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ORIGINAL ARTICLE

Implementation of Methodology for Quality Improvement in Pediatric Cardiac Catheterization: A Multi-center Initiative by the Congenital Cardiac Catheterization Project on Outcomes—Quality Improvement (C3PO-QI)

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Abstract The Congenital Cardiac Catheterization Project on Outcomes (C3PO) launched in 2007 as a multi-center collaborative to establish standardized and comparable metrics for pediatric cardiac catheterization procedures. The limitations of larger registries at the time led to the development of the next phase in 2013, C3PO-Quality Improvement (C3PO-QI), focusing on instituting QI initiatives within the field. The objective of this manuscript is to provide a detailed overview of C3PO-QI and report data on case characteristics and outcome metrics being explored. C3PO-QI was designed to cultivate institutional collaboration during implementation of its initiatives. A database and website were developed to support data entry and on-demand reporting. The registry prospectively captures pediatric cardiac catheterization data among 15 hospitals. The present study includes case demographic data (n) and quality metric reporting by case type, age, and radiation dose variables. This dataset includes 13,135 cases entered into the database between 1/1/2014 and 12/31/2015. Interventional cases make up the highest percentage by case mix distribution (48 %), and patients <1 years make up the highest percentage by age distribution (26 %). The ratio of diagnostic and interventional procedures performed changes by age group. Application of QI metric shows all procedure types surpassing metric goals. Large volume data collection, such as in C3PO-QI, allows for

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meaningful interpretation of data. C3PO-QI is uniquely poised to deliver fast-paced changes in the field. Although the project initiatives are specific to pediatric cardiac catheterization, the implementation of the project and utilization of real-time reporting is generalizable to other specialties and multi-center collaboratives.

Keywords Quality improvement · Pediatric cardiology · Catheterization · Congenital heart disease · Multi-center initiative

Introduction

The use of cardiac catheterization procedures in the treatment of children with congenital heart disease (CHD) has increased over recent decades. Technological advancements augmenting catheterization techniques have expanded the scope of the field into more complex procedures [1]. However, the relative novelty of these procedures has led to a lack of standardization in care delivery, making it difficult to compare outcomes across providers and institutions [2]. The Congenital Cardiac Catheterization Project on Outcomes (C3PO) was launched in 2007 as a multi-institutional effort to establish standardized metrics for pediatric cardiac catheterization procedures, which included the development of procedural risk categories and hemodynamic vulnerability measurement tools [3–6]. These risk variables were then used to develop a risk adjustment model, Congenital Heart Adjustment for Risk Method (CHARM), which made the equitable comparison of adverse event rates among providers and institutions possible via a standardized adverse events ratio (SAER) calculation [2, 4–6].

While C3PO offered the ability to compare intra- and inter-institutional cardiac catheterization procedures and practices, at the time, few nationwide quality improvement (QI) initiatives existed aiming to improve baseline standards of care for pediatric and adult cardiac catheterization patients. In recent years, a handful of cardiac catheterization QI projects have been established, such as Improving Pediatric and Adult Congenital Treatment (IMPACT) and Congenital Cardiac Interventional Study Consortium (CCISC) registries, enabling large-scale data collection and implementation of important multi-institutional efforts to identify best practices and areas requiring improvement [2, 7, 8]. While participation in such QI projects offers many benefits, limitations such as lack of customized reporting and incomplete adverse event data capture restrict the interpretability of data and delay progress. The Congenital Cardiac Catheterizations Project on Outcomes—Quality Improvement (C3PO-QI) was formed in 2013 as a collaboration of 15 participating peer institutions in an effort to overcome these challenges and improve the quality of care delivered to pediatric patients undergoing cardiac catheterization procedures. C3PO-QI is well positioned to successfully accomplish these goals within its tightly managed registry, interactive small group participation and capacity to develop on-demand, dynamic reporting tools. C3PO-QI's first QI initiative aims to reduce radiation exposure by improving benchmark performance and by establishing new performance expectations [9]. The objective of this report is to provide a detailed overview of the C3PO-QI program and report data on case characteristics and outcome metrics being explored.

Methods

Project Design

C3PO-QI is a multi-institutional collaborative database launched in 2013 with 15 nationwide participants and is sponsored by Boston Children's Hospital Cardiovascular Program (Table 1). C3PO-QI initiatives are conducted using established QI methodology. Rapid cycle assessments on the impact of interventions pursued utilize the Plan, Do, Study, and Act (PDSA) methodology: (1) propose new changes (Plan), (2) implement these changes (Do), (3) measure or describe the effect (Study), and (4) review and upgrade the process (Act) [10]. As part of the PDSA methodology, a key driver diagram was created to highlight the goals of C3PO-QI's first QI initiative and outline steps for execution (Fig. 1).

Table 1 C3PO-QI participating sites

C3PO-QI participating sites
Boston Children's Hospital
Children's Healthcare of Atlanta
Cincinnati Children's Hospital
Children's Hospital of Pittsburgh
Nationwide Children's Hospital
St. Louis Children's Hospital
Children's Hospital of Wisconsin
Oregon Health and Sciences University
University of Michigan
Joe DiMaggio Children's Hospital
Rady Children's Hospital
Children's Hospital of Philadelphia
Morgan Stanley Children's Hospital
Kosair Children's Hospital of Louisville
University of Virginia Medical Center

Website

An external and an internal website were created for C3PO-QI. The external C3PO-QI website (https://c3po-qi.chboston.org/) provides an overview of the project for interested parties (Fig. 2). Here, external users can read C3PO-QI-related project publications, access the SAER calculator, and view QI-related resources. The internal website, for use by C3PO-QI institutions, facilitates data entry and provides a working area to guide progress and access reporting tools (Fig. 3). Institutions are able to chronicle adjustments in their practice throughout their participation in the initiative, thus tracking QI project performance and changes which may affect outcomes. An online area is also dedicated to manuscript submission.

Data Registry

C3PO-QI focuses on collecting pediatric cardiac catheterization procedural data prospectively. Users enter data directly onto the C3PO-QI website, where they have the option of updating a previously entered case or creating a new case entry. Data variables collected include patient demographics, type of procedure (biopsy, diagnostic, interventional or other), adverse events, and procedural outcomes. Radiation dose is reported in total air kerma (mGy) and total dose area product (DAP, $\mu Gy*M^2$) to estimate the short-term, deterministic and long-term, stochastic effects of radiation exposure, respectively. Complete procedural data are further collected on the following six interventional procedures: (1) transcatheter pulmonary valve (TPV) placement; (2) aortic valvuloplasty (AV); (3) treatment of coarctation of the aorta (COA); (4) patent ductus arteriosus (PDA) closure; (5) pulmonary valvuloplasty (PV); and (6) atrial septal defect (ASD) closure (Fig. 4). These procedures were selected because of their potential to show homogeneity in outcomes, while allowing for identification and adjustment of important confounding factors for outcomes explored in order to make valid comparison across institutions.

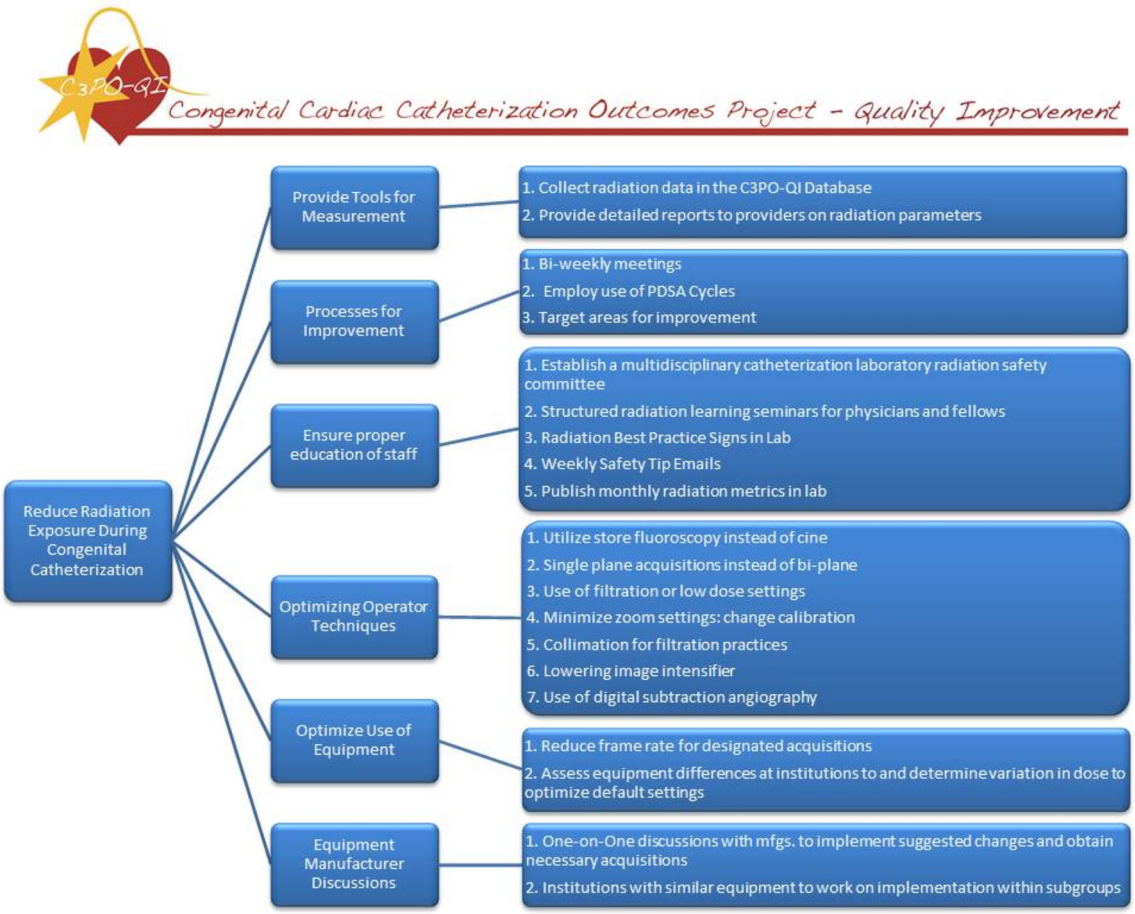

Fig. 1 C3PO-QI key driver diagram used in the implementation of C3PO-QI's first QI initiative to reduce radiation exposure in the catheterization laboratory serves as a proposed outline of the strategies incorporated to reach the project's goals

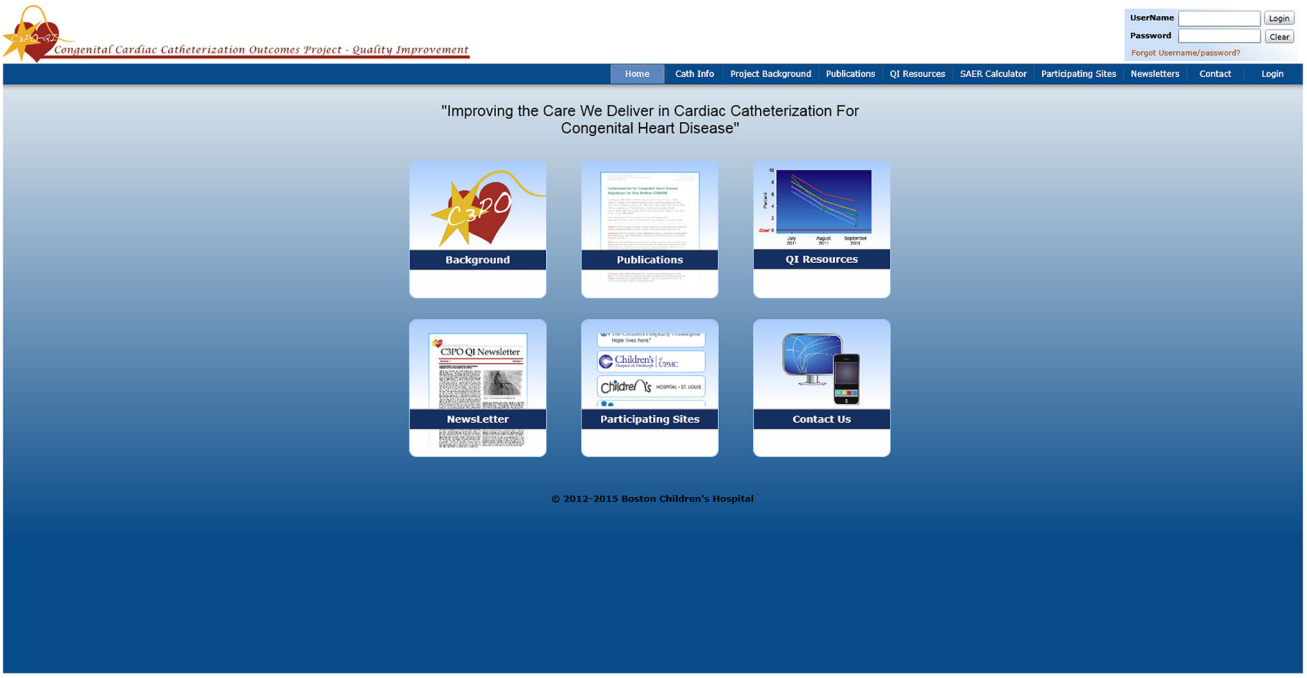

Fig. 2 C3PO-QI public website homepage

Reporting

C3PO-QI employs both static and dynamic reporting tools to review data. On the internal website, two types of on-demand, static reporting tools are available: Comparison Reports and QI Reports. Comparison Reports give sites a general overview of cases entered in the database. Conversely, QI Reports allow sites to view progress within specific QI measures, such as radiation dose levels (>1 and >2 Gy) by case type and procedure type. These reports apply the C3PO-QI quality metric, endorsed by the American College of Cardiology (ACC), defined as the proportion of cases receiving doses not exceeding the 95th percentile of a predefined dataset. Initial radiation dose benchmarks for this metric were established by Ghelani et al. retrospectively in 2014, with the intent to be periodically updated longitudinally with data collected prospectively. All reports can be stratified by date range, age group, severity level and admission source. Data can also be segregated at the institutional or individual physician level. The website reports are available on-demand or can be set to auto-generate at any desired frequency (weekly, monthly, quarterly, etc.).

Data Quality

It is vital to ensure accurate data capture while minimizing data entry error in order to maintain a comprehensive data registry. Cardiac catheterization database vendors, such as PedCath^{TM} (Scientific Software Solutions, Charlottesville, VA) and CardioAccess^{TM} (Clinical Outcomes Software Solutions, Fort Lauderdale, FL), have partnered with C3PO-QI in order to integrate C3PO-QI-specific data elements into existing export modules. Currently, 46 % of C3PO-QI's data elements are exported automatically, while the rest are manually entered by hospital staff (i.e., nurses or physicians) at participating sites upon case completion. All adverse events reported are reviewed for proper classification of severity and preventability by the project sponsor and a designee physician. Institutions can ensure maintenance of complete and proper data collection by generating Completeness Reports and Validation Reports. Completeness Reports produce a list of site-specific data entry omissions to verify complete case capture, while the Validation Reports highlight any out-of-range field discrepancies for site review. Sites run both reports on a regularly basis according to institutional practice to maintain data quality. Yearly, on-site independent audits are performed at each participating institution which includes a review of 5–10 % of cases to verify accurate and complete data capture by cross-referencing source medical records.

Data

Data presented in this study represent an overview of all cases currently captured in the C3PO-QI database among all 15 participating institutions between January 1, 2014 and December 31, 2015. Total demographic distribution data was reported by case type (biopsy, diagnostic,

Fig. 3 C3PO-QI user-specific website homepage

interventional, other) and age group (<1 year of age, 1–4 years of age, 5–9 years of age, 10–15 years of age and >15 years of age). In order to highlight utilization of the QI reports, the quality metric was applied to the six interventional procedures (ASD, AV, COA, PDA, PV, TPV) stratified by age and radiation outcome variables. Radiation outcomes were reported by total air kerma and DAP.

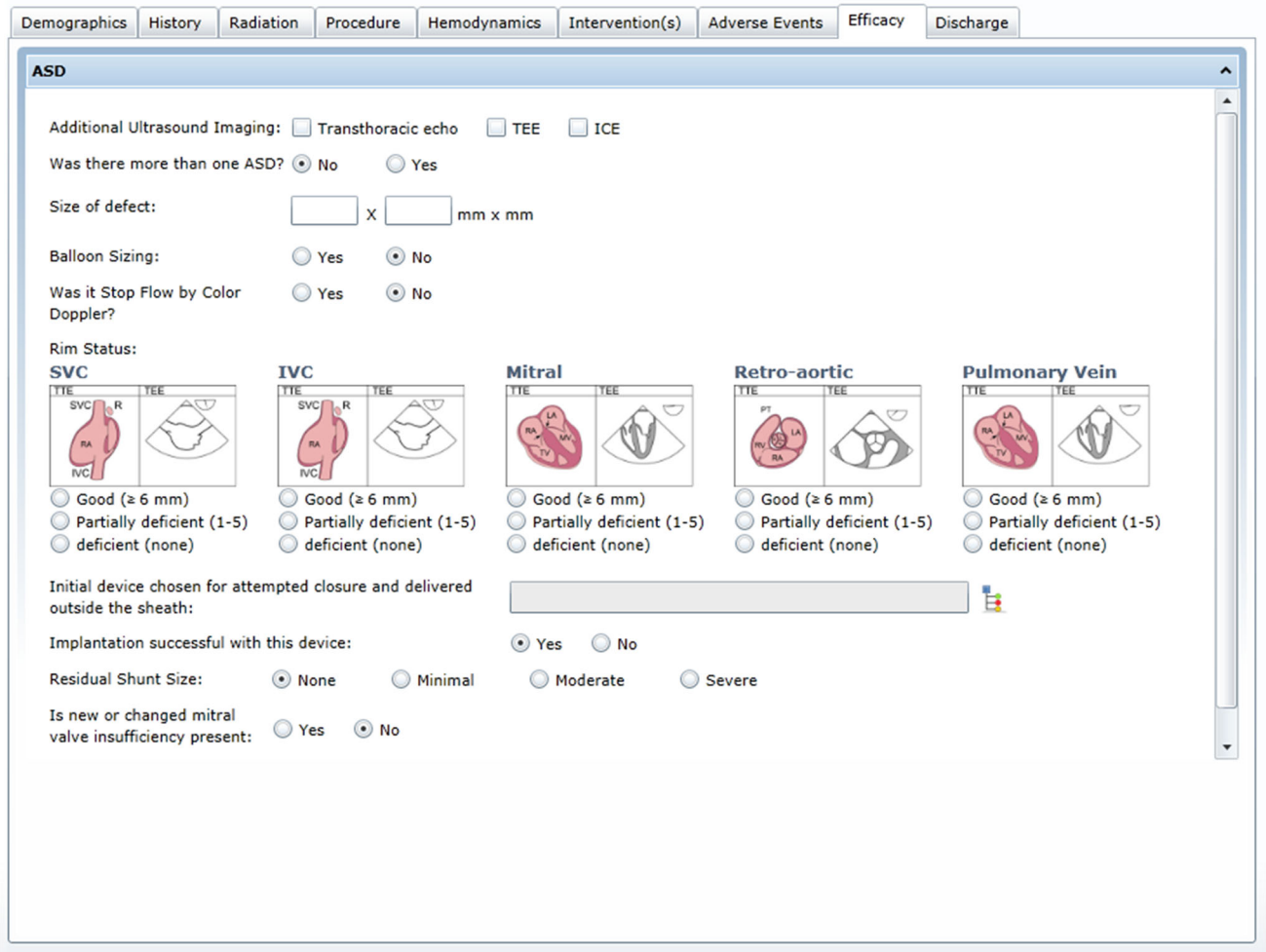

Fig. 4 C3PO-QI database module for ASD procedures

Statistical Analysis

C3PO-QI demographic data were reported as total case count (n) by case type and age group. Cases not assigned to an age group or case type were excluded ($n = 5$). In order to display the application of the quality metric, QI reports were generated on the C3PO-QI internal website to show radiation dose metric data by total air kerma and DAP among all interventional procedures for their largest volume age group to determine percentages not exceeding the 75th and 95th percentile of radiation dose.

Results

A total of 13,135 unique cases entered in the C3PO-QI database by the 15 sites between January 1, 2014 and December 31, 2015, were included, median 534 cases. By January 2014, most participants were providing complete data entry on all procedures taking place at their respective institution (Fig. 5). Among the C3PO-QI case distribution by case type, interventional cases made up the highest percentage (48 %; Table 2). For C3PO-QI case distribution by age category, patients <1 years made up the highest percentage (26 %) (Fig. 6). When further stratified by age group, the largest proportion of biopsy cases performed were among patients 10–15 years (36 %), and the largest proportion of diagnostic and interventional cases performed were among patients <1 years (36 and 58 %, respectively; Table 2). Among diagnostic and interventional procedures stratified by age group, the ratio of case type is seen to increase across age group (Fig. 7).

To apply the quality metric, website reports were generated for the highest count interventional procedures stratified by age (Fig. 8). For graphs not exceeding both 75th and 95th percentiles across all interventional procedures for total air kerma and DAP, all percentages were below the quality metric goal. Among the reports generated, for total air kerma, the lowest percentage not exceeding the 75th % was seen among COA procedures for

patients <1 years (80 %) and the lowest percentage not exceeding the 95th % was seen among AV for patients <1 years (92 %). For DAP, the lowest percentage not exceeding the 75th % was seen among TPV placement in patients >15 years (86 %), and the lowest percentage not exceeding the 95th % was seen in ASD closures in patients 1–4 years (97 %).

Discussion

This study sought to provide a detailed overview of the C3PO-QI program and report data on case characteristics and outcome metrics being explored. The volume of cases being collected by the 15 participating institutions, greater than ten thousand cases over 2 years, facilitates application of the quality metric and provides C3PO-QI the ability to make meaningful interpretations regarding metrics. Additionally, the homogenous distribution of data by case type and age group seen in the C3PO-QI demographic data enhances the generalizability of future data analytics and conclusions. Registries such as C3PO-QI allow for collaboration across institutions, provide large datasets for comparative assessment and improve the ability to generate outcome assessments. These benefits are particularly important for multi-center efforts involving rare diseases, such as CHD, in order to identify risk factors and standardize adverse events across interventions and institutions.

C3PO-QI aims to utilize its large data registry to improve quality of care across all of its participating institutions and share the successes, challenges and failures of the project with the pediatric cardiology community at large. C3PO-QI's small group participation allows for rapid user feedback in the implementation of its initiatives and tools. Requested changes to the database can be made on an ongoing basis and data elements are reviewed regularly to determine utility.

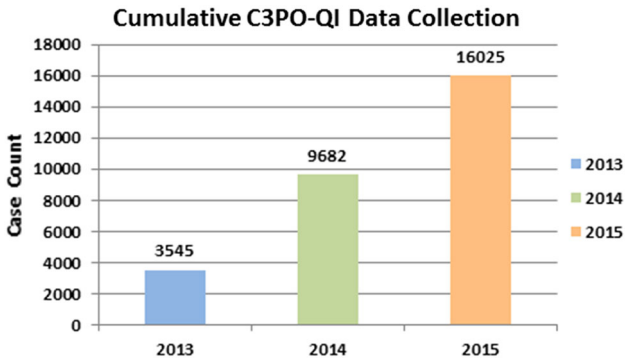

Fig. 5 Cumulative C3PO-QI data collection from January 2013 to December 2015

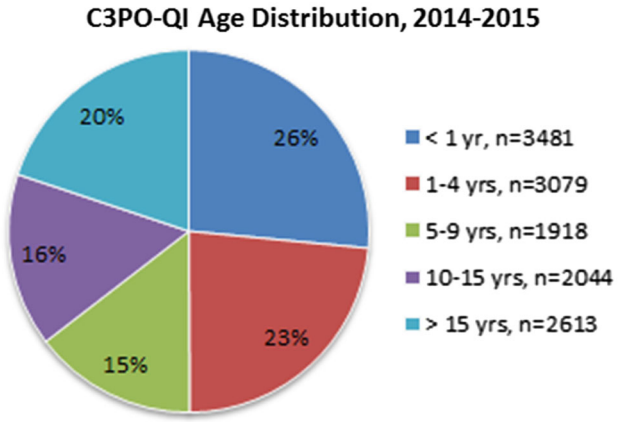

Fig. 6 Percent (%) of total cases stratified by age group (n = 13,135)

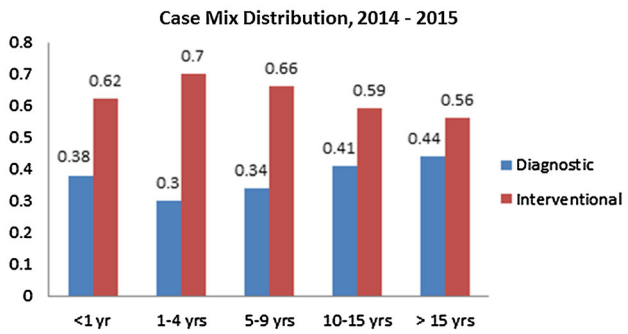

Fig. 7 Percent (%) of total cases stratified by diagnostic and interventional procedures and by age group

Table 2 C3PO-QI database case entry between January 1, 2014 to December 31, 2015, stratified by case type and age group (n = 13,135)

Case type	Total no.	Age distribution				
		<1 years	1–4 years	5–9 years	10–15 years	>15 years
Total no.		3481	3079	1918	2044	2613
Biopsy	2839 (22 %)	117 (3 %)	545 (18 %)	571 (30 %)	737 (36 %)	869 (33 %)
Diagnostic	3681 (28 %)	1261 (36 %)	747 (24 %)	454 (24 %)	512 (25 %)	704 (27 %)
Interventional	6301 (48 %)	2030 (58 %)	1761 (57 %)	871 (45 %)	730 (36 %)	912 (35 %)
Other	314 (2 %)	71 (2 %)	26 (1 %)	21 (1 %)	64 (3 %)	127 (5 %)

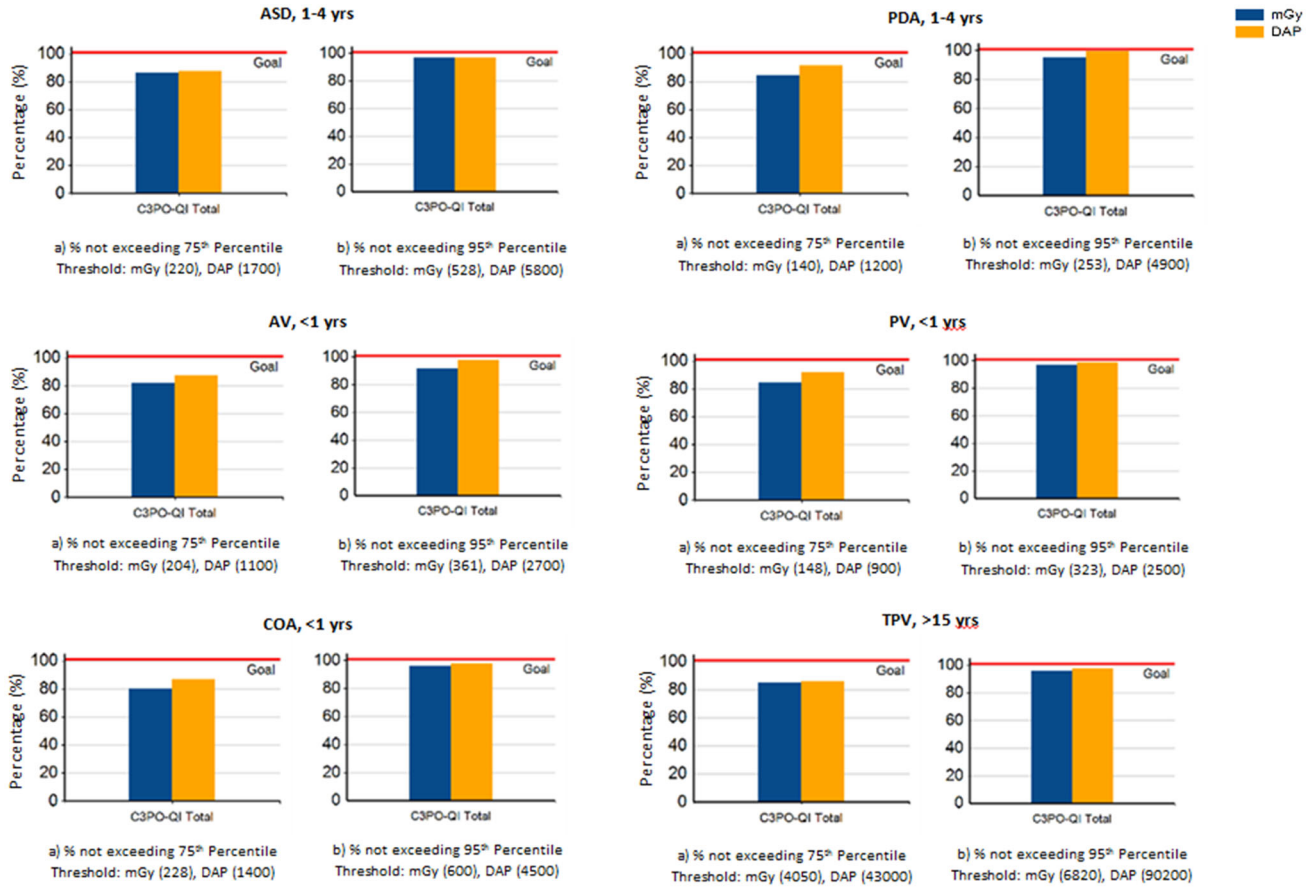

Fig. 8 Application of the quality metric to show radiation by procedure type for percentage (%) of cases not exceeding 75th and 95th percentiles for both total air kerma (*blue*) and DAP (*yellow*)

In addition to the online reporting tools, C3PO-QI purchased a license for Tableau™ (Tableau Software, Seattle, Washington), a computer program that allows for real-time exploration of data networks through the creation of customized dashboards. Interactive displays of data are created and shown on custom-built dashboards in order to highlight and sort queries, while stratifying the data in real-time by different elements (Fig. 9). Each dashboard features variable filters such as 'by hospital,' 'by physician,' 'by age,' 'by case type' and 'by procedure type' that can be selected to look at the outcome of interest (for example, longitudinal radiation exposure). Additional dashboards have been created to determine if, for example, equipment manufacturer, equipment age, or the presence of a pediatric cardiology fellow during a case affects the patient's radiation dose. These analyses are still exploratory examples of data to be rigorously reviewed in the future. The functionality of Tableau™ lies in its powerful capabilities in displaying data based on the interest of the user. Participants are able to view comparisons between physicians at their institution, between institutions with similar case mix, and compared to the aggregate C3PO-QI population. Using this software, C3PO-QI is able to query existing variable relationships and understand how variables interact in a matter of seconds as the dashboards adapt to selected queries. The dashboards are developed by the sponsor site, with feedback from participating sites, on a continual basis as the needs of the C3PO-QI initiative evolve.

The online generated reports and Tableau™ dashboards are incorporated into bi-monthly webinars and yearly face-to-face meetings with the participating C3PO-QI institutions in order to steer discussions and facilitate implementation of PDSA methodology. Real-time manipulation of data displays allows for identification of high and low performers within and among institutions. High performing sites are then able to share best practices, and even lead group webinars, in order to accelerate improvement within the collaborative. Individual sites can take relevant practices and techniques learned from the C3PO-QI group back to their home institution. In accordance with PDSA methodology, individual centers will, (1) propose incorporation of new technique (i.e., regular review of local radiation dose data during catheterization morbidity and mortality conferences, lowering fluoroscopy frame rate),

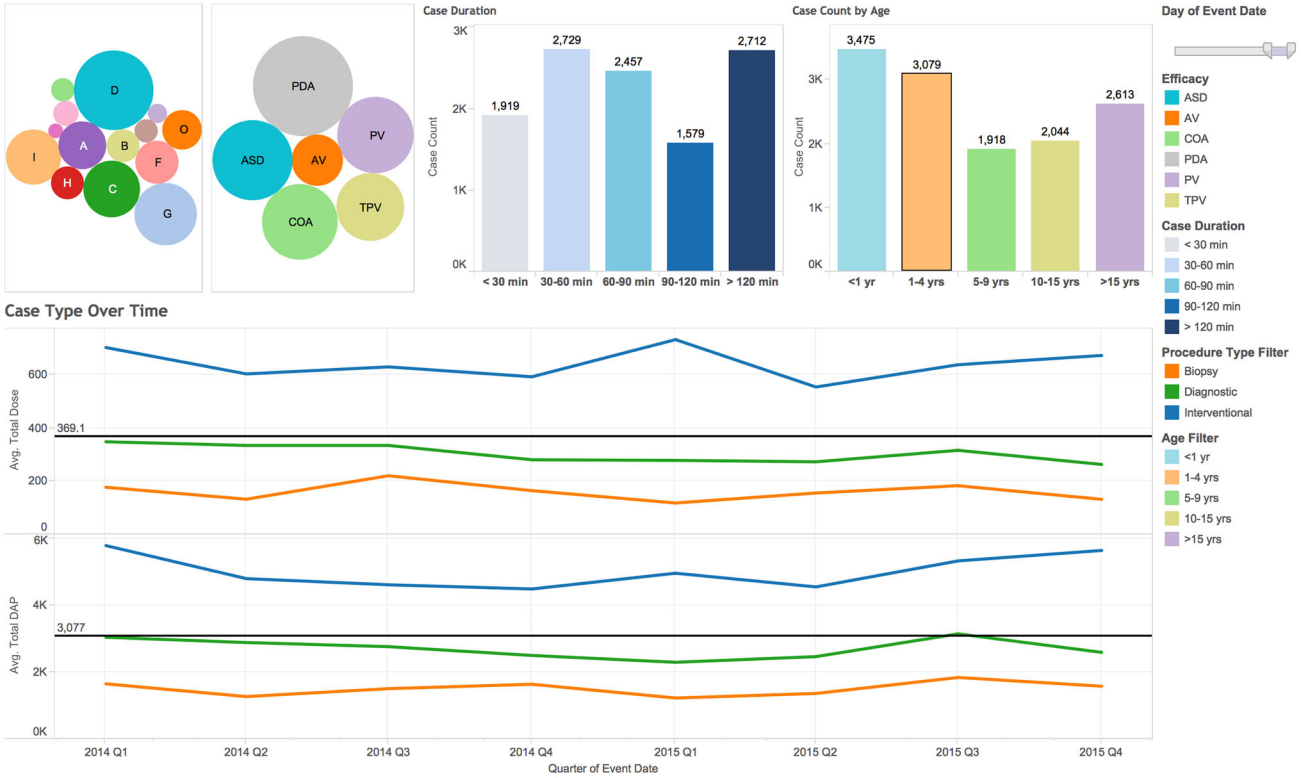

Fig. 9 Tableau™ radiation dashboard showing longitudinal radiation dose in total air kerma and total dose area product between Quarter 1, 2014 and Quarter 2, 2015

(2) implement technique in every day practice, (3) measure its effect on radiation dose, and (4) review longitudinal radiation dose data using Tableau to determine the impact of the new technique. Site-specific webinars are scheduled regularly to review site data in comparison to the aggregate group and to receive feedback on participation and improvement. The group's progress is shared in a quarterly newsletter to highlight improvements and project updates. This iterative process allows for continued assessment of the collaborative's QI efforts over time.

While other multi-institutional QI initiatives exist, C3PO-QI is unique among them in terms of registry size and data methodology. Over 90 institutions currently contribute both pediatric and adult CHD data to the IMPACT registry [7]. Albeit smaller than IMPACT, CCISC includes participants throughout North America, Europe, and Latin America [8]. While large registries are strengthened by their diverse patient populations and inclusiveness, which improve generalizability of the observed outcomes, such sizable populations can make the assessment of risk in pediatric cardiac catheterization challenging [8]. C3PO-QI's robust and validated risk adjustment methodology, along with its detailed assessment of both efficacy and safety outcomes, distinguish it from other existing registries. Interactive, small group site participation allows C3PO-QI to classify adverse events specific to its unique patient populations, while rigorously maintaining data quality. The project's individual site-oriented approach allows participants to engage in more personalized and frequent data reviews in order to understand differences in practice and how they impact outcomes compared to other institutions. Now that the methodology of the collaborative has been established and support for expanded participation has been assured, five additional sites will be joining C3PO-QI in 2016.

Limitations

While participating in a multi-institutional registry offers many benefits, limitations certainly exist. C3PO-QI is still in the early stages of the project. While some data have been reported following validation, predictors of outcomes related to radiation exposure and AE occurrence still need to be reviewed in detail. Participating sites often have difficulty obtaining and maintaining institutional support to fulfill commitments to complete data entry in the registry. However, with its powerful reporting tools, C3PO-QI is able to share institutional progress with hospital administration in order to generate enthusiasm for continued participation in the project. While vendor partnership has

decreased the data entry burden, institutions often need to seek additional staff support to maintain up-to-date on data entry in the database. By expanding vendor collaboration to accommodate more automatic data transfer, C3PO-Qi is attempting to reduce the inherent burden and risk of errors of manual data entry. Fast-paced QI efforts require constant site participation and feedback. While it is often difficult to keep physicians engaged in the iterations of the project due to their demanding schedules, C3PO-QI accommodates its program to participant needs. By offering individual site webinars and regular sites specific check-ins, C3PO-QI is able to keep sites up to speed on the progress of the entire collaborative.

Conclusion

The large volume and heterogeneity of cases collected through C3PO-QI will allow the group to make meaningful progress in its quality improvement initiatives, while driving change through comparative reporting and collaborative sharing of successful strategies.

Ultimately, C3PO-QI will use its platform to expand and pursue other QI initiatives. Future C3PO-QI efforts will prospectively establish new radiation dose benchmarks. These benchmarks will be based upon data from the participating sites that have complete data capture since 2014 and will be reassessed as the project moves forward. The continued collection of information specific to the six interventional procedures will enable a large cohort analysis on trends and anomalies within these specific populations. C3PO-QI future publications will focus on these trends and the effects of variations in practice on radiation exposure.

In the next decade, registries and standardization practices will continue to allow for the development of more patient-centered care and risk reduction methods. C3PO-QI is well poised to deliver fast-paced QI improvements in the field of pediatric interventional cardiology. Although C3PO-QI initiatives are specific to pediatric and congenital catheterization, the overall design and implementation of the project, as well as the utilization of real-time reporting, are generalizable to QI projects in other specialties and in other multi-center collaboratives.

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Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflicts of interest.

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