Meeting The Joint Commission’s Dose Incident Identification and External Benchmarking Requirements Using the ACR’s Dose Index Registry

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Abstract

Purpose: The purpose of this investigation was to evaluate the potential of using the ACR’s Dose Index Registry\textsuperscript{®} to meet The Joint Commission’s requirements to identify incidents in which the radiation dose index from diagnostic CT examinations exceeded the protocol’s expected dose index range.

Methods: In total, 10,970 records in the Dose Index Registry were statistically analyzed to establish both an upper and lower expected dose index for each protocol. All 2015 studies to date were then retrospectively reviewed to identify examinations whose total examination dose index exceeded the protocol’s defined upper threshold. Each dose incident was then logged and reviewed per the new Joint Commission requirements.

Conclusions: Facilities may leverage their participation in the ACR’s Dose Index Registry to fully meet The Joint Commission’s dose incident identification review and external benchmarking requirements.

Key Words: CT, The Joint Commission, dose incidents, external benchmarking

INTRODUCTION

The Joint Commission (TJC) released its updated diagnostic imaging requirements on August 10, 2015 [1]. The section titled “Element of Performance for PI.02.01.01.A6” is one of the most challenging for TJC-accredited facilities. This section requires organizations to

\begin{itemize}
  \item review and analyze incidents in which the radiation dose index from diagnostic CT examinations exceeds expected dose index ranges established for organizations’ protocols and
  \item compare these incidents with external benchmarks.
\end{itemize}

TJC defines radiation dose index as the examination’s total radiation dose index as indicated by the volumetric CT dose index (CTDI\textsubscript{vol}), total dose-length product (DLP), or size-specific dose estimate (SSDE) and allows facilities to choose which index they wish to use when establishing their protocols’ expected dose index ranges. It should be noted that CTDI\textsubscript{vol}, DLP, and SSDE are useful for monitoring the relative radiation output of equipment, but they do not represent a patient’s actual imparted radiation dose.

Historically, facilities had no need to establish protocol-specific, total expected radiation dose index ranges. Through the practice improvement release, PI.02.01.01.A6, the TJC has required that accredited facilities adhere to this new monitoring criterion. However, TJC does not prescribe what the ranges should be, leaving it up to each facility to establish site-specific parameters. It is worth noting that TJC’s use of the word range implies that facilities need to identify both an upper and a lower expected dose.

Although the regulations for monitoring radiation dose are new, there is a long-standing philosophy within radiology of minimizing patient dose. The principle of “as low as reasonably achievable” balances image quality with radiation exposure. In the same way, a dose index range...
should attempt to identify when the dose is possibly so low that image quality may be sacrificed, influencing patient care. Alternatively, radiation doses that exceed the threshold should identify those patients in whom the dose was higher and provide an explanation to ensure patient safety. Establishing expected dose index ranges and comparing actual total examination doses with the expected range is not a trivial task. First, there is no single, all-encompassing source of recommended dose index ranges for every protocol and scanner combination, and second, although the American Association of Physicists in Medicine (AAPM) published a set of recommended notification and alert values for several (but not all) CT scan regions, the AAPM values leave some protocols without recommended dose index ranges [2]. However, TJC stated unequivocally that “all protocols need to have an expected dose index range included” [3]. This means that it is up to each facility, working with its medical physicist, to establish and document each protocol’s “expected range,” against which an examination’s dose index will be compared, and then develop a process to identify and review dose incidents that exceed the expected dose index range.

Facilities whose scanners meet the National Electrical Manufacturers Association’s XR-29 standard requiring scanners to incorporate dose alert and notification capabilities are in a better position than facilities whose scanners are not XR-29 compliant [4]. However, TJC facilities with XR-29-compliant scanners still need to address how they will develop the lower dose index range values and the expected dose index ranges for examinations that do not have AAPM reference values. Facilities with non-XR-29-compliant scanners have the additional burden of establishing both an upper and a lower dose index for each protocol and then identifying dose incidents when these values are exceeded.

Our TJC-accredited imaging centers operate two XR-29-compliant scanners. However, in working with our vendors, we found that although the XR-29 dose alerts were based on the AAPM’s recommended dose index ranges, they did not fully meet TJC’s requirement for establishing expected dose index ranges for every protocol we use. Additionally, because XR-29’s alerts are primarily prescan alerts, while TJC’s requirement is solely a postscan test, we did not feel that they would fully meet TJC’s requirements without significant modifications [5]. Therefore, we needed to identify a solution that enabled us to establish lower and upper dose index threshold limits for our scan protocols, identify dose incidents when the upper limit was exceeded, and provide us with external benchmark data for incident comparison purposes.

Because our facility has been participating in the ACR’s Dose Index Registry (DIR) since January 2013, we wanted to explore the potential of using the DIR to facilitate the establishment of expected dose index ranges and incident identification for purposes of complying with TJC’s requirement to identify dose incidents. We found that by using the approach described in this report and with the appropriate involvement of the facility’s physicist, we could leverage our participation in the DIR to implement a comprehensive yet cost-effective dose management program that is fully compliant with TJC PL.02.01.01 (ie, establish expected dose index ranges for every protocol, identify and review all dose incidents, and compare the incidents against an external benchmark) and do so with little to no change in staff workflow.

**METHODS**

We have participated in the ACR’s DIR since January 2013, and at the time of data export, nearly three years of CT data had accumulated. Using the DIR’s data-export capabilities, we exported dose information by examination for the 10,970 CT examinations submitted between January 2013 and September 2015 in our DIR database and examination name mapping data to Microsoft Excel (Microsoft Corporation, Redmond, Washington). During this period, no scanners were replaced or had undergone significant upgrades or non-routine maintenance. The dose information by examination data included several discrete data elements for each record useful to our analysis, including study date, study time, study description, scanner name, total CTDIvol, and total DLP. The examination name mapping data allowed us to build a table to list every examination name and the radiology protocol identifier (RPID) to which we assigned it. This included RPIDs for both adult and pediatric protocols. We uploaded both tables into Microsoft Access. Then, using Microsoft Access’s query function, we built a series of queries that calculated the mean and standard deviation for each RPID on the basis of the 10,970 examinations in our database. We chose to use CTDIvol as our dose measurement, but we could have used DLP.

Next, using the mean and standard deviation, we were able to apply the statistical analysis known as the normal distribution to develop our expected dose index

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1 Notable resources to assist facilities include [http://www.imagegently.org](http://www.imagegently.org) and [http://www.imagewisely.org](http://www.imagewisely.org).
range for each protocol. The general properties of a normal distribution are that most values within a sample cluster around the mean and then taper off in both directions, ending with tiny percentages of samples at the “tails.” For our purposes, the expected range is the area under the middle portion of the curve, with the tails representing areas outside the expected range. Examinations whose doses lie in the upper tail would be considered incidents and subject to further review and analysis (see Fig. 1). Applying the standard normal distribution formula, \( X = \mu + Z\sigma \), where \( X \) is the dose threshold, \( \mu \) is the mean dose for the given RPID, \( \sigma \) is the RPID’s calculated standard deviation, and \( Z \) is the number of standard deviations, it is possible to estimate the number of studies one would expect to find given the mean and standard deviation in the sample data. Because \( \mu \) and \( \sigma \) are known, \( Z \) determines the threshold value and thus the estimated number of samples that should be in the tail. Howard et al [6] wrote that the AAPM wanted its alert value set at the 95th percentile. In a one-sided test, this implies that the AAPM set \( Z \) to 1.645. We chose to test the process using \( Z \) factors of 1.645, 2.0, and 3.0.

We found that at the higher \( Z \) factors, this method resulted in lower thresholds of less than zero for a few RPIDs, which are not valid. This occurs when the data do not conform to a normal distribution. All lower threshold values that are less than or equal to zero should be set to equal zero during the initial creation phase and then manually adjusted upward by the facility and medical physicist by performing image quality metrics to establish a minimum dose index range that provides acceptably diagnostic examinations. Once both thresholds are established, the lower value should be monitored and adjusted for industry standards for diagnostic image quality, and the upper value should be monitored and adjusted according to industry standards for radiation exposure in medical imaging procedures. In addition to developing the expected doses ranges, we also needed a process for comparing actual examination doses with the expected dose table for the purpose of identifying and reviewing studies whose doses exceeded the dose index range as required under TJC’s Element of Performance PI.02.01.01. We felt that there were two possible approaches:

1. Have staff members manually compare each study’s dose at its completion against a hard-copy printout of the protocol dose table, recording an “incident” in a log book for later review when the actual dose exceeded the table’s upper dose limit of the relevant RPID.
2. Create a database query designed to identify only those studies whose doses exceeded the doses in the protocol dose table and provide a report on a periodic basis to the staff for review.

**RESULTS**

According to the normal distribution tables, \( Z \) factors of 1.645, 2.0, and 3.0 would result in 5%, 2.28%, and
Table 1. Impact of Z factor on the number of dose incidents identified

<table>
<thead>
<tr>
<th>Z Factor</th>
<th>Predicted Number by Standard Normal Distribution Theory</th>
<th>Actual Number of Incidents Exceeding Upper Dose Range</th>
<th>Predicted Percentage Exceeding Threshold</th>
<th>Actual Upper Threshold Incident Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.645</td>
<td>181</td>
<td>120</td>
<td>5.0%</td>
<td>3.3%</td>
</tr>
<tr>
<td>2.0</td>
<td>83</td>
<td>88</td>
<td>2.3%</td>
<td>2.4%</td>
</tr>
<tr>
<td>3.0</td>
<td>5</td>
<td>41</td>
<td>0.13%</td>
<td>1.1%</td>
</tr>
</tbody>
</table>

Note: The table shows the predicted and actual numbers and percentages of dose incidents identified by use of various Z factors considered for use.

0.13%, respectively, of studies exceeding the upper dose index range threshold. Simulating the process we would use if we were to undergo a TJC inspection in late 2015, we compared the total CTDIvol examination dose for every CT study we submitted to the DIR between January 1, 2015, and September 30, 2015 (3,618) with each of the three dose index range tables developed on the basis of the three Z factors. As expected, each produced a different result (Table 1):

- A Z factor of 3.0 resulted in 41 of the 3,618 scans identified as exceeding their expected dose index range (1.1%), whereas the normal distribution tables predicted that only 5 scans would exceed it (0.13%).
- A Z factor of 2.0 resulted in 88 of the 3,618 scans identified as exceeding their expected dose index range (2.4%), whereas the normal distribution tables predicted that 83 scans would exceed it (2.3%).
- A Z factor of 1.645 resulted in 120 of the 3,618 scans identified as exceeding their expected dose index range (3.3%), whereas the normal distribution tables predicted 181 scans (5%).

Each succeeding Z-factor test included all incidents identified in the previous Z factor (ie, the 41 dose incidents identified when using a Z factor of 3.0 were included in the 88 dose incidents identified when we used a Z factor of 2.0, and the 88 dose incidents identified when using a Z factor of 2.0 were included in the 120 dose incidents identified when we used a Z factor of 3.0). Next, we reviewed each of the 120 dose incidents. Our review of the 120 dose incidents revealed that every identified dose incident using a Z factor of 1.645, and the 88 when using a Z factor of 2.0, was a result of an appropriate variation of a routine examination (eg, an extraordinarily large patient, additional series, repeated series because of motion). This resulted in staff members’ reviewing an inordinate number of higher-than-average dose indexes that were, essentially, to be expected in the normal course of a day. However, our review of the 41 dose incidents identified using a Z factor of 3.0 indicated that although most identified incidents were still appropriate variations of routine examination, three examinations were what we considered to have teachable elements on the basis of our review. We also noted that, as indicated previously, the actual parentage of studies exceeding the thresholds when using a Z factor of 3.0 (1.1%) exceeded the statistically predicted percentage value (0.13%) by a factor of 8.5, while the actual values for the other Z factors were equal to or less than predicted.

On the basis of our review, we felt that using a Z factor of 3.0 would be most appropriate for our facility at this time. We arrived at this Z factor because we felt that using a Z factor of 3 would result in the identification of examinations that have the potential to be incidents or learning experiences on the basis of our initial experience,

- would minimize the chance of staff members’ experiencing alert fatigue from having to review examinations that were almost certain to be normal variations with little likelihood being true dose incidents, and
- help us determine why our actual results using a Z factor of 3 were eight times higher than what the normal curve predicted (1.1% instead of 0.13%).

We then tested the two approaches of comparing each examination’s total dose with a dose index range table and how staff members would identify, log, and review the dose incidents identified by the process. Staff members began by testing approach 1, described previously. It quickly became apparent the manual nature of checking the displayed dose at examination completion against a multipage dose table containing 173 different examination names, and then recording the incident in a separate log for review and analysis later, was an obstacle. The nature of this approach meant that staff members were performing a significant task that 95% to 99% of the time would return a normal result in order to identify the 1% to 5% of examinations that exceeded the threshold. Staff members expressed concern that this process may not be a viable long-term solution, particularly during times of high volume or other periods of stress.
Staff members had a much more positive reaction to approach 2, which used a query process to automate the identification of incidents. Using the same Access tables to establish the dose table, we developed a query that was designed to identify only those studies whose dose exceeded the upper dose limit in the protocol dose table. This allowed us to present staff members with a pre-populated spreadsheet listing every potential dose incident, with space for them to record their findings. This required little to no change in daily workflow. Staff members felt that the automated process virtually eliminated the risk for human error in performing the dose check. They found it easy to review the specific examinations identified as potential outliers and record their findings on the worksheet we provided them. These worksheets also serve as our records for TJC compliance purposes.

**DISCUSSION**

Determining the Z factor was the critical decision in this project. This determined the dose index range, which therefore determined the nature of the “incidents” we would identify. Conceptually, we viewed the identification of dose incidents using this process as one part of a three-part program, with the other two parts consisting of the XR-29-type dose alerts and notifications and our general participation in the DIR. We felt that each part had a primary purpose. Our participation in the DIR provides us with the ability to compare our doses with others at a macro level, and the XR-29 alerts and notifications add an important safety check during the scanning process, prompting staff members to stop the line when an alert is received, and agree with the AAPM’s targeting about a 5% alert rate. We viewed TJC’s dose incident process as encouraging us to identify any study whose dose seemed truly aberrant that it warrants further investigation. On the basis of this approach, and the results we received when we tested the three Z factors, we felt that using a Z factor of 3.0 achieved our goal: it identifies studies that have the potential to be truly aberrant, while avoiding the risk for dose incident fatigue.

We found the exported DIR data required no alteration before uploading into Access. Although the DIR’s study date and time are in an alphanumeric format (yyyyymmdd) and not in standard date and time formats, they are hierarchical, which allows easy recognition and can be readily used in formulas and calculations.

One of our biggest concerns after producing a list of examinations that exceeded the dose index range was the DIR’s lack of patient-identifying information, due to HIPAA regulations that prevent DIR software from
transferring any electronic personal health information to the DIR [7]. This meant that when we presented staff members with the list of dose incidents, it did not contain patients’ names, dates of birth, and medical record numbers. This proved not to be an obstacle. By including the study date, study time, study name, total dose, and scanner name information, staff members could readily identify the specific patient by reviewing either the daily log or the radiology information system or PACS. For example, one of our incidents included the following information:

- Study name: HeadIAC
- Scanner: 50743
- Study date: 20150106
- Study time: 160836
- Total dose: CTDIvol of 171 mGy

Staff members, knowing that this was an internal auditory canal study performed on January 6, 2015, at 4:08 PM on scanner 50743 that resulted in a total dose of 171 mGy, had no difficulty identifying the specific patient within a very short period of time, allowing them to perform their incident review and benchmarking tasks required by TJC.

We also explored using one of several third-party solutions to provide this benchmark data and identify dose incidents. We found that although they generally offer easy-to-use interfaces and perform other functions, the costs were more than we felt comfortable with at this time, particularly if we could leverage our participation in the DIR. In the end, we found using the DIR to be the most cost effective option allowing us to meet these requirements. For those yet to enroll in the National Radiology Data Registry, the cost to enroll is based on the combination of the number of facilities and radiologists involved [8]. For example, the cost to enroll a facility with one to five sites will likely be $500 to $750, depending on the number of radiologists. For facilities already enrolled in one of the other of the ACR’s registries (eg, Lung Cancer Screening Registry), some or all of these fees may have already been paid. The software is free, but facilities will need to set up small servers to use with the software. Each CT scanner will need to be configured to send the required data to the DIR server, a simple process but one that likely requires the service engineer’s assistance. For TJC-accredited facilities, enrollment in the DIR has yet another advantage: compliance with the Element of Performance PI.02.01.01 requirement for facilities to compare their incidents’ doses with an external benchmark [1]. TJC recently issued a written response to an inquiry acknowledging that the ACR’s DIR meets the benchmarking requirements under PI.02.01.01 [9]. This means that facilities can leverage their participation in the DIR to meet every element contained in PI.02.01.01. We incorporated this into our review spreadsheet, discussed previously.

We also found this process provided us with other opportunities to enhance our radiation dose review program. For example, using the DIR data, we created a scatterplot representing the total CTDIvol dose for all 2015 data points we reviewed for incident identification (see Fig. 2). Interestingly, three of the four studies represented by the highest dose data points in the scatterplot did not exceed their expected dose index range and therefore were not identified as dose incidents for further review. However, by incorporating this step into our ongoing radiation safety program, we are able to identify these specific high-dose studies and review them as well.

**TAKE-HOME POINTS**

- The ACR’s DIR is a cost-effective solution for identifying dose incidents for further review and analysis as well as for comparing dose incidents against an external benchmark as required by TJC Element of Performance PI.02.01.01.
- Using the exported data, dose index ranges were developed by determining the mean and standard deviation. Our facility used three standard deviations greater than the mean as the upper threshold.
- Moderate to advanced Microsoft Access and Excel skills are likely required.
- We found that once the process was developed, automation allowed the identification of dose incidents while avoiding significant changes to staff workflow.
- This process, used in combination with ongoing review of the DIR results, will provide the facility with a robust and meaningful CT dose review program.
- Although this process works well for all scanners, it may be particularly useful for non-XR-29-compliant scanners, which lack the ability to produce dose alerts and dose notifications.
- This process will also likely enhance users’ comfort with the DIR data and their results, increasing the likelihood of identifying other creative ways to review their dose data.
REFERENCES


