Methods

This study was approved by the University of Washington Human Subjects Committee (Applications #47317 and 43939), which waived the requirement for written informed consent. This article adheres to the Consolidated Standards of Reporting Trials (CONSORT), adhering to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist for observational studies.[1] The project was initiated by the SASM Death and Near Miss Registry (OSA Registry) Committee, which developed the case report form. Case report forms were publicly available on the Closed Claims Project (CCP) website from 2014 to 2016. To elicit cases, the project was publicized through the CCP website, by newsletter articles[2-7] and public presentations to elicit case reporting. Cases were also collected from anesthesiologist malpractice insurers by CCP anesthesiologist-reviewers during 2014-2016 in conjunction with regular data collection for the CCP and passed through to the OSA Registry. In addition, a query of the CCP database was conducted to capture previously collected cases in that project database that met OSA Registry inclusion criteria and had sufficient details to complete the OSA case report form. Cases were collected without patient, physician, or hospital identifiers. Case submission was permanently closed at the end of 2016.

There were three sets of registry case submission criteria related to patients, events, and outcomes. Patient Inclusion criteria were age ≥18 years at the time of the event and diagnosed or screened at high risk of OSA. Inclusion criteria for events were occurrence in 1993 or later, within 30 days of surgery, and deemed to be related to OSA. Outcome inclusion criteria were unanticipated death, brain damage diagnosed by

a neurologist, or other critical events (e.g. urgent or emergent transfer to an intensive care unit (ICU), respiratory arrest, Code Blue or Advanced Cardiac Life Support protocol) that occurred within 30 days of surgery and was determined to be related to OSA. Cases were required to meet all patient, event, and outcome criteria for inclusion in the registry. There were no exclusion criteria. The current analysis includes events that occurred during recovery from anesthesia (after end of anesthesia care) or later. Events that occurred during emergence from general anesthesia before transfer of the patient to recovery (n=6) or during sedation or monitored anesthesia care (n= 3) were not included.

The case report form included demographics; medical history (comorbidities); OSA history; medications; procedure and anesthesia details; post anesthesia care unit, ward and ICU details; event details; autopsy results; and a narrative summary of events. A copy of the case report packet is included as supplemental digital content (Supplemental Digital Content File 2).

Definition of variables

The primary outcomes were defined prior to data analysis as 1) death or brain damage vs. 2) other critical events (Code Blue, respiratory arrest, urgent transfer to ICU).

OSA diagnosis was defined as diagnosis by polysomnogram. High risk of OSA was defined as results from screening tools such as STOP Questionnaire (STOP), STOP-Bang Questionnaire (STOP-Bang), or Berlin Questionnaire,[8,9] or identification as high risk of OSA from patient history. Mild OSA was defined as Apnea-Hypopnea Index (AHI) 5 - <15, moderate OSA as AHI 15 - 30, and severe OSA as AHI >30 events per

hour. [10] Respiratory arrest was defined as prolonged apnea not responsive to vigorous stimulation (see Supplemental Digital Content File 2). Administration of naloxone in the absence of respiratory arrest as defined above did not meet study criteria for inclusion. Cases with death or brain damage were combined for analysis and comparison to all other cases ("other critical events").

Comorbidities were grouped as cardiovascular or pulmonary. Cardiovascular comorbidities included coronary artery disease, cardiac arrhythmias, hypertension, congestive heart failure, and miscellaneous cardiovascular diseases. Pulmonary comorbidities included chronic obstructive pulmonary disease, asthma, airway disease (tumors or obstruction), and miscellaneous severe pulmonary diseases. Other comorbidities included diabetes mellitus, renal disease, cerebrovascular disease, peripheral artery disease, and substance abuse. Cardiovascular and pulmonary comorbidities were combined for analysis.

Opioids taken by the patient or administered within 24 hours of the event were calculated in oral morphine milligram equivalents (MME). Opioids administered intravenously (IV) were first converted to IV morphine equivalents, then the result converted to oral morphine equivalents. [11] Neuraxial administration of morphine was converted as 100 mg IV morphine = 10 mg epidural morphine = 1 mg spinal morphine.[12] Fentanyl administered via epidural route was considered equivalent to IV fentanyl for conversion to MME.[13] Epidural hydromorphone was converted as 0.2 mg epidural = 1 mg IV,[14] and then converted to MME as above. For cases with missing data, a range was calculated based on available data, infusion settings and timing. Total MME for each case was recorded as known values if all opioid administrations were reported and

ranges when data was partially unknown. Ranges were converted to estimates using three methods: 1) minimum using the lowest estimated MME; 2) maximum using highest estimated MME; and 3) average using average of estimated MME values. For minimum estimates, most cases had a known opioid administration plus statements of potentially additional opioids from home medications, possible additional bolus administrations, or were missing data from some locations such as the post anesthesia care unit (PACU). Maximum estimates used the maximum MME that might have been administered based on device settings or orders. Average took the arithmetic mean between minimum and maximum estimates.

Non-opioids with potential to suppress ventilatory drive (referred to as "sedatives") were tabulated by drug class: benzodiazepines, antihistamines, other drugs with sedating properties (including non-benzodiazepine sedatives; pain adjuvants; anticonvulsants; adrenergic drugs; dopamine and serotonin receptor antagonists; and other anti-nausea drugs), and non-opioid pain medications. Inhalational anesthetics, propofol and nitrous oxide administered during the procedure were not included. Alcohol and marijuana use were also tabulated. Only drugs within 24 hours of the event were included.

An event was classified as monitored if any intermittent or continuous respiratory monitoring (pulse oximetry, chest impedance, and/or end tidal carbon dioxide) was reported as in place at the time of the event. The OSA-related event was classified as witnessed if this was explicitly reported on the case report form. In the case of missing data, cases with an outcome of urgent or emergent transfer to an ICU after naloxone administration in the absence of respiratory arrest were classified as witnessed.

OSA Event Contribution Assessment

All cases were adjudicated by three of the physician-authors (NB, FC, KD) for inclusion criteria. Each of these authors independently assessed the contribution of OSA to the event using a 6-point scale ranging from 1=definitely no contribution to 6=definite contribution. A score of 4 was defined as more likely than not (>50:50 but close call) and 5 = probable contribution. Prior to evaluating each case, the authors were instructed that cases scored 1-3 would not be included in the final analysis and cases scored 4-6 would be included as OSA having more likely than not contributed to the event. Agreement by 2 of the 3 authors on the collapsed scoring categories (1-3 vs 4-6) was required for classification.

Statistical analysis

Factors associated with outcomes were compared by chi square, Fisher exact test (for 2x2 tables or larger tables with expected cell counts <5 for 25% or more cells), two-sample unpaired t-test, and Mann Whitney U-test (for variables with non-normal distributions) with $p<0.05$ the criterion for statistical significance. For tables greater than 2x2 but expected cell counts of <5 in >25% of cells, Fisher exact test with Monte Carlo significance was calculated based on 10,000 randomly sampled tables. Odds ratios (OR) and their 95% confidence intervals (CI) were calculated by logistic regression. All statistical analysis employed IBM SPSS Statistics 26 (International Business Machines Corporation, Armonk, New York). The sample size was based on available data; no *a priori* power analysis was conducted.

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Obstructive Sleep Apnea Registry

Packet for Health Care Providers

Submitting Case Report Forms

For Health Care Professionals Completing Case Report Forms

OSA Death and Near Miss Registry

Sponsored by the Society of Anesthesia and Sleep Medicine (SASM)
and the Anesthesia Quality Institute (AQI)

Contents:

- -Instructions
- -Case Report Cover Sheet
- -Case Report Form

For questions, comments, requests for additional case report materials, or to submit cases, contact:

Karen Posner, Ph.D.
Department of Anesthesiology and Pain Medicine
University of Washington
Box 356540
Seattle, WA 98195-6540
U.S.A.
Telephone: 206-616-2630
FAX: 206-543-2958
Email: posner@uw.edu

Please note that we cannot guarantee the confidentiality of any information sent via email.

Instructions for the Obstructive Sleep Apnea Registry

Goals of Database:

1. Retrospectively identify common themes or factors associated with unanticipated perioperative deaths (and near misses) in patients with obstructive sleep apnea (OSA)
2. Attempt to provide insight regarding the scope of the problem
3. Identify the level of monitoring used when deaths (or nears misses) occurred
4. Determine if the data can in any way provide a better understanding into why the adverse events occurred, and what (if anything) can be done to limit these adverse events.
5. Provide insight regarding how to best construct prospective studies to answer many of the questions surrounding the best practices for care of patients with OSA during the perioperative period.
6. Determine if any useful information can be gleaned from autopsy information.

Before completing the case report, check that your case meets <u>all four</u> (4) inclusion criteria specified below:

1. Patient was 18 years or older at the time of the event.
2. Event occurred in 1993 or later.
3. Patient was diagnosed or suspected to have OSA.
    - □ Diagnosed with OSA by polysomnogram (PSG)
    - □ Identified as "*high risk" for OSA by screening tool such as STOP, STOP BANG, or Berlin Questionnaire
    - □ Identified as "*high risk" for OSA by history
    - * Note: even if OSA identified/suspected after the critical event
4. At least one of the following events <u>suspected to be related to OSA</u> must have occurred.
    - □ Unanticipated death within 30 days of surgery suspected to be <u>related to OSA</u>
    - □ Brain injury (diagnosed by a neurologist) within 30 days of surgery suspected to be related to an adverse event <u>related to OSA</u>
    - □ Event or outcome within 30 days of surgery suspected to be <u>related to OSA</u>
        - □ Urgent/Emergent transfer to ICU from general ward due to respiratory distress
        - □ Respiratory Arrest (prolonged apnea not responsive to vigorous stimulation)
        - □ Code Blue or ACLS protocol

IF NONE OF THE ABOVE APPLY – THE CASE DOES NOT MEET INCLUSION CRITERIA AND SHOULD NOT BE SUBMITTED.

Case Report Submission: Please complete the Case Report Cover Sheet. Print legibly or type the requested identifying information for the person submitting the case report on the Case Report Cover Sheet. *This information will be separated from the case report form.* It will be used only for creation of a mailing list for contacting participants if necessary. Case report forms should *not* contain names of patients, physicians, hospitals, or any other health care entities. Completed case report forms should be sent to the Registry Coordinating Office:

Karen Posner, Ph.D.
Department of Anesthesiology and Pain Medicine
University of Washington
Box 356540
Seattle, WA 98195-6540

Questions about submission of case reports or study procedures should be addressed to Dr. Posner at the above address. Dr. Posner can also be contacted by telephone (206-616-2630), FAX (206-543-2958) or electronic mail (posner@uw.edu). Please note that we cannot guarantee the confidentiality of any information sent via e-mail.

Confidentiality of Case Reports: Each case report will have a unique *coded* study identifier for the purpose of detecting duplicate submission of case reports; this coded study ID will not enable the research team to identify the source of the case report or persons or institutions involved in the case. Do *NOT* include identifying information (names of patients, care providers, hospitals, etc.) on the case report form.

IRB (Human Subjects) Review: The procedures for coordination of the Obstructive Sleep Apnea Registry have been reviewed and approved by the University of Washington Human Subjects Review Committee. This approval includes collection of cases submitted without identification of patients or health care providers involved in the cases. The University of Washington IRB does not require individual sites that release health information to obtain IRB review and approval because the release of health information does not engage those institutions in this research activity. Although, if you have questions about the need of IRB approval at your institution, you should seek advice from your institution's IRB.

If you have any questions or need assistance, contact the Dr. Posner at the Registry Coordinating Office (see above for contact information).

HIPPA: The University of Washington IRB has issued a waiver of HIPAA authorization for the disclosure and use of protected health information for this research study. However, it is your responsibility to see if the Privacy Board at your institution will need to issue their own waiver of HIPAA authorization, or if they will require you to obtain authorization from the patient before abstracting information for submission to the Obstructive Sleep Apnea Registry. If you have any questions or need assistance, contact Dr. Posner at the Registry Coordinating Office (see above for contact information).

Coded Study ID: Create a 7-digit case report identifier using the following algorithm (example below):

1	2	3	4	5	6	7

Digit	Information from Medical Record
1	First letter of patient's last name
2-3	Month of surgery (01-12)
4-5	Day of birth (01-31)
6-7	Last 2 letters of hospital city

Example of ID Creation

Medical Record Data		Algorithm	Output
Patient Name	**Mincer**	First letter of patient's last name	**M**
Date of Surgery	**1/21/99**	Month of surgery (01-12)	**01**
Date of Birth	**7/19/66**	Day of birth (01-31)	**19**
Hospital City	**Seattle**	Last 2 letters of hospital city	**LE**

Case Report ID

M	0	1	1	9	L	E
1	*2*	*3*	*4*	*5*	*6*	*7*

Do *NOT* include any other identifying information (names of patients, care providers, hospitals, etc.) on the case report.

Sources of Information for the Obstructive Sleep Apnea Registry Case Report

You will need access to the medical records to complete the case report. The following medical records should contain most of the required information.

- History and physical
- PSG or OSA screening
- Pre-anesthesia assessment
- Anesthesia record
- PACU record
- Nursing and post-op records
- Autopsy report

Use any medical records, notes, narrative summaries, consultant reports, risk management or other available documents to complete the case report. Other sources of information (in addition to those listed) may be used to supplement the medical record in order to complete the case report.

Obstructive Sleep Apnea Registry
Case Report Cover Sheet

When your case is received by the Obstructive Sleep Apnea Registry Coordinating Center, this cover sheet will be detached from the case so that it will not be possible to identify the source of any individual case report. This identifying information will be used to acknowledge receipt of the report and to create a mailing list of reporters for future communication.

Your Name: _____

If Professional Status: 0 Anesthesiologist 0 CRNA
0 Risk Manager or QI Staff

0 Surgeon (specialty)_____

0 Other (specify)_____

Your Hospital (optional): _____

Complete Mailing Address: _____

_____

_____

_____

Email: _____

Return this sheet with completed case report to:

Obstructive Sleep Apnea Registry
Karen Posner, Ph.D.
Department of Anesthesiology & Pain Medicine
University of Washington
Box 356540
Seattle, WA 98195-6540

Obstructive Sleep Apnea Death and "Near Miss" Database

Case Report ID: | | | | | | | |

IMPORTANT: See instructions for creating a coded case report ID

Form Completed By: ○ **Anesthesiologist** ○ **Surgeon** ○ **Risk Manager** ○ **Other** _____

SECTION 1: INSTRUCTIONS-INCLUSION/EXCLUSION CRITERIA

Before completing the case report, check that your case meets all four (4) inclusion criteria specified below

1. Patient was 18 years or older at the time of the event: ☐ Yes

2. Event occurred in 1993 or later: ☐ Yes

3. Patient was diagnosed or suspected to have OSA (check all that apply):

☐ Diagnosed with OSA by polysomnogram (PSG)

☐ Identified as "*high risk" for OSA by screening tool such as STOP, STOP BANG, or Berlin Questionnaire (other _____)

☐ Identified as "*high risk" for OSA by history (describe: _____ _____)

* Note: even if OSA identified/suspected after the critical event

4. At least one of the following events suspected to be related to OSA must have occurred (check all that apply):

☐ Unanticipated death within 30 days of surgery suspected to be related to OSA

☐ Brain Injury* (diagnosed by a neurologist) within 30 days of surgery suspected to be related to an adverse event related to OSA.
(*Please indicate severity of brain damage)

- ☐ A return to normal cerebral function and normal living (CPC-1*)
- ☐ Cerebral disability but sufficient function for independent ADL (CPC-2)
- ☐ Severe Disability, limited cognition, inability to carry out independent existence (CPC-3)
- ☐ Coma or vegetative state (CPC-4)
- ☐ Brain Death (CPC-5)

(*CPC = Cerebral performance category)

☐ **E**vent or outcome within 30 days of surgery suspected to be related to OSA (check all that apply)

- ☐ Urgent/Emergent transfer to ICU from general ward due to respiratory distress
- ☐ Respiratory Arrest (prolonged apnea not responsive to vigorous stimulation)
- ☐ Code Blue or ACLS protocol

IF NONE OF THE ABOVE APPLY – THE CASE DOES NOT MEET INCLUSION CRITERIA

Version: 3/13/2015

SECTION 1: CONTINUED

If your case meets *all four* inclusion criteria, indicate what records you are using to complete the case report:

Medical Records:

- ☐ History and Physical
- ☐ PSG results
- ☐ OSA screening results
- ☐ Pre-anesthesia assessment
- ☐ Anesthesia record
- ☐ Surgeon's operative note
- ☐ PACU record
- ☐ Nursing and Post-Op Records
- ☐ X-rays, lab tests, toxicology reports
- ☐ Discharge summary
- ☐ Follow-up evaluation by medical consultants or primary caregiver

Other Records:

- ☐ QA/QI review or root cause analysis
- ☐ Autopsy record
- ☐ Deposition transcripts or summaries
- ☐ Narratives from involved parties
- ☐ Expert or peer reviews
- ☐ Malpractice claims manager evaluation, notes or summary
- ☐ Attorney evaluation, notes or summary

Other:

- ☐ Other documents

(specify) _____

SECTION 2: PATIENT INFORMATION

1. Age (yrs) _____
2. Sex ☐ Male ☐ Female
3. Height _____ (inches) _____ Cm
4. Weight _____ (pounds) _____ Kg
5. BMI _____
6. ASA Physical Status ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ Unknown
7. Emergency ☐ Yes ☐ No
8. Race
   - ☐ Black/African-American
   - ☐ White/Caucasian
   - ☐ Latino/Hispanic
   - ☐ Native American
   - ☐ Asian
   - ☐ Other _____
   - ☐ Unknown

SECTION 3: PAST MEDICAL HISTORY

Pre-existing conditions – Check all that apply **IF NONE, CHECK HERE** ☐

1. Diabetes Mellitus ☐
   - -Insulin dependent?
     - ☐ Yes
     - ☐ No
2. Hypertension ☐
3. COPD ☐
4. Atrial Fibrillation/Flutter ☐
   - -Check if
     - ☐ Current
     - ☐ Past
5. Congestive Heart Failure ☐
6. CAD ☐
   - ☐ Previous MI
   - ☐ PTCA
   - ☐ CABG
7. Renal Disease ☐
   - -Dialysis?
     - ☐ Yes
     - ☐ No
8. Peripheral Vascular Disease ☐
9. Cerebrovascular Disease ☐
   - ☐ Carotid Endarterectomy
   - ☐ Previous CVA/Stroke
   - ☐ TIA
10. Substance Abuse ☐
    - ☐ Alcohol
    - ☐ Drugs

    Specify:_____

    _____
11. Please specify any other significant medical history:

    _____

    _____

SECTION 4: OSA HISTORY

1. OSA diagnosed (section 1.1) or suspected (section 1.2)

1.1. Diagnosed ☐ Yes

☐ Mild (AHI 5-15) ☐ Moderate (AHI 15-30) ☐ Severe (AHI > 30)

☐ PSG Results: AHI _____

-Sleep Study Type

☐ Study type unknown

☐ Type 1 = Laboratory PSG

☐ Type 2 = Home PSG

☐ Type 3 or 4 = Home limited channel studies

☐ Other :_____

OR

1.2. OSA Suspected ☐ Yes, by:

☐ STOP

☐ STOP-BANG

☐ Berlin Questionnaire

☐ Other Questionnaire_____

☐ History

For each device, check if prescribed or not. If prescribed, list preoperative prescribed settings for that device

2. CPAP prescribed ☐ or ☐ NOT prescribed: CPAP settings _____

-Did patient use CPAP as prescribed ☐ Most of the time

☐ Sometimes

☐ Rarely/not at all

☐ Unknown

Section 4: OSA HISTORY CONTINUED

3. Bilevel Pressure prescribed ☐ or ☐ NOT prescribed: bilevel pressure settings _____

-Did patient use Bilevel Pressure as prescribed
- ☐ Most of the time
- ☐ Sometimes
- ☐ Rarely/not at all
- ☐ Unknown

4. Home oxygen therapy prescribed ☐ or ☐ NOT prescribed: Oxygen FiO_2 _____

-Did patient use O_2 as prescribed
- ☐ Most of the time
- ☐ Sometimes
- ☐ Rarely/not at all
- ☐ Unknown

5. Oral appliance device prescribed ☐ or ☐ NOT prescribed

-Did patient use the appliance as prescribed
- ☐ Most of the time
- ☐ Sometimes
- ☐ Rarely/not at all
- ☐ Unknown

6. Diagnosis of Obesity Hypoventilation Syndrome

☐ Yes ☐ No ☐ Unknown

-If Obesity Hypoventilation Syndrome

-RA arterial blood gas: pH____ PCO_2____ PO_2____ Saturation____

-(Specify FiO_2 if supplemental oxygen in use _____)

-Serum bicarbonate level _____

7. Previous OSA or related surgery

- ☐ Bariatric surgery (specify procedure_____)
- ☐ Uvulopalatopharyngoplasty (UPPP)
- ☐ Tonsillectomy and/or adenoidectomy (T&A)
- ☐ Other OSA procedures (list)_____
- ☐ NONE

SECTION 5: HOME /PREOPERATIVE MEDICATIONS

Home Medication History – Medications taken within the last 24 hours PRECEDING the surgery or procedure.

1. Was the patient prescribed or taking any OPIOIDS preoperatively (at home or in the hospital)?

☐ Yes

☐ No

-If yes, please list (list drug names even if other details are unavailable)

Drug Name	Dose	Frequency	Time of last dose before procedure (hours)

2. Was the patient prescribed or taking any non-opioid medications or other substances that may depress ventilatory drive (VD) preoperatively? Include prescription or non-prescription medications, alcohol and illicit drugs. Drugs that may depress VD include sedatives, anti-emetics, benzodiazepines, hypnotics, butyrophenones, phenothiazines, antihistamines, etc.

☐ Yes

☐ No

-If yes, please list

Drug Name	Dose	Frequency	Time of last dose before procedure (hours)

SECTION 6: PROCEDURE OVERVIEW

1. Surgical (or non-surgical) procedure_____

2. Date of procedure Day_____ Month_____ Year_____

3. Indicate planned setting of surgery ☐ Inpatient ☐ Ambulatory ☐ Office/Clinic

4. Anesthesia Start Time_____ Anesthesia End Time_____ Anesthesia Total Time_____ (mins)
   (use 24hr clock)

5. Anesthetic technique (check all that apply)

   ☐ General anesthesia (Complete GA Section)

   ☐ Regional anesthesia/peripheral nerve block (Complete RA/PNB Section)

   ☐ Sedation (Complete MAC/Sedation Section)

SECTION 7: GENERAL ANESTHESIA DETAILS

If no GA, then CHECK HERE ☐ and skip this section

1. Airway management
   - ☐ LMA
   - ☐ Intubation
   - ☐ Trach
   - ☐ Other_____

2. Difficult Intubation* recorded (*Grade III or IV laryngoscopic view, or 3 or more attempts)
   - ☐ Yes (comment in narrative, Section 14)
   - ☐ No

3. Laryngoscopy grade
   - ☐ I
   - ☐ II
   - ☐ III
   - ☐ IV
   - ☐ Unknown

4. Inhaled agent utilized
   - ☐ Isoflurane
   - ☐ Desflurane
   - ☐ Sevoflurane
   - ☐ Halothane
   - ☐ Enflurane

5. Other general anesthetic agents (TIVA)
   - ☐ Propofol
   - ☐ Other agent (Specify)
     _____

Section 7: GA DETAILS CONTINUED

6. Intraoperative opioids used ☐ Yes ☐ No

(if yes: specify name of each, total doses, and time of last dose)

Name	Total Dose	Time of last dose

7. Intraoperative sedatives/hypnotic used ☐ Yes ☐ No

(if yes: specify name of each, total doses, and time of last dose)

Name	Total Dose	Time of last dose

SECTION 8: REGIONAL ANESTHESIA AND PERIPHERAL NERVE BLOCK DETAILS

If none, CHECK HERE ☐ and skip this section

1. Type of regional/peripheral nerve block _____

2. Agents in block:
   -Local anesthetics_____ or ☐ None
   -Opioids_____ or ☐ None

SECTION 9: MAC/SEDATION DETAILS

If none, CHECK HERE ☐ and skip this section

1. Sedation Start Time_____ Sedation End Time_____ Sedation Total Time_____ (mins)
   (use 24hr clock)

2. Please check all medications used during sedation and indicate dosage

Name of Sedative/Opioid Used	Total Dose (If available) (include units)
☐ Propofol bolus	
☐ Propofol infusion	
☐ Benzodiazepine_____	
☐ Opioids_____	
☐ Other_____	

3. Was mask ventilation required during sedation ☐ Yes ☐ No

4. Was naloxone required during or following sedation for respiratory depression ☐ Yes ☐ No

5. Was sidestream end-tidal CO_2 monitoring used during sedation ☐ Yes ☐ No

SECTION 10: POST ANESTHESIA CARE UNIT (PACU) COURSE

1. PACU admission time _____(use 24 hour clock 0:00 – 24:59)

2. PACU admission vital signs (if available)
   Temp_____ HR_____ BP_____ RR_____ Oxygen Saturation_____ FiO_2_____

3. PACU Admission and Discharge Scores
   - PACU Admission Aldrete Score _____
   -PACU Discharge Aldrete Score _____
   Note: If using PACU scoring system "OTHER" than Aldrete, please indicate
   -Name of "OTHER" PACU scoring system _____
   -"OTHER" PACU admission score _____
   -"OTHER" PACU discharge score _____

4. Were apneic episodes recorded in PACU
   ☐ No
   ☐ Yes
   -Total number of apneic episodes recorded_____
   -If number is unknown, were they described as frequent ☐ Yes ☐ No

5. Lowest oxygen saturation recorded in PACU_____

6. Total number of oxygen saturation recordings less than 90% in PACU_____

7. Lowest respiratory rate recorded in PACU_____

8. Supplemental O_2 ☐ Yes ☐ No
   -Type_____

9. Was positive pressure therapy (CPAP or Bi-level pressure support) initiated in PACU
   ☐ Yes, Please list type and settings _____
   ☐ No

Section 10: PACU COURSE CONTINUED

10. PACU Medications: Include all opioids and other medications that potentially suppress ventilatory drive (e.g. sedatives, anti-emetics, benzodiazepines, hypnotics, butyrophenones, phenothiazines, antihistamines, etc.)

Time Administered	Drug name	Route of administration (oral, buccal, patch, IV, IM, PCA, PCEA, epidural, PNB)	Dose (if PCA or PCEA, provide bolus, basal rate, & lock-out)

* Attach additional sheets if needed

11. Please describe any adverse respiratory or cardiac events occurring in the PACU _____

_____

12. PACU discharge time _____ (if unavailable, estimated duration of PACU stay)_____mins

13. Disposition upon discharge from PACU

- ☐ General floor with no special monitoring
- ☐ General floor with special monitoring (check all that apply)
  - ☐ Monitoring includes intermittent (spot) pulse oximetry
  - ☐ Monitoring includes continuous pulse oximetry
  - ☐ Monitoring includes CO_2 monitoring
  - ☐ Monitoring includes other monitoring (specify)_____
- ☐ Step down with continuous pulse oximetry
- ☐ Intensive care unit
- ☐ Home (skip to Section 12: Discharge Medications)

SECTION 11: GENERAL WARD/STEP DOWN/ICU COURSE

If patient did not spend time on ward, step down unit or ICU, CHECK HERE ☐ and skip this section

1. Specify ☐ Ward ☐ Step Down ☐ ICU

2. Were apneic episodes noted ☐ Yes ☐ No

3. Lowest oxygen saturation recorded _____

4. Lowest respiratory rate recorded _____

5. Total number of oxygen saturations recorded at < 90% _____

6. Postoperative medications: Include all opioids and other medications that potentially suppress ventilatory drive (e.g. sedatives, anti-emetics, opioids benzodiazepines, hypnotics, butyrophenones, phenothiazines, antihistamines, etc.) – include medications for pain management **during the last 24 hours on the ward/unit (Excluding medications administered in the OR or PACU)**

Time administered	Drug name	Route of administration (oral, buccal, patch, IV, IM, PCA, PCEA, epidural, PNB)	Dose (if PCA or PCEA, provide bolus, basal rate, & lock-out)

* Attach additional sheets if needed

Section 11: WARD, STEP DOWN, ICU CONTINUED

7. Please describe any respiratory/cardiac event(s) occurring while on the general ward, step down, or in the ICU

_____

_____

_____

_____

_____

SECTION 12: DISCHARGE MEDICATIONS

If patient was not discharged, CHECK HERE ☐ and skip this section

1. List all discharge medications ordered for the patient. Include all opioids and other medications that potentially suppress ventilatory drive (e.g. sedatives, anti-emetics, benzodiazepines, hypnotics, butyrophenones, phenothiazines, antihistamines, etc.)

Drug Name	Route of Administration	Dose	Amount Prescribed

***** Attach additional sheets if needed

SECTION 13: EVENT DETAILS

1. Was there a perioperative OSA patient care protocol in place at the institution at the time of the critical event
   - ☐ Yes
     - -If Yes, was the perioperative OSA protocol properly followed
       - ☐ Yes
       - ☐ No
       - ☐ Unknown
   - ☐ No
   - ☐ Unknown

2. Location of the critical event
   - ☐ Intraop
   - ☐ PACU
   - ☐ General ward
   - ☐ Step down
   - ☐ ICU
   - ☐ Home
     - ☐ Bed
     - ☐ Couch
     - ☐ Recliner

3. Date of the critical event Day_____ Month_____ Year_____

4. Was the event witnessed ☐ Yes ☐ No

5. Time of critical event (use 24 hour clock) _____ (provide best estimate if unwitnessed)

6. Was the patient intubated/re-intubated in response to the event ☐ Yes ☐ No

7. Was mask ventilation initiated ☐ Yes ☐ No

8. Was naloxone administered for respiratory distress/apnea ☐ Yes ☐ No

Section 13: EVENT DETAILS CONTINUED

9. Monitoring present at the time of the critical event

- ☐ No special monitoring
- ☐ Intermittent (spot) pulse oximetry
- ☐ Continuous pulse oximetry with no central monitoring
- ☐ Continuous pulse oximetry with central monitoring
- ☐ Carbon dioxide (CO_2) monitoring
- ☐ Continuous pulse oximetry AND CO_2 monitoring
- ☐ Chest impedance monitoring

10. Was the patient receiving supplemental oxygen at the time of the event ☐ Yes ☐ No

-If yes, list supplemental flow rate or FiO_2 in use at time of event (e.g. 2L by nasal cannula, 40% by face mask)

_____

11. Was positive pressure device (e.g. CPAP, bilevel pressure) in use at time of event ☐ Yes ☐ No

-If yes, was positive pressure device from ☐ Patient ☐ Medical facility

-Positive Pressure Device in use at time of event ☐ CPAP ☐ Bilevel pressure

-Was positive pressure device set with preop prescribed settings ☐ Yes ☐ No ☐ N/A

-Settings of device at time of event_____

12. Was the patient receiving parenteral (I.V.) opioids at the time ☐ Yes ☐ No

13. Was the patient receiving PCA at the time of the critical event ☐ Yes ☐ No

-If yes, did it contain opioids ☐ Yes ☐ No

-If yes, did it contain a local anesthetic agent ☐ Yes ☐ No

-If yes, did the PCA have a basal rate ☐ Yes ☐ No

14. Was the patient receiving PO (oral) opioids at the time of the critical event

- ☐ Yes, time of last dose_____
- ☐ No

15. Was the patient receiving opioids by any other method immediately prior to the critical event? (e.g. skin patch, buccal, IM, injection, etc)

-Opioid_____ Route_____ Dose_____

Section 13: EVENT DETAILS CONTINUED

16. Was the patient receiving sedatives or other medications (e.g. anti-emetics, benzodiazepines, hypnotics, butyrophenones, phenothiazines, antihistamines, etc.) that potentially suppress ventilatory drive at the time of the critical event

- ☐ Yes
- ☐ No

-If yes, please list

Drug Name	Dose	Time of Last Dose

17. If this event occurred after discharge estimate the total dose of opioid and non-opioid medications received in the **24 hours** prior to the critical event

Drug Name	Dose	Time of Last Dose

Section 13: EVENT DETAILS CONTINUED

18. Nursing/Physician notes preceding critical event

Please document the time, personnel involved, and summarize the assessments/comments of the medical personnel during the two visits immediately **prior to** the critical event (do not include the visit that discovered the patient obtunded). If only vital signs were recorded and not comments made, please enter time of last vital signs and enter the vital signs in the summary/comments section.
If the event occurred after discharge, provide the last two assessments from the hospital.

Assessment #1:

Time prior to event = _____ mins. By ☐ Nurse ☐ Physician ☐ Other_____(specify)

Summary/Comments_____

_____

_____

_____

Assessment #2:

Time prior to event = _____ mins. By ☐ Nurse ☐ Physician ☐ Other_____(specify)

Summary/Comments_____

_____

_____

_____

SECTION 14: AUTOPSY RESULTS

1. Was an autopsy performed ☐ Yes ☐ No

-If No, Check reason

- ☐ Patient did not die
- ☐ Patient died, but no autopsy performed or don't know if autopsy performed
- ☐ Patient died, but autopsy results unavailable

2. Official cause of death_____

3. Autopsy findings_____

_____

_____

4. Lung weights if recorded_____

5. Did gross exam reveal lung exudate ☐ Yes ☐ No

6. Did microscopic exam reveal evidence of interstitial/alveolar edema ☐ Yes ☐ No

7. Please make sure to share all comments related to the lungs_____

_____

_____

_____

_____

_____

SECTION 15: NARRATIVE SUMMARY

Summary of critical event (or near miss): Please provide a detailed narrative description of the sequence of events, details not otherwise included on this form, including factors contributing to event or outcome

Section 15: NARRATIVE SUMMARY CONTINUED:

*Attach additional sheets if needed

Supplemental Digital Content File 3

OSA Supplementary Tables

Supplemental Table 1: OSA Details

Characteristic	Descriptive Statistics n (column %)
OSA status	
Diagnosed	55 (83%)
Suspected	11 (17%)
CPAP (n=61)	
Prescribed	37 (61%)
CPAP used as prescribed (n=37)	
Most of the time	15 (41%)
Sometimes	2 (5%)
Rarely or not at all	9 (24%)
Unknown	11 (30%)
BiPAP (n=47)	
Prescribed	1 (2%)[1]

Percentages based on 66 cases unless otherwise indicated. Cases with missing data excluded from calculation of statistics.

OSA = Obstructive sleep apnea; CPAP=Continuous Positive Airway Pressure; BiPAP= Bilevel Positive Airway Pressure

[1] Unknown if BiPAP used as prescribed

Supplemental Table 2: Association Between Other Patient and Case Factors with Outcomes

	Death or Brain Damage n (row %)	Other Critical Events n (row %)	Odds Ratio (95% CI)	P value
Sex				=0.106
Male (n=43)	31 (72%)	12 (28%)	2.368 (0.824-6.802)	
Female (n=23)	12 (52%)	11 (48%)	Reference	
ASA Physical Status (n=64)				=0.251
1-2 (n=22)	12 (55%)	10 (45%)	0.538 (0.186-1.559)	
3-4 (n=42)	29 (69%)	13 (31%)	Reference	
Elective or Emergent (n=62)				>0.999*
Elective (n=56)	36 (64%)	20 (36%)	0.900 (0.151-5.354)	
Emergency (n=6)	4 (67%)	2 (33%)	Reference	
Inpatient vs Outpatient (n=64)				=0.337
Inpatient (n=51)	32 (63%)	19 (37%)	0.505 (0.123-2.069)	
Outpatient (n=13)	10 (77%)	3 (23%)	Reference	
OSA Diagnosed vs. Suspected				=0.050
Diagnosed (n=55)	33 (60%)	22 (40%)	0.150 (0.018-1.256)	
Suspected (n=11)	10 (91%)	1 (9%)	Reference	

Cardiovascular or pulmonary comorbidity				=0.380
Present (n=42)	29 (69%)	13 (31%)	1.593 (0.562-4.519)	
Not noted (n=24)	14 (58%)	10 (42%)	Reference	
Continuous variables	Mean (SD)	Mean (SD)	Odds Ratio (95% CI)	P value
Hours between anesthesia end time and event (n=63): Mean (SD)	18 (19)	13 (13)	1.016 (0.982-1.051)	=0.359
Age: years, mean (SD)	50 (15)	57 (15)	0.969 (0.935-1.003)	=0.071
BMI ($kg/m^{2,}$): mean (SD)	38 (7)	37 (11)	1.023 (0.963-1.088)	=0.463

N=66 unless otherwise specified. Percentages based on row totals. Cases with missing data excluded.

ASA= American Society of Anesthesiologists physical status score; BMI= body mass index; CI = confidence interval; OSA = obstructive sleep apnea; SD= standard deviation

OSA diagnosed= sleep study; OSA suspected = by history or screening test

Odds ratio for death compared to critical events (reference).

* Fisher's exact test with Monte Carlo significance due to >25% of cells with <5 expected counts; all other tests of differences in proportions by chi square test

p-values for continuous variables by two sample unpaired t-test