

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.)

Seven procedure types are currently collected:

- Diagnostic Cath
- ASD Closure
- Coarctation Procedure
- Aortic Valvuloplasty
- Pulmonary Valvuloplasty
- PDA Closure
- Proximal PA Stenting

The Episode of Care information (admission/discharge, insurance, patient history,...), 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 vender.

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.

The venous and artery access sites are now chosen from a pick-list, rather than free text as in PedCath 7. Closure methods are new to PedCath 8 and are part of the IMPACT submission.

Hemodynamics

PedCath will send select measurements from your first set of hemodynamics to IMPACT. 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.

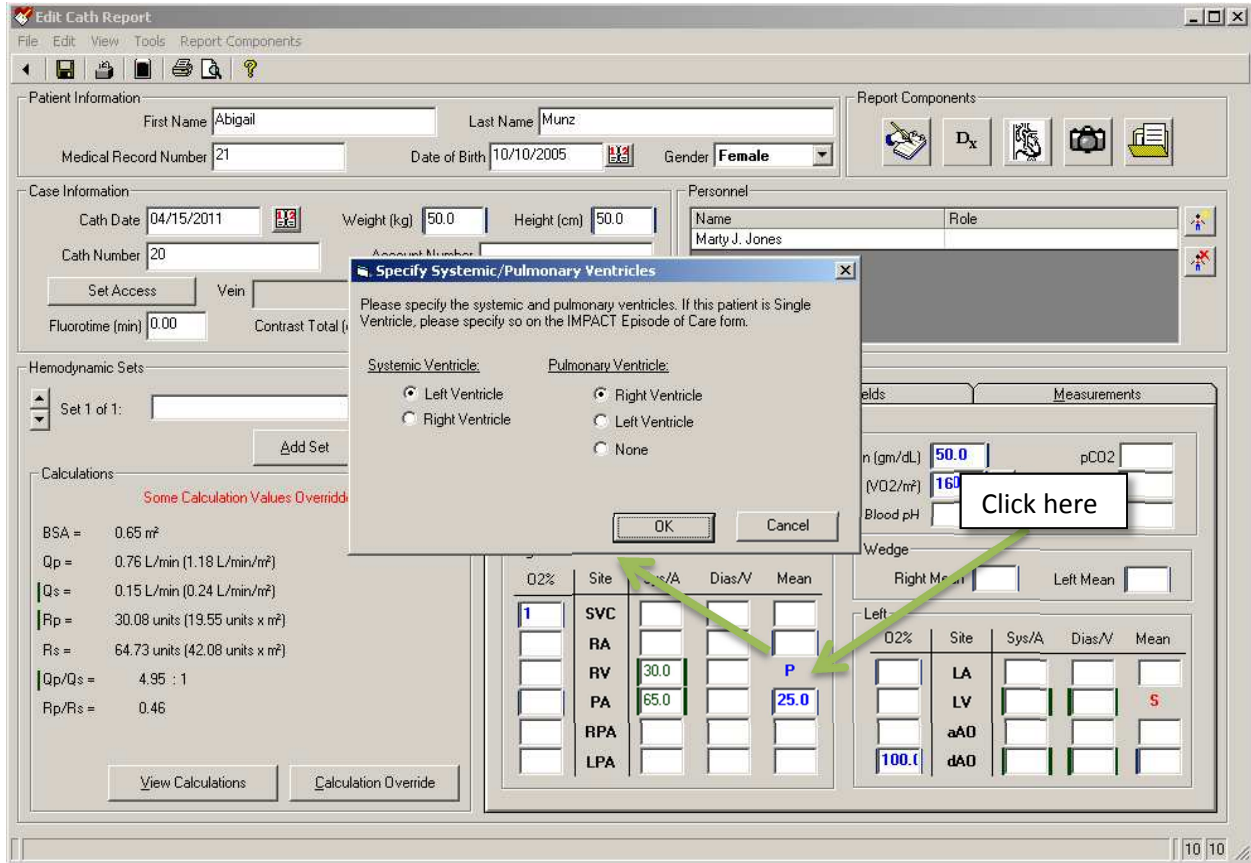
IMPACT Data Collected	PedCath Field
Systemic Artery Saturation	dAO sat, or SA sat override if specified
Mixed Venous Saturation	SVC sat, or MV sat override if specified
Systemic Ventricular Systolic/End Diastolic	If systemic ventricle is LV: LV Systolic, LV End Diastolic If systemic ventricle is RV: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

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.

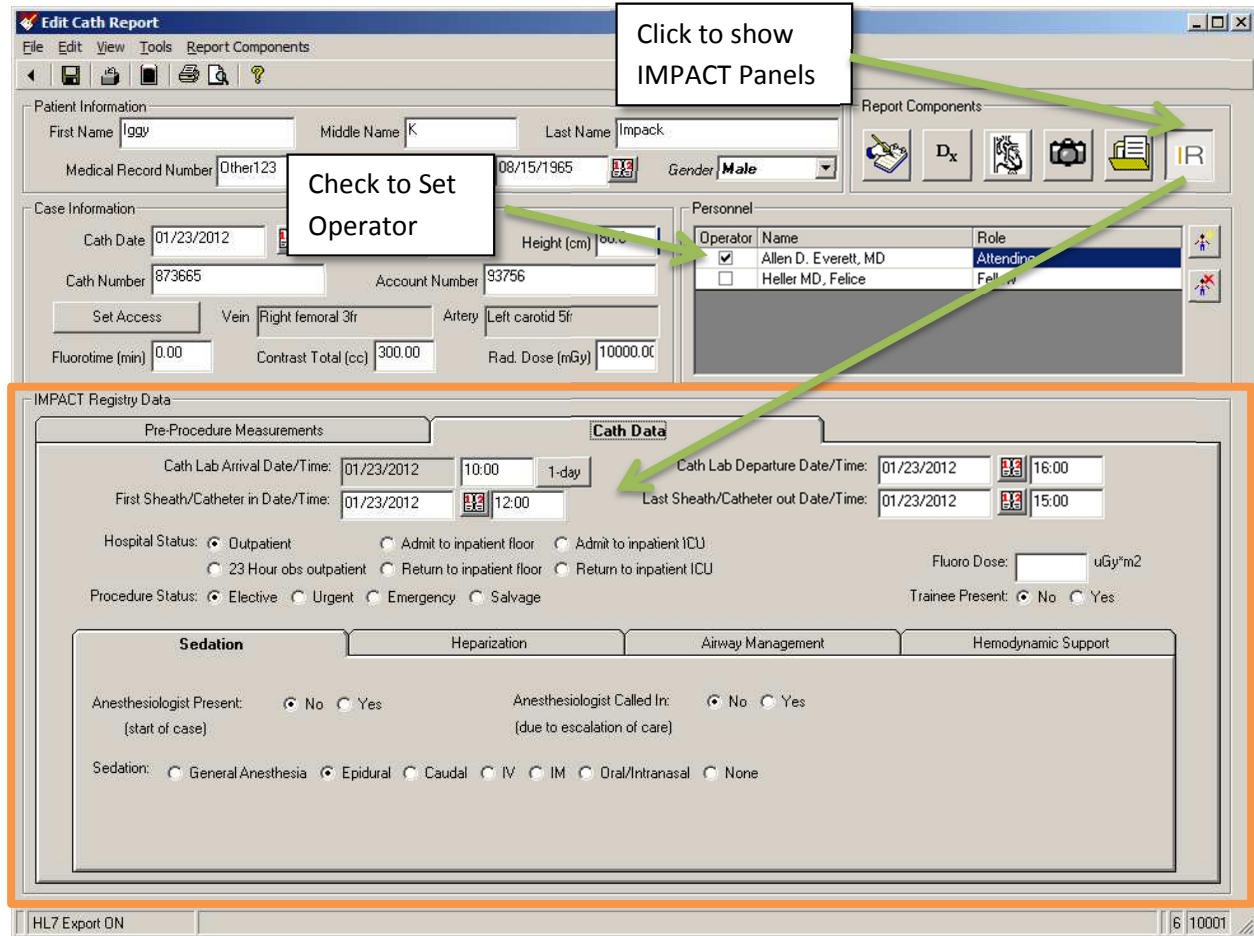


Access IMPACT Data on Edit Screen

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 'Report Components' group at the top right contains several icons, including one labeled 'IR'. A callout box with the text 'Click to show IMPACT Panels' has a green arrow pointing to this 'IR' icon. Below the patient and case information, there is a 'Personnel' grid. A callout box with the text 'Check to Set Operator' has a green arrow pointing to the 'Operator' column of this grid, where the checkbox for 'Allen D. Everett, MD' is checked. The bottom portion of the screen is highlighted with an orange border and contains the 'IMPACT Registry Data' section. This section is divided into 'Pre-Procedure Measurements' and 'Cath Data'. The 'Cath Data' sub-section includes fields for arrival and departure dates/times, hospital status, procedure status, sedation type, and other clinical details. A green arrow points from the 'IR' icon to the 'Cath Data' section.

IMPACT Registry Data

Pre-Procedure Measurements

Cath Data

Cath Lab Arrival Date/Time: 01/23/2012 10:00 1-day
Cath Lab Departure Date/Time: 01/23/2012 16:00
First Sheath/Catheter in Date/Time: 01/23/2012 12:00
Last Sheath/Catheter out Date/Time: 01/23/2012 15:00

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

Fluoro Dose: _____ uGy*m2
Trainee Present: No Yes

Sedation **Heparization** **Airway Management** **Hemodynamic Support**

Anesthesiologist Present: No Yes (start of case) Anesthesiologist Called In: No Yes (due to escalation of care)

Sedation: General Anesthesia Epidural Caudal IV IM Oral/Intranasal None

IMPACT Registry Module

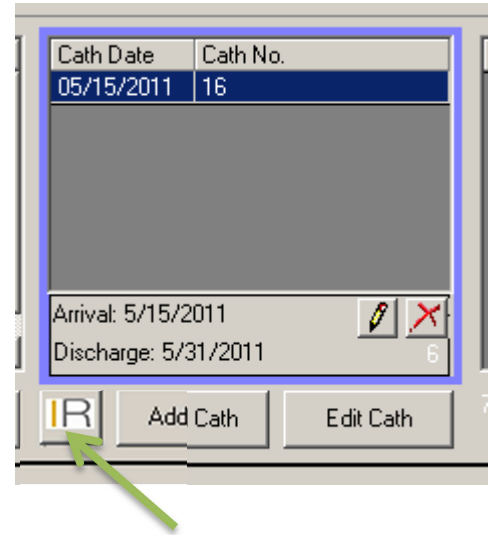
To load the IMPACT Registry Module, simply highlight a cath report and click the “IR” button. This will start a new IMPACT episode of care and case record if they have not been started yet; otherwise it will allow you to view or edit the existing data.

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

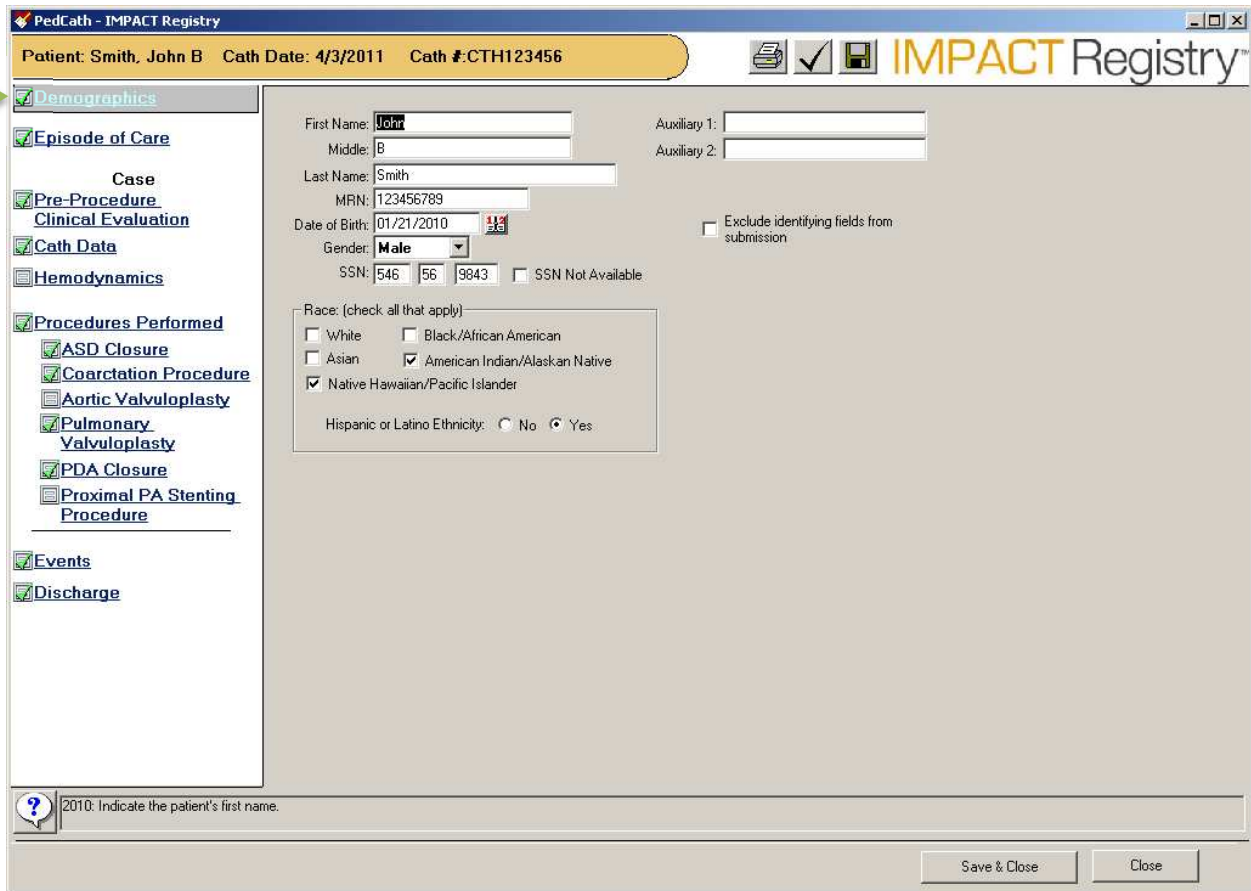
Coding Instructions

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 IMPACT Registry software interface. At the top, the window title is "PedCath - IMPACT Registry". Below the title bar, a yellow banner shows "Patient: Smith, John B", "Cath Date: 4/3/2011", and "Cath #: CTH123456". To the right of the banner are icons for print, check, and save, followed by the "IMPACT Registry" logo. A green arrow points to the "Demographics" tab in the left-hand navigation pane. The main content area shows the following fields:

- First Name: John
- Middle: B
- Last Name: Smith
- MRN: 123456789
- Date of Birth: 01/21/2010
- Gender: Male
- SSN: 546 56 9843
- Auxiliary 1: (empty)
- Auxiliary 2: (empty)
- Exclude identifying fields from submission: (checkbox unchecked)
- Race (check all that apply):
 - White
 - Black/African American
 - Asian
 - American Indian/Alaskan Native
 - Native Hawaiian/Pacific Islander
- Hispanic or Latino Ethnicity: No Yes

At the bottom left, a help icon and a note state: "2010: Indicate the patient's first name." At the bottom right, there are "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 cath and surgeries, genetic conditions and risk factors.

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



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.

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.

The screenshot shows the 'PedCath - IMPACT Registry' application window. At the top, it displays patient information: 'Patient: Smith, John B', 'Cath Date: 4/3/2011', and 'Cath #: CTH123456'. The left sidebar contains a navigation menu with the following items: 'Demographics', 'Episode of Care', 'Case', 'Procedures Performed', 'Pre-Procedure Clinical Evaluation' (highlighted with a green arrow), 'Cath Data', 'Hemodynamics', 'Procedure-Specific Data', 'ASD Closure', 'Coarctation Procedure', 'PDA Closure', 'Proximal Pulmonary Artery Stenting Procedure', 'Events', and 'Discharge'. The main content area is titled 'Pre-Procedure Clinical Evaluation' and contains the following fields and options:

- Pre-Procedure Diagnosis Code(s):** A text box containing '20. ASD: Secundum' and an 'Edit' button.
- Height:** 53.3 cm
- Weight:** 2 kg
- Pre-Procedure Labs:** Hemoglobin: 5 g/dL, Creatinine: 5 mg/mL, O2 Sat: 70 %
- Pre-Procedure Conditions:** Necrotizing Enterocolitis (if < 30 days old): No Yes; Sepsis: No Yes; Pregnant: No Yes
- Pre-Procedure Medications:** (check all that apply) Antiarrhythmics, Anticoagulants, Antihypertensives, Antiplatelets, Beta Blockers, Diuretics, Prostaglandins, Sedatives, 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, Other

At the bottom left, there is a help icon and a note: '3000: Indicate the date the patient arrived at your facility.' At the bottom right, there are 'OK' and 'Cancel' buttons.

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, heparization, 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

Patient: Smith, John B Cath Date: 4/3/2011 Cath #: CTH123456

IMPACT Registry™

Cath Data

Cath Lab Arrival Date/Time: 04/03/2011 01:00 1-day Cath Lab Departure Date/Time: 04/03/2011 04:32
First Sheath/Catheter in Date/Time: 04/03/2011 01:40 Last Sheath/Catheter out Date/Time: 04/03/2011 03:59

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 Trainee Present: No Yes

Operator: Marty J. Jones (NPI=0445556667)

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 Trans thoracic
 Umbilical Other

Venous Sheath Size: 5 French (largest)

Venous Closure Methods: Add Remove
[18] Sealant - On-Site [Datascopie Corp.]
[18] Sealant - On-Site [Datascopie Corp.]
 Method not documented

Fluoro Time/Dose:
6.5 minutes
OR 568 mGy
OR uGy*m2

Contrast Volume: 26 mL

Sedation Heparization Airway Management Hemodynamic Support

Anesthesiologist Present (start of case): No Yes
Anesthesiologist Called In (due to escalation of care): No Yes

Sedation: General Anesthesia Epidural Caudal IV IM Oral/Intranasal None

Auxiliary 5: Auxiliary 6:

5041: Indicate the time the patient entered the cath lab.

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
Patient: Smith, John B Cath Date: 4/3/2011 Cath #: CTH123456

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
 Events
 Discharge

Baseline Hemodynamics

Systemic Arterial Saturation: % Mixed Venous Saturation: %

Systemic Ventricular Pressure: PA Pressure:
(Systolic) mmHg (Systolic) mmHg
(End Diastolic) mmHg (Mean) mmHg

Systemic Blood Pressure:
(Systolic) mmHg Pulmonary Ventricular Systolic Pressure: mmHg
(Diastolic) mmHg Pulmonary Ventricular Resistance Index: Wood Units*m2
(Mean) mmHg Cardiac Index: L/min/m2
Qp/Qs ratio:

(Data Entered on PedCath Edit Screen)

Using LV as Systemic Ventricle
Using RV as Pulmonary Ventricle

? 6000: Indicate the systemic arterial saturation obtained during the procedure in %.

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 displays the IMPACT Registry software interface for a patient named John B. Smith, with catheterization performed on 4/3/2011 (Cath # CTH123456). The left sidebar contains a navigation menu with the following sections: Demographics, Episode of Care, Case, Pre-Procedure Clinical Evaluation, Cath Data, Hemodynamics, Procedures Performed, Events, and Discharge. The 'Procedures Performed' section is currently selected and expanded, showing a list of procedures with checkboxes: ASD Closure, Coarctation Procedure, Aortic Valvuloplasty, Pulmonary Valvuloplasty, PDA Closure, and Proximal PA Stenting Procedure. A green arrow points to the 'Procedures Performed' link in the sidebar. The main content area shows a list of procedures with checkboxes: Diagnostic Cath, ASD Closure, Coarctation Procedure, Aortic Valvuloplasty, Pulmonary Valvuloplasty, PDA Closure, and Proximal PA Stenting Procedure. Below this list is a text box labeled 'Specific Procedure(s):' containing the text '35. Conduit: Sano modification-with valve (RV to PA valved conduit) (Balloon dilation)' and an 'Edit' button. A callout box points to the 'Procedures Performed' link in the sidebar, stating 'Procedure-Specific Data Panel links show here'. At the bottom of the window, there is a status bar with a question mark icon and the text '3000: Indicate the date the patient arrived at your facility.' and two buttons: 'Save & Close' and 'Close'.

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.

PedCath - IMPACT Registry

Patient: Smith, John B Cath Date: 4/3/2011 Cath #: CTH123456

IMPACT Registry™

Demographics

Episode of Care

Case

Pre-Procedure

Clinical Evaluation

Cath Data

Hemodynamics

Procedures Performed

ASD Closure

ASD Closure Procedure

Aortic Valvuloplasty

Pulmonary Valvuloplasty

PDA Closure

Proximal PA Stenting Procedure

Events

Discharge

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

Total Septal Length: 23 mm Atrial Septal Aneurysm Present: No Yes

ASD Multi-Fenestrated: No Yes

Add Defect Remove Defect

Defect 1 Defect 2 Defect 3

ASD Size: 34 mm Rim Measurement Performed: No Yes

Balloon Sizing Performed: No Yes IVC Rim Length: 34 mm

Stretched Diameter Performed: No Yes Aortic Rim Length: 23 mm

Size: 5 mm Defect Treated: No Yes

Stop Flow Technique Performed: No Yes Reason Not Treated: Residual Shunt Size:

Size: 6 mm Insufficient rims None to trivial (<3 mm)
 Other Significant (>=3 mm)

Devices

Num	Device ID	Associated Defect(s)	Outcome of Device
1	40	1, 2	Implanted, not released
		Balloon - HIGHSAIL Coronary Dilatation Catheter 3.75 mm x 8 mm [Abbott Vascular]	
2	65	3	Implanted, released
		Balloon - Jocath Maestro PTCA Catheter 4.5 mm x 11 mm [Abbott Vascular]	

7000: Indicate the primary reason the atrial septal defect (ASD) procedure is being performed.

Save & Close Close

Coarctation Procedure

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

To add one or more devices you must first set Defect Treated to Yes. 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

Patient: Smith, John B Cath Date: 4/3/2011 Cath #: CTH123456

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

Events

Discharge

Primary Procedure Indication: Abnormal ventricular function Congestive heart failure Exercise hypertension
 Systemic hypertension High resting gradient Angiographic appearance

Pre-Procedure Coarctation Diameter: 5.4 mm Pre-Procedure Coarctation Peak Systolic Gradient: 64 mmHg

Defect Treated: No Yes

Post-Procedure Coarctation Diameter: 4.3 mm

Post-Procedure Coarctation Peak Systolic Gradient: 54 mmHg

Add Device Remove Device

Device 1

Device ID: 65 Balloon - Jocath Maestro PTCA Catheter 4.5 mm x 11 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: 23 atm(s) In Stent Diameter Post-Procedure: mm

Outcome: Inflated with rupture Inflated without rupture

? 7100: Indicate the primary reason the Coarctation procedure is being performed.

Save & Close Close

Aortic Valvuloplasty

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

To add one or more inflations you must first set Defect Treated to Yes. 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 more than one inflation, click the Add Inflation button. Clicking the Remove Inflation button will remove the currently active inflation tab.

PedCath - IMPACT Registry

Patient: Smith, John B Cath Date: 4/3/2011 Cath #: CTH123456

IMPACT Registry™

Demographics
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 ASD Closure
 Coarctation Procedure
 Aortic Valvuloplasty
 Pulmonary Valvuloplasty
 PDA Closure
 Proximal PA Stenting Procedure
 Events
 Discharge

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: (used to select balloon) mm Pre-Procedure Peak Systolic Gradient: mmHg

Defect Treated: No Yes

Add Inflation Remove Inflation

Inflation 1 Inflation 2

Balloon Technique: Single Double

Device ID: ...

Balloon - HIGHSAIL Coronary Dilatation Catheter 2.5 mm x 15 mm [Abbott Vascular]

Balloon Stabilization: No Yes

Max Inflation Pressure: atm(s)

Outcome: Inflated with rupture
 Inflated without rupture

Post-Procedure Coarctation Peak Systolic Gradient: mmHg

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

? 7200: Indicate the primary reason the aortic valvuloplasty (AV) procedure is being performed.

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 16 for more information.

PedCath - IMPACT Registry

Patient: Smith, John B Cath Date: 4/3/2011 Cath #: CTH123456

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

Events

Discharge

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: (used to select balloon) mm Pre-Procedure Peak Systolic Gradient: mmHg

Defect Treated: No Yes

Add Inflation Remove Inflation

Inflation 1 Inflation 2

Balloon Technique: Single Double

Device ID Balloon 1: Device ID Balloon 2:

Balloon - HIGHSAIL Coronary Dilatation Catheter 3.75 mm x 13 mm [Abbott Vascular] Balloon - Sterling Monorail Balloon Dilatation Catheter 6.5 mm x 15 mm [Boston Scientific Corporation]

Balloon Stabilization: No Yes Balloon Stabilization: No Yes

Max Inflation Pressure: atm(s) Max Inflation Pressure: atm(s)

Outcome: Inflated with rupture Inflated without rupture Outcome: Inflated with rupture Inflated without rupture

Post-Procedure Coarctation Peak Systolic Gradient: mmHg

Post Procedure Pulmonary Valve Insufficiency: None 3+ (moderately severe) 1+ (mild) 4+ (severe) 2+ (moderate)

? 7400: Indicate the primary reason the pulmonary valvuloplasty (PV) procedure is being performed.

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 one or more devices you must first set Defect Treated to Yes.

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: Smith, John B Cath Date: 4/3/2011 Cath #: CTH123456

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

PDA Diameter Aortic Side: 23 mm PDA Minimum Lumenal Diameter: 32 mm PDA Length: 44 mm

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

Defect Treated: No Yes

PA Obstruction: (caused by implant) No Yes Aortic Obstruction: (caused by implant) No Yes Residual Shunt Size: (immed after device placement) None to trivial (<3 mm) Significant (>=3 mm)

Devices:

Num	Device ID	Outcome of Device
1	917	Implanted, released Occluder - AMPLATZER Septal Occluder 16 mm [AGA Medical]
2	1043	Implanted, not released Occluder - MReye Flipper Detachable Embolization Coil 35-3-3 [Cook Medical]

7600: Indicate the primary reason the patent ductus arteriosis (PDA) procedure is being performed.

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 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 2 and Defect 3, type "2, 3" in the grid cell.

PedCath - IMPACT Registry
Patient: Smith, John B Cath Date: 4/3/2011 Cath #: CTH123456

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

Defect Management: Add Defect Remove Defect
Defect 1 Defect 2 Defect 3

Defect Location: Right proximal PA Left proximal PA

Distal Stenosis Present: No Yes
Distal Obstruction Present: No Yes
Sidebranch Jailing: No Yes
Intended: No Yes
Artery: Proximal Artery Lobar Artery
Decreased Flow: No Yes

Hemodynamics:
Pre-Procedure: Proximal Systolic Pressure: 21 mmHg, Distal Systolic Pressure: 21 mmHg, Proximal Diameter: 35 mm, Distal Diameter: 15 mm, PA Vessel Diameter Minimum: mm
Post-Procedure: Defect Treated: No Yes

Devices Table:

Num	Device ID	Associated Defect(s)	Outcome of Device
1	1131	1	Stent not deployed
		Stent - FlexMaster F1 Coronary 2.75 mm x 9 mm [Abbott Vascular]	
2	1193	2, 3	Stent not deployed
		Stent - MULTI-LINK MINI VISION Rx Coronary Stent 2.0 mm x 23 mm [Abbott Vascular]	

7700: Indicate the primary reason the pulmonary artery (PA) stenting procedure is being performed.

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
Patient: Smith, John B Cath Date: 4/3/2011 Cath #: CTH123456

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

Events

Discharge

Cardiac Arrest: No Yes

Airway Event Requiring Intubation: No Yes

Arrhythmia: No Yes

Event Requiring ECMO: No Yes

Antiarrhythmic Medication: No Yes

Event Requiring LVAD: No Yes

Cardioversion: No Yes

Bleeding Event: No Yes

Temporary Pacemaker: No Yes

Bleeding at Access Site: No Yes

Permanent Pacemaker: No Yes

Hematoma at Access Site: No Yes

New Heart Valve Regurgitation: No Yes

Size: <3 cm 3-5 cm >5-10 cm >10 cm

Tamponade: No Yes

Retropitoneal Bleeding: No Yes

Air Embolus: No Yes

GI Bleed: No Yes

Embolic Stroke: No Yes

GU Bleed: No Yes

Device Malposition or Thrombus: No Yes

Other Bleed: No Yes

Device Embolization: No Yes

RBC/Whole Blood Transfusion: No Yes

Retrieved via Catheterization: No Yes

Hgb Prior to Transfusion: 10 g/dL

Retrieved via Surgery: No Yes

Other Vascular Complications Req Rx: No Yes

New Requirement for Dialysis: No Yes

No To All

Other Events: No Yes

Choose...

2310. Angiographic catheter rupture (Equipment/General)
2250. General Equipment failure (Equipment/General)
2310. Angiographic catheter rupture (Equipment/General)

Post-Procedure Treatments

Planned Cardiac Surgery: No Yes

Unplanned Cardiac Surgery: No Yes

Unplanned Cardiac Surgery: No Yes

Due to Cath Complication: No Yes

Unplanned Vascular Surgery: No Yes

Subsequent Cardiac Cath: No Yes

8000: Indicate if there was a cardiac arrest event that required CPR.

Save & Close Close

Discharge

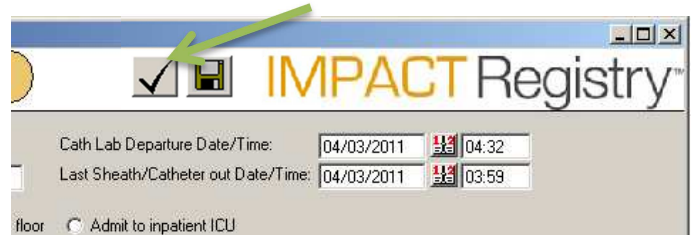
The Discharge section will allow you to enter the discharge date and status. Any cases without a discharge date will not be submitted to IMPACT.

The screenshot shows the 'PedCath - IMPACT Registry' application window. At the top, a yellow header bar displays 'Patient: Smith, John B', 'Cath Date: 4/3/2011', and 'Cath #: CTH123456'. To the right of the header are icons for print, checkmark, and save, followed by the 'IMPACT Registry' logo. The main interface is divided into a left sidebar and a main content area. The sidebar contains a list of sections with checkboxes: Demographics, Episode of Care, Case, Pre-Procedure Clinical Evaluation, Cath Data, Hemodynamics, Procedures Performed (with sub-items: ASD Closure, Coarctation Procedure, Aortic Valvuloplasty, Pulmonary Valvuloplasty, PDA Closure, Proximal PA Stenting Procedure), Events, and Discharge. A green arrow points to the 'Discharge' section in the sidebar. The main content area shows the 'Discharge' form with the following fields: 'Discharge Date' (04/10/2011), 'Discharge Status' (radio buttons for 'Alive' and 'Deceased'), 'Death in Lab' (radio buttons for 'No' and 'Yes'), and 'Primary Cause of Death' (radio buttons for Cardiac, Neurologic, Renal, Vascular, Infection, Valvular, Pulmonary, Unknown, and Other). At the bottom left, a help icon and a text box state: '? 9000: Indicate the date on which the patient was discharged from your facility.' At the bottom right, 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.

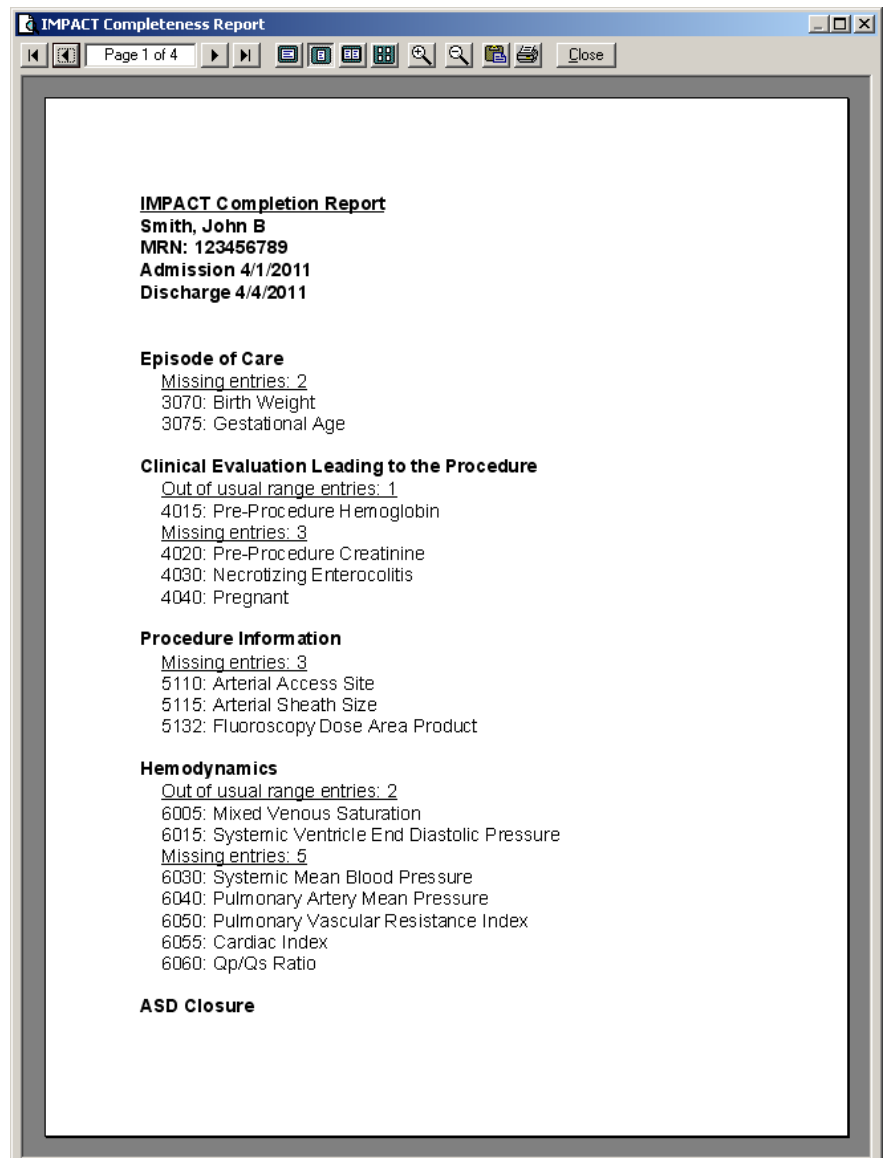
Clicking the validation button will allow you to see if there are any logical errors that would need to be corrected before submitting the data to IMPACT. If there are any errors, you will receive a message and PedCath will jump to the appropriate section.



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.



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.

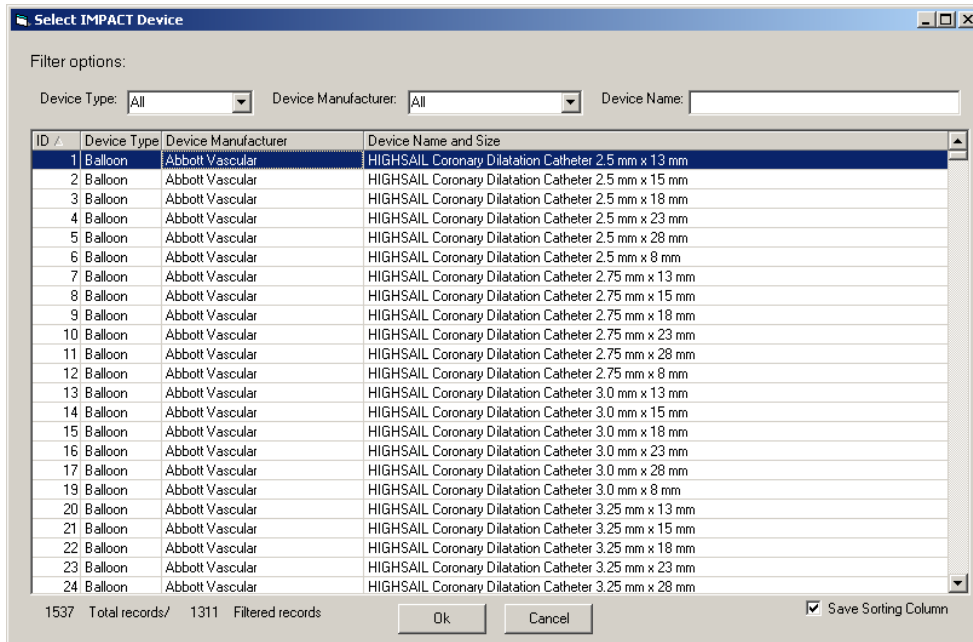
To filter by the device type, enter the name in the Device Type box or choose it from the pull down menu.

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.



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

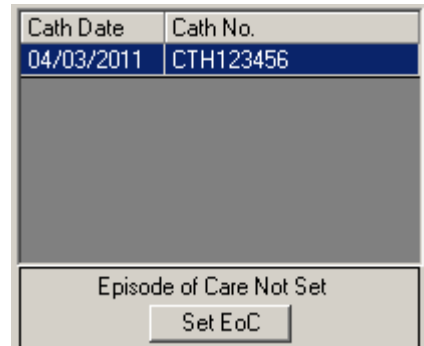
Managing Episodes of Care

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.

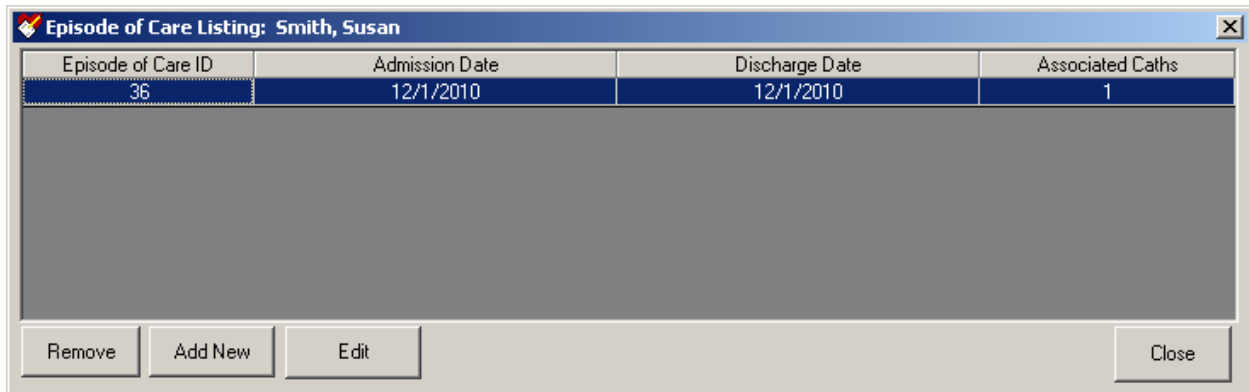


Managing a Patient’s Episode of Care Listing

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

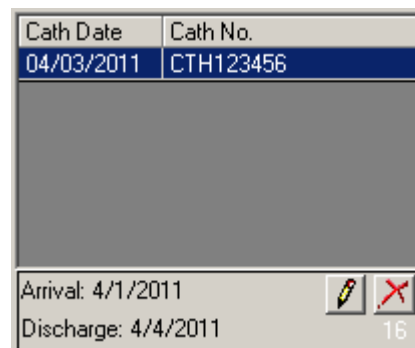
Here you can add, edit, and remove Episode of Care records.



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.



Administration

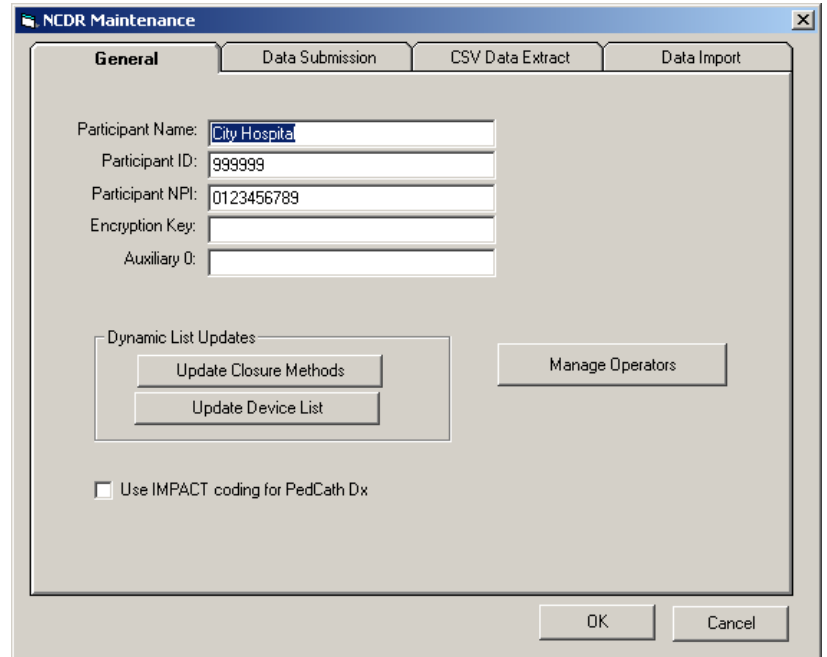
The PedCath IMPACT Registry Tool may be administered from within PedCath:

- 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.



The screenshot shows the 'NCDR Maintenance' dialog box with the 'General' tab selected. The fields are as follows:

Field	Value
Participant Name:	City Hospita
Participant ID:	999999
Participant NPI:	0123456789
Encryption Key:	
Auxiliary 0:	

Buttons and options include:

- Dynamic List Updates: Update Closure Methods, Update Device List
- Manage Operators
- Use IMPACT coding for PedCath Dx
- OK, Cancel

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.

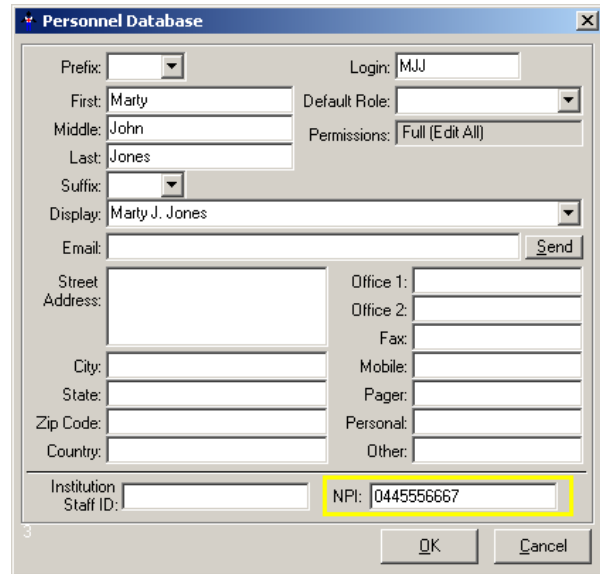
To use this option check the box labeled **Use IMPACT coding for PedCath Dx**.

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.

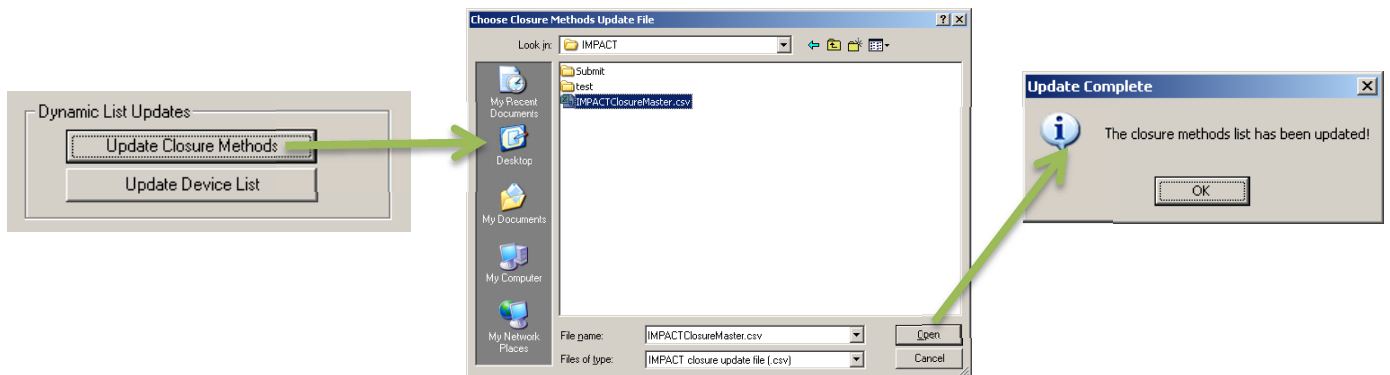


The Personnel Database dialog box contains the following fields and controls:

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

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 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.



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.

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

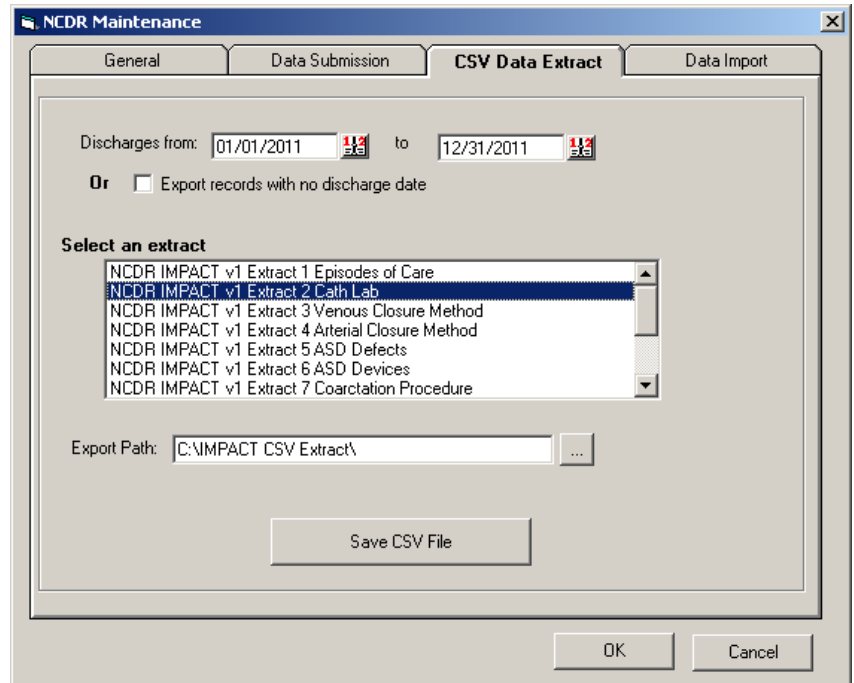
The screenshot shows the 'NCDR Maintenance' dialog box with the 'Data Submission' tab selected. The dialog has four tabs: 'General', 'Data Submission', 'CSV Data Extract', and 'Data Import'. The 'Data Submission' tab contains a 'Quarter' section with four rows: 'Quarter 1 (Jan 1 to Mar 31)', 'Quarter 2 (Apr 1 to Jun 30)', 'Quarter 3 (Jul 1 to Sep 30)', and 'Quarter 4 (Oct 1 to Dec 31)'. Each row has a checkbox and a 'View Report' button. The first two quarters are checked. To the right of the quarters is a 'Validation/Completeness' section with a 'Check Missing Discharge Dates' button. Below the quarters is a 'Year' dropdown menu set to '2011'. Below that is an 'Export Path' text box containing 'C:\For IMPACT\' and a browse button. At the bottom of the main area is a checkbox for 'Exclude NCDR Patient Identifiers from export' and a 'Create Submission File(s)' button. At the bottom of the dialog are 'OK' and 'Cancel' buttons.

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 12-extracts available:

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



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.)
- Highlight one of the 12 extract types
- 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.

To run the import simply browse for the file location and click **Import IMPACT Data**.

