|  | World SIVA adverse sedation event reporting tool   |
|--|--|
| С  | orld SIVA adverse sedation event recording tool configured for a web page or paper form.<br>ompletion of this tool requires execution of all five steps. Responses to each step will often<br>ccupy different columns.   |
| St   | ep 1: Was there one or more adverse events associated with this sedation encounter?  |
| 0  | No, this form is now complete. o Yes, fill out remainder of form below.  |
| St   | ep 2: Please DESCRIBE the adverse events(s). Check all that apply.   |
|  | inimal risk descriptors Minor risk descriptors Sentinel risk descriptors   |
| 0000   | Aminina instruction protocomplexity <ul> <li>Minina instruction protocomplexity</li> <li>Minina instruction protocomplexity</li> <li>Minina instruction protocomplexity</li> <li>Oxygen desaturation (75–90%)</li> <li>Oxygen desaturation, severe (&lt;75% at any specify time) or prolonged</li> <li>Muscle rigidity, o Airway obstruction</li> <li>Airway obstruction</li> <li>(&lt;90% for &gt;60 s)</li> <li>Apnoea, not prolonged</li> <li>Minina instruction</li> <li>Airway obstruction</li> <li>(&lt;90% for &gt;60 s)</li> <li>Apnoea, prolonged (&gt;60 s)</li> </ul> <li>Hypersalivation</li> <li>All ergic reaction without anaphylaxis</li> <li>Cardiovascular collapse/shock<sup>g</sup></li> <li>Prolonged recovery<sup>d</sup></li> <li>Tachycardia<sup>f</sup></li> <li>Cardiac arrest/absent pulse</li> <li>Hypertension<sup>f</sup></li> <li>Seizure</li>  |
| St   | ep 3: Please note the INTERVENTIONS performed to treat the adverse events(s). Check all that apply.  |
| Ac<br>o<br>o   | No intervention performed       o       Airway repositioning       o       Bag valve mask-assisted ventilation       o       Chest compressions o       O Other, specify below         dministration of:       o       Tactile stimulation of: or the administration of: or or or the administration of: or or the administration of: or t |
|  |  |
| St   | ep 4: Please note the OUTCOME of the adverse events(s). Check all that apply.  |
|  | inimal risk outcome Moderate risk outcome Sentinel outcome   |
| _  | No adverse outcome         O         Unplanned hospitalisation<br>or escalation of care <sup>h</sup> O         Death         O         Other,<br>specify<br>below           O         Pulmonary aspiration syndrome <sup>i</sup> O         Death         O         Other,<br>specify<br>below  |
| 0  | No adverse outcome O Unplanned hospitalisation or escalation of care <sup>h</sup> O Death O Other, specify   |
| o<br>St<br>o<br>o<br>o<br>A  | No adverse outcome       • Unplanned hospitalisation or escalation of care <sup>h</sup> • Death       • Other, specify below         ep 5: Assign a SEVERITY rating to the adverse event(s) associated with this sedation encounter.       • Pulmonary aspiration syndrome <sup>i</sup> • Other, specify below         ep 5: Assign a SEVERITY rating to the adverse event(s) associated with this sedation encounter.       • Pulmonary aspiration syndrome <sup>i</sup> • Other, specify below         ep 5: Assign a SEVERITY rating to the adverse event(s) associated with this sedation encounter.       • If there are any options checked in the Sentinel columns above, then this is a Sentinel <sup>i</sup> adverse event.       • If the most serious option(s) checked above are Moderate risk, then this is a Minor <sup>1</sup> risk adverse event.         If the most serious option(s) checked above are Minor risk, then this is a Minor <sup>1</sup> risk adverse event.       • If the most serious option(s) checked above are Minimal risk, then this is a Minor <sup>1</sup> risk adverse event.         If the most serious option(s) checked above are Minimal risk, then this is a Minimal <sup>m</sup> risk adverse event.       • If the most serious option(s) checked above are Minimal risk, then this is a Minimal <sup>m</sup> risk adverse event.         Idditional details (including 'other' enteries):       • Other, specify below         *Subclinical respiratory depression <sup>m</sup> is defined as capnographic abnormalities suggesting respiratory   |
| o<br>St<br>o<br>o<br>Ac<br>=oc   | No adverse outcome       • Unplanned hospitalisation or escalation of care <sup>h</sup> • Death       • Other, specify below         ep 5: Assign a SEVERITY rating to the adverse event(s) associated with this sedation encounter.       If there are any options checked in the Sentinel columns above, then this is a Sentinel <sup>1</sup> adverse event.       If there are any option(s) checked above are Moderate risk, then this is a Moderate <sup>k</sup> risk adverse event.       If the most serious option(s) checked above are Minor risk, then this is a Minor <sup>1</sup> risk adverse event.         If the most serious option(s) checked above are Minor risk, then this is a Minor <sup>1</sup> risk adverse event.       If the most serious option(s) checked above are Minor risk, then this is a Minor <sup>1</sup> risk adverse event.         If the most serious option(s) checked above are Minor risk, then this is a Minor <sup>1</sup> risk adverse event.       If the most serious option(s) checked above are Minor risk, then this is a Minor <sup>1</sup> risk adverse event.         If the most serious option(s) checked above are Minimal risk, then this is a Minor <sup>1</sup> risk adverse event.       If the most serious option(s) checked above are Minimal risk, then this is a Minor <sup>1</sup> risk adverse event.         If the most serious option(s) checked above are Minimal risk, then this is a Minimal <sup>m</sup> risk adverse event.       If the most serious option(s) checked above are Minimal risk, then this is a Minimal <sup>m</sup> risk adverse event.         If the other serious option(s) checked above are Minimal risk, then this is a Minimal <sup>m</sup> risk adverse event.       If the other serious option(s) checked above are Minimal risk, then this is a Minimal <sup>m</sup> risk adverse event.  |
| St<br>o<br>o<br>o<br>A<br>c<br>a.  | No adverse outcome       • Unplanned hospitalisation or escalation of careh       • Death       • Other, specify below         ep 5: Assign a SEVERITY rating to the adverse event(s) associated with this sedation encounter.       • Pulmonary aspiration syndrome <sup>1</sup> • Other, specify below         If there are any options checked in the Sentinel columns above, then this is a Sentinel <sup>1</sup> adverse event.       If the most serious option(s) checked above are Moderate risk, then this is a Moderate <sup>k</sup> risk adverse event.       If the most serious option(s) checked above are Minor risk, then this is a Minor <sup>1</sup> risk adverse event.         If the most serious option(s) checked above are Minor risk, then this is a Minor <sup>1</sup> risk adverse event.       If the most serious option(s) checked above are Minor risk, then this is a Minor <sup>1</sup> risk adverse event.         If the most serious option(s) checked above are Minimal risk, then this is a Minimal <sup>m</sup> risk adverse event.         If the most serious option(s) checked above are Minimal risk, then this is a Minimal <sup>m</sup> risk adverse event.         If the most serious option(s) checked above are Minimal risk, then this is a Minimal <sup>m</sup> risk adverse event.         Idditional details (including 'other' enteries):         "Subclinical respiratory depression" is defined as capnographic abnormalities suggesting respiratory   |
| 0<br>0<br>0<br>0<br>0<br>0<br>0<br>0<br>0<br>0<br>0<br>0<br>0<br>0<br>0<br>0<br>0<br>0<br>0  | No adverse outcome       • Unplanned hospitalisation<br>or escalation of care <sup>h</sup> • Death<br>• Permanent neurological deficit<br>• Pulmonary aspiration syndrome <sup>i</sup> • Other,<br>specify<br>below         ep 5: Assign a SEVERITY rating to the adverse event(s) associated with this sedation encounter.       • Other,<br>Pulmonary aspiration syndrome <sup>i</sup> • Other,<br>specify<br>below         ep 5: Assign a SEVERITY rating to the adverse event(s) associated with this sedation encounter.       • Other,<br>Pulmonary aspiration syndrome <sup>i</sup> • Other,<br>specify<br>below         if there are any options checked in the Sentinel columns above, then this is a Sentinel <sup>i</sup> adverse event.       • If the most serious option(s) checked above are Moderate risk, then this is a Moderate <sup>k</sup> risk adverse event.         If the most serious option(s) checked above are Minor risk, then this is a Minor <sup>1</sup> risk adverse event.       • If the most serious option(s) checked above are Minimal risk, then this is a Minor <sup>1</sup> risk adverse event.         If the most serious option(s) checked above are Minor risk, then this is a Minor <sup>1</sup> risk adverse event.       • If the most serious option(s) checked above are Minimal risk, then this is a Minor <sup>1</sup> risk adverse event.         If the most serious option(s) checked above are Minimal risk, then this is a Minor <sup>1</sup> risk adverse event.       • If the most serious option(s) checked above are Minimal risk, then this is a set of the adverse event.         If the most serious option(s) checked above are follower as abnormal risk, then this is a set of the adverse event.       • If the most serious option(s) checked above are follower as a set of the adverse event.         "Paradoxica   |
|  | No adverse outcome       O Unplanned hospitalisation<br>or escalation of care <sup>h</sup> O Death<br>O Permanent neurological deficit<br>Pulmonary aspiration syndrome <sup>i</sup> O Other,<br>specify<br>below         ep 5: Assign a SEVERITY rating to the adverse event(s) associated with this sedation encounter.       Pulmonary aspiration syndrome <sup>i</sup> O Other,<br>specify<br>below         ep 5: Assign a SEVERITY rating to the adverse event(s) associated with this sedation encounter.       If there are any options checked in the Sentinel columns above, then this is a Sentinel <sup>i</sup> adverse event.       If the most serious option(s) checked above are Moderate risk, then this is a Moderate <sup>k</sup> risk adverse event.         If the most serious option(s) checked above are Minor risk, then this is a Minor <sup>1</sup> risk adverse event.       If the most serious option(s) checked above are Minimal risk, then this is a Minimal <sup>m</sup> risk adverse event.         If the most serious option(s) checked above are Minimal risk, then this is a Minimal <sup>m</sup> risk adverse event.       If the most serious option(s) checked above are Minimal risk, then this is a Minimal <sup>m</sup> risk adverse event.         If the most serious option(s) checked above are Minimal risk, then this is a Minimal <sup>m</sup> risk adverse event.       If the most serious option(s) checked above are Minimal risk, then this is a Minimal <sup>m</sup> risk adverse event.         If the most serious option(s) checked above are Minimal risk, then this is a Sentinel <sup>i</sup> adverse event.       If the most serious option(s) checked above are Minimal risk, then this is a Minimal <sup>m</sup> risk adverse event.         If the most serious option(s) checked above are flow as caphographic abnormalities suggesting respiratory depression that d  |
| St       0    <  | No adverse outcome       • Unplanned hospitalisation or escalation of careh       • Death       • Other, specify below         ep 5: Assign a SEVERITY rating to the adverse event(s) associated with this sedation encounter.       • Pulmonary aspiration syndromei       • Other, specify below         ep 5: Assign a SEVERITY rating to the adverse event(s) associated with this sedation encounter.       • Pulmonary aspiration syndromei       • Other, specify below         ep 5: Assign a SEVERITY rating to the adverse event(s) associated with this sedation encounter.       If there are any options checked in the Sentinel columns above, then this is a Sentinel <sup>1</sup> adverse event.       If the most serious option(s) checked above are Moderate risk, then this is a Moderate <sup>k</sup> risk adverse event.         If the most serious option(s) checked above are Minor risk, then this is a Minor <sup>1</sup> risk adverse event.       If the most serious option(s) checked above are Minor risk, then this is a Minor <sup>1</sup> risk adverse event.         If the most serious option(s) checked above are Minor risk, then this is a Minor <sup>1</sup> risk adverse event.       If the most serious option(s) checked above are Minor risk, then this is a Minor <sup>1</sup> risk adverse event.         If the most serious option(s) checked above are Minor risk, then this is a Minor <sup>1</sup> risk adverse event.       If the most serious option(s) checked above are Minor risk, then this is a Sentinel <sup>1</sup> dditional details (including 'other' enteries):       ************************************   |
| St         0 <t< td=""><td>No adverse outcome       • Unplanned hospitalisation<br/>or escalation of care<sup>h</sup>       • Death<br/>• Permanent neurological deficit<br/>• Pulmonary aspiration syndrome<sup>i</sup>       • Other,<br/>specify<br/>below         ep 5: Assign a SEVERITY rating to the adverse event(s) associated with this sedation encounter.       • Pulmonary aspiration syndrome<sup>i</sup>       • Other,<br/>specify<br/>below         ep 5: Assign a SEVERITY rating to the adverse event(s) associated with this sedation encounter.       • If there are any options checked in the Sentinel columns above, then this is a Sentinel<sup>i</sup> adverse event.       • If the most serious option(s) checked above are Moderate risk, then this is a Moderate<sup>k</sup> risk adverse event.         If the most serious option(s) checked above are Minor risk, then this is a Minor<sup>1</sup> risk adverse event.       • If the most serious option(s) checked above are Minor risk, then this is a Minimal<sup>m</sup> risk adverse event.         If the most serious option(s) checked above are Minor risk, then this is a Minimal<sup>m</sup> risk adverse event.       • If the most serious option(s) checked above are Minor risk, then this is a Minimal<sup>m</sup> risk adverse event.         If the most serious option(s) checked above are Minor risk, then this is a Minimal<sup>m</sup> risk adverse event.       • If the most serious option(s) checked above are Minor risk, then this is a Sentinel<sup>i</sup> adverse event.         If the most serious option(s) checked above are Minor risk, then this is a dimmal<sup>m</sup> risk adverse event.       • If the most serious option(s) checked above are Minor risk, then this is a Minimal<sup>m</sup> risk adverse event.         If the most serious option(s) checked above are formalitis is a defined as unanticipated restlessness or agitation in resp</td></t<> | No adverse outcome       • Unplanned hospitalisation<br>or escalation of care <sup>h</sup> • Death<br>• Permanent neurological deficit<br>• Pulmonary aspiration syndrome <sup>i</sup> • Other,<br>specify<br>below         ep 5: Assign a SEVERITY rating to the adverse event(s) associated with this sedation encounter.       • Pulmonary aspiration syndrome <sup>i</sup> • Other,<br>specify<br>below         ep 5: Assign a SEVERITY rating to the adverse event(s) associated with this sedation encounter.       • If there are any options checked in the Sentinel columns above, then this is a Sentinel <sup>i</sup> adverse event.       • If the most serious option(s) checked above are Moderate risk, then this is a Moderate <sup>k</sup> risk adverse event.         If the most serious option(s) checked above are Minor risk, then this is a Minor <sup>1</sup> risk adverse event.       • If the most serious option(s) checked above are Minor risk, then this is a Minimal <sup>m</sup> risk adverse event.         If the most serious option(s) checked above are Minor risk, then this is a Minimal <sup>m</sup> risk adverse event.       • If the most serious option(s) checked above are Minor risk, then this is a Minimal <sup>m</sup> risk adverse event.         If the most serious option(s) checked above are Minor risk, then this is a Minimal <sup>m</sup> risk adverse event.       • If the most serious option(s) checked above are Minor risk, then this is a Sentinel <sup>i</sup> adverse event.         If the most serious option(s) checked above are Minor risk, then this is a dimmal <sup>m</sup> risk adverse event.       • If the most serious option(s) checked above are Minor risk, then this is a Minimal <sup>m</sup> risk adverse event.         If the most serious option(s) checked above are formalitis is a defined as unanticipated restlessness or agitation in resp  |
| St<br>o<br>o<br>o<br>Ad<br>Foc<br>a.   | No adverse outcome       • Unplanned hospitalisation<br>or escalation of care <sup>h</sup> • Death<br>• Permanent neurological deficit<br>• Pulmonary aspiration syndrome <sup>i</sup> • Other,<br>specify<br>below         ep 5: Assign a SEVERITY rating to the adverse event(s) associated with this sedation encounter.       • Pulmonary aspiration syndrome <sup>i</sup> • Other,<br>specify<br>below         ep 5: Assign a SEVERITY rating to the adverse event(s) associated with this sedation encounter.       • Pulmonary aspiration syndrome <sup>i</sup> • Other,<br>specify<br>below         if there are any options checked in the Sentinel columns above, then this is a Sentinel <sup>i</sup> adverse event.       • If the most serious option(s) checked above are Moderate risk, then this is a Minor <sup>1</sup> risk adverse event.         If the most serious option(s) checked above are Minor risk, then this is a Minor <sup>1</sup> risk adverse event.       • If the most serious option(s) checked above are Minor risk, then this is a Minimal <sup>m</sup> risk adverse event.         If the most serious option(s) checked above are Minor risk, then this is a Minor <sup>1</sup> risk adverse event.       • If the most serious option(s) checked above are Minimal risk, then this is a Minimal <sup>m</sup> risk adverse event.         If the most serious option(s) checked above are Minimal risk, then this is a Sentinel <sup>i</sup> adverse event.       • If the most serious option(s) checked above are Minimal risk, then this is a Sentinel <sup>i</sup> adverse event.         If the most serious option(s) checked above are Minimal risk, then this is a Sentinel <sup>i</sup> adverse event.       • If the most serious option(s) checked above are Minimal risk, then this is a Sentinel <sup>i</sup> adverse event.         "Buttotical respiratory   |
|  | No adverse outcome       • Unplanned hospitalisation<br>or escalation of care <sup>h</sup> • Death<br>• Permanent neurological deficit<br>• Pulmonary aspiration syndromei       • Other,<br>specify<br>below         ep 5: Assign a SEVERITY rating to the adverse event(s) associated with this sedation encounter.       • Pulmonary aspiration syndromei       • Other,<br>specify<br>below         ep 5: Assign a SEVERITY rating to the adverse event(s) associated with this sedation encounter.       • Other,<br>specify<br>below         If there are any options checked in the Sentinel columns above, then this is a Sentinel <sup>1</sup> adverse event.       • Other,<br>specify<br>the most serious option(s) checked above are Moderate risk, then this is a Moderate <sup>k</sup> risk adverse event.         If the most serious option(s) checked above are Minor risk, then this is a Minorl <sup>1</sup> risk adverse event.       • Other,<br>specify<br>the most serious option(s) checked above are Minor risk, then this is a Minorl <sup>1</sup> risk adverse event.         If the most serious option(s) checked above are Minor risk, then this is a Minorl <sup>1</sup> risk adverse event.       • Other,<br>specify<br>the most serious option(s) checked above are Minor risk, then this is a Minorl <sup>1</sup> risk adverse event.         If the most serious option(s) checked above are Minor risk, then this is a Minorl <sup>1</sup> risk adverse event.       • Other,<br>specify<br>the most serious option(s) checked above are Minor risk, then this is a Minorl <sup>1</sup> risk adverse event.         If the most serious option(s) checked above are Minor risk, then this is a Minorl <sup>1</sup> risk adverse event.       • Other,<br>specify<br>depression that do not manifest clinically.         "Paradoxical respiratory depression" is defined as unanticipated restl  |

- k. "Moderate" adverse events are those that, while not sentinel, are serious enough to quickly endanger the patient if not promptly managed. Once clinically concluded, they warrant timely reporting within sedation care systems, and periodic peer scrutiny for continuous quality improvemet.
- I. "Minor" adverse events are those encountered periodically in most sedation settings, and that pose little threat given appropriate sedationist skills and monitoring.
- m. "Minimal" adverse events are those that alone present no danger of permanent harm to the patient.

Fig 1 World SIVA adverse sedation event-reporting tool.