

Improving the effectiveness and efficiency of a skin dose investigation protocol in interventional radiology

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ABSTRACT

Cardiac catheterisation is an invasive procedure carried out under fluoroscopic guidance, which exposes the patient's skin to X-ray radiation. In some cases, the skin receives a radiation dose, which is sufficiently high to cause a radiation injury. To ensure the timely identification of patients at risk of such an injury, a skin dose investigation protocol was implemented within the United Lincolnshire Hospitals Trust. However, two shortcomings with the new protocol were identified: first, it was possible for a patient to receive a clinically significant skin dose without the protocol being triggered; second, the investigation protocol increased staff workload. The Radiation Protection Department undertook to resolve these issues by making use of two software packages (openSkin and OpenREM) to automate key processes in the skin dose investigation protocol. The automation was introduced over three distinct Plan-Do-Study-Act cycles. The introduction of openSkin and OpenREM eliminated the possibility of a high skin dose procedure failing to trigger an investigation. The time spent by staff on skin dose investigations was reduced by an estimated 94%.

PROBLEM

The United Lincolnshire Hospitals Trust carries out around 300 cardiac catheterisation procedures per month. Approximately 3% of these procedures result in a radiation dose to the skin which has the potential to cause a radiation injury. In 2013, the Trust implemented a radiation skin dose investigation protocol to ensure patients who had received a clinically significant radiation dose to the skin during a cardiac catheterisation procedure were identified so that they could be treated in good time. Following its implementation two problems with the protocol became apparent. First: it was, in principle, possible for a patient to accumulate a clinically significant radiation dose to the skin over the course of two or more low-dose procedures without this triggering a skin dose investigation. Second, it was estimated that staff were spending approximately 13 working days per year on skin dose investigation tasks which could, in principle, be automated. Hence, the skin dose investigation protocol was found to

be ineffective under certain circumstances and also inefficient with respect to staff time.

The aim of this project was to make use of newly implemented dose management software to improve the effectiveness and efficiency of a high skin dose investigation protocol in interventional radiology.

BACKGROUND

Cardiac catheterisation is an invasive procedure, which involves the insertion of a catheter into the blood vessels and chambers of the heart for diagnostic and treatment purposes. The procedure is carried out under fluoroscopic guidance and so exposes the patient's skin to multiple low doses of X-ray radiation. The operator undertakes to spread these exposures over different regions of the patient's skin to avoid delivering a clinically significant radiation dose to any one area. Nevertheless some procedures could result in an accumulation of radiation dose which is sufficiently high to cause a radiation injury to a region of skin. An absorbed skin dose of 2–5 Gy may result in transient erythema and epilation from which the patient should eventually recover.^{1 2} Higher absorbed doses may result in skin injuries, which require treatment or even surgery. The signs of skin injury may only become apparent many months after a cardiac catheterisation procedure. There is, therefore, a risk that the patient or their general practitioner may not associate signs of skin injury with the cardiac catheterisation procedure. This could result in a clinically significant delay between the appearance of symptoms and appropriate treatment. Furthermore, absorbed skin dose may accumulate over the course of multiple separate procedures days or even weeks apart. Therefore, multiple low-dose cardiac catheterisation procedures could result in a clinically significant radiation dose to the patient's skin.

In 2013, the International Commission on Radiological Protection published



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recommendations for the management of occupational and patient radiation doses in cardiology.³ This report included a number of recommendations regarding the management of patient skin dose due to fluoroscopically guided procedures. In response to these recommendations, the United Lincolnshire Hospitals NHS Trust (ULHT) implemented a protocol for identifying patients who may have received a clinically significant absorbed

skin dose; alerting clinicians to any clinically significant results; and recording all relevant dose data.

The ULHT skin dose investigation protocol is represented as a process map in figure 1. The Radiation Protection Department is notified by radiology whenever the cumulative reference air kerma at the patient entrance reference point, K_{air} , for a procedure exceeds 2 Gy. The K_{air} is a simple indicator of absorbed skin dose, which is

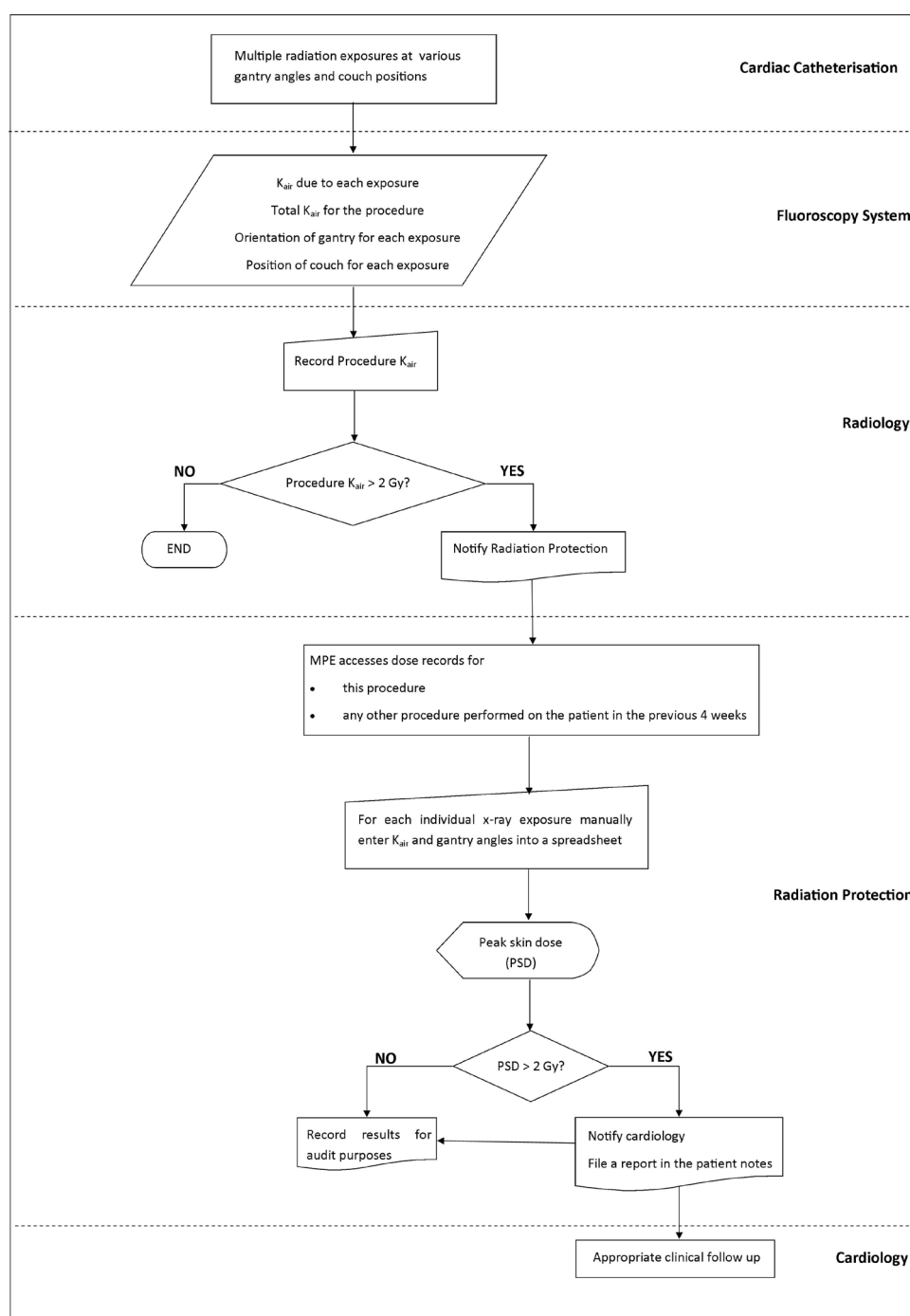


Figure 1 The skin dose investigation protocol implemented at ULHT in 2013. The protocol has two key components: (1) the triggering of a skin dose investigation by radiology based on the K_{air} recorded by the fluoroscopy system for a single procedure; (2) the calculation of the peak skin dose, the maximum accumulated dose to the skin taking into account changes in gantry angle and any additional dose due to prior procedures. MPE, Medical Physics Expert; ULHT, United Lincolnshire Hospitals NHS Trust.

displayed by the fluoroscopy X-ray system. The K_{air} does not account for X-ray beam angulation, backscattered radiation dose or the patient shape; hence K_{air} is usually an overestimate of the air kerma incident at any one area of the skin. A Medical Physics Expert then undertakes a skin dose investigation to calculate the peak skin dose (PSD), that is, the maximum accumulated air kerma incident at any one point on the skin. This calculation accounts for the geometry and K_{air} recorded for each individual X-ray exposure for the current procedure and any other procedures carried out on the patient in the preceding 4 weeks. The geometry and K_{air} data are manually transcribed from bitmapped electronic dose records into a PSD calculation spreadsheet. The spreadsheet calculates an estimate of the PSD accounting for changes in gantry angle. If the PSD exceeds 2 Gy then a report is enclosed in the patient's electronic notes and the relevant clinician is informed.

Figure 1 shows that a skin dose investigation is only triggered if the K_{air} exceeds 2 Gy for a single cardiac catheterisation procedure. However, approximately 6% of cardiac catheterisation patients will undergo two or more procedures over the course of several weeks or months. If K_{air} remains below the alert level for each individual procedure then no skin dose investigation will be triggered for these patients, even if K_{air} summed over the multiple procedures exceeds the alert level. Such patients may, therefore, receive a clinically significant skin dose that is not followed up. In addition, the manual data transcription for each skin dose investigation is time-consuming. In 2018, for example, 119 studies at ULHT exceeded the K_{air} alert level; it is estimated that data transcription took an average of 41 min for each of these studies. The data entry component of the investigation alone was therefore occupying more than two working weeks of Radiation Protection Department time.

The Radiation Protection Department installed a new dose management system (OpenREM) which incorporates openSkin software for PSD calculations.⁴ The cardiac catheterisation X-ray systems were configured to automatically send detailed information to OpenREM at the end of each procedure. This information includes data on the geometry, exposure factors and K_{air} of each individual X-ray exposure that takes place during a procedure. The Radiation Protection Department recognised that OpenREM could be configured to automate a number of key processes within the skin dose investigation protocol. In particular the time-consuming data entry tasks could be automated, and OpenREM could be modified to add a high-dose alert feature for fluoroscopy procedures which exceeded predefined high skin dose trigger levels. The Radiation Protection Department, therefore, undertook to automate much of the skin dose investigation protocol to improve its effectiveness and efficiency.

MEASUREMENT

It was estimated that approximately 13 working days per year are spent on skin dose investigations within the ULHT. Automation of data entry and other administrative tasks was expected to significantly reduce this. This was tested by comparing estimates of the time taken to complete a typical skin dose investigation when following the original and automated protocols. A typical procedure, that is, one for which an average quantity of data had been entered into the dose calculation spreadsheet was selected from 2018. The time taken to complete an investigation of this typical procedure was measured for the original and automated protocols. The measured times were then multiplied by the total number of dose alerts in 2018 ($n=119$). This provided an estimate of the total staff time that would have been spent on skin dose investigations in 2018 using the original and automated protocols.

It was expected that for certain patients the automated protocol would trigger a dose alert while the original protocol would not. This was tested by comparing the number and content of non-automatic dose alerts received from Radiology with the automated dose alerts received from OpenREM over a 4-month period following Plan-Do-Study-Act (PDSA) cycle 2. This number was then multiplied by three to obtain an estimate of the additional number of skin dose investigations that would have been triggered in the whole of 2018 had the automated protocol been in place. This approach was considered valid because the same number of dose alerts were received from radiology in the 4-month period which followed automation (November 2018–February 2019) as were received over the corresponding period in the previous year (November 2017–February 2018).

DESIGN

The Radiation Protection Department installed and configured a new dose management system (OpenREM) to automate a number of key processes in the skin dose investigation protocol. Radiation protection team members were asked to suggest processes which could most usefully be automated and to identify any issues that might arise. These processes, and the expected impact of their automation on the effectiveness and efficiency of the skin dose investigation protocol, are illustrated in figure 2. The automation of the triggering of skin dose investigations was expected to eliminate the possibility that a high K_{air} accumulated over multiple low-dose procedures would fail to trigger an alert. The replacement of the skin dose calculation spreadsheet with openSkin was expected to reduce the time spent by staff on PSD calculations.

The main issue identified by the Radiation Protection team was that the sustainability of the automated protocol would be contingent on continued internal technical support for OpenREM and openSkin. It was concluded that once the various reconfigurations had been implemented only minimal support would be required and that members of the radiation protection team could be

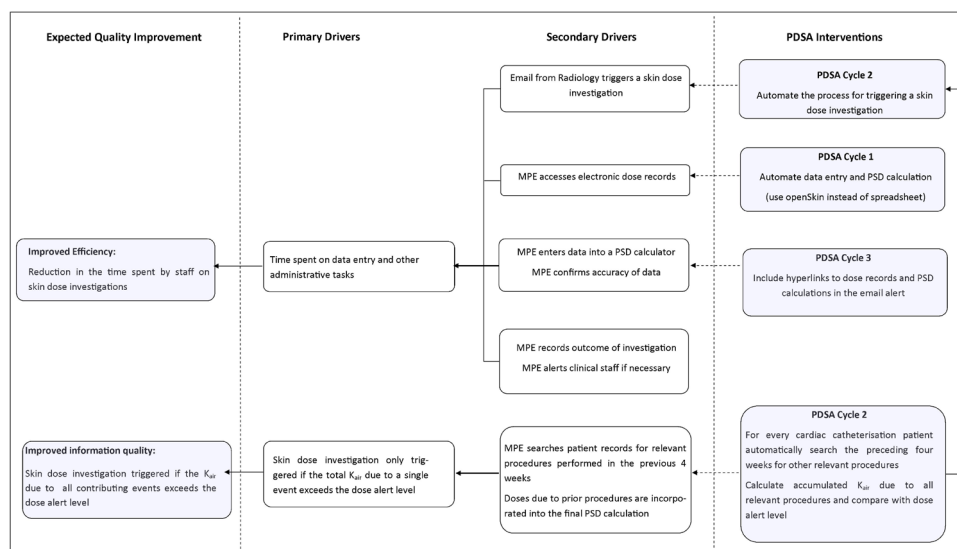


Figure 2 Diagram illustrating the impact on the efficiency and effectiveness of the skin dose investigation protocol, which was expected to follow the automation of key processes. Also shown are the proposed action points of the three PDSA cycles. MPE, Medical Physics Expert; PDSA, Plan-Do-Study-Act; PSD, peak skin dose.

trained to provide it without difficulty. The radiographers in the Cardiac Catheter Laboratory were also consulted. They were concerned that automation of the process for triggering a skin dose investigation would result in a reduction in awareness of skin dose among staff. It was, therefore, decided that the Cardiac Catheter radiographers would continue to keep their own record of patients who had received a K_{air} in excess of 2 Gy.

Plan-Do-Study-Act cycle 1

The aim of the first PDSA cycle was to remove the need for Radiation Protection to manually enter data into a PSD calculation spreadsheet. This was expected to significantly reduce the amount of staff time spent on skin dose investigations. Data entry and skin dose calculation tasks were automated by: replacing the PSD spreadsheet calculations with openSkin; configuring OpenREM to automatically trigger openSkin calculations for all cardiac catheterisation procedures and to provide the necessary data.

Over the months which followed PDSA cycle 1, it became clear that the intervention had been successful. The dose records for procedures which had exceeded an alert level could easily be found in OpenREM given the procedure date and K_{air} . The corresponding PSD calculated by openSkin could then be displayed by simply selecting the dose record. The staff time saved per year as a result was evaluated by comparing estimates of the total time that would have been spent on skin dose investigations in 2018 before and after the intervention. The success of PDSA cycle 1 suggested that further changes to OpenREM could enable improvements in the effectiveness of the skin dose investigation protocol (PDSA cycle 2) as well as further improvements in its efficiency (PDSA cycle 3).

Plan-Do-Study-Act cycle 2

The aim of PDSA cycle 2 was to modify the skin dose investigation protocol so that dose alerts would be triggered

by both accumulated K_{air} and single-study K_{air} values as opposed to single-study K_{air} values only. This was expected to eliminate the possibility that a high K_{air} accumulated over multiple low K_{air} procedures would fail to trigger a skin dose investigation. The modification was achieved by adding several features to OpenREM: calculation of accumulated K_{air} for studies with matching patient ID over a defined time period; automatic email notification to OpenREM users when a dose alert is exceeded; and the use of both accumulated and single-study K_{air} values to trigger email notifications.

The total K_{air} due to multiple procedures is calculated by simply adding together the K_{air} values recorded for all procedures carried out over the defined time period, that is, no attempt was made to account for skin recovery between procedures. The total K_{air} is currently accumulated over a 4-week period as per the original protocol. This time period was originally selected as roughly corresponding to the latent period for the manifestation of early-onset effects; however, it is trivial to set a more appropriate time period in the OpenREM configuration. The patient ID matching process relies on each study's Digital Imaging and Communications in Medicine (DICOM) Patient ID attribute value which is extracted by OpenREM from each received study. The X-ray systems use a DICOM Modality Worklist that automatically populates the Patient ID value in the DICOM data at the time of the study. Radiation protection continued to receive manual dose alert emails from radiology to enable a comparison to be made between the number and content of dose alerts received through the original and automated protocols.

In the months following PDSA cycle 2, it became clear that the automation of the dose alert process had been successful. For every manual email alert received from radiology, a corresponding automatic alert was received

from OpenREM. In addition to correctly identifying the procedure which had triggered the alert, the automated emails correctly identified all other procedures carried out on the patient in the preceding 4 weeks. As a result Radiation Protection staff no longer needed to search the patient records for additional contributing procedures. In addition, automated email alerts were occasionally received from OpenREM when no corresponding alert was received from radiology. These additional alerts were for patients for whom a high K_{air} had accumulated over multiple low dose K_{air} procedures so that they had been missed by the original protocol.

Plan-Do-Study-Act cycle 3

The aim of PDSA cycle 3 was to remove the need for radiology to provide radiation protection with the information necessary to locate dose records on OpenREM and to remove the need for Radiation Protection staff to search OpenREM for dose records. This was expected to further reduce the time spent by staff on skin dose investigations. The OpenREM email notifications were reconfigured to include hyperlinks to all the relevant dose records and PSD calculations. The staff time saved per year as a result of this change was evaluated by comparing estimates of the total time that would have been spent on skin dose investigations in 2018 before and after the intervention.

Following PDSA cycle 3, it became clear that the reconfiguration of the automatic dose alerts had been successful. The time saving due to this change was small in comparison with that achieved by PDSA cycle 1. However, this change enabled the instantaneous evaluation of PSD following a dose alert so that Radiation Protection staff could quickly identify and therefore prioritise clinically significant dose alerts.

RESULTS

Impact on protocol effectiveness

In the 6-month period which followed the automation of processes for triggering a skin dose investigation (PDSA cycle 2) Radiation Protection received 59 dose alerts from OpenREM and 56 alerts from radiology. The original protocol failed to trigger a skin dose investigation in three cases of high accumulated K_{air} . In one of these cases the calculated PSD exceeded 2 Gy, that is, the original protocol had failed to identify one clinically significant skin dose over a 6-month period. Assuming this 6-month period was representative this result suggests that in 2018 six high K_{air} cases failed to trigger a dose alert under the original protocol, two of which were clinically significant. The modified protocol has eliminated the possibility of this occurring in the future.

Impact on protocol efficiency

Figure 3 compares estimates of the time that would have been spent on skin dose investigations in 2018 if either the original or automated protocols had been in place. Following the automation of data entry tasks (PDSA

cycle 1) the estimated time spent on skin dose investigations was reduced by 88% from 13.4 to 1.6 working days per year. This was primarily due to the replacement of the PSD calculation spreadsheet with openSkin. This relieved Radiation Protection staff of data entry tasks saving 10.8 working days per year. The use of OpenREM also simplified the process for manually locating dose records and so introduced a further time saving of 2.6 working days per year. Following the automation of procedures for locating dose records (PDSA cycles 2 and 3), the estimated time spent on skin dose investigations was further halved from 1.6 to 0.8 working days per year. Overall the automated skin dose investigation protocol is expected to reduce the time spent by staff on skin dose investigations by approximately 12.6 working days per year, an efficiency saving of approximately 94%.

LESSONS AND LIMITATIONS

The effectiveness of the modified protocol was evaluated by comparing the ability of the original and modified protocols to correctly identify all clinically significant PSDs. Based on data collected over a 6-month period, it was estimated that the original protocol failed to identify two clinically significant PSDs per year. This analysis assumed that the 6-month period over which data were collected was representative; however, this was not verified in the study. This analysis also assumed that PSDs in excess of 2 Gy should be considered clinically significant. However, at other centres the threshold for a clinically significant PSD is considered to be 3 Gy. At such centres, this study would indicate that no clinically significant skin doses were being missed by the original protocol, that is, that the modifications introduced in PDSA cycle 2 did not improve the effectiveness of the skin dose investigation protocol. Finally, none of the patients who were followed up as a result of this protocol reported any symptoms consistent with a radiation skin injury. Hence, it is possible that the improvement in protocol effectiveness described here will not have any impact on the identification and care of patients who suffer a skin injury due to cardiac catheterisation procedures at ULHT.

When evaluating improvements in protocol efficiency the time spent each year on skin dose investigations was estimated by measuring the time taken to investigate a typical procedure using the original and automated protocols, and then multiplying the result by the total number of procedures carried out in 2018. This assumes a linear relationship between the number of data entries and the time spent on data entry tasks under the original protocol. In practice, procedures having an above-average number of data entries took disproportionately longer to investigate than those having a below-average number. There were two main reasons for this: first, when exceptionally large quantities of data had to be entered mistakes became more likely and took longer to locate; second, the system containing the

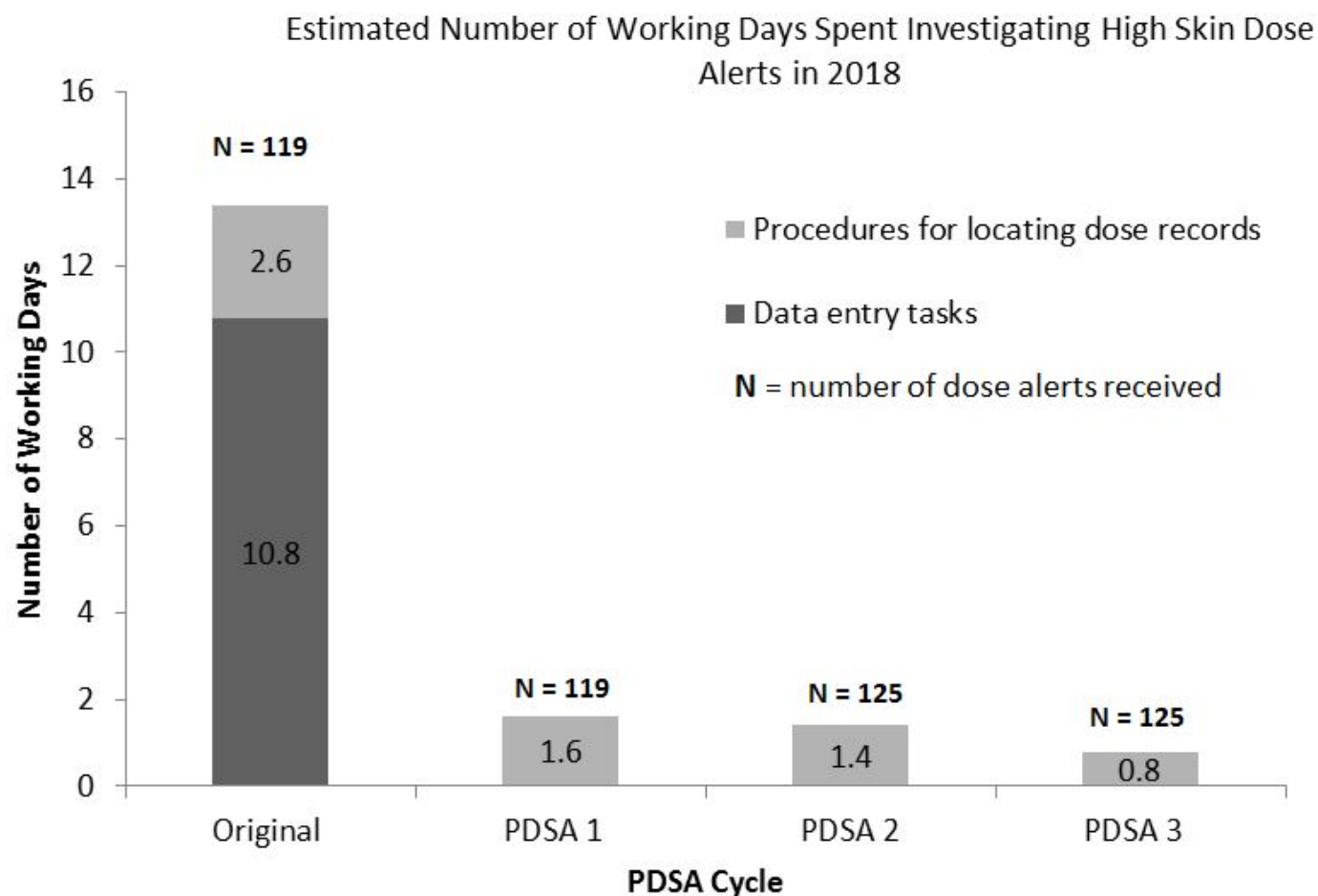


Figure 3 Estimates of the number of working days that would have been spent investigating dose alerts in 2018 following: the original protocol; the automation of data entry tasks (PDSA 1); the automation of dose alert procedures (PDSA 2) and the automation of procedures for locating dose records and peak skin dose calculations (PDSA 3). The estimated number (N) of dose alerts that would have been received from OpenREM is also indicated. PDSA, Plan-Do-Study-Act.

bitmapped electronic dose records would time-out part way through lengthy data entry tasks, interrupting the process by several minutes. Therefore, the method used to estimate the time spent by staff on skin dose investigations when following the original protocol may be invalid. However, there is no doubt that the removal of the need for staff to manually enter dose data into a spreadsheet has significantly improved the efficiency of the protocol.

CONCLUSION

A small proportion of patients who undergo cardiac catheterisation procedures will receive a radiation dose which is sufficiently high to cause a skin injury. It is important that patients who have received a potentially significant PSD are identified quickly so that appropriate clinical follow-up can be arranged. Although modern fluoroscopy systems display the cumulative reference air kerma at the patient entrance reference point, K_{air} , this quantity provides only a rough indication of PSD. PSD must instead be calculated from K_{air} by taking into account additional factors such as X-ray beam angulation. Within

the ULHT this is done by manually entering data into a skin dose calculator for any single procedure having a K_{air} in excess of 2 Gy. However, this method was considered to be unnecessarily time-consuming and also liable to miss potentially significant PSDs, which had accumulated over multiple low K_{air} procedures.

The radiation protection team installed and configured a dose management system (OpenREM) that enabled the automation of skin dose investigations over three PDSA cycles. The first PDSA cycle effectively automated data entry tasks. The second PDSA cycle automated the dose alert procedure so that skin dose investigations were triggered by accumulated as well as single-event K_{air} values. The third PDSA cycle automated processes for locating relevant dose records. The impact of automation on protocol effectiveness was evaluated by comparing the quantity and content of dose alerts received under the original and automated protocols. It was estimated that the original protocol was failing to detect two cases of clinically significant PSD per year and that the modified protocol would identify these cases. However, it was not demonstrated that this would improve the identification and care of skin injuries in cardiac catheterisation

patients. The impact of protocol automation on staff workload was evaluated by comparing estimates of the number of working days per year that would have been spent on skin dose investigations in 2018 when following the original and automated protocols. It was estimated that the automated protocol reduced the time spent on skin dose investigations by approximately 94% (from 13.4 to 0.8 working days per year). Finally, once an automatic dose alert has been received access to the corresponding PSD calculation is instantaneous. This makes it possible to evaluate which alerts require an immediate response, enabling the prioritisation of skin dose alerts by radiation protection staff.

In conclusion, the implementation of new technology (OpenREM and openSkin) has enabled the automation of a protocol in interventional radiology which has improved efficiency and which has the potential to improve its effectiveness.

Correction notice This article has been corrected since it was published. Figures are updated.

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