Radiation Overdose as a Reviewable Sentinel Event

The Joint Commission recently added two new items to its list of events that are reviewable under its Sentinel Event Policy:

- Neonatal serum bilirubin >30 milligrams/deciliter
- Prolonged fluoroscopy with cumulative dose >1500 rads to a single field or any delivery of radiotherapy to the wrong region or >25% above the planned dose.

Both of these events could be associated with death or major permanent loss of function. However, these outcomes often do not occur for months or years after the event itself. Also, both of these events are considered to be preventable. For these reasons, whenever one of these events is identified, it is reviewable under the Sentinel Event Policy. The organization is required to conduct a root cause analysis and is encouraged to voluntarily report the event to the Joint Commission, even though the outcome has not yet become evident. As with all sentinel events, the intent is to analyze, learn from, and share knowledge about the event, its causes, and strategies for prevention.

The following **Frequently Asked Questions (FAQs)** and answers have been developed in collaboration with experts in the field of medical physics and radiation oncology. They are provided in response to queries about the rationale for, and precise definition of the terms used in specifying these new reviewable events:

The parameters that specify when these events are reviewable seem very high; in fact, much higher than are specified by the relevant practice guidelines and regulations. Why is that?
It is important to recognize that the purpose of the Sentinel Event Policy is to promote improvement in patient safety, not to regulate practice. The parameters defining these sentinel events were intentionally selected to identify only the most extreme cases—those that should never occur. On those rare occasions when these limits are reached, it is clear that a root cause analysis is appropriate to identify the systems factors that allowed such a significant variation to occur. This is in contrast to practice guidelines and regulations that set limits on the acceptable range of practice variation.

What, exactly, is intended by "any delivery of radiotherapy to the wrong region"? Are even minor variations in the field considered sentinel events?
The intent here is the same as requiring a root cause analysis for a wrong site surgery. The fact of a wrong site delivery of radiotherapy carries implications of system problems that should be understood and, as appropriate, redesigned. With regard to "minor variations," it is recognized that as with any process, there will be some degree of *common cause variation*, which is within the range of acceptability for that procedure. Any variation from the intended field of treatment that is within the range considered by the medical physics community as acceptable would not be considered by the Joint Commission to be a reviewable sentinel event. A variation greater than that, i.e., a *special cause variation*, should be managed as a sentinel event. Additional detail on this topic is available from the NRC for radiopharmaceuticals and the FDA for radiation-generating equipment.

Does the phrase ">25% above the planned dose" refer to the total planned dose or a single (fractionated) does?
It refers to the total planned dose.

Does the term "single field" refer to the location on the skin through which the radiation is directed or the target internal organ, or both?
As it relates to fluoroscopy, the specification of "1500 rads to a single field" refers to a location on the skin through which the fluoroscopic beam is directed. The issue here is the magnitude of the dose to that portion of the skin that receives the maximum or peak skin dose. This may be the situation that results from using several different x-ray beam projections or fields-of-view whose beam areas on the patient's skin overlap in a specific location to produce a region of highest radiation dose. In fluoroscopically-guided interventional procedures, many different projections or x-ray beam directions are often used, with many overlapping fields-of-view or imaged areas.

Are we now required to keep track of the cumulative fluoroscopy dose for all patients having fluoroscopy exams and report when they have a cumulative dose of 1500 rads?
This new "reviewable sentinel event" does not mandate any measurement activities that are not expected as part of the usual standard of practice for fluoroscopy and radiotherapy. One of the main reasons for adding this event to the Joint Commission's list of reviewable sentinel events was to raise awareness of the severity of the associated outcomes—often overlooked or unrecognized because of the delay in their appearance. That said, routine monitoring of the parameters identified in this new sentinel event definition would be an appropriate patient safety precaution.

How do we go about monitoring fluoroscopy doses?
Most fluoroscopic x-ray equipment can provide an estimate of the total (cumulative) dose that would have resulted to a point on the skin if the x-ray beam was stationary during the complete procedure. Such an estimate is derived from the fluoroscopic technique factors and the total fluoroscopic exposure time, including any image recording, or from built-in dosimetry systems found on some newer equipment. However, these systems, known as dose-area-product meters (DAP meters) or some similar term, do not directly provide skin dose information without further knowledge of the sizes of the x-ray beam during the entire procedure. The relationship between cumulative skin dose and peak skin dose is highly variable, as has been demonstrated in a number of publications. However, for purposes of estimating peak dose, one could establish a "trigger" for reporting peak skin dose based on a fraction, say 75%, of the cumulative skin dose. Further recommendations for monitoring, recording and patient follow-up for high dose imaging procedures are available from the FDA at http://www.fda.gov/cdrh/radhealth.html.

Is "cumulative" defined as a life-time dose?
No; monitoring "life-time dose" is neither practical nor necessary with respect to fluoroscopic procedures. While tissue damage from radiation is dependent on the total (cumulative) dose delivered over time, we recognize that skin sensitivity is, to a degree, repairable and that monitoring cumulative dose over a period of six months to a year would be reasonable.

Does "delivery of radiotherapy" apply to radioisotope therapy or radiation producing machines, or both?
It applies to both.

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