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Sustained radiation reduction following initial quality improvement intervention in a paediatric cardiac catheterisation laboratory

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Abstract

Background: As part of a quality improvement project beginning in October 2011, our centre introduced changes to reduce radiation exposure during paediatric cardiac catheterisations. This led to significant initial decreases in radiation to patients. Starting in April 2016, we sought to determine whether these initial reductions were sustained. *Methods:* After a 30-day trial period, we implemented (1) weight-based reductions in preset frame rates for fluoroscopy and angiography, (2) increased use of collimators and safety shields, (3) utilisation of stored fluoroscopy and virtual magnification, and (4) hiring of a devoted radiation technician. We collected patient weight (kg), total fluoroscopy time (min), and procedure radiation dosage (cGy-cm2) for cardiac catheterisations between October, 2011 and September, 2019. *Results:* A total of 1889 procedures were evaluated (196 pre-intervention, 303 in the post-intervention time period, and 1400 in the long-term group). Fluoroscopy times (18.3 ± 13.6 pre; 19.8 ± 14.1 post; 17.11 ± 15.06 long-term, $p = 0.782$) were not significantly different between the three groups. Patient mean radiation dose per kilogram decreased significantly after the initial quality improvement intervention (39.7% reduction, $p = 0.039$) and was sustained over the long term ($p = 0.043$). Provider radiation exposure was also significantly decreased from the onset of this project through the long-term period (overall decrease of 73%, $p < 0.01$) despite several changes in the interventional cardiologists who made up the team over this time period. *Conclusion:* Introduction of technical and clinical practice changes can result in a significant reduction in radiation exposure for patients and providers in a paediatric cardiac catheterisation laboratory. These reductions can be maintained over the long term.

During cardiac catheterisation procedures, patients, interventional cardiologists, and catheterisation lab staff are all exposed to ionising radiation used to produce fluoroscopic and angiographic X-ray images. Ionising radiation has been previously shown to have negative effects on exposed human tissues. Deterministic effects are those which are dose-related including skin necrosis and development of cataracts. Stochastic effects are those that have a higher probability of occurring with increased doses but can occur even from lower doses, such as radiation-induced cancers.[1]

While a single, short catheterisation procedure can be done using a relatively small amount of radiation, the need for repeat, prolonged, or high-dose procedure types can increase the likelihood of radiation-induced injury and damage.[2] The paediatric patient population constitutes a particularly high-risk group because their still-developing bodies have a greater sensitivity to radiation.[3] Because of these potential negative effects, it is important to strive to reduce patient exposure during cardiac catheterisation procedures. The ALARA principle aims to limit radiation doses to As Low As Reasonably Achievable, so as to reduce exposure to patients without compromising image quality, procedural success, or patient safety.[2]

Techniques for radiation reduction in paediatric cardiac catheterisation labs have been well described for over a decade.[4] Utilisation of the ALARA principle is particularly important for paediatric patients with complex CHD. Small children can be more sensitive to radiation exposure, and their small size and frequent need for multiple and/or prolonged procedures can lead to significant cumulative dosage over a lifetime.[5]

Several recent reports have shown successful efforts to reduce radiation exposure for patients in congenital cardiac catheterisation labs,[6–8] such as utilising lower fluoroscopy and digital angiography doses, additional staff and physician training, and reducing the default fluoroscopy and digital angiography doses.[1–3] Nearly a decade ago, our centre initiated a project aimed at decreasing radiation exposure to paediatric patients during cardiac catheterisations. By manipulating technical factors affecting radiation dose exposure, including X-ray beam quality, X-ray

geometry, and fluoroscopic imaging dose rate settings,[9] we sought to reduce radiation exposure while maintaining the same high-quality care for each patient.

In particular, stored fluoroscopy allows for image capture of portions of a procedure previously captured with angiography at lower frame rates. Virtual magnification as opposed to manual magnification increases the on-screen size of cardiac structures without increasing the relative radiation dose. Both of these technological advances allow for decreases in radiation doses while minimally degrading the quality of the image. In applicable clinical situations where optimum image clarity is not needed, such as during balloon angioplasty, both of these modalities allow for decreased radiation doses to the patient.

Long-term studies of the sustainability of radiation reduction practices are needed to determine if radiation reduction can be sustained in paediatric and adult cardiac catheterisation labs. The purpose of this paper is to review the interventions undertaken by our institution, discuss how the interventions led to reduced radiation exposure for both patients and providers, and demonstrate that there was sustained long-term efficacy of these changes.

Material and methods

All required and appropriate reviews and approvals were obtained through the institution's paediatric Institutional Review Board prior to the initiation of this project.

Hospital equipment and lab procedures

The institution's angiography equipment (Toshiba Infinix Bi Plane) was upgraded and installed in 2010, prior to the start of the study period. No major changes or upgrades were implemented during the study period. New interventionalists who were hired during the study period underwent an extensive onboarding process, where their first 10 cases were observed by one of the current interventionalists, and where radiation reduction techniques were also introduced. Radiation technicians were present during each case to help remind current interventionalists and to assist in teaching new interventionalists, about all radiation-reducing techniques utilised in the catheterisation lab. As part of ongoing assessment of best practices, fluoroscopy times and dose area product were included in final reports, and individual operator doses per each case were reviewed during weekly catheterisation lab team meetings.

Data collection

Patient and procedural data from clinically indicated cardiac catheterisation procedures were gathered from patient charts and institutional catheterisation software from our centre. Electrophysiology and hybrid procedures, pericardiocentesis and endomyocardial biopsies were excluded. These procedures were excluded for multiple reasons: (1) electrophysiology procedures often require higher amounts of fluoroscopy due to extended amount of time needed to determine the exact point where electrical conduction disruptions occur, and this small population of patients would highly skew our data and not represent the general cardiac catheterisation population; (2) pericardiocentesis procedures were also excluded as they are not considered cardiac catheterisation procedures, and these procedures only utilise angiography to visualise the exterior of the heart and no intracardiac views are obtained; (3) endomyocardial biopsies were excluded as they are almost entirely performed on patients who have undergone cardiac transplantation and are not performed for the diagnostic purposes of the general paediatric cardiac catheterisation population.

Cardiac catheterisation procedures examined in this project, included, but were not limited to, diagnostic catheterisations, atrial septal defect closures, aortic coarctation ballooning and/or stent placements, pulmonary valvuloplasty procedures, and patent ductus arteriosus closures.

Data collection included patient weight (kg), procedure type, total fluoroscopy time (min), and procedure total radiation dosage (cGy-cm2). In addition, annual deep dose equivalent levels (mrem) were retrospectively collected from dosimeter badges for all interventional cardiologists during the study period.

Interventions implemented

Pre-intervention data were collected from all cardiac catheterisation procedures from October 2011 to March 2012. During April 2012, all of our interventional cardiologists engaged in a trial to determine the lowest acceptable fluoroscopy and cineangiography frame rates that allowed for adequate image quality for performing the procedure and recording angiograms. New weight-based frame rates were decided upon by the team (Table 1). Lower frame rates were chosen where there was not consensus, recognising that each provider could increase from the new presets, if desired, due to poor image quality, but might be less likely to reduce frame rates if imaging was adequate at higher present rates.

Starting in May 2012, the first two interventions were introduced. These included the implementation of the weight-based reductions in preset frame rates for fluoroscopy and angiography, as well as the increased use of collimators and safety shields. In June 2012, the third intervention was implemented, utilising stored fluoroscopy and virtual magnification. The fourth intervention in the initial study period was the hiring of a devoted radiation technician in December 2012. One of the roles of this new staff person was to provide reminders to utilise all of the above radiation reduction strategies when possible.

Post-intervention data were collected from the first 6 months of 2013 and 2014. This time frame was utilised due to the ability to access all needed data elements, and these time periods allowed for the most robust amount of data to determine post-intervention outcomes. To assess for sustained improvement, we collected data from April 2016 to October 2019.

Patient population

Patients were divided into three groups: a pre-intervention group, a post-intervention group, and a long-term patient group. A total of 196 patients underwent paediatric cardiac catheterisation procedures between October 2011 and March 2012, 303 patients from January 2013 to June 2013, and January 2014 to June 2014 – the post-intervention phase, and 1400 patients from April 2016 to October 2019 were included in the long-term group. From the total population of 1899 patients, 10 patients were documented to have total radiation doses far greater than 14,000 cGy-cm2. These patients were identified as having undergone multiple complex interventions as part of one catheterisation and were therefore excluded from the analysis.

Measures

Patient radiation exposure was expressed as dose area product indexed to patient weight (cGy-cm2/kg). This measure was

Table 1. Pre-interventional manufacturer preset (baseline) fluoroscopy and angiography frame set rates, and weight-based frame set rate changes implemented by cardiovascular laboratory team.

Weight (kg)	Fluoroscopy	Angiography
Baseline (all weights)	15/second	30/second
Post-intervention		
Weight-based frame rates decided on by Cardiovascular Laboratory Team at beginning of change implementation		
0–5	7.5/second	30/second
5–15	7.5/second	15/second
15–45	7.5/second	15/second
45–90	5/second	15/second
>90	5/second	15/second

kg = kilograms

proposed as the best way to standardise radiation dose reporting in paediatric patients undergoing cardiac catheterisation to control for the wide variation in size in this population[2] and has subsequently been adopted by the majority of centres reporting on radiation exposure reduction.

Statistical analysis

Standard quality improvement X-charts were created to analyse the data to help determine if the process changes implemented demonstrated change in outcome over time. These charts included a monthly average rad/kg analysis during the pre-intervention, post-intervention, and long-term data periods. A similar X chart using quarterly average rad/kg was used to show the data for the entire study period. Average fluoroscopy time/case was also evaluated to serve as a balancing measure (QI Macros, Microsoft, 2019). Individual and aggregate provider annual dosimeter badge deep dose equivalents were also compared for each year of the study. Equal variances were analysed with two-tailed t-tests. A p-value of <0.05 was used to determine statistical significance (SPSS 24, IBM, 2016).

Results

Patient reduction

A total of 1889 patients undergoing cardiac catheterisations were included in the study analysis. There was a 39.7% decrease in the average monthly patient total radiation dose per kilogram (86.42 to 52.07 cGy-cm2/kg) from the pre-intervention period to the post-intervention period (Fig 1) (p = 0.039).

Due to the increased number of total patients included in the long-term group, we looked at average quarterly (as opposed to the monthly) patient total radiation dose per kilogram data from October 2011 to October 2019. There was a sustained and slight further decrease in average radiation dose per kilogram during the long-term period (Fig 2) (p = 0.043).

As a balancing measure, we analysed the total fluoroscopy times for each procedure on a quarterly basis (Fig 3). Average fluoroscopy times did not change over the course of the study period (p = 0.168), indicating that radiation reduction was the result of decreased radiation dose, and not reduced use of fluoroscopy or angiography.

Provider reduction

Provider radiation exposure as measured by dosimeter badge deep dose equivalents (mrem) decreased by 73% (p < 0.01) over the entire study period. This reduction was noted despite several changes in the interventional cardiologists who made up the team (Fig 4). The decrease in provider exposure was also analysed for the post-intervention (2013) through the long-term period (2020). This demonstrated a 12.4% decrease in radiation exposure during this time period (p = 0.002). As a balancing measure for this outcome, the number of procedures performed each year was analysed and was found to have not decreased significantly over the study time frame, ranging from a high of 452 cases in 2019 to a low of 297 cases in 2013.

Discussion

While several centres and quality improvement registries have previously published successful reductions in radiation exposure for patients in congenital cardiac catheterisation labs,[6–8] ours is the first to demonstrate sustained improvement over an extended period, up to 8 years after initial improvement efforts. And while at least one adult study has published reduced exposure to catheterisation lab staff,[10] we believe our study is the first to report decreased provider radiation exposure in a paediatric cardiac catheterisation lab.

In our initial quality improvement project, we instituted the following changes: (1) weight-based reductions in preset frame rates for fluoroscopy and angiography, (2) increased use of collimators and safety shields, (3) utilisation of stored fluoroscopy and virtual magnification, and (4) hiring a devoted radiation technician. Our interventions resulted in an almost 40% reduction in patient radiation dose (dose area product/kg). These results are comparable to the reported radiation reductions achieved in other single-centre and collaborative quality improvement initiatives.[6–8,11] These improvements were sustained over the next 7 years, a finding that has not-to-date been reported by other paediatric single-centre or collaborative studies.

In addition, we saw a 66% decrease in physician radiation badge reading during the first 2 years of this quality initiative. Physician radiation exposure continued to decrease over the next 7 years (total of 73% exposure). It is worth noting that between the initial and the long-term periods, there was a significant turnover in our interventional team, with only one of the four physicians who took part in the initial project being part of the group in the long-term period. We believe this speaks to the creation of a culture change around radiation reduction and emphasises the importance of collaboration amongst the entire catheterisation lab team, including operators and staff. As part of this culture of change was also the aforementioned hiring of a dedicated radiology technician for the cardiac catheterisation laboratory. With the consistent presence of this staff person in the catheterisation lab, we believe the goals and process changes implemented throughout this project were able to be seamlessly communicated between providers even in the midst of staff changeover.

The lack of change in fluoroscopy mean times indicates that radiation reduction was the result of decreased radiation dose, and not a significantly reduced use of fluoroscopy or angiography.

There are several limitations to our study. This is a single-centre retrospective study. We implemented several quality improvement interventions over the course of the first few months of the study, making it not possible to identify whether
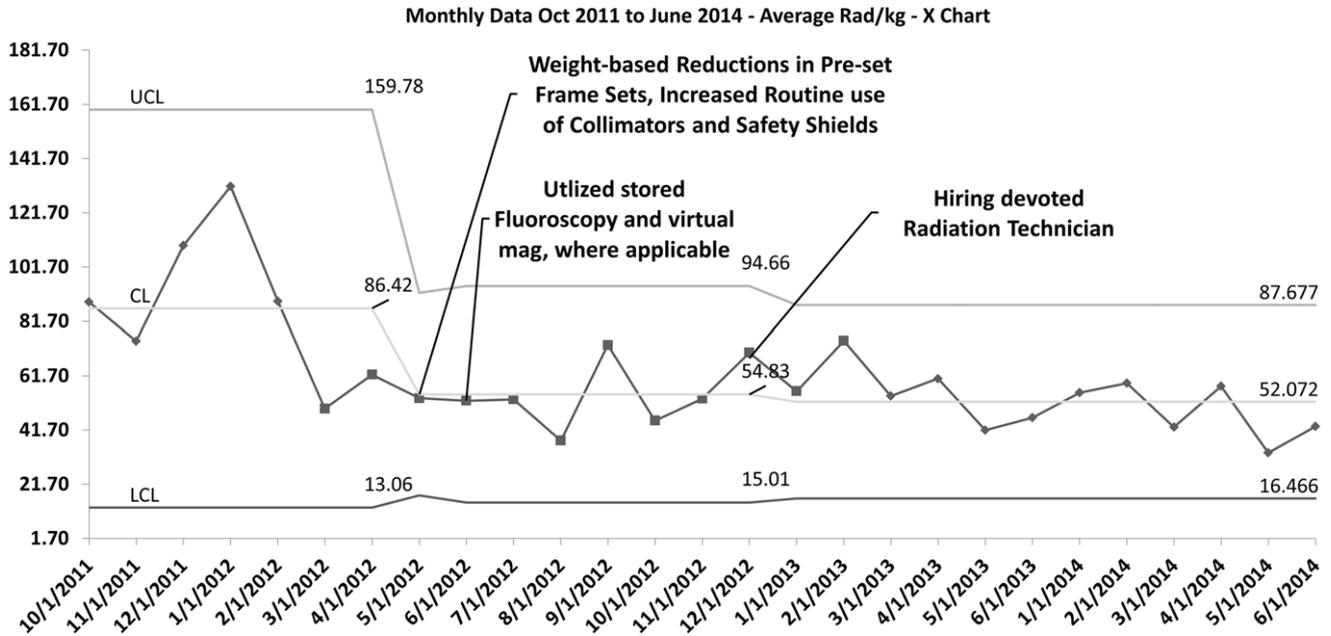
Figure 1. Average monthly patient radiation dose per kilogram showing the changes in amount of patient exposure after implementation of each intervention. A statistically significant decrease in radiation exposure was noted (p = 0.039) with a 39.7% decrease in the average monthly patient total radiation dose per kilogram (86.42 to 52.07 cGy-cm2/kg) from the pre-intervention period to the post-intervention period. CL = centre line; LCL = lower confidence limit; UCL = upper confidence limit.
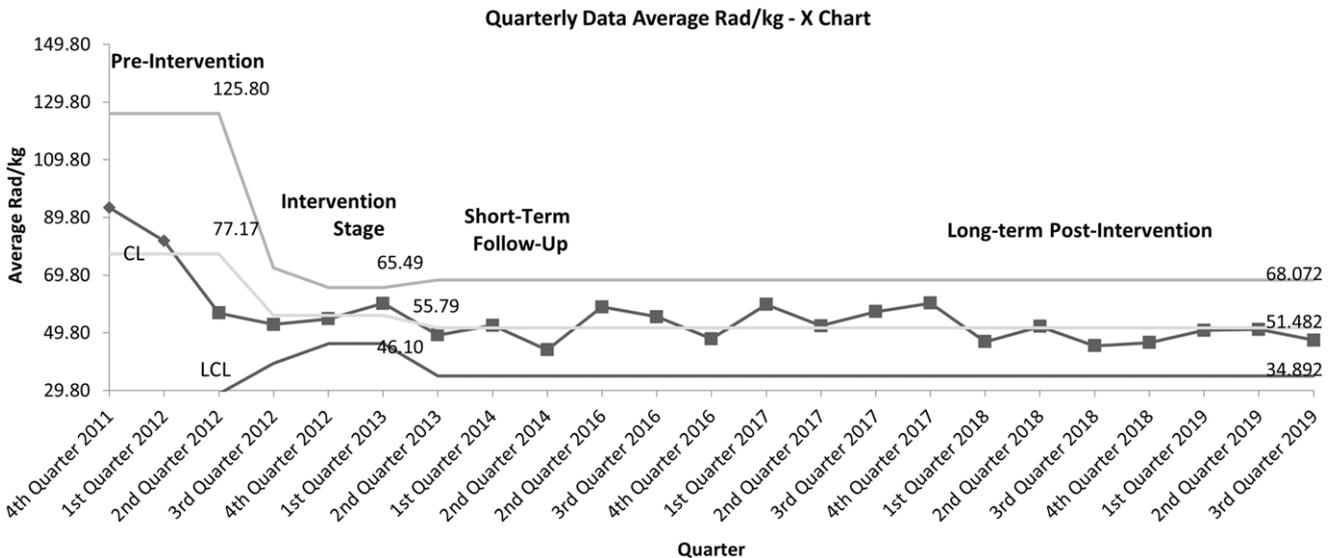

Figure 2. Average quarterly patient radiation dose per kilogram showing the initial reduction and sustained improvement over the 7-year long-term data period. CL = centre line; LCL = lower confidence limit; UCL = upper confidence limit.

one intervention had more of an impact relative to the others. We did not stratify cases by type or complexity and therefore we cannot account for possible variation in case mix from year to year over time. There were significant changes in our interventional team over time and previous studies have shown that there are significant differences in practice of radiation exposure reduction between operators relative to level of experience.[8] Some of the reductions particularly in the long-term period could have been related to personnel changes, as opposed to the interventions described in this project, possibly reflecting personal practice preferences related to radiation exposure that happened to fall in line with the radiation reduction strategies already implemented at our institution.

Introduction of technical and clinical practice changes can result in a significant reduction in radiation exposure for patients and providers in a paediatric cardiac catheterisation laboratory. These reductions can be maintained over the long term.
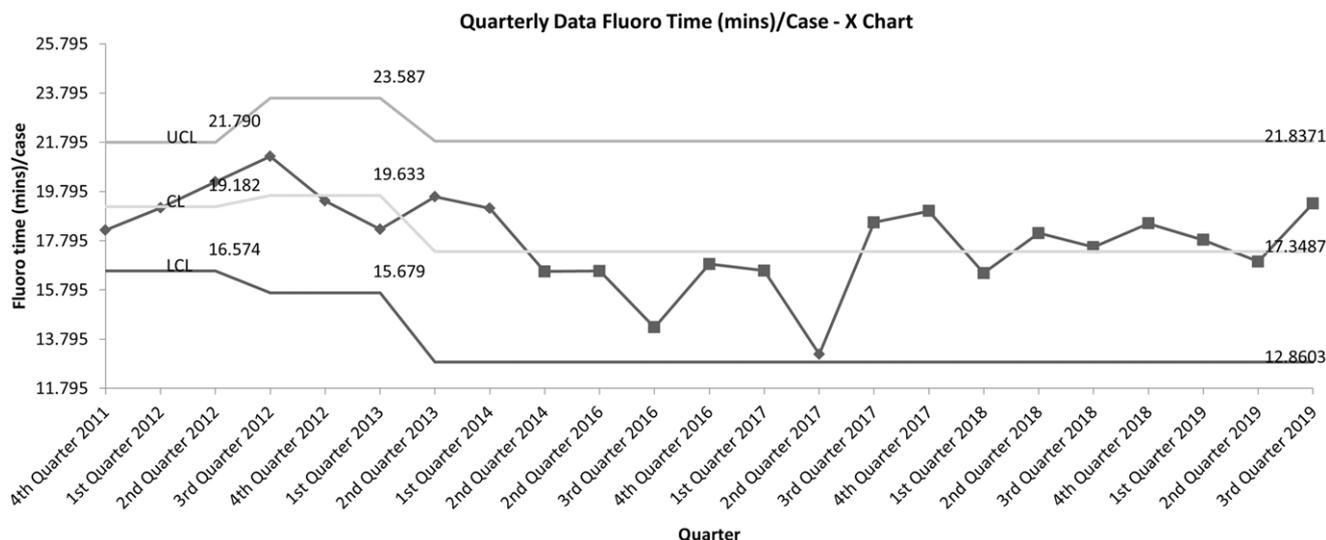
Figure 3. Average fluoroscopy time (in minutes) per case over the entire project timespan. CL = centre line; LCL = lower confidence limit; UCL = upper confidence limit.
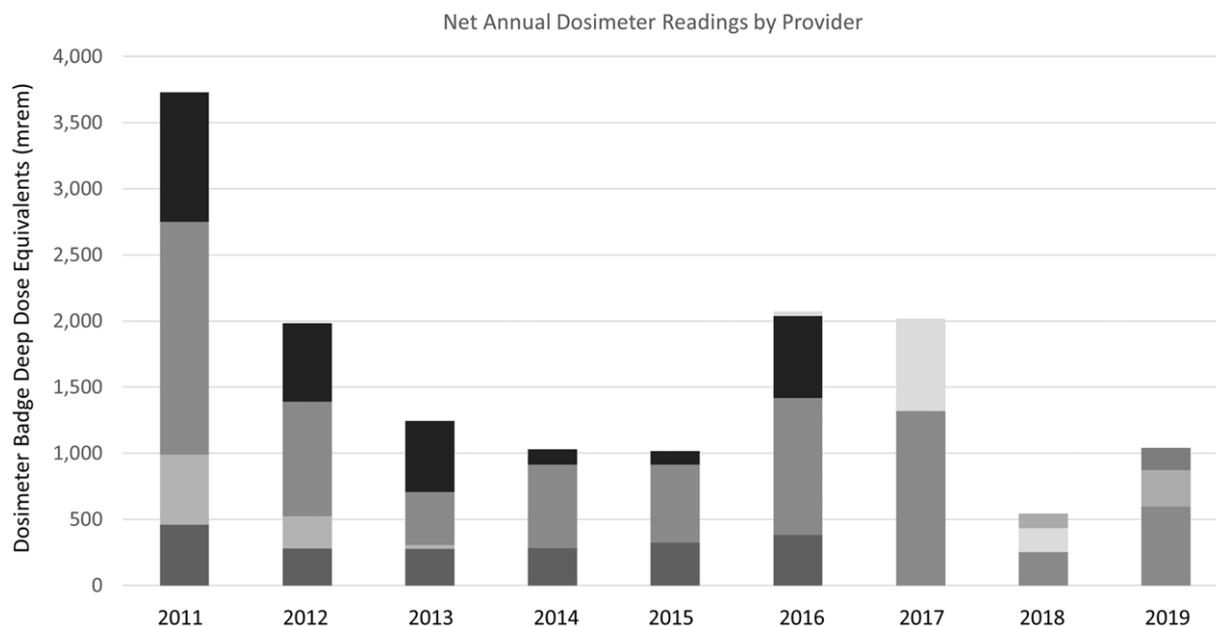

Figure 4. Net annual dosimeter badge reading by provider. Each different shading in each year indicates different providers, with the length of provider's bar indicating the amount of radiation exposure the provider experienced.

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