



**User Guide for the 2021
ACS NSQIP Pediatric Surgical
Antibiotic Prophylaxis
Participant Use Data File
(SAP PUF)**

**American College of Surgeons National Surgical
Quality Improvement Program - Pediatric**

Released:
January 2023



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1. Introduction

This document is designed to accompany the 2021 Pediatric Surgical Antibiotic Prophylaxis Participant Use Data File (SAP PUF) available for download on the American College of Surgeons National Surgical Quality Improvement Program Pediatric (ACS NSQIP Pediatric) website (www.facs.org/quality-programs/childrens-surgery/pediatric). The sections contained herein will provide the user with information on how to request the Pediatric Surgical Antibiotic Prophylaxis PUF, the contents of the data files, the data collection background, the inclusion and exclusion criteria for cases and hospitals, the data limitations, and the data point definitions and descriptions.

This user guide applies specifically to the 2021 Pediatric SAP PUF. Hospitals utilizing the Pediatric PUF from a different year should refer to the user guide specifically tailored to that particular data set.

2. Merging Cases with the ACS NSQIP Pediatric PUF

Using the unique CASE ID variable, target-specific variables can be merged to the main ACS NSQIP Pediatric PUF.

3. Data Request Process

An individual who has an official appointment at a fully enrolled Pediatric site and wants to obtain a copy of the Pediatric SAP PUF can do so by visiting www.facs.org/quality-programs/childrens-surgery/pediatric and following the steps listed below:

1. From the ACS NSQIP Pediatric main page the requestor can click on “Request Participant Use Data File” link under Quality Support Tools.
2. Following a brief introduction, the requestor can click on “Request Data Set.”
3. This will take the requestor to the Data Use Agreement. This is a 3-page document that implements the data protections of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the ACS NSQIP Hospital Participation Agreement. Delivery of the PUF is contingent on agreement to the terms and conditions specified within the Data Use Agreement. The requestor can read the Data Use Agreement from this page or download the 3-page document. The requestor is then required to type in their first and last name and click on “Request Data File.” By clicking on “Request Data File” the requestor agrees to the terms and conditions of the Data Use Agreement.
4. Requestors will then be required to complete a brief online form to provide ACS with basic information about themselves, including the participating hospital in which they are

currently employed and in what capacity, as well as how the requestor plans on using the Pediatric PUF data. Once all of the required fields are completed, the requestor clicks “Submit.”

5. ACS NSQIP staff will review the request in a timely manner. Program contacts at participating sites will be contacted at this time to confirm the requestor’s affiliation with the hospital and confirm internal approval of the PUF request.
6. Following receipt and confirmation of the information submitted, an email will be sent to the requestor containing a username and password along with the URL to download the data. The web link will be active from the time of the email for 10 full days (240 hours).
7. The file will be available in 3 different formats (Text, SAS, SPSS) and depending on the connection speed should take between 5 and 30 minutes to download.
8. The requestor may be contacted to confirm receipt of the data file and allow for feedback on the delivery mechanism, data points contained, and data file format.

4. File Description

Each fall a Pediatric PUF will be made available for the previous calendar year’s data. The Pediatric SAP PUF is available in one of three different formats – Text, SAS, and SPSS. A brief description of the different formats follows:

File Name	Type	Uncompressed File Size	Description
PEDS_SAP_PUF_2021.txt	tab delimited TXT file	7.5 MB	Contains 16 HIPAA compliant variables on 89,342 cases submitted from 150 sites in 2021.
PEDS_SAP_PUF_2021.sas7bdat	SAS 9.4 data file	37.2 MB	Same information as stated above in SAS data format.
PEDS_SAP_PUF_2021.sav	SPSS 16.0 data file	41.2 MB	Same information as stated above in SPSS data format.

5. Data Collection Background and Data Quality

The ACS NSQIP Pediatric collects data on over 150 variables, including preoperative risk factors, intraoperative variables, and 30-day postoperative mortality and morbidity outcomes for patients undergoing major surgical procedures in both the inpatient and outpatient setting. A site's trained and certified Surgical Clinical Reviewer (SCR) captures these data using a variety of methods including medical chart abstraction.

Required data variables are entered via web-based data collection to the ACS NSQIP Pediatric website. Portions of the data may be automatically populated by a software program that was developed to extract data from the participating hospital's existing information systems. Requestors should contact the SCR(s) at their hospital for detailed information on how the hospital collects its ACS NSQIP Pediatric data.

To ensure the data collected are of the highest quality, the ACS NSQIP Pediatric has developed a host of different training mechanisms for the SCRs and conducts a Data Audit of selected participating sites. In addition to an initial web-based training program, the ACS NSQIP Pediatric requires SCRs to complete a series of web-based training modules followed by a certification exam that must be taken annually. The modules and certification exam focus on the program, processes, and analysis; preoperative, intraoperative, and postoperative definitions; and case studies. These modules are complemented by a growing online decision support system that ensures the SCRs have the knowledge and resources available to collect high-quality data.

The Data Audit is a fundamental tool of ACS NSQIP Pediatric to assess the quality of the data collected at participating sites. The process involves the review of multiple charts, some of which are selected randomly and others selected based on criteria designed to identify potential reporting errors. For example, cases with five or more preoperative risk factors and no reported mortality or morbidity or cases with two or fewer preoperative risk factors and reported mortality or morbidity will be selected for chart review. Operating room logs are also audited to ensure correct sampling of cases.

The combined results of the audits completed to date revealed an overall disagreement rate of approximately 2% for all assessed program variables. The ACS NSQIP Pediatric has determined that a Data Audit disagreement rate of 5% or less is acceptable. Sites that have higher than a 5% disagreement rate are not provided a hospital odds ratio in the ACS NSQIP Pediatric Semiannual Report and may be required to undergo an additional audit following recommendations from the ACS NSQIP Pediatric.

6. Sampling Process and Case Exclusion Criteria

Systematic Sampling Process

Large surgical services normally experience a significant volume of surgical cases. This presents the SCRs with the problem of managing an overwhelming workload. Therefore, a systematic sampling system called the 8-day cycle was developed to prevent bias in choosing cases for assessment. The SCR uses the 8-day cycle to select completed cases from the hospital's final operative log. The final operative log includes any emergent, urgent or add-on procedures that were performed and excludes any scheduled procedures that were not performed. The operative log is sorted by the date of the operation, "Patient In Room" time, and finally Operating Room Suite Number. The 8-day cycle schedule works as follows: If the first cycle begins on a Monday, it continues through to include the following Monday (an 8-day period of time). The next cycle begins on Tuesday and continues through to include the following Tuesday, and so on. There are 46 8-day cycles in 1 year, and the program recommends that data be submitted for 40 of those cycles. The process ensures that cases have an equal chance of being selected from each day of the week.

Hospitals with a high volume of surgical cases capture the first 35 consecutive cases meeting the inclusion/exclusion criteria in the 8-day cycle following the systematic sampling guidelines.

Case Inclusion Criteria

The following inclusion criteria were applied to cases collected in 2021. For the current inclusion/exclusion criteria please contact the ACS NSQIP Pediatric Clinical Support Team at clinicalsupport@pediatric.acsnsqip.org.

- The ACS NSQIP Pediatric includes all cases with CPT codes that are listed on the CPT inclusion list.

Case Exclusion Criteria

The following exclusion criteria were applied to cases collected in 2021. For the current inclusion/exclusion criteria please contact the ACS NSQIP Pediatric Clinical Support Team at clinicalsupport@pediatric.acsnsqip.org.

- Patients 18 years of age, or older.
- Cases involving Hyperthermic Intraperitoneal Chemotherapy (HIPEC), regardless of if the procedure performed has an included CPT code(s).
- ASA 6 – (Declared brain-dead patient whose organs are being removed for donor purposes).
- Concurrent Case – An additional operative procedure performed by **a different surgical team** (e.g., a different specialty/service) **under the same anesthetic**. An additional operative procedure with a CPT code different from that of the Primary Procedure

performed by a different surgical team under the same anesthetic is listed as a concurrent procedure. A concurrent procedure is not included.

- Multiple cases within 30 days – Multiple cases for the same patient within 30 days are excluded. (Only one case, per patient, per 30 day time frame can be abstracted for NSQIP-PEDs).
- Exclude a return to the operating room/ICU setting as the primary procedure, if it is related to an occurrence or complication from any procedure (surgical or otherwise) regardless of where the procedure was performed, within 30 days or within the same admission.
- Exclude a procedure performed by a surgical service not reviewed in Pediatric NSQIP.
- Transplant Cases – Specifically: A patient who is admitted to the hospital for solid organ transplant surgery, and has additional surgical procedures performed during the same hospital stay, is excluded. Any operation performed after the patient has been discharged from the transplant stay is included.
- **Trauma and Abuse Cases:** Any case caused by a trauma or abuse with a principal ICD-10 diagnostic code within the ranges of S00-T14, T20-T79, T83-T85, and V00-Y99 will be excluded from sampling.
 - **Exception to Trauma/Abuse criteria:** When not caused by abuse, include trauma cases with included CPT codes that involve a fracture to a single limb section, with no other injuries. Capture cases with a single break, even if it crosses over multiple bones.
 - Exclude any surgical procedure related to the index trauma procedure(s) which occur during the same hospitalization. Any operation performed after the patient has been discharged from the trauma stay will be included; if they meet NSQIP-Pediatric program inclusion criteria.
 - Exclude any subsequent surgical procedure that is a direct result of abuse, regardless of timeframe.

Hospital Exclusion Criteria

In addition to the case inclusion/exclusion criteria, hospital inclusion/exclusion criteria are also imposed. To maintain the highest level of data quality, only cases included in the odds ratio analysis are included in the Pediatric PUF. These cases go through an additional level of scrutiny as they are passed from data collection to statistical analysis. Sites that exhibit issues with either data quality or 30-day follow-up are reviewed for exclusion to ensure the integrity of PUF data.

Surgical Antibiotic Prophylaxis Exclusion Criteria

Extensive feedback from the ACS NSQIP Pediatric Specialty Advisory Councils (SACs) was incorporated in the refinement of selection and exclusion criteria, as well as in the development of rules for assessing and comparing SAP utilization. Exclusion criteria to limit the inclusion of patients where patient-level factors may influence the choice for SAP include the following:

- Patients currently receiving antibiotics for a pre-existing infection (either related or unrelated to the procedure performed)
- Procedures defined as emergent (except procedures performed for pyloric stenosis)
- Comorbidities associated with compromised immune function and/or increased risk of infection which may have influenced the choice and/or approach to SAP
- Medications associated with compromised immune function and/or increased risk of infection which may have influenced the choice and/or approach to SAP
- Procedures where intraoperative findings may dictate the need for postoperative antibiotic treatment (e.g., interval appendectomy with findings of purulent fluid). In these cases, it would not be possible to determine whether postoperative antibiotic treatment represents prolongation of prophylaxis or treatment of an infection identified intraoperatively.
- Allergy to cephalosporins or penicillin antibiotics
- Concurrent procedures where more than one service line performs procedures under the same anesthetic. In these cases, the indication and choice of antibiotic prophylaxis may be different depending on the nature and sequence of procedures being performed by the different services
- Procedures where choice of SAP may be influenced by a previous infection involving the surgical site or preoperative culture results (e.g., urinary diversion procedures, mastoidectomy)

Case Selection

Step 1: Collect Procedure Targeted Cases with Procedure Specific Variables

- Once cases meeting criteria for inclusion have been identified, the Procedure Targeted cases with procedure specific variables are selected first, as they occur in consecutive order, utilizing the procedure targeted CPT list.
 - Each of these cases has a limit of 4 per 8-day cycle. These cases include:
 - Appendectomy
 - Spinal Fusion
 - CSF Shunt
 - Vesicoureteral Reflux
 - Tracheostomy

Step 2: Collect Procedure Targeted Cases without Procedure Specific Variables

- Next, all possible Procedure Targeted cases without procedure specific variables are selected, in consecutive order, utilizing the procedure targeted CPT list. The Procedure Targeted CPT Code Inclusion List is located in the appendices section of the Operations Manual.
- There is a 4 case per cycle limit for Gastrostomy and Laparoscopic Cholecystectomy procedures.

Step 3: Collect Surgical Specialty Cases

- If, after selecting all procedure targeted cases as outlined above, the cycle does not meet 35 cases, the hospital will now select all remaining surgical specialty cases, as they occurred in consecutive order, utilizing the Full CPT list.
- At this point in case selection, case limits on procedure targeted cases are still maintained (only four cases for appendectomy, spinal fusion, CSF shunt, vesicoureteral reflux, tracheostomy, gastrostomy and laparoscopic cholecystectomy).
- Collect all cases until reaching a total of 35 cases.

Step 4: Rounding Out Your Cases to Achieve 35 Cases per Cycle

- If less than 35 cases are abstracted for a cycle after a hospital selects all cases as described in steps 1-3 above, a hospital may opt to collect additional cases to round up to 35 cases utilizing the following process, or they may choose to identify the cycle as “Max cases” under the “Manage Cycles” section of the “My Account” tab in the Workstation.
- If the cycle does not total 35 cases after following the three previous steps, the hospital may opt to “Max Cases” or may continue to capture additional cases of the “limited procedures” Appendectomy, Spinal Fusion, CSF Shunt, VUR, Laparoscopic Cholecystectomy, Gastrostomy, and Tracheostomy, while still following the current sampling methodology (primary procedure, only one case per patient per 30 days, etc).
- If the cycle still does not total 35 cases, the hospital will identify the cycle as “Max Cases” in the Workstation.

7. Data Limitations

While every effort has been made to make the Pediatric PUF as complete as possible, the data do have certain limitations. Some of these limitations have been deliberately introduced to safeguard the privacy of patients (such as removal of absolute dates). Other limitations are due to resource constraints (such as the collection of generic surgical variables only). The following items represent the most salient limitations of the data:

- Because such a wide variety of operations are tracked, the variables are necessarily generic in nature. This limitation may pose difficulties for researchers attempting in-depth research on specific conditions or operations. However, surgical Targeted PUF datasets are now available which address target-specific predictors and outcomes for many types of operations.
- Patients are followed after surgery for a maximum of 30 days. Complications or death after that period are not included.
- In order to comply with HIPAA requirements, all absolute dates have been removed. The most critical of these is the date of surgery, which has been reduced to year of surgery only. Some dates (hospital entry, dates of laboratory tests, and so on) have been recoded into durations e.g. Date of Admission and Date of Discharge is recoded into Hospital Length of Stay.
- In order to comply with the Hospital Participation Agreement (HPA) that is agreed to between the ACS and participating sites, facility identifiers as well as geographic information regarding the case have been removed. The HPA stipulates that the ACS does not identify participating sites. Site identification could be possible even with blinded identifiers through advanced statistics. A stipulation of access to the Pediatric PUF is completion of the Data Use Agreement that strictly prohibits attempts to identify hospitals, health care providers, or patients.
- While many risk factors are tracked, preventative measures are not recorded which can lead to an overestimation of the risk of certain conditions when such measures are routinely taken before surgery.
- The data are submitted from hospitals that are participating in the ACS NSQIP Pediatric and do not represent a statistically valid nationally representative sample. \
- Most patients do not receive all possible preoperative laboratory tests, so some of these variables have a high percentage of missing values (53% to 87%, depending on the tests). This high percentage of missing data can make it problematic to use these variables in a traditional logistic regression model as well as in many other types of analysis.

This list may not include all data limitations and additional limitations may apply in future versions of the data.

8. Contact Information

All questions about the Pediatric SAP User Guide or PUF, as well as comments and suggestions for improvements are welcome and may be directed to Brian Matel, ACS NSQIP Statistical Reports Manager via email at bmatel@facs.org.

9. Frequently Asked Questions

Request Process

Q: Who has access to this file?

A: Any individual with an official appointment at a fully participating pediatric site will be given access to the file following completion of the Data Use Agreement and a short set of questions that are available on the website.

Q: Is the file available to individuals from nonparticipating sites?

A: At this time the data files are only available to individuals with official appointments at fully participating pediatric sites.

Q: I am at a pediatric NSQIP-participating site and would like to work on a research project with others from a different site that is not participating. Will I be allowed to do that?

A: Yes, however, the NSQIP affiliated researcher must be the lead investigator on all PUF-based research projects and is responsible for the PUF dataset, even if forwarded to someone else. The non-participating collaborator must also sign the DUA.

Q: How do I obtain a copy of this file?

A: Please see the “Data Request Process” on page 1 of this document for a step-by-step approach on how to do so.

Contents of the Files

Q: What is in this file?

A: The file contains Health Insurance Portability and Accountability Act (HIPAA) de-identified data from sites participating in the ACS NSQIP Pediatric that received odds ratios in 2021. The variable name, variable label, data definition, and other pertinent information are provided in Section 10: Data Variables and Definitions.

Q: Where can I find the SAP variables and definitions?

A: You can contact your site’s SCR for the SAP Variables and Definitions.

Q: Where can I find more details on the SAP inclusion/exclusion and categorization criteria?

A: You can contact your site’s SCR for the applicable version of the SAP Rules.

Q: Are site identifiers included in the database?

A: At this time we do not provide any geographic or site-specific identification. We took this approach to ensure the privacy of both the participating sites and surgeons.

Q: Are there surgeon-specific identifiers included in the database?

A: At this time we do not provide any surgeon-specific information. We took this approach to ensure the privacy of both the participating sites and surgeons.

Q: Why does the Pediatric PUF exclude specific dates?

A: In order to release the Pediatric PUF, certain adjustments to the data are required to ensure proper protection of patient information. To meet these requirements, we remove all elements of dates (except admission year) for dates directly related to an individual. For more information on the 18 data elements that are required for removal, please visit: <https://privacyruleandresearch.nih.gov/> or https://privacyruleandresearch.nih.gov/pdf/HIPAA_Booklet_4-14-2003.pdf

Q: Are other Pediatric PUF data sets available?

A: There are 31 other Pediatric PUFs available for request / download:

PUF Year	PUF Type	Cases	Sites	PUF Year	PUF Type	Cases	Sites
2012	Pediatrics	51,008	50	2019	Pediatrics	132,881	141
2013	Pediatrics	63,387	56	2019	Appendectomy	20,658	134
2014	Pediatrics	68,838	64	2019	Spinal Fusion	6,153	124
2015	Pediatrics	84,056	80	2019	CSF Shunt	2,298	131
2015	Appendectomy	10,570	20	2020	Pediatrics	128,395	148
2016	Pediatrics	101,887	101	2020	Appendectomy	21,445	140
2016	Appendectomy	13,114	101	2020	Spinal Fusion	6,019	131
2016	Spinal Fusion	3,728	93	2020	CSF Shunt	2,096	131
2016	CSF Shunt	1,452	96	2020	Vesicoureteral Reflux (VUR)	1,742	124
2017	Pediatrics	113,922	109	2021	Pediatrics	141,843	150
2017	Appendectomy	14,463	106	2021	Appendectomy	22,212	140
2017	Spinal Fusion	4,260	98	2021	Spinal Fusion	7,125	139
2017	CSF Shunt	1,128	102	2021	CSF Shunt	2,411	135
2018	Pediatrics	119,486	127	2021	Vesicoureteral Reflux (VUR)	1,807	126
2018	Appendectomy	16,986	122				
2018	Spinal Fusion	5,333	112				
2018	CSF Shunt	1,493	115				

Values in the Data

Q: Why do some cases have complications that do not have a known duration from operation to complication?

A: In each of these cases, the date of the complication was invalid, which inhibited the calculation of duration. The number of days from operation to complication variable is coded as -99 for these cases.

Q: Why do some of the preoperative lab values have duration from lab to operation, but a value of -99 for the lab value?

A: The results of the lab tests can be entered manually and thus are susceptible to data entry error. Depending on the preoperative lab variable roughly 1% of the cases had invalid values and these invalid values were set to -99 to simplify analysis. It is also possible that some cases have valid lab values, but are missing duration from lab to operation variable. This discrepancy is also related to a data entry error and the program continues to improve the data collection software to minimize the potential for data entry errors.

Q: When performing analysis on the five digit CPT codes in the Other and Concurrent variables, how should I interpret those cases with a valid five digit CPT code but a CPT description set to NULL?

A: If the case has a valid five digit CPT code that procedure occurred and should be evaluated as such. The CPT description is a secondary variable and provided for convenience. In the processing of large amounts of data some descriptions are purposefully or inadvertently removed.

File Formats

Q: In what file formats are the data available?

A: The data files are made available in a tab delimited TXT, SAS, and SPSS formats.

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Advisement: When a change in definitions across PUF years is noted, users should attend to this if they merge files. It is suggested that they evaluate variable categories across years and combine them in a manner appropriate to their research objectives

Position #	Variable Name	Data Type	Variable Label	Search Term in Chapter 4	Variable Options	Comments
				Notes: Please search exactly as stated * Variables not included in Chapter 4		
1	PUFYEAR	Num	Year of PUF	* Year of PUF		
2	CaseID	Num	Case Identification Number	Variable Name: Identification Number MRN/IDN		Chapter 4 Variable Required to Merge Data
3	PED_SAP_INFECTION	Char	SAP: Procedure Indication for Infection	Variable Name: Procedure Indication for Infection	Yes; No	
4	PED_SAP_CONGENITAL	Num	SAP: Immunodeficiency Diagnosis	Variable Name: Immunodeficiency Diagnosis	Yes; No	-99 = No Response
5	PED_SAP_BEFORE	Char	SAP: Received IV Antibiotics Before Prophylaxis Window	Variable Name: Received IV Antibiotics Before Prophylaxis Window	Yes; No	NULL = No Response
6	PED_SAP_PROPHYLAXIS	Char	SAP: Received Surgical IV Antibiotic Prophylaxis	Variable Name: Received Surgical IV Antibiotic Prophylaxis	Yes; No	NULL = No Response
7	PED_SAP_ALLERGY	Char	SAP: Allergy to Penicillin or Cephalosporins	Variable Name: Allergy to Penicillin or Cephalosporins	Yes; No	NULL = No Response
8	PED_SAP_NAME1	Char	SAP: Antibiotic #1 Name	Variable Name: Antibiotic #1 Name	Amikacin Ampicillin WITHOUT sulbactam Ampicillin/sulbactam (Unasyn) Azithromycin Aztreonam CeFAZoLin (Kefzol) CefOXitin CefTAZidime (Fortaz/Tazicef) CefTRIAxone (Rocephin) Cefepime (Maxipime) CefoTEtan (Cefotan) Cefotaxime (Claforan) Ceftizoxime sodium Cefuroxime Ciprofloxacin Clindamycin (Cleocin) Doxycycline Ertapenem (Invanz) Gentamicin (Garamycin) Imipenem/cilastatin (Primaxin) Levofloxacin (Levaquin) Linezolid Meropenem (Merrem) Metronidazole (Flagyl) Nafcillin Other Oxacillin Piperacillin/tazobactam (Zosyn) Sulfamethoxazole/trimethoprim (Bactrim/Septtra) Tobramycin Vancomycin	NULL = No Response
9	PED_SAP_NAME2	Char	SAP: Antibiotic #2 Name	Variable Name: Antibiotic #2 Name		
10	PED_SAP_NAME3	Char	SAP: Antibiotic #3 Name	Variable Name: Antibiotic #3 Name		
11	PED_SAP_TIME1	Num	SAP: Time from Antibiotic 1 to Procedure/Surgery Start	* Time from Antibiotic 1 to Procedure/Surgery Start in Minutes		-9999 = No Response Valid range is -180 to +30
12	PED_SAP_TIME2	Num	SAP: Time from Antibiotic 2 to Procedure/Surgery Start	* Time from Antibiotic 2 to Procedure/Surgery Start in Minutes		-9999 = No Response Valid range is -180 to +30
13	PED_SAP_TIME3	Num	SAP: Time from Antibiotic 3 to Procedure/Surgery Start	* Time from Antibiotic 3 to Procedure/Surgery Start in Minutes		-9999 = No Response Valid range is -180 to +30
14	PED_SAP_REDOSED	Char	SAP: IV Antibiotics Redosed During Case	Variable Name: IV Antibiotics Re-dosed During Case	Yes; No	NULL = No Response
15	PED_SAP_FINISH	Char	SAP: IV Antibiotics Continued After Procedure Finish	Variable Name: IV Antibiotics Continued After Procedure Finish	Yes; No	NULL = No Response
16	PED_SAP_TIMELAST	Num	SAP: Time to Last Dose of Antibiotics	Variable Name: Date/Time of Last Dose of IV Prophylactic Antibiotics in Minutes		-9999 = No Response Valid range is -180 to +30

