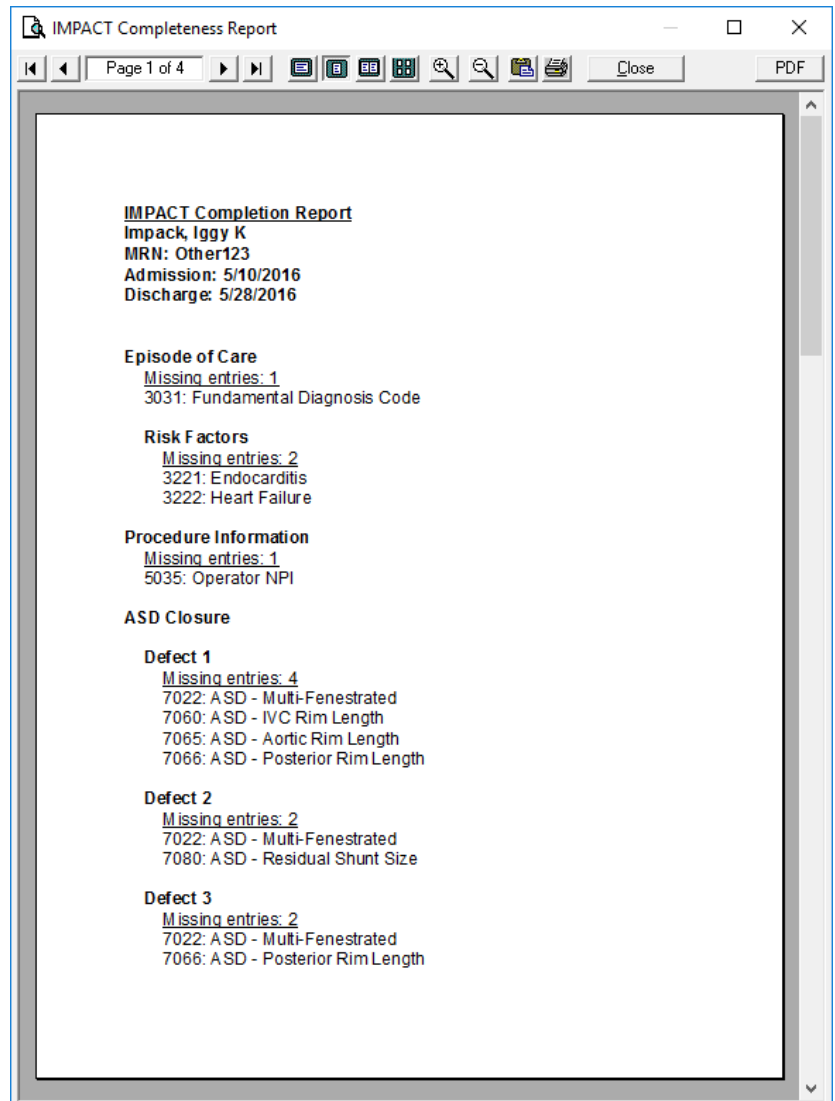
Clicking the validation button will allow you to see if there are any logical errors that would need to be corrected before submitting the data to IMPACT. If there are any errors, you will receive a message and PedCath will jump to the appropriate section.



If there are not any errors found, the case data is valid for IMPACT submission. You will be prompted to view a completeness report. This will list any fields that are missing data or out of the usual range.

The report may be printed and the completeness report window may be left open while corrections are made.

It is not required to fill in the data 100% to be able to submit to IMPACT, however it is recommended to fill in the forms as thoroughly as possible.

A screenshot of the 'IMPACT Completeness Report' window. The window title is 'IMPACT Completeness Report'. The report content is as follows:  
**IMPACT Completion Report**  
Impack, Iggy K  
MRN: Other123  
Admission: 5/10/2016  
Discharge: 5/28/2016  
  
**Episode of Care**  
Missing entries: 1  
3031: Fundamental Diagnosis Code  
  
**Risk Factors**  
Missing entries: 2  
3221: Endocarditis  
3222: Heart Failure  
  
**Procedure Information**  
Missing entries: 1  
5035: Operator NPI  
  
**ASD Closure**  
**Defect 1**  
Missing entries: 4  
7022: ASD - Multi-Fenestrated  
7060: ASD - IVC Rim Length  
7065: ASD - Aortic Rim Length  
7066: ASD - Posterior Rim Length  
  
**Defect 2**  
Missing entries: 2  
7022: ASD - Multi-Fenestrated  
7080: ASD - Residual Shunt Size  
  
**Defect 3**  
Missing entries: 2  
7022: ASD - Multi-Fenestrated  
7066: ASD - Posterior Rim Length

## Device Lookup

Many of the procedure-specific data panels as well as the vein and artery closure methods will require a list of devices used to be specified. The data panels will allow you to type in the device ids directly or look them up with the Device Lookup form.

The Device Lookup dialog initially shows a listing of all the devices available.

## Filtering

There are filter options at the top of the screen that can be used to narrow down the list.

To filter by the device type, enter the name in the Device Type box or choose it from the pull down menu.

The available device manufacturers for that device type will be available in the Device Manufacturer box. Typing in or choosing the manufacturer in the drop-down list will filter the device listing with that manufacturer only.

Entering a device name in the Device Name box will highlight the device with that name in the listing.

## Sorting the List

You can also sort by any of the columns in the grid, by clicking the column header. Each time you click the column header the list will toggle between ascending and descending order for that column. If you check the box "Save Sorting Column", the ordering will be retained the next time the listing is opened.

Filter options:

Device Type: All Device Manufacturer: All Device Name:

ID /	Device Type	Device Manufacturer	Device Name and Size
1	Balloon	Abbott Vascular	HIGHSAIL Coronary Dilatation Catheter 2.5 mm x 13 mm
2	Balloon	Abbott Vascular	HIGHSAIL Coronary Dilatation Catheter 2.5 mm x 15 mm
3	Balloon	Abbott Vascular	HIGHSAIL Coronary Dilatation Catheter 2.5 mm x 18 mm
4	Balloon	Abbott Vascular	HIGHSAIL Coronary Dilatation Catheter 2.5 mm x 23 mm
5	Balloon	Abbott Vascular	HIGHSAIL Coronary Dilatation Catheter 2.5 mm x 28 mm
6	Balloon	Abbott Vascular	HIGHSAIL Coronary Dilatation Catheter 2.5 mm x 8 mm
7	Balloon	Abbott Vascular	HIGHSAIL Coronary Dilatation Catheter 2.75 mm x 13 mm
8	Balloon	Abbott Vascular	HIGHSAIL Coronary Dilatation Catheter 2.75 mm x 15 mm
9	Balloon	Abbott Vascular	HIGHSAIL Coronary Dilatation Catheter 2.75 mm x 18 mm
10	Balloon	Abbott Vascular	HIGHSAIL Coronary Dilatation Catheter 2.75 mm x 23 mm
11	Balloon	Abbott Vascular	HIGHSAIL Coronary Dilatation Catheter 2.75 mm x 28 mm
12	Balloon	Abbott Vascular	HIGHSAIL Coronary Dilatation Catheter 2.75 mm x 8 mm
13	Balloon	Abbott Vascular	HIGHSAIL Coronary Dilatation Catheter 3.0 mm x 13 mm
14	Balloon	Abbott Vascular	HIGHSAIL Coronary Dilatation Catheter 3.0 mm x 15 mm
15	Balloon	Abbott Vascular	HIGHSAIL Coronary Dilatation Catheter 3.0 mm x 18 mm
16	Balloon	Abbott Vascular	HIGHSAIL Coronary Dilatation Catheter 3.0 mm x 23 mm
17	Balloon	Abbott Vascular	HIGHSAIL Coronary Dilatation Catheter 3.0 mm x 28 mm
18	Balloon	Abbott Vascular	HIGHSAIL Coronary Dilatation Catheter 3.0 mm x 33 mm
19	Balloon	Abbott Vascular	HIGHSAIL Coronary Dilatation Catheter 3.0 mm x 8 mm
20	Balloon	Abbott Vascular	HIGHSAIL Coronary Dilatation Catheter 3.25 mm x 13 mm
21	Balloon	Abbott Vascular	HIGHSAIL Coronary Dilatation Catheter 3.25 mm x 15 mm
22	Balloon	Abbott Vascular	HIGHSAIL Coronary Dilatation Catheter 3.25 mm x 18 mm
23	Balloon	Abbott Vascular	HIGHSAIL Coronary Dilatation Catheter 3.25 mm x 23 mm

3474 Total records/ 2945 Filtered records

Ok Cancel  Save Sorting Column

Locate and click the device you're looking for in the list by using the filters/sorting methods and click OK.

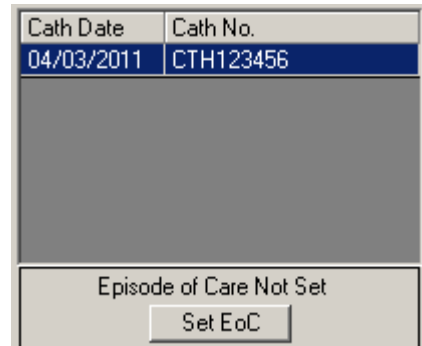
## Managing Episodes of Care

### Creating an Episode of Care

As described in the previous section, you can create an episode of care by launching the IMPACT Registry module.

You can also create a new Episode of Care by clicking the “Set EoC” button underneath the cath grid on the PedCath Browse screen. If one exists that is in range of the cath date, you will be prompted to associate it to the selected cath report.

The Episode of Care listing manager will also allow you to create new episodes of care that are not initially linked to a cath procedure.

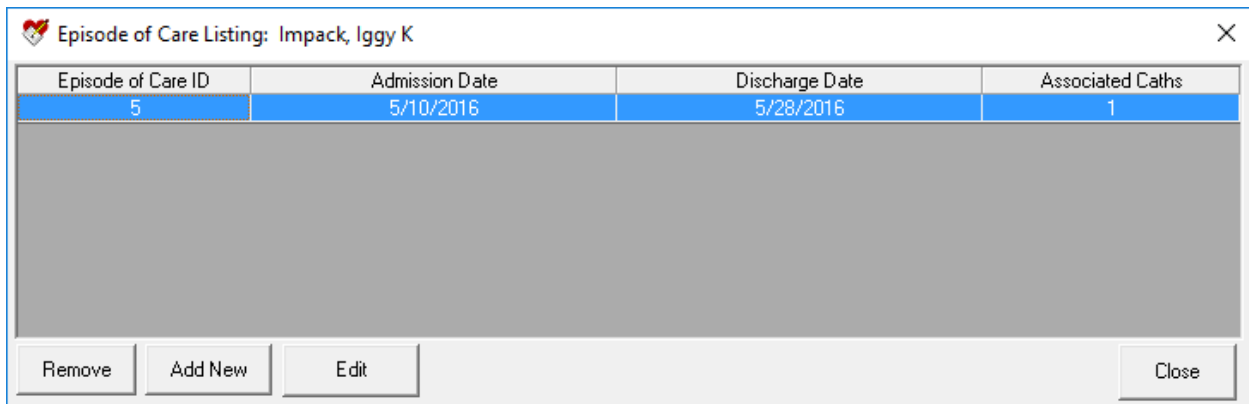


### Managing a Patient’s Episode of Care Listing

To see all of the Episode of Care records for a patient, select their name on the PedCath Browse screen and from the main menu choose:

IMPACT Registry > Patient Episode of Care List

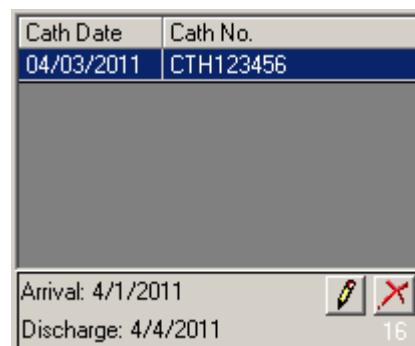
Here you can add, edit, and remove Episode of Care records.



### Editing/Disassociating an Episode of Care

Once the Episode of Care has been set you can edit it in a stand-alone editor outside of the IMPACT module by clicking the Pencil button, or disassociate it from the current cath report by clicking the X button.

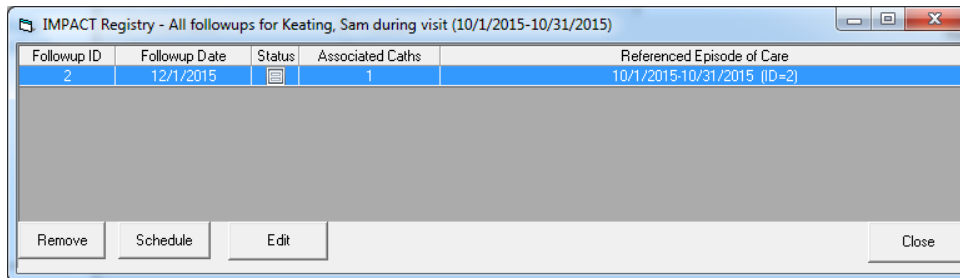
Disassociating the Episode of Care from the cath record will not actually delete the Episode of Care data.



## Collecting Follow-up Data

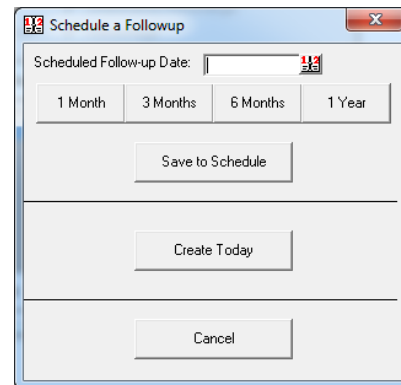
**PedCath** allows you to collect follow-up data for IMPACT v2 after a patient's discharge.

Clicking the Follow-ups button on the Discharge panel of the IMPACT Registry module will show a list of follow-up records linked to the current episode of care. Here you will be able to create, edit or remove follow-up records as well as schedule one for a future date.



Click the Schedule button to schedule a follow-up and enter a date for a planned follow-up consultation. You can also click one of the predefined timespans to set the date (e.g. clicking "1 Month" will schedule a follow-up for one month in the future). Click Save to Schedule to schedule the follow-up.

Clicking Create Today will allow you to fill out a follow-up record at that time without scheduling for a future date.



**Follow-up**

**Follow-Up Main** | Electrophysiology Ablation Procedure

Follow-up Assessment Date: 12/01/2015

Referred Procedures: (check all that apply)  
 10/10/2015 Cath Number: 2

Method(s) to Determine Status:  
 Office Visit  Medical Records  Letter from Medical Provider  
 Phone call  Social Security Death Master File  Hospitalized  
 Other

Follow-up Status:  Alive  Deceased  Lost to Follow-up

Date of Death: [Date Picker]

Cause of Death:  
 Renal  Cardiovascular procedure  Hemorrhage  
 Infection  Cardiovascular hemorrhage  Non-cardiovascular procedure or surgery  
 Pulmonary  Other cardiovascular reason  Trauma  
 Acute myocardial infarction  Gastrointestinal  Suicide  
 Sudden cardiac death  Hepatobiliary  Neurological  
 Heart failure  Pancreatic  Malignancy  
 Stroke  Inflammatory/Immunologic  Other non-cardiovascular reason

Events Since Discharge: \_\_\_\_\_

Readmitted:  No  Yes  
 Readmission Length of Stay: 3 days  
 Readmission Date: 11/10/2015  
 Hospitalized at time of Follow-up:  No  Yes

Follow-up Complete

[12033\_F\_Hosp] **Coding Instructions:** Indicate that the length of stay cannot be calculated because the patient was currently hospitalized during the readmission period.  
**Target Value:** The value on follow-up

A follow-up record is linked to one or more studies during a patient's visit.

Specific follow-up questions are collected for the ASD, EAP, and TVPR studies.

Checking the Follow-up Complete box indicates that the follow-up record has been completed and reviewed (and will also hide it from the scheduled follow-up listing). All follow-up records filled out during a given quarter will be included in the submission file whether the Follow-up Complete box is checked or not.

You can view and manage the list of follow-ups occurring in the near future (or overdue) from the PedCath Browse screen. From the main menu choose:

IMPACT Registry > Follow-ups > All Scheduled or In Progress

Any follow-ups that have been started but not checked off will be included in this list as well.

The other menu commands will allow you to view the entire follow-up database, or view follow-ups for the selected patient.

The screenshot displays the IMPACT Registry software interface. The main menu is open, showing the path: IMPACT Registry > Follow-ups > All Scheduled or In Progress. The background shows a data table with columns for IR, Cath Date, Cath No., and Staff Name. The selected row shows IR 05/22/2003, Cath No. 03c-0123, and Staff Name Administrator. Below the table are buttons for Add Patient, Edit Patient, IR, Add Cath, and Edit Cath. At the bottom, there is a Calculations section with a dropdown menu set to 'Set 1 of 2: Room Air Rest', a red warning 'Some Calculation Values Overridden', and values for Qp (5.51 L/min) and Qs (1.60 L/min). To the right, a Diagnoses section lists 130. VSD, 20. ASD, s, 176. Seco, and 79. Persist.

IR	Cath Date	Cath No.	Staff Name
05/22/2003	03c-0123		Administrator

Calculations

Set 1 of 2: Room Air Rest

Some Calculation Values Overridden

Qp = 5.51 L/min (10.03 L/min/m2)

Qs = 1.60 L/min (2.90 L/min/m2)

Diagnoses /

130. VSD,  
20. ASD, s  
176. Seco  
79. Persist.

## Administration

The PedCath IMPACT Registry Tool may be administered from within PedCath:

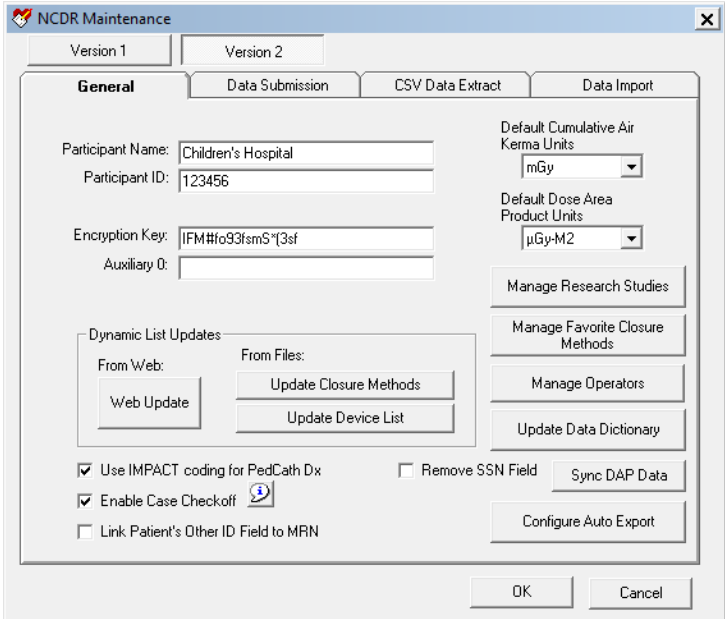
- From the Browse screen main menu choose:

IMPACT Registry > Administration

Here you can set IMPACT options, upgrade lookup tables, create the submission and extract files, and run a data import.

You will need to fill in the registration information received from NCDR on the General tab before submitting any data. These are global settings that need to be entered only once for your institution.

Different features are available for each version of IMPACT. Make sure to select the version you would like to apply options to.



The screenshot shows the 'NCDR Maintenance' application window with the 'General' tab selected. The window has two tabs at the top: 'Version 1' and 'Version 2'. The 'General' tab contains several input fields and buttons. On the left, there are fields for 'Participant Name' (Children's Hospital), 'Participant ID' (123456), 'Encryption Key' (IFM#to93fsmS\*13sf), and 'Auxiliary 0'. On the right, there are dropdown menus for 'Default Cumulative Air Kerma Units' (mGy) and 'Default Dose Area Product Units' (µGy-M2). Below these are buttons for 'Manage Research Studies', 'Manage Favorite Closure Methods', 'Manage Operators', and 'Update Data Dictionary'. At the bottom, there are checkboxes for 'Use IMPACT coding for PedCath Dx' (checked), 'Enable Case Checkoff' (checked), and 'Link Patient's Other ID Field to MRN' (unchecked). There are also buttons for 'Web Update', 'Update Closure Methods', 'Update Device List', 'Remove SSN Field', 'Sync DAP Data', and 'Configure Auto Export'. The window ends with 'OK' and 'Cancel' buttons.

## General Options

### Diagnosis

Your institution has a choice to use the IMPACT procedures, diagnoses, and events for your main coding on the PedCath report. If the IMPACT coding is sufficient for your PedCath report, this will save some time by preventing double coding.

To use this option check the box labeled **Use IMPACT coding for PedCath Dx**.

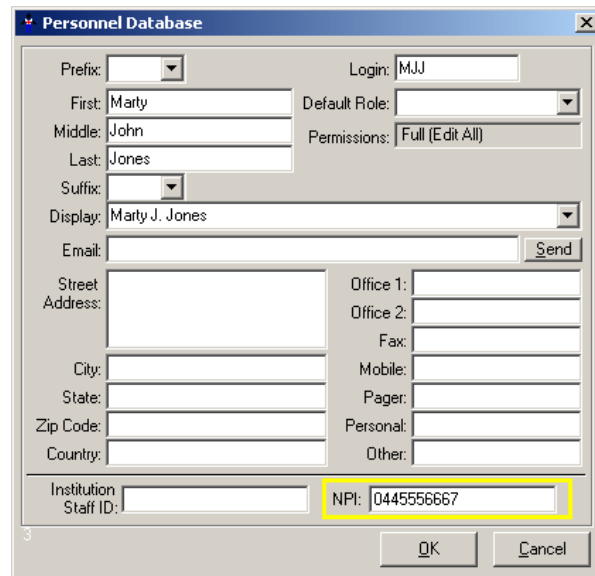
All codes will be available from your legacy reports if you choose this option.



## Managing Operators

Clicking the **Manage Operators** button will bring up the standard PedCath Staff Listing dialog. You may add, edit, and disable staff members here. See the PedCath User's guide for more information about editing staff.

For any staff member who is to be designated as the Operator for the case, their staff NPI number must be specified prior to submission on the Staff Edit screen.



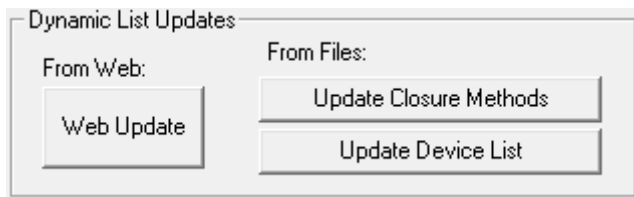
The screenshot shows a 'Personnel Database' dialog box with the following fields and values:

- Prefix: [Dropdown]
- First: Marty
- Middle: John
- Last: Jones
- Suffix: [Dropdown]
- Display: Marty J. Jones
- Email: [Text] [Send]
- Street Address: [Text]
- City: [Text]
- State: [Text]
- Zip Code: [Text]
- Country: [Text]
- Office 1: [Text]
- Office 2: [Text]
- Fax: [Text]
- Mobile: [Text]
- Pager: [Text]
- Personal: [Text]
- Other: [Text]
- Login: MJJ
- Default Role: [Dropdown]
- Permissions: Full (Edit All)
- Institution Staff ID: [Text]
- NPI: 0445556667 (highlighted)

## Updating Closure Methods and Devices

NCDR will release updated device and closure method lists from time to time. To update the list in PedCath simply click the Web Update button. That will automatically download and install the latest devices and closure methods.

Alternately you can download the .CSV files from the NCDR website to your computer, and click either **Update Closure Methods** or **Update Device List** and locate the appropriate file. If you go this route make sure to download the files that are sorted by ID.



The screenshot shows a 'Dynamic List Updates' dialog box with the following buttons:

- From Web: [Web Update]
- From Files: [Update Closure Methods], [Update Device List]

The device list is shared between IMPACT v1 and v2. Make sure the latest IMPACT version is selected at the top of the dialog when running this and all versions will be updated.

## Field Units

You can set the Cumulative Air Kerma units here as well as Fluoro DAP. The values set here will be the default units for new cases (they can be changed on a case-by-case basis). Any previous cases will use the units that they were entered in. Rad dose on the cath report will use the same units as Cumulative Air Kerma. For more information please refer to the PedCath Radiation Reporting white paper.

### **Manage Research Studies**

This will allow you to manage a master list of study names. These will be referenced within a patient's episode of care record if they are involved in any research studies. **PedCath** users can also enter in the study name directly and manage the master list from the episode of care record.

### **Manage Favorite Closure Methods**

This feature will allow you to manage a favorite closure methods listing. Once set users will be able to quickly choose most frequently used closure methods from a drop-down list. Up to 5 may be chosen.

### **Update Data Dictionary**

This feature will download and install the latest data dictionary from the web, and update coding instructions and field definitions. It's recommended to do this once per quarter.

### **Sync DAP Data**

When running this feature, Dose Area Product values that have been entered in the IMPACT section will be migrated to the PedCath report for existing cases. The values in the IMPACT module will no longer be editable within the IMPACT module and will be taken from the value on the PedCath report. Any PedCath report that has been locked will be left alone.

### **Configure Auto-Export**

PedCath can automatically export IMPACT data for individual patients, cases, or episodes in XML format whenever data changes, to be picked up by your CVIS/EMR system. This requires a license.

## Data Submission

PedCath will allow you to create submission files to send to the IMPACT Registry with all the cases within a particular quarter (based on the discharge date).

It is recommended to first run the **Check Missing Discharge Dates** function, to check for any cases that have an episode of care without a discharge date set. Any cases without a discharge date will not be included in the submission file.

To create a submission file, check the quarters that you would like to include, select the year, and enter an export path location to write the submission files to. One submission zip file will be created per quarter.

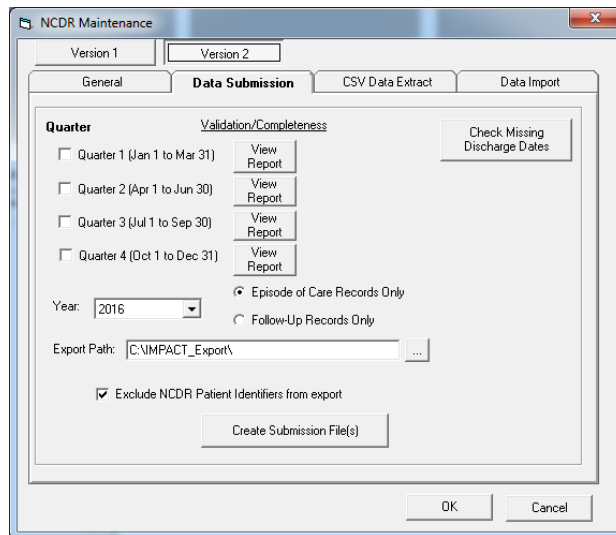
It's recommended to click the **View Report** button next to the quarters you're creating. This will validate the cases to make sure there are no errors and give you a report if any are found. The submission files will not be created if there are any errors.

The query will also give you the option to include cases that are missing any fields or values outside of the normal range in the results.

Click **Create Submission Files** to create the files. Each file should be uploaded to the Registry via the NCDR IMPACT web site.

For IMPACT v2, in addition to the standard submission you will also need to run a Follow-up submission to send all follow-up records collected during a given quarter.

**Note:** Make sure the registration fields on the General tab are filled out before creating the submission files.

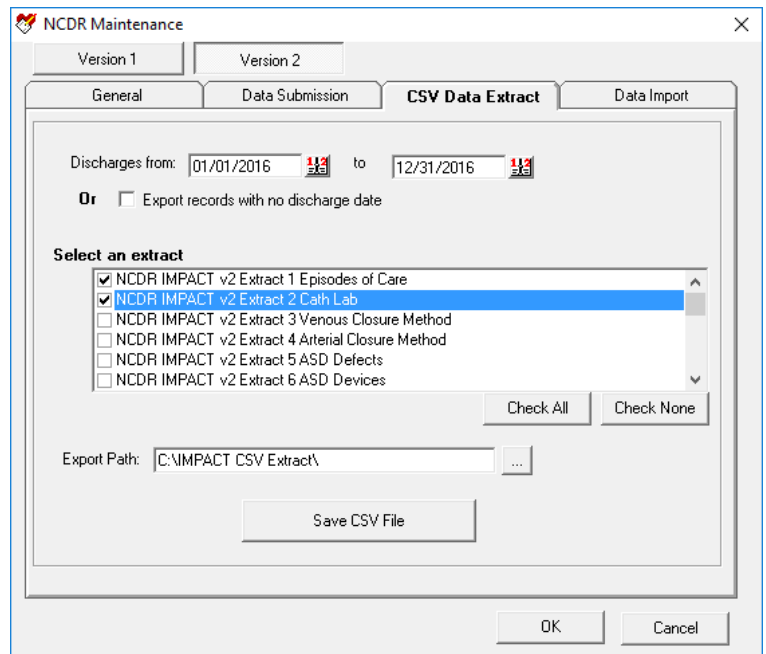


## Data Extract

The IMPACT data can be extracted to comma-delimited files (.CSV). These can be viewed in a spreadsheet program such as Microsoft Excel.

There are 22-extracts available (13-22 are IMPACT v2 only):

1. Episodes of Care
2. Cath Lab
3. Venous Closure Method
4. Arterial Closure Method
5. ASD Defects
6. ASD Devices
7. Coarctation Procedure
8. Aortic Valvuloplasty
9. Pulmonary Valvuloplasty
10. PDA Devices
11. Proximal PA Stenting Defects
12. Proximal PA Stenting Devices
13. Electrophysiology Ablation
14. Electrophysiology Ablation Catheters
15. Transcatheter Pulmonary Valve Replacement (TPVR)
16. History and Risk Factors Multi Select
17. Electrophysiology Ablation Procedure Multi Select
18. Follow-up ASD Closure
19. Follow-up Electrophysiology Ablation Catheters
20. Follow-up Transcatheter Pulmonary Valve Replacement (TPVR)
21. Follow-up Multi Select
22. Intra and Post-Procedure Events Multi Select



To run a data extract:

- Either specify a date range or check **Export records with no discharge date**. (Results are returned based on the Episode of Care discharge date.)
- Check off one or more extracts.
- Enter or browse for the export path.
- Click **Save CSV File**.

## Data Import

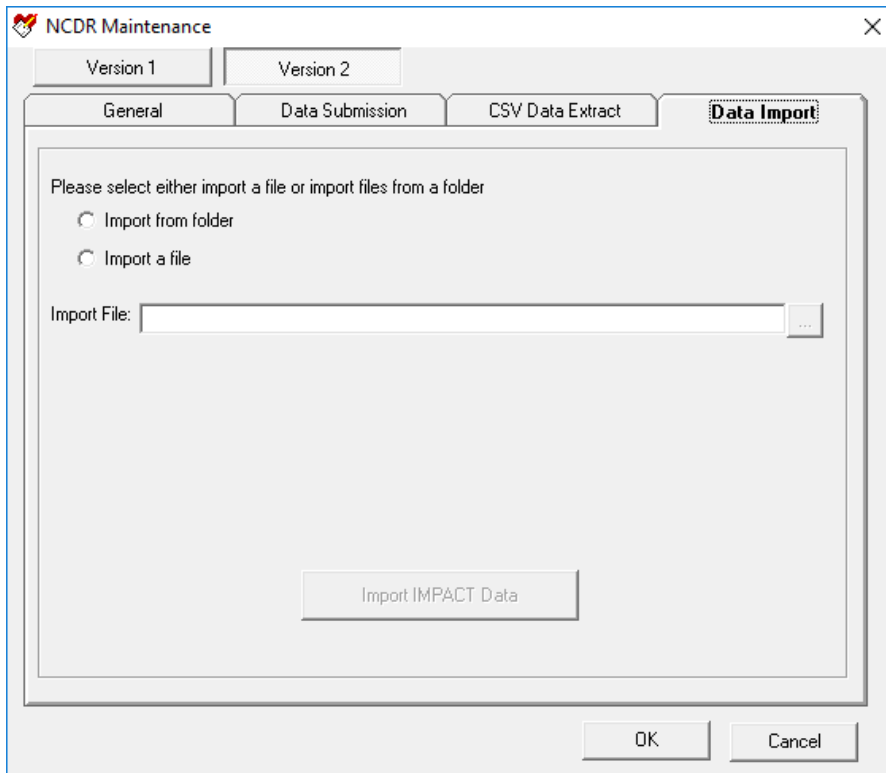
PedCath will allow you to import IMPACT data from another IMPACT-certified vendor.

This will bring in the patient demographics, episode of care, and IMPACT case data that is contained within the file. A new PedCath report will be generated for each case brought in.

While no existing PedCath data will be overwritten, it is recommended to backup up the PedCath database before running the data import.

You can specify a file to import (.zip or .xml) or a folder if you are importing multiple quarters.

To run the import, browse to the file(s) location and click **Import IMPACT Data**.



You will be required to enter an unlock code when you are ready to import the data. Please contact Scientific Software for the code and assistance with the import.