

SINUPLASTY GUIDANCE STATEMENT

AUTHORSHIP AND EDITING

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STATES COVERED BY CASE SUBMISSIONS BY DATE

JUNE 16, 2020: CALIFORNIA, CONNECTICUT, FLORIDA, INDIANA, TEXAS

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

CASE DATA REVIEWED BY DATE

JULY 02, 2020: Total Cases Submitted 551, Total Procedures 987

181 NASAL ENDOSCOPY CASES REVIEWED (DATABASE USED: SINUS SURGERY RESPONSES LOCKED 07-02-20-12-50)

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

1,345 NASAL ENDOSCOPY 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

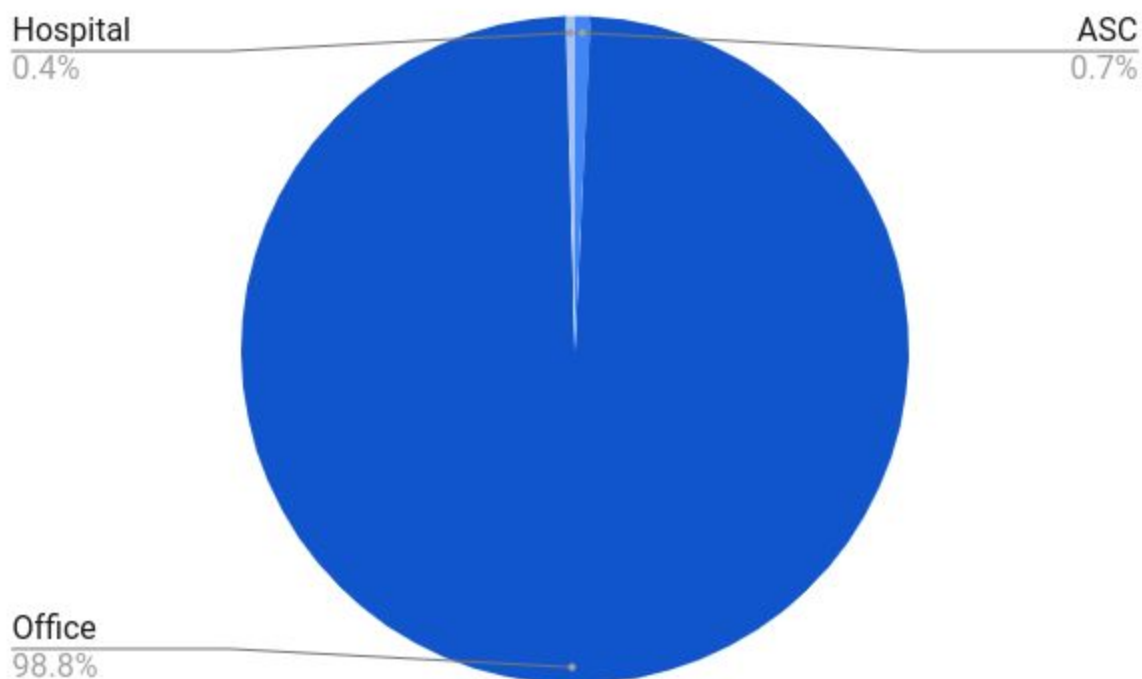
PRIMARY FINDINGS

Data submitted up to June 16, 2020 Primary Outcomes:

- Number of Nasal Endoscopy procedures reviewed: 1,345 consecutive 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

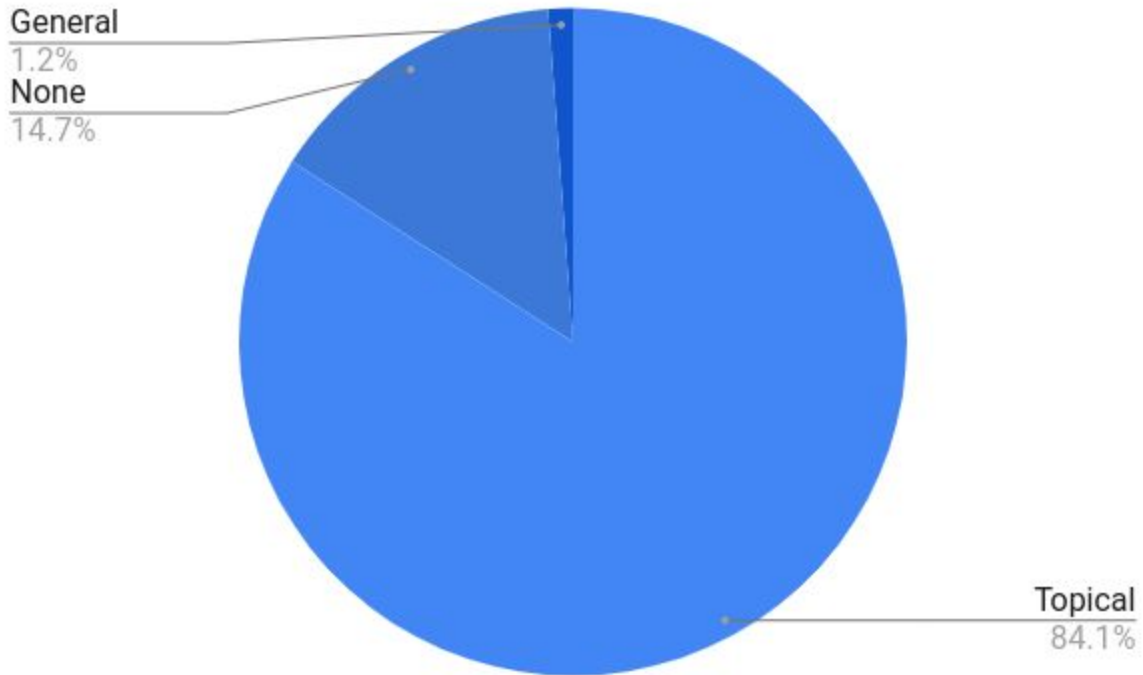
GUIDANCE ON THE SAFETY OF PERFORMING NASAL ENDOSCOPY

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



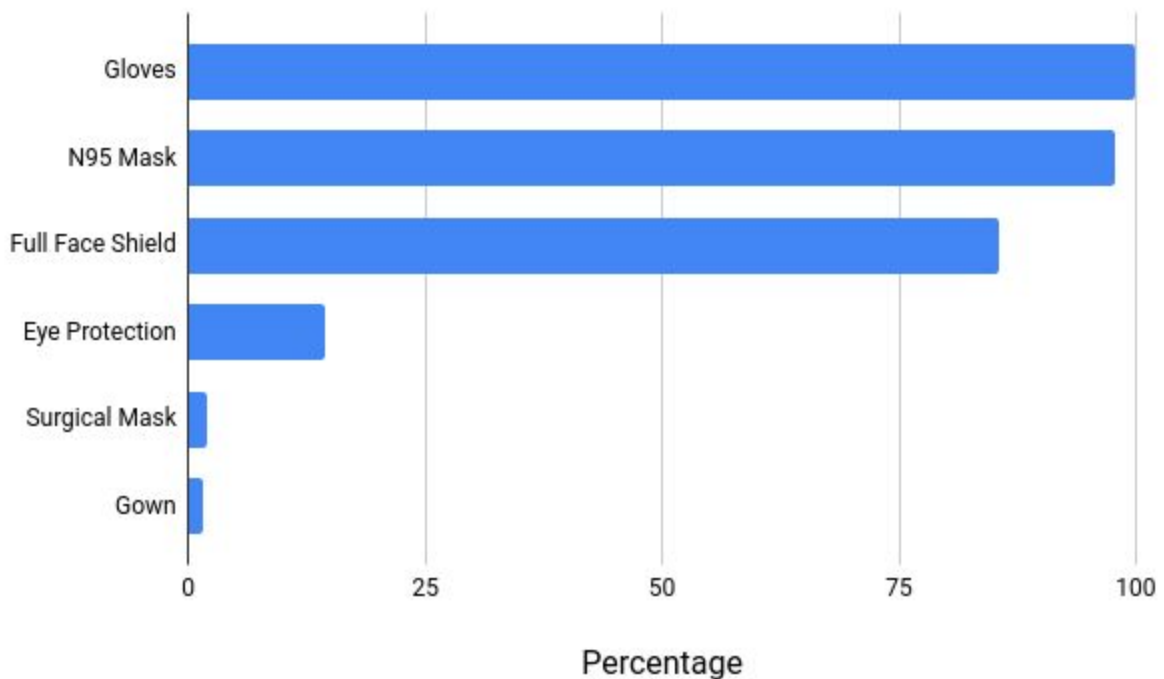
Discussion: The data set reviewed showed that the majority of cases were performed in the office setting with no change in risk profile associated with site of service.

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

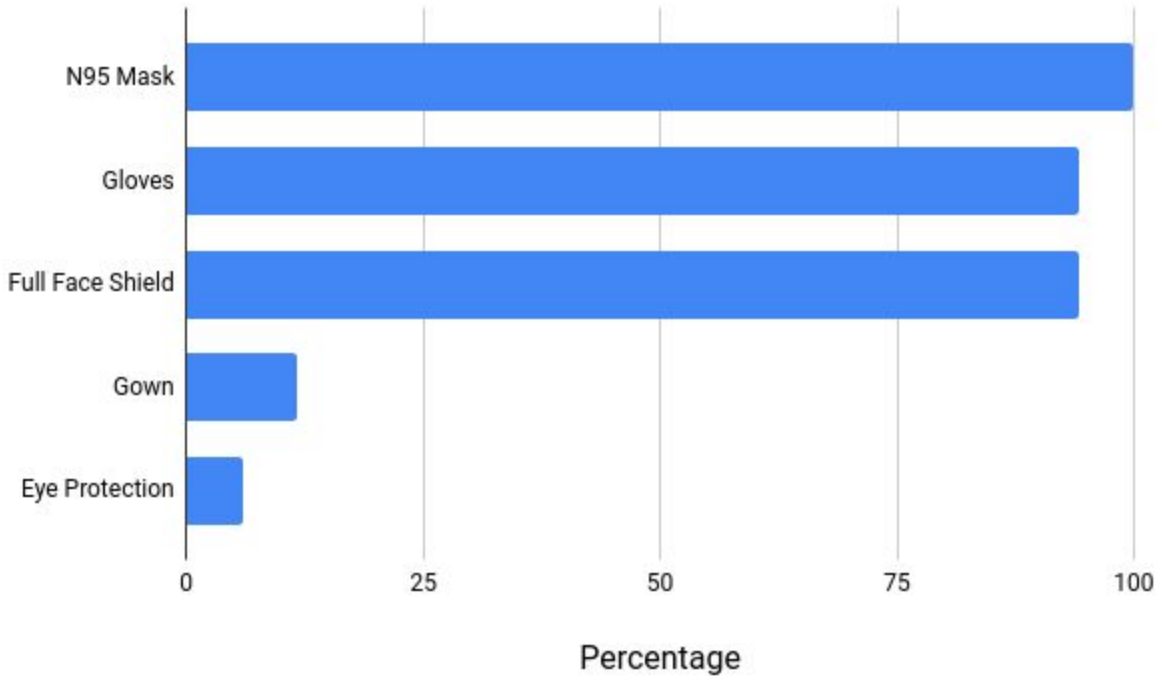


Discussion: The data set reviewed showed that the majority of cases were performed in the office setting using a combination of topical or no anesthesia. The use of topical anesthesia did not increase the risk of disease transmission in this cohort of patients.

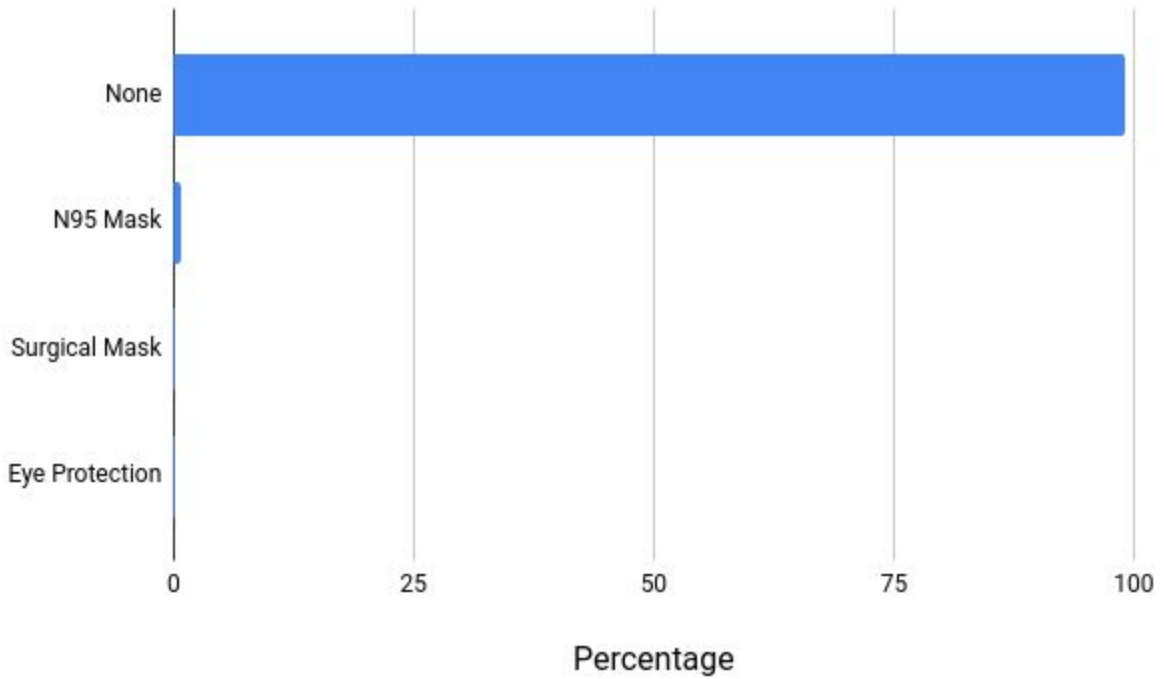
Data submitted up to July 13, 2020 PPE used during the procedure by the Doctor



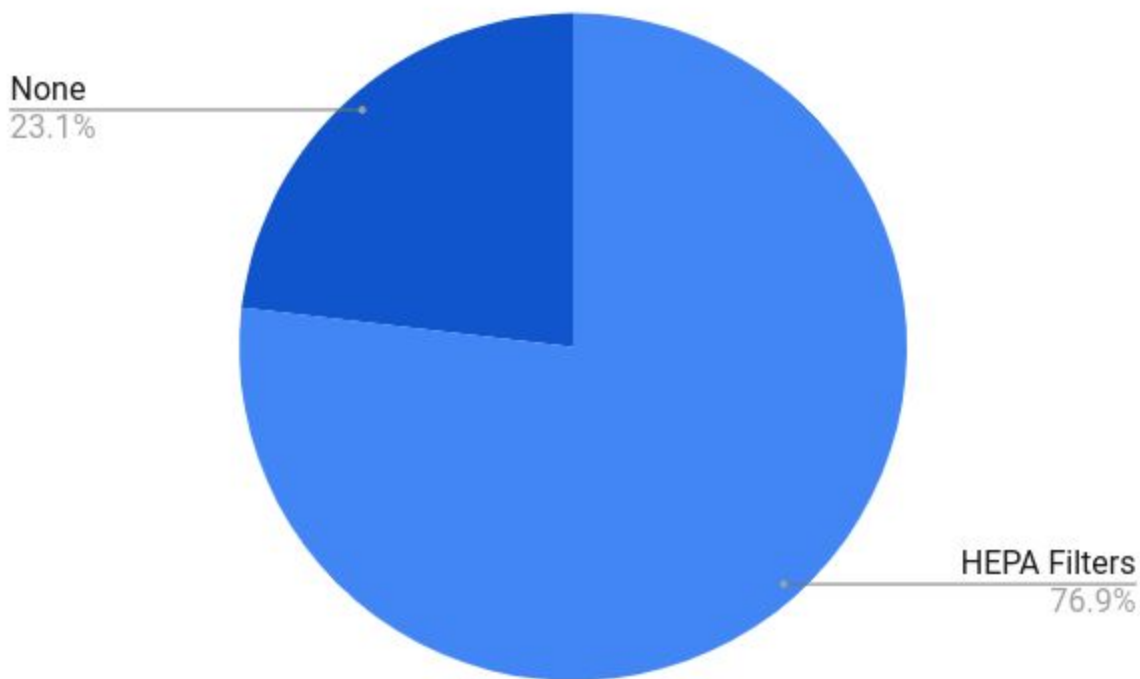
Data submitted up to July 13, 2020 PPE used during the procedure by the Staff



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



Data submitted up to June 16, 2020 PPE Additional Safety Measures Used



Discussion: This dataset reports on the risk of performing Nasal Endoscopy in the office setting. Over 1,300 consecutive cases were reported without a case of disease transmission occurring. The majority of cases performed in this data set showed use of N95 surgical masks, gloves, and full face shields or eye protection by both the surgeon and staff. Gowns were infrequently used for this minor procedure and there were no reports of PAPR use by any physician.

A small minority of patients were required to use N95 face masks during their nasal endoscopy while the majority of procedures were performed on patients who were not wearing any PPE. When additional safety measures were studied, HEPA filtration was used in a large portion of the dataset. About one in four procedures were performed without using additional safety measures. There does not appear to be an increase in safety with the use of additional safety measures in the office setting when performing this procedure.

Safety Opinion: As of July 13, 2020 Nasal Endoscopy is safe to perform using reasonable precautions in the office setting in the states of California, Connecticut, Florida, Georgia, Michigan, New Jersey, New York, Indiana, Texas.

NEXT REVIEW

WHEN NASAL ENDOSCOPY CASES EXCEED 1,500 SUBMISSIONS on SINUSOUTCOMES.ORG