

SMR TURBS GUIDANCE STATEMENT

AUTHORSHIP AND EDITING

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STATES COVERED BY CASE SUBMISSIONS BY DATE

JUNE 25, 2020: CALIFORNIA, CONNECTICUT, FLORIDA, INDIANA, MICHIGAN, NEW YORK, TEXAS

JULY 13, 2020: CALIFORNIA, CONNECTICUT, FLORIDA, GEORGIA, MICHIGAN, NEW JERSEY, NEW YORK, INDIANA, TEXAS

CASE DATA REVIEWED BY DATE

JUNE 25, 2020: Total Cases Submitted 303, Total Procedures 674

115 SMR TURBS CASES REVIEWED (DATABASE USED: SINUS SURGERY RESPONSES LOCKED 6-25-20-12-42)

JULY 13, 2020: Total Cases Submitted 2458, Total Procedures 2919

265 SMR TURBS CASES REVIEWED (DATABASE USED: SINUS SURGERY RESPONSES LOCKED 07-13-20-12-38)

PRIMARY CONSIDERATIONS

- Individual procedures on sinusoutcomes.org are considered for review after approximately 100 cases of the particular procedure have been submitted. Previously reviewed procedures are considered for additional review after every 100 subsequent procedures have been submitted. Each review attempts to determine safety considerations based on data related to the primary outcomes reported.
- Since the onset of the pandemic, the United States has seen different disease characteristics for the virus, state by state, based on multiple factors. Each review of the data will show the size of the data set and the states included in the data set. Results from one set of state specific data or report cannot necessarily be extrapolated to states that have not yet reported data.
- The primary outcomes reported are:
 - Was there any COVID-19 infections reported in the dataset
 - Was there any presumed transmission of COVID-19 to patients
 - Was there any presumed transmission of COVID-19 to surgeons
 - Was there any presumed transmission of COVID-19 to staff

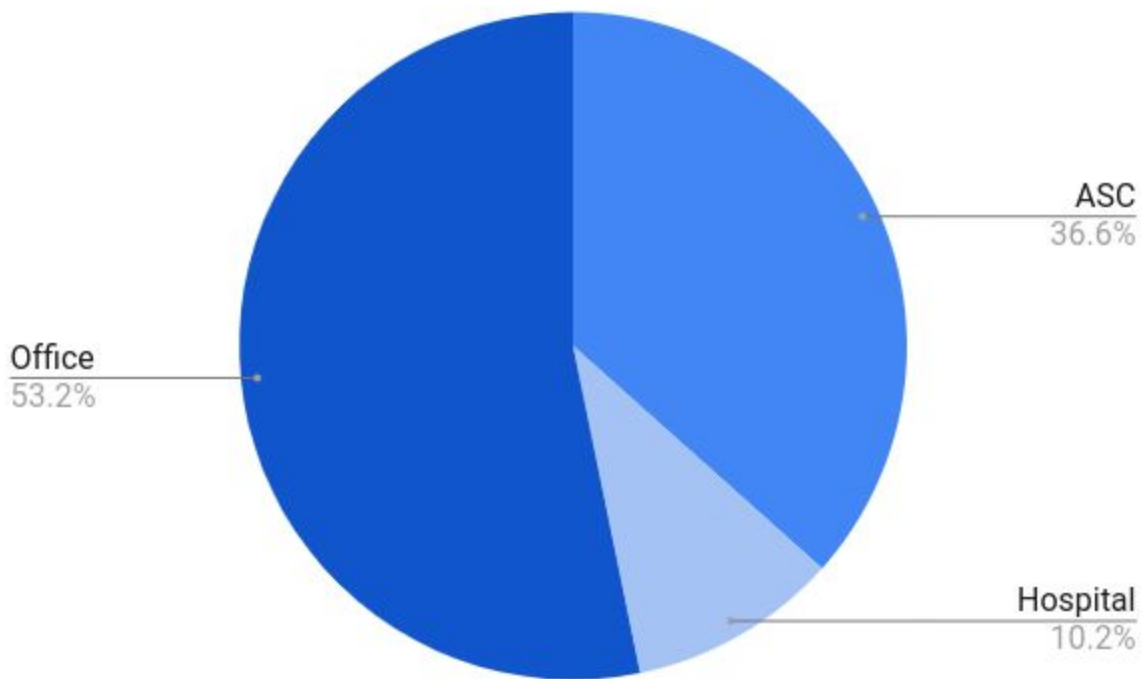
PRIMARY FINDINGS

Data submitted up to July 13, 2020 Primary Outcomes:

- Number of SMR Turbs Cases Reviewed: 265 cases
- COVID-19 infections reported in the dataset: none reported
- Presumed transmission of COVID-19 to patients: none reported
- Presumed transmission of COVID-19 to surgeons: none reported
- Presumed transmission of COVID-19 to staff: none reported

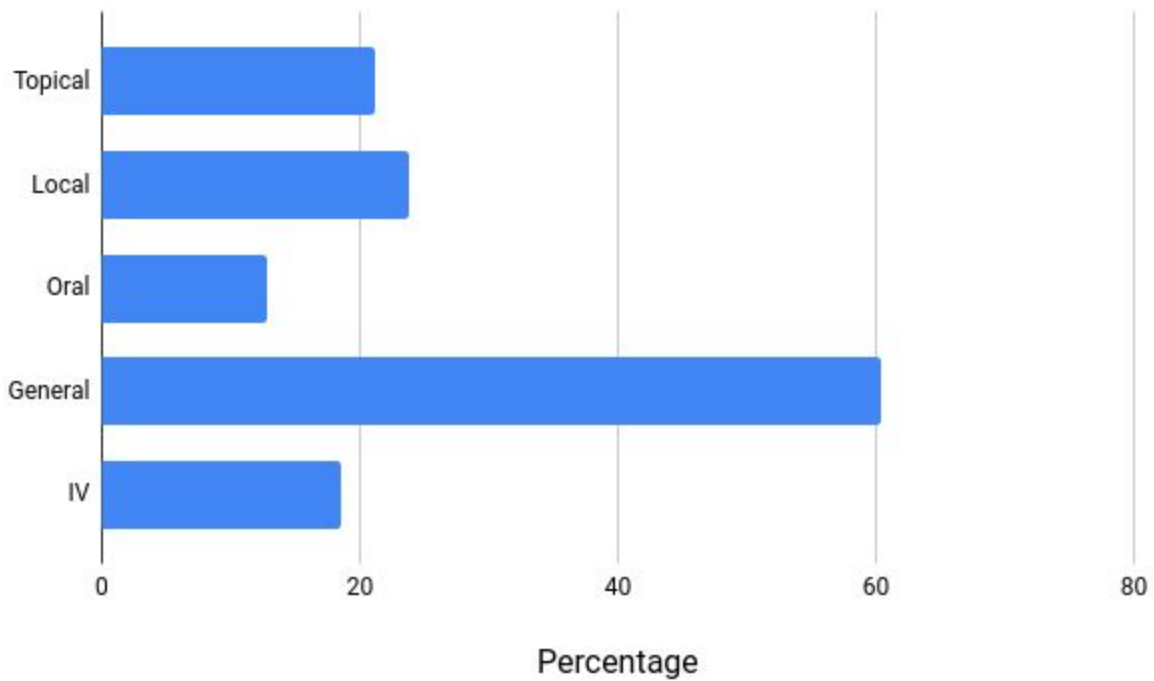
GUIDANCE ON THE SAFETY OF PERFORMING SMR Turbs

Data submitted up to July 13, 2020 General Case Data on Site of Service



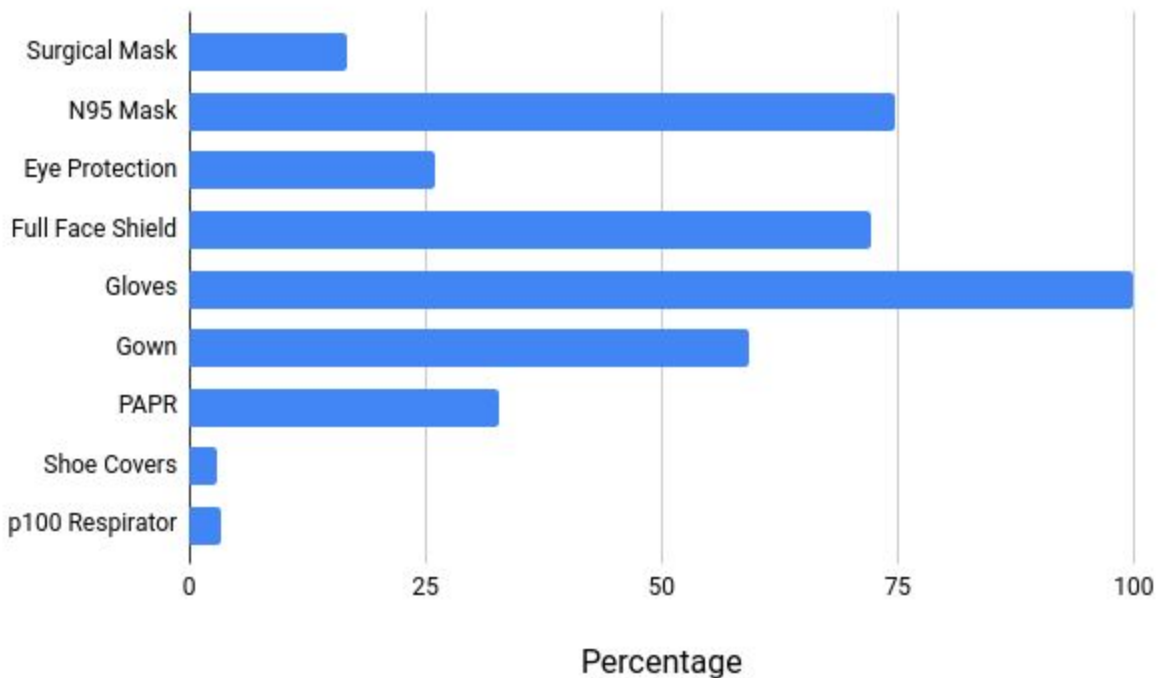
Discussion: The data reviewed showed that about half of all SMR Turbs procedures were performed in the office setting. The other 50% was split between ASC and hospital operating rooms, with more procedures taking place in ASC. There did not appear to be any change in risk profile based on site of service for the reported data. All locations appeared safe.

Data Submitted up to July 13, 2020 General Case Data on Anesthesia Used

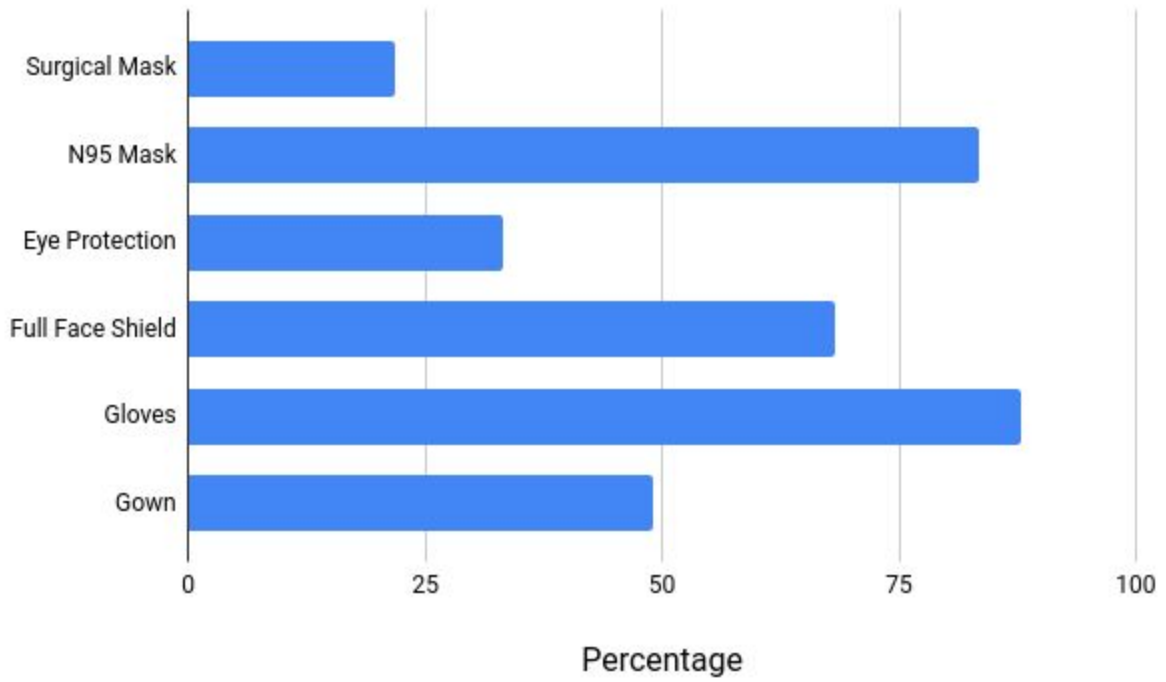


Discussion: The data shows a variety of anesthesia types being used, with a majority of cases using general anesthesia. No particular type of anesthesia showed any increased risk profile for the covered period.

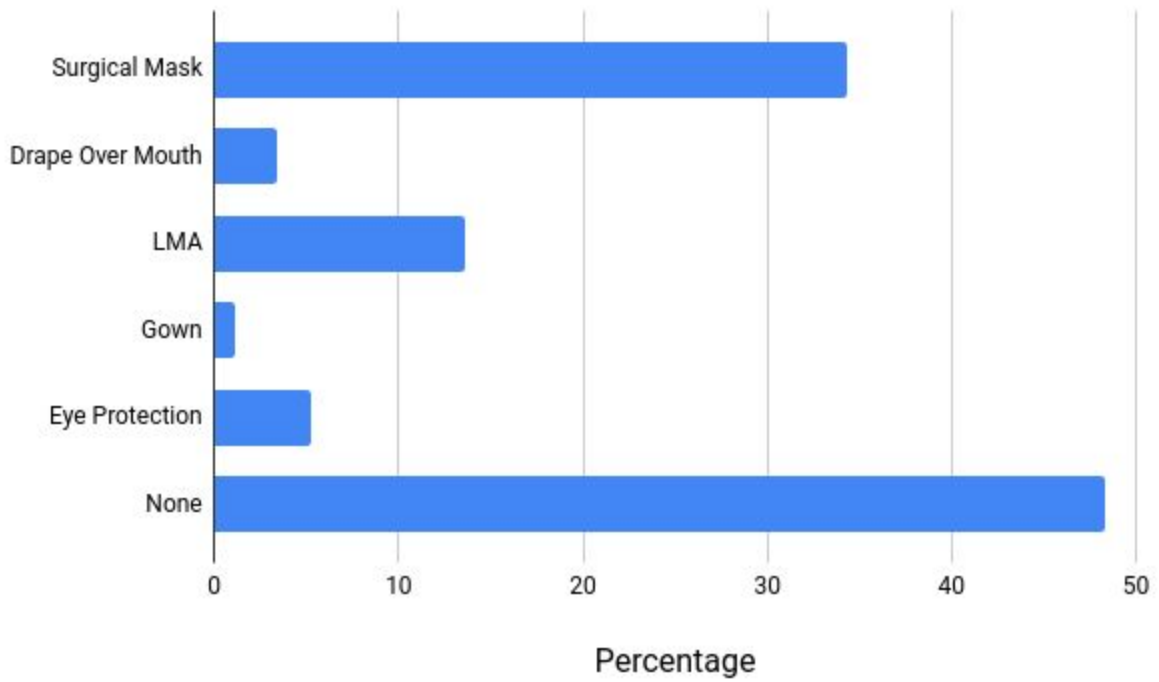
Data submitted up to July 13, 2020 PPE used during the procedure by the Doctor



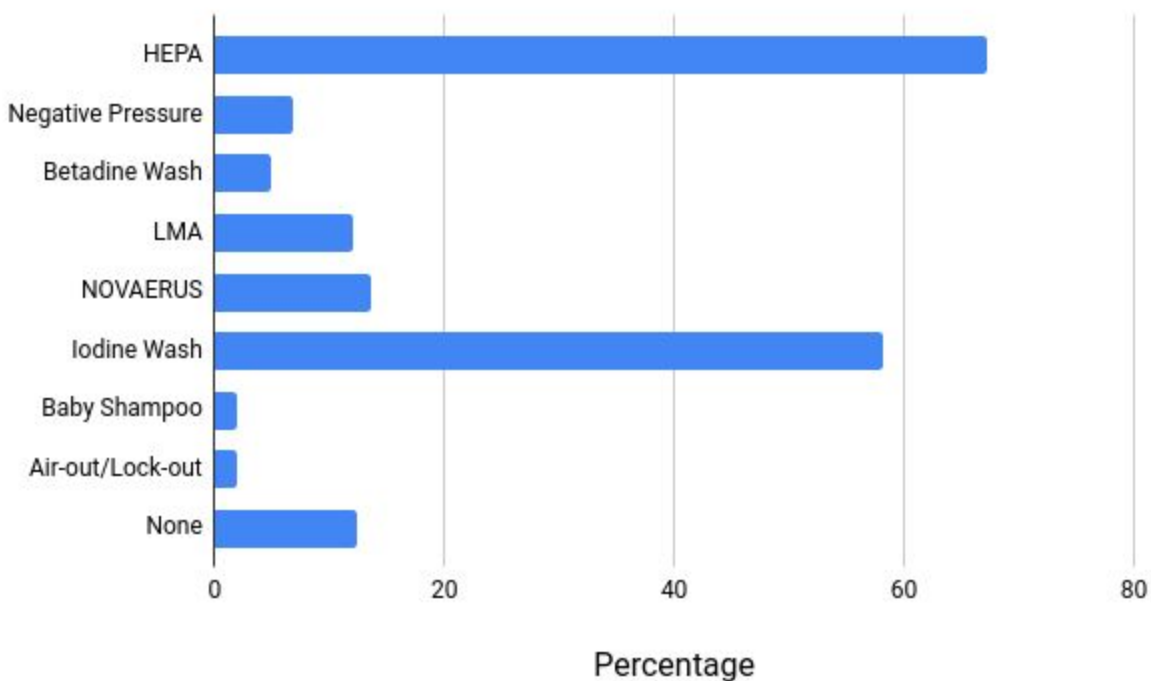
Data submitted up to July 13, 2020 PPE used during the procedure by the Staff



Data submitted up to July 13, 2020 PPE used during the procedure by the Patient



Data submitted up to July 13, 2020 PPE Additional Safety Measures Used



Discussion: The majority of cases performed in this data set showed use of gloves and either an N95 face mask or a full face shield by both the surgeon and staff. While a PAPR was not used by the staff during any procedures, a little over 25% of physicians reported using a PAPR during the procedure. No single safety measure reported showed any correlation with a change in risk profile for case transmission to doctor, staff or other patients.

At the time of the last guidance statement on SMR Turbs, the data showed a majority of respondents (around 80%) reported the use of either a surgical mask or LMA by the patient, with only around 10% of patients not using any PPE. However, it has now been reported that almost 50% of respondents did not have their patients use any form of PPE. Surgical site HEPA filters were used about 65% of the time in the procedure room and iodine wash was used about 60% of the time prior to the procedure. A few other additional safety measures were used in the procedure room in some instances, such as Baby Shampoo, air-out/lock-out systems, preoperative betadine wash, surgical site negative pressure rooms, and NOVAERUS. In this data set there does not appear to be any change in risk profile based on PPE used by the patient or any additional safety measures used in the procedure room.

Safety Opinion: As of July 13, 2020 SMR Turbs is safe to perform using reasonable precautions in the office, ASC and hospital operating room settings in the states of California, Connecticut, Florida, Georgia, Indiana, Michigan, New York, New Jersey, and Texas.

NEXT REVIEW

WHEN SMR TURB CASES EXCEED 300 SUBMISSIONS on SINUSOUTCOMES.ORG