Brief Report – CRISP Registry

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CRISP Registry Organizers

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Executive Summary

This brief report presents the results of an interim analysis from the CRISP Registry. Version 3 of the registry was re-launched in late 2023 and has rapidly evolved into a robust, multicenter collaborative effort. As of this report, **9,217 cases** have been enrolled from **19 participating centers**.

The first CRISP Registry webinar was held on **November 19, 2025**, during which early registry data were presented. This document provides an overview of the collected data, highlighting the performance of the **CRISP and CRISA risk prediction models** and current progress on the **radiation exposure dosage project**.

This report is **not a formal publication**, but an internal summary intended to illustrate the registry's current progress and share initial insights with participating centers. The findings reflect the registry's present status.

The registry continues to expand its participating sites and cumulative case enrollment through collaborative efforts. The registry organizers remain committed to providing timely feedback, promoting data sharing, and improving care in congenital cardiac catheterization laboratories.

Document Content

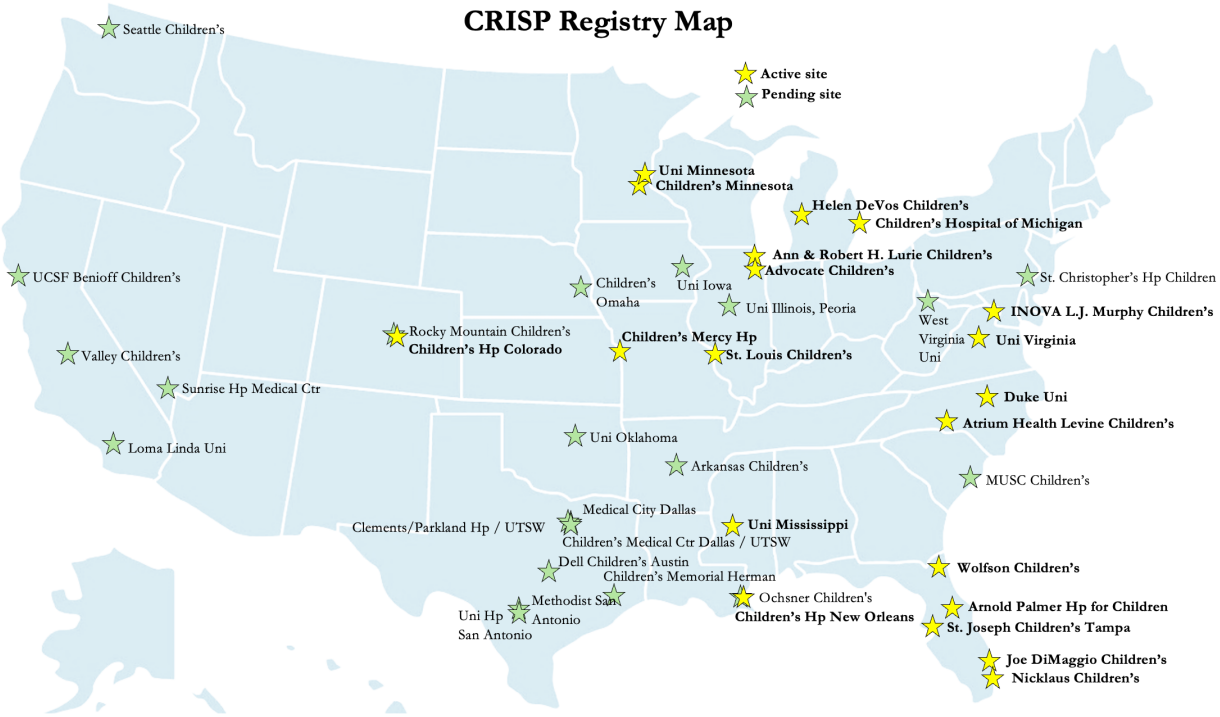
This brief report summarizes early updates and insights from the ongoing multicenter CRISP Registry, presenting:

1. Progress of the CRISP Registry
2. Significant Adverse Event and Risk Prediction Model
3. Radiation Exposure Dosage
4. New CRISP Radiation Exposure Category
5. Procedure Time

1. Progress of the CRISP Registry

The growth of the CRISP Registry has been substantial. Only **4 centers** were participating in **2024 Q1**, whereas **20 centers** have now completed the participation process. The cumulative case count has exceeded **9,000 cases**. An additional **20+ centers** are currently undergoing onboarding, and the registry anticipates engaging **over 40 U.S. centers in 2026**.

The following map illustrates **current participating centers (yellow) and prospective centers (green).**



2. Significant Adverse Event and Risk Prediction Model

The dataset for this analysis was downloaded on **November 17, 2025**. SAE analysis was performed on **9,207 cases**, excluding only **10 cases** with missing CRISP/CRISA score assignment. This reflects strong data completeness and integrity.

All adverse events underwent centralized adjudication by a single reviewer (DK), ensuring uniform severity grading. A total of **378 SAEs (4.1%)** were recorded across all cases. The severity distribution is presented in the accompanying table.

Of the total cohort, **7,757 cases (84%)** were pediatric and **1,450 cases (16%)** were adult. SAE rates were similar between children and adults (**4.2% vs. 3.9%, $p = 0.611$**, Chi-square test).

Version 3 assigns CRISP and CRISA categories exclusively from **pre-procedural** variables, strengthening the registry's capacity for true pre-procedural risk prediction.

Table. Frequency of severity grades in 378 significant adverse events

Significant adverse event n=378				
Catastrophic	Major	Moderate		
Level 5	Level 4	Level 3c	Level 3b	Level 3a
n=13 (3%)	n=71 (19%)	n=72 (19%)	n=78 (21%)	144 (n=38%)

Risk Model Performance

Using binary logistic regression:

- The **CRISP model (children)** demonstrated a c-statistic of **0.663**, suggesting moderate discrimination.
- The **CRISA model (adults)** demonstrated stronger performance, with a c-statistic of **0.704**.

These findings support the validity of the current risk models while highlighting the opportunity for refinement as Version 3 data accumulate.

Figure. Case volume and SAE rate based on CRISP Score/Category for Children

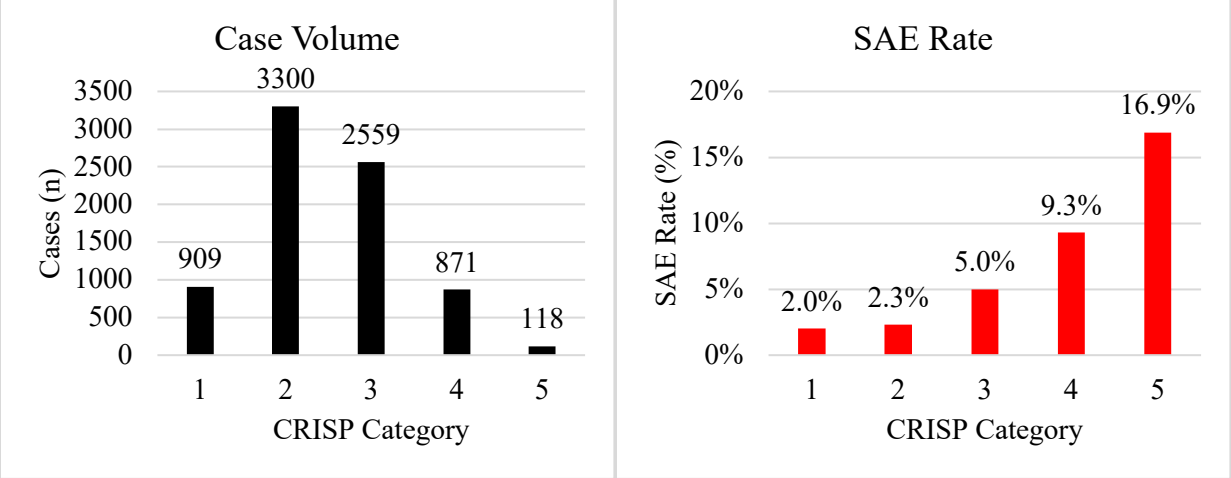
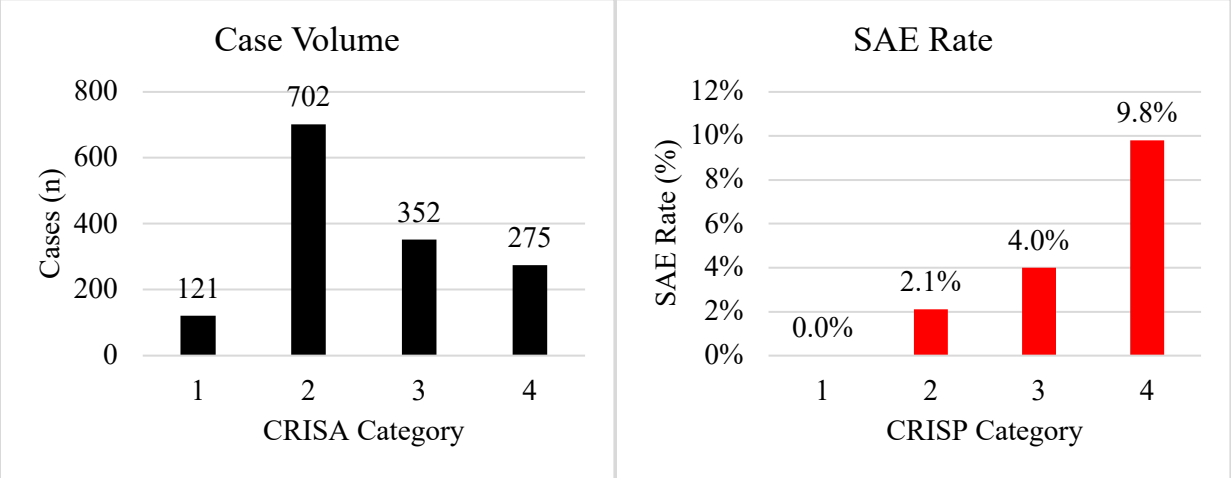


Figure. Case volume and SAE rate based on CRISA Score/Category for Adults



New potential predictors

Ventricle Physiology

Version 3 incorporates several important pre-procedural predictors not collected previously. Ventricular physiology is a key new variable. **Biventricular physiology was present in 75% of cases (n = 6,941), while single-ventricle physiology was present in 25% (n = 2,266).** Patients with single-ventricle physiology had a **significantly higher SAE rate (5% vs. 3.8%, $p = 0.015$)**. The registry also captures surgical stages of single-ventricle palliation. **Patients without any prior palliation had the highest SAE rate**, reinforcing the elevated physiologic risk among pre-palliation single-ventricle patients.

Table. Number of cases and SAE rates based on the stages of single ventricle palliation

Stages of single ventricle palliation	Total (n)	SAE (%)
No palliation	302	40 (13.2%)
S/p Aortopulmonary shunt	132	7 (5.2%)
S/p PDA stent	104	4 (3.8%)
S/p Norwood/DKS	249	13 (5.2%)
S/p BDG/Hemi-Fontan	553	16 (2.9%)
S/p Fontan	770	24 (3.1%)

Pre-Procedural Echocardiography

Moderate-to-severe ventricular dysfunction was present in **7% of cases (n = 633)** and was associated with a **significantly higher SAE rate ($p < 0.001$)**. Moderate-to-severe systemic AV valve regurgitation (AVVR) was present in **8% of cases (n = 764)** and was also associated with **significantly higher SAE rates ($p < 0.001$)**.

Table. Number of cases and SAE rates based on the pre-procedural echocardiography

Ventricular dysfunction	Total	SAE (%)	Systemic AVVR	Total	SAE (%)
None/mild	8,574	329 (3.8%)	None/mild	8,443	329 (3.9%)
Moderate	333	27 (8.1%)	Moderate	611	33 (5.4%)
Severe	300	22 (7.3%)	Severe	153	16 (10.5%)

Pre-Procedural Patient Location

Patients arrived for catheterization from various clinical locations. Those presenting from the ICU experienced **significantly higher SAE rates (7%, $p < 0.001$)**. As expected, ICU patients represent a higher-acuity population with greater physiologic instability.

Table. Number of cases and SAE rates based on the pre-procedural patient location

Patient Location	Total (n)	SAE (%)
Outpatient	3,263	89 (2.7%)
Inpatient floor	356	13 (3.7%)
Inpatient ICU	1,251	88 (7%)

Pre-Procedural Airway Status

Airway status prior to catheterization was strongly associated with adverse events. **Twelve percent of patients (n = 1,108)** were intubated before the procedure and exhibited a **significantly higher SAE rate (7.2%, $p < 0.001$)** compared with those arriving with their own airway or a tracheostomy.

Table. Number of cases and SAE rates based on the pre-procedural airway status

Patient Location	Total (n)	SAE (%)
Own airway	7,880	290 (3.7%)
Tracheostomy	219	8 (3.7%)
Endotracheal tube	1,108	80 (7.2%)

Insight from the CRISP Registry Organizers

It has been **10 years** since the original CRISP score was published in **2016** (reference 1). Version 3 of the registry introduces a significantly enhanced data collection structure, separating pre- and post-catheterization variables and incorporating a new set of physiologic predictors.

Earlier CRISP/CRISA diagnosis-based and procedure-based categories were developed largely from expert opinion. With the growing Version 3 dataset, the registry organizers intend to develop an **updated, data-driven risk prediction model** that more accurately reflects current practice in congenital cardiac catheterization.

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3. Radiation Exposure Dosage

Radiation dosage was evaluated using **DAP/kg** in **9,136 cases**, excluding **71 cases** with missing values. The primary radiation metric is **dose–area product (DAP) normalized to body weight**.

The registry has implemented a two-step radiation oversight system:

1. **Real-time self-check:** Each case prompts users to review radiation data at case completion.
2. **Centralized adjudication:** All cases that exceed predefined DAP/kg thresholds are reviewed by registry organizers, who notify sites and help ensure correction of any erroneous entries.

The CRISP interface also provides each center's **quarterly median DAP/kg** along with national benchmarks, supporting ongoing quality improvement.

C3PO Radiation Exposure Category (REC)

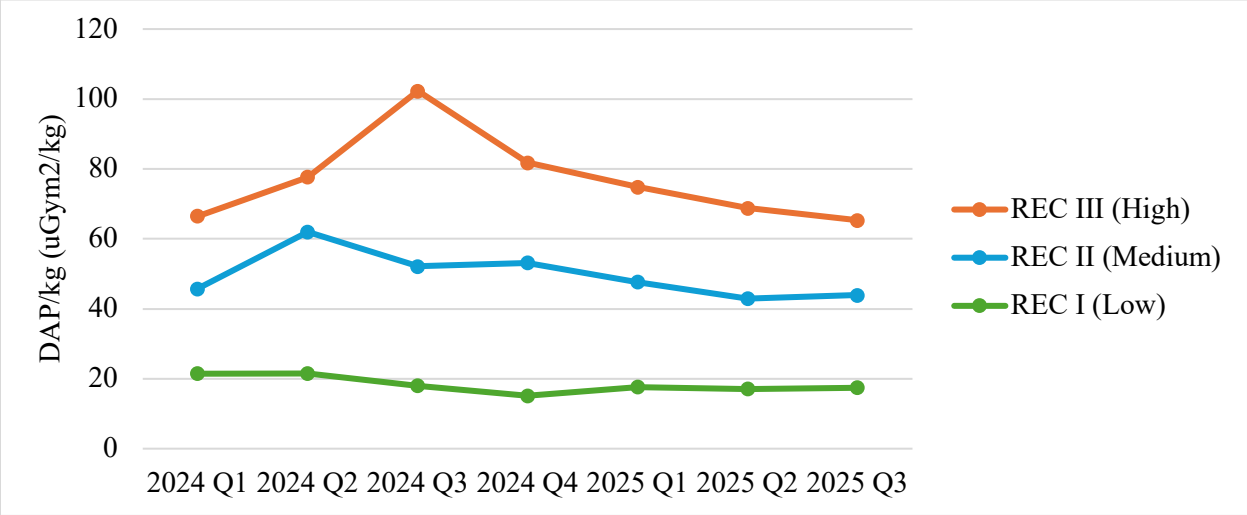
The registry currently applies the **C3PO REC** framework, categorizing procedures into **REC I (low)**, **REC II (medium)**, and **REC III (high)** based on 40 procedure types (references 2, 3).

REC I accounted for **two-thirds of all cases**, reflecting the predominance of diagnostic and lower-complexity procedures. As anticipated, **median DAP/kg increased across REC categories**. A mild downward trend in radiation exposure was observed from **2024 Q1 through 2025 Q3**.

Table. Number of cases and median DAP/kg based on C3PO radiation exposure category (REC)

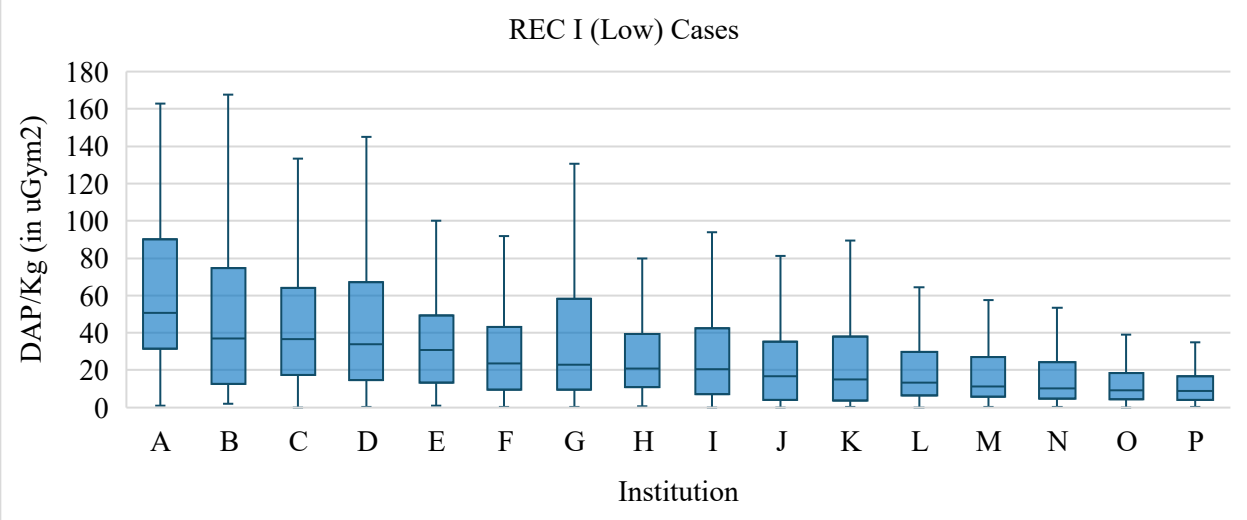
	Total (%)	Median DAP/kg (IQR)
REC I (Low)	6,141 (67%)	17.5 (7.0 – 41.3)
REC II (Medium)	1,169 (13%)	47.5 (22.7 – 89.1)
REC III (High)	667 (7%)	72.2 (38.0 – 144.9)
NA (not applicable)	1,159 (13%)	44.9 (21.6 – 973)

Figure. Quarterly trend of median DAP/kg in the benchmark CRISP registry dataset, stratified by C3PO radiation exposure category (REC)



Despite this improvement, **substantial inter-institutional variation** persists. Among REC I cases, median DAP/kg differed by approximately **two- to three-fold** between low- and high-dose centers, highlighting an important opportunity for quality improvement.

Figure. Box-plots showing median DAP/kg of REC I cases between CRISP participating centers



4. New CRISP Radiation Exposure Category (REC)

The registry has developed a **CRISP-specific radiation exposure categorization** to address limitations of the C3PO system in congenital practice (reference 4). The CRISP REC classifies procedures into:

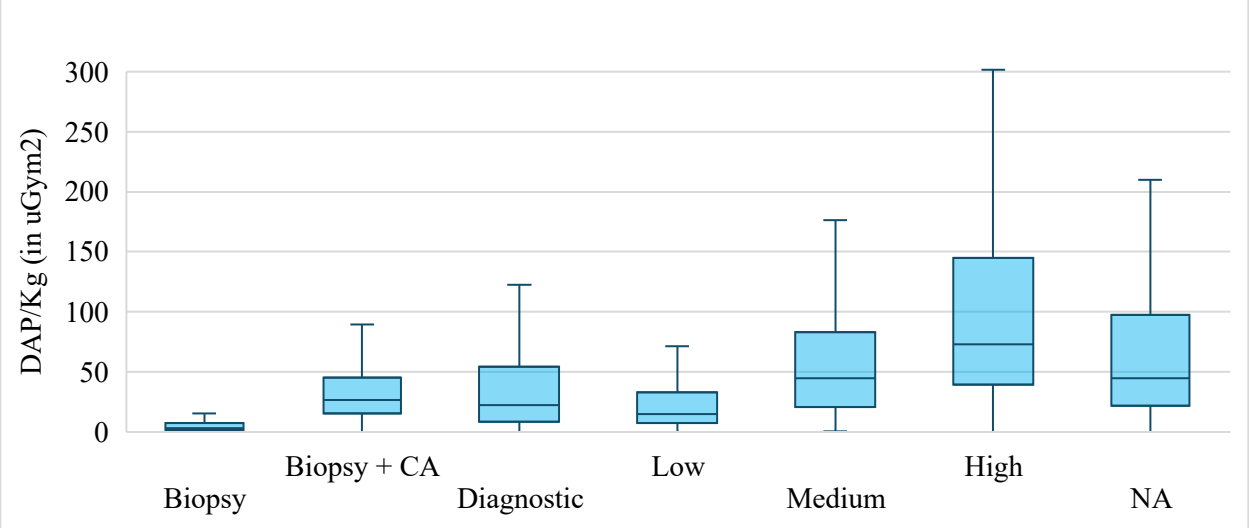
- Biopsy only
- Biopsy with coronary angiography
- Diagnostic study
- Low-complexity intervention
- Medium-complexity intervention
- High-complexity intervention

This structure separates groups previously combined under C3PO REC I. Median DAP/kg increased appropriately across categories.

Table. Number of cases and median DAP/kg based on CRISP radiation exposure category (REC)

	Total (%)	Median DAP/kg (IQR)
Biopsy only	634	3.2 (1.7 – 7.2)
Biopsy with coronary angiography	780	26.7 (15.6 – 45.3)
Diagnostic study	2,374	22.2 (8.4 – 54.2)
Interventional Low	2,092	14.8 (7.4 – 33.1)
Interventional Medium	1,441	44.5 (20.7 – 83.0)
Interventional High	656	72.7 (39.3 – 144.8)
NA (Not applicable)	1,159	44.9 (21.6 – 97.3)

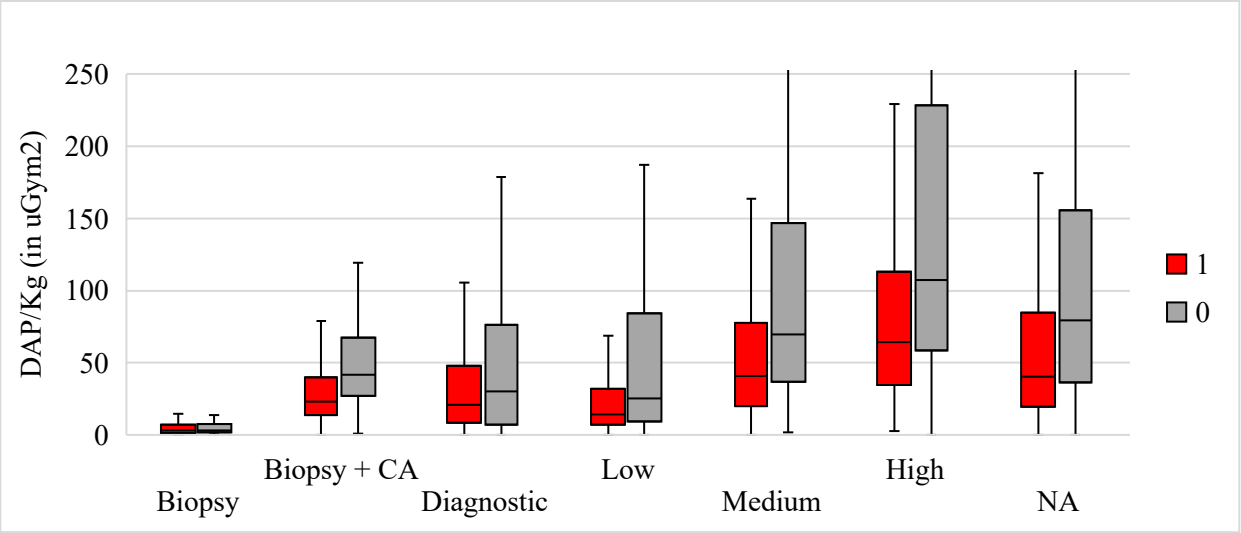
Figure. Box-plots showing median DAP/kg based on the CRISP REC



Impact of Adult Patients on Radiation Dosage

Adult patients demonstrated significantly higher radiation exposure, with median DAP/kg **1.5–2 times higher** than pediatric patients. The proportion of adult cases varied widely across centers (**5% to 39%**), underscoring the need for **age-stratified benchmarking**.

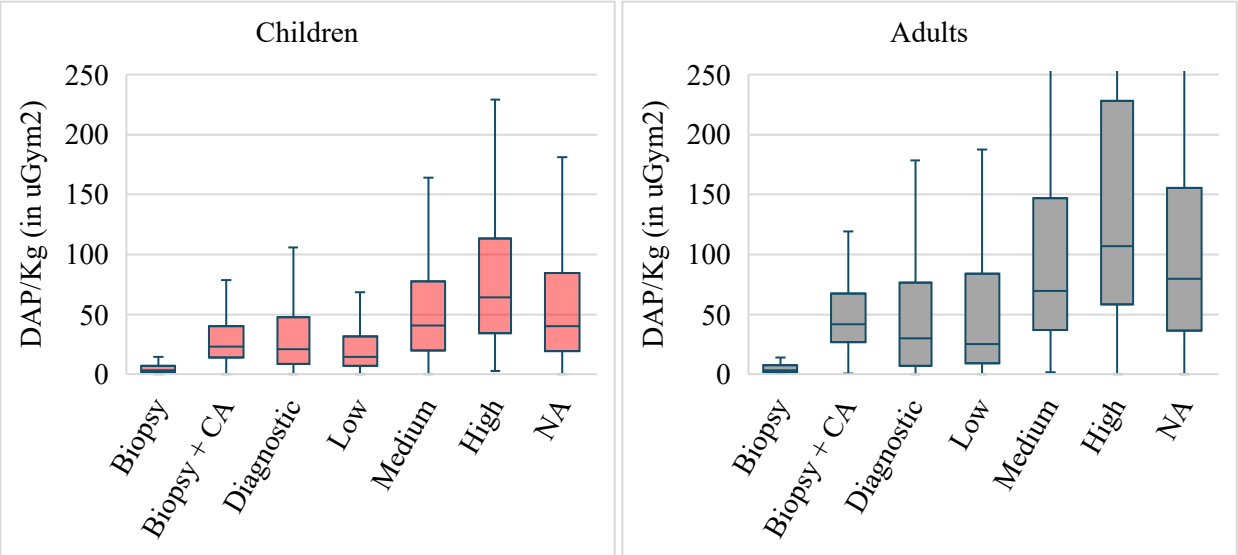
Figure. Box-plots comparing DAP/kg based on CRISP REC between children (red) and adults (gray)



Future direction of DAP/kg self-check

A new DAP/kg self-check system is under development. Radiation exposure will be displayed in real time according to CRISP REC categories and stratified by **children versus adults**, providing an improved framework for operator interpretation and dose optimization.

Figure. Upcoming DAP/kg self-check system in the CRISP Registry interface



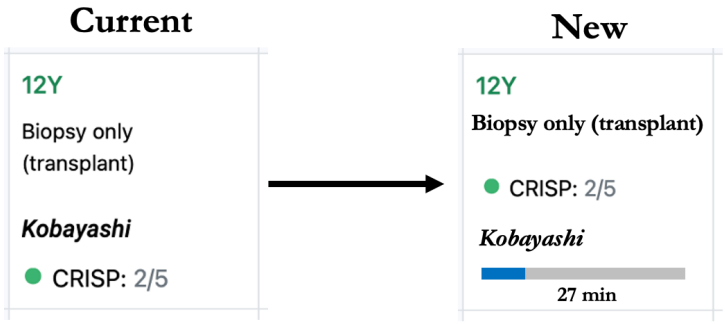
5. Procedure Time

Procedure duration was assessed by pre-catheterization primary procedure type. The registry will incorporate **expected median procedure time** into the weekly dashboard to support scheduling, planning, and allocation of resources.

Table. Median procedure time based on the pre-catheterization primary procedure types

Pre-cath primary procedure type	Median procedure time (min)
Diagnostic study	
Pre-Fontan diagnostic ± collaterals	81
Post-Fontan diagnostic ± collaterals	79
Pre-BDG diagnostic ± collaterals	68
Diagnostic	61
Transplant biopsy	
Biopsy with coronary study	52
Biopsy only	27
Interventions with long procedure time	
Atretic pulmonary valve perforation	121
Angioplasty Stent / RVOT conduit	121
Angioplasty Stent / Atrial baffle	121
Closure / Venous collateral	115
Angioplasty Stent / Pulmonary vein (only 1 vessel)	111
Angioplasty Stent / Sano shunt	109
Transcatheter valve implantation / Pulmonary	106
Angioplasty Stent / Systemic-to-pulmonary shunt	105
Angioplasty Stent / PA (only 1 vessel)	104
Thrombectomy / thrombolysis (PE)	102
Interventions with short procedure time	
Closure / ASD	61
Valvuloplasty / Pulmonary (>30 day old)	60
Valvuloplasty / Pulmonary (≤30 day old)	57
Closure / Systemic vein (Caval or non-Caval vein)	56
Closure / PDA (≥2 kg)	55
Closure / PFO	48
Balloon atrial septostomy (BAS)	46
Closure / PDA (<2 kg)	39
Pericardiocentesis and/or pericardial drain	29

Figure. New weekly dashboard showing "expected median procedure time"



REFERENCE

1. Nykanen DG, Forbes TJ, Du W, Divekar AA, Reeves JH, Hagler DJ, Fagan TE, Pedra CA, Fleming GA, Khan DM, Javois AJ, Gruenstein DH, Qureshi SA, Moore PM, Wax DH; Congenital Cardiac Interventional Study Consortium (CCISC). CRISP: Catheterization RISk score for Pediatrics: A Report from the Congenital Cardiac Interventional Study Consortium (CCISC). Catheter Cardiovasc Interv. 2016 Feb 1;87(2):302-9. doi: 10.1002/ccd.26300. Epub 2015 Nov 3. PMID: 26527119.
2. Quinn BP, Armstrong AK, Bauser-Heaton HD, Callahan R, El-Said HG, Foerster SR, Goldstein BH, Goodman AS, Gudausky TM, Kreutzer JN, Leahy RA, Petit CJ, Rockefeller TA, Shahanavaz S, Trucco SM, Bergersen L; Congenital Cardiac Catheterization Project on Outcomes-Quality Improvement (C3PO-QI). Radiation Risk Categories in Cardiac Catheterization for Congenital Heart Disease: A Tool to Aid in the Evaluation of Radiation Outcomes. Pediatr Cardiol. 2019 Feb;40(2):445-453. doi: 10.1007/s00246-018-2024-3. Epub 2018 Nov 30. PMID: 30506273.
3. Quinn BP, Cevallos P, Armstrong A, Balzer D, El-Said H, Foerster S, Glatz AC, Goodman A, Goldstein B, Hainstock M, Janssen D, Kreutzer J, Latson L, Leahy R, Petit C, Shahanavaz S, Trucco S, Whiteside W, Zampi JD, Bergersen L. Longitudinal Improvements in Radiation Exposure in Cardiac Catheterization for Congenital Heart Disease: A Prospective Multicenter C3PO-QI Study. Circ Cardiovasc Interv. 2020 May;13(5):e008172. doi: 10.1161/CIRCINTERVENTIONS.119.008172. Epub 2020 May 15. PMID: 32408819.
4. Hiremath G, Samayoa JC, Javois A, Aldoss O, Leahy R, Chamberlain R, Amin E, Vezmar M, Ebeid M, Sathanandam S, Nykanen D, Forbes T, Curzon C, Bocks M, Kobayashi D. Trends in Radiation Exposure With the Refinement of Radiation Exposure Categories in Congenital Cardiac Catheterization: Insights From the CRISP Registry. J Soc Cardiovasc Angiogr Interv. 2025 Jul 23;4(8):103727. doi: 10.1016/j.jscai.2025.103727. PMID: 41019894; PMCID: PMC12462090.