

# Write good SAE narratives

Tell a story

Be concise but complete (not comprehensive)

- Include only the pertinent PMH and HPI
- Describe the event
- Describe the response
- Describe the outcome
- And say when each of those happened

Look for and respond to queries promptly

# How are SAE narratives used?

Medical safety monitor

FDA (occasionally)

DSMB

Study Leadership



# Example

Depressed level of consciousness

A 42 yo with epilepsy and prior TBI had status epilepticus, received lorazepam 4 mg, and was enrolled on 3/15/17 at 9:02PM. Seizures continued at 9:22PM and she received additional midazolam 5 mg. Seizures stopped. She remained sedated but was maintaining an airway at 10:02PM and was admitted to the ICU. She was endotracheally intubated in the ICU on 03/16/17 at 02:41 for airway protection due to continued decreased level of consciousness, and possibly respiratory depression. Extubated on 03/16/17 at 07:50 am without complication.

# Narrative template - intubation

A [age] year old with [concise relevant history, e.g. epilepsy] had status epilepticus, received [benzodiazepine, dose, route], and was enrolled on [date] at [time]. Seizures [stopped/continued]. [Additional treatment, dose, route, time, response]. Because of [continued seizures / persistent decreased consciousness / respiratory depression / hypoxia / hypercarbia / other], endotracheal intubation was performed at [time] with [induction and paralytic agents] and then sedated with [agent]. Admitted to the ICU. [Extubated [on date] [at time] / Remained intubated as of [date] because of [suspected etiology]]

# Another example

## Respiratory Depression

A 38 year old with a history of seizures, was found seizing and was enrolled on 9/1/2009 at 20:45 . The patient stopped convulsing after study drug administration. He subsequently underwent endotracheal intubation with etomidate and rocuronium for respiratory depression with hypoxia in the ED at 21:20. He was not seizing at the time of intubation, but was felt to have respiratory depression from the combination of alcohol intoxication and benzodiazepines. He was sedated with propofol and admitted to the ICU. He was subsequently extubated on 9/2/2009.

# Too much

35 y.o. male with a history of anxiety, bipolar affective disorder, schizophrenia, and previous seizure event thought to be EtOH related presented to enrolling center ED via EMS 2/8/17 at 20:47 with seizures. Seizure in route abated with 4mg midazolam IM EMS administered. On initial assessment patient was sedated, but responded to noxious stimuli. Sedation thought to be due to EtOH, versed, and post-ictal state. Labs and CT head ordered. In CT patient had repeat seizure. He was given midazolam 3 mg IM and was brought back to ER. He appeared to continue to be having seizure so additional midazolam 3 mg IV was given. Seizure appeared to resolve. Neurology consulted to ER. Patient return of seizures occurred at approximately 2240. He was given an additional lorazepam 2 mg IV. Seizure continued for 5 minutes so ESETT drug was given. Study drug infusion started at 23:01. During infusion, pt appeared to have aspiration event. Infusion completed and patient stopped seizing and withdrew from nailbed pressure. At 20 minute assessment he was still responding to noxious stimulation. He was intubated for airway protection due to apparent aspiration event. He was sedated with propofol post intubation. Pt was admitted to the ICU for further diagnosis and management. 60 minute assessment at 00:15 revealed pt was sedated but withdrew from nailbed pressure. On 2/10/17 about 13:15 he was electively extubated. 2/10/17 1900 many verbally aggressive outbursts noted. 2/11/17 09:03 patient left AMA, after psychiatric evaluation

# Too much - continued

~~35 y.o. male with a history of anxiety, bipolar affective disorder, schizophrenia, complex psychiatric history and previous seizure event thought to be EtOH-related and prior alcohol related seizures... presented to enrolling center ED via EMS 2/8/17 at 20:47 with seizures. Seizure in route abated with 4mg midazolam IM EMS administered. On initial assessment patient was sedated, but responded to noxious stimuli. Sedation thought to be due to EtOH, versed, and post ictal state. Labs and CT head ordered. In CT patient had repeat seizure. He was given midazolam 3 mg IM and was brought back to ER. He appeared to continue to be having seizure so additional midazolam 3 mg IV was given. Seizure appeared to resolve. Neurology consulted to ER. Patient return of seizures occurred at approximately 2240. He was given an additional lorazepam 2 mg IV. Seizure continued for 5 minutes so ESET drug was given. Study drug infusion started at 23:01. During infusion, pt appeared to have aspiration event.~~

~~...had stuttering status epilepticus, received midazolam 10 mg and lorazepam 2 mg in divided doses over 2 hours, and enrolled on 2/8/17 at 23:01 for study by an aspiration event and transient hypoxia. ....~~

# Too much - continued

~~Infusion completed and patient stopped seizing and withdrew from nailbed pressure. At 20 minute assessment he was still responding to noxious stimulation. He was intubated for airway protection due to apparent aspiration event.~~

~~He stopped seizing but remained poorly responsive. He was endotracheally intubated at 23:25 for airway protective and decreased level of consciousness and risk of further aspiration.~~

~~He was sedated with propofol post intubation. Pt was admitted to the ICU for further diagnosis and management. 60 minute assessment at 00:15 revealed pt was sedated but withdrew from nailbed pressure. He was sedated with propofol and admitted to ICU. Normal CXR and no sequelae of aspiration on 2/9/17.~~

~~On 2/10/17 about 13:15 he was electively extubated. 2/10/17 1900 many verbally aggressive outbursts noted. 2/11/17 09:03 patient left AMA, after psychiatric evaluation  
Extubated on 2/10/17.~~





# Too much - resolution

35 y.o. male with a history of anxiety, bipolar affective disorder, schizophrenia, and previous seizure event thought to be EtOH related presented to enrolling center ED via EMS 2/8/17 at 20:47 with seizures. Seizure in route abated with 4mg midazolam IM EMS administered. On initial assessment patient was sedated, but responded to noxious stimuli. Sedation thought to be due to EtOH, versed, and post-ictal state. Labs and CT head ordered. In CT patient had repeat seizure. He was given midazolam 3 mg IM and was brought back to ER. He appeared to continue to be having seizure so additional midazolam 3 mg IV was given. Seizure appeared to resolve. Neurology consulted to ER. Patient return of seizures occurred at approximately 2240. He was given an additional lorazepam 2 mg IV. Seizure continued for 5 minutes so ESETT drug was given. Study drug infusion started at 23:01. During infusion, pt appeared to have aspiration event. Infusion completed and patient stopped seizing and withdrew from nailed pressure. At 20 minute assessment he was still responding to noxious stimulation. He was intubated for airway protection due to apparent aspiration event. He was sedated with propofol post intubation. Pt was admitted to the ICU for further diagnosis and management. 60 minute assessment at 00:15 revealed pt was sedated but withdrew from nailed pressure. On 2/10/17 about 13:15 he was electively extubated. 2/10/17 1900 many verbally aggressive outbursts noted. 2/11/17 09:03 patient left AMA, after psychiatric evaluation



A 35 yo with complex psychiatric history and prior alcohol related seizures had stuttering status epilepticus, received midazolam 10 mg and lorazepam 2 mg in divided doses over 2 hours, and enrolled on 2/8/17 at 23:01, followed by an aspiration event and transient hypoxia. He stopped seizing but remained poorly responsive. He was endotracheally intubated at 23:25 for airway protective and decreased level of consciousness and risk of further aspiration. He was sedated with propofol and admitted to ICU. Normal CXR and no sequelae of aspiration on 2/9/17. Extubated on 2/10/17.

# Not enough

- Blood culture positive for beta hemolytic strep, left peripheral line. Patient started Levaquin 750 mg oral tablet qd x 10 days

# Not enough

- ~~Blood culture positive for beta hemolytic strep, left peripheral line. Patient started Levaquin 750 mg oral tablet qd x 10 days~~
- A 42 yo with epilepsy and prior TBI was enrolled on 3/15/17 at 9:02PM. On [date?] she had fever, leukocytosis, and underwent a workup for an infectious source. Blood culture grew strep agalactiae sensitive to ceftriaxone and levofloxacin, but no other source was found. She was treated with ceftriaxone IV x 4 days, and levofloxacin PO x 10 days, and had no further fevers.

# Style points

- Use generic drug names
- Use a spell checker
- Have the site PI read critically





*“I just have to create a few loose ends for other people to clear up, and then I can out of here.”*



**Established  
Status  
Epilepticus  
Treatment  
Trial**