Adverse event reporting tool for sedation

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Sedation practice today is experiencing revolutionary changes. One of them is a re-evaluation of what is defined as an adverse event during sedation.

The World Health Organization (WHO) and the US Food and Drug Administration (FDA) have provided existing definitions of what an adverse event constitutes. The question is: as sedation practitioners, do these definitions provide us with any value?

The International Sedation Task Force (ISTF) is a World Society of Intravenous Anaesthesia Onlus (WorldSIVA) committee, that identify certain "sedation questions and controversies" and attempts to provide acceptable, scientific answers to such questions. One of them covers the definition of adverse events during sedation. Members of the ISTF believe that adverse events are untoward medical occurrences, which occur as a causal result of the sedation, and which require an intervention. These intervention-based events, for which regular tracking and peer scrutiny is recommended, may be indicated for quality improvement within sedation care.

Serious adverse events are those events that are critical enough to warrant immediate reporting within the sedation care system, and automatic peer scrutiny, to ensure continuous quality improvement.

These interventions have been defined as "airway intervention" and "pharmacological intervention". Within each category above, there is a list of root causes, which must be identified.

Lesser adverse events are those that might be optionally tracked within sedation care systems, depending on local concerns and resources. These are clinically-based observations, and may not require an intervention. These events might be ignored,as often, they happen at home. They include displays of aggression, double vision, crying, or unhappiness about what happened during sedation, and we don't know about it.

Our intent, at the ISTF, was to present a terminology containing definitions for a set of adverse events that are objective, reproducible, applicable to all settings worldwide, and which focus upon events that are of clinical significance.

In addition to defining individual adverse events, members of the ISTF believe that it is practical to structure adverse events into a hierarchy based upon clinical importance, e.g. critical, standard, and lesser adverse events. These will be discussed.

Intervention-based definitions were chosen for logical and compelling reasons. The primary argument is that the adverse events of most importance are those which require intervention. An important consideration was how drugs contribute to adverse events, as well as the severity of adverse events.

This led to the development of a WorldSIVA adverse sedation event reporting tool, available through Internet access.

This tool represents five steps, which will be explained:

- Questioning whether one, or more, adverse events, was associated with the sedation procedure
- Providing a description of the adverse events
- Detailing the interventions performed to treat the adverse events
- Outlining the outcome of the adverse events
- Assigning a severity rating.

The WorldSIVA adverse event reporting tool is a means of collecting, and tracking the registrant's own sedation data. This will contribute to a global repository of sedation outcome to benefit knowledge of safety and outcomes.