

User Guide for the 2015 ACS NSQIP Pediatric Procedure Targeted Participant Use Data File (PUF)

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Contents

Secti	ection	
1.	Introduction	1
2.	Merging Cases with the ACS NSQIP PUF	1
3.	Data Request Process	1
4.	File Description	2
5.	Data Collection Background and Data Quality	2
6.	Sampling Process and Case Exclusion Criteria	3
7.	Data Limitations	6
8.	Contact Information	7
9.	Frequently Asked Questions	8
10.	Data Variables and Definitions	11

1. Introduction

This document, along with the Procedure Targeted User Guide Table, is designed to accompany the 2015 Pediatric Procedure Targeted Participant Use Data File (PUF) available for download on the American College of Surgeons National Surgical Quality Improvement Program Pediatric (ACS NSQIP Pediatric) website (<u>www.facs.org/quality-programs/pediatric</u>). The data contained in this version of the Pediatric Procedure Targeted PUF covers dates of surgery from January 1, 2015 to December 31, 2015. The sections contained herein will provide the user with information on how to request the Pediatric Procedure Targeted 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 2015 Pediatric Procedure Targeted 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 Procedure Targeted PUF can do so by visiting <u>www.facs.org/quality-programs/pediatric</u> and following the steps listed below:

- 1. From the ACS NSQIP Pediatric main page (<u>www.facs.org/quality-programs/pediatric</u>) 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. You 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, SPSS, SAS) 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 Procedure Targeted PUF is available in one of three different formats - SAS, SPSS and Text.

File Name	Туре	File Size	Variables	Cases
PUF_TAR_APP_P_2015	SAS	3008 KB	20	10570
PUF_TAR_APP_P_2015	SPSS	2533 KB	20	10570
PUF_TAR_APP_P_2015	TEXT	1321 KB	20	10570

A brief description of the different formats follows:

5. Data Collection Background and Data Quality

The ACS NSQIP Pediatric collects data on approximately 120 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 an Inter-Rater Reliability (IRR) 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 IRR 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 5 or more preoperative risk factors and no reported mortality or morbidity or cases with 2 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 an IRR 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 operative log. The schedule works as follows: If the first cycle begins on a Monday, it continues through to the following Monday (an 8-day period of time). The next cycle begins on Tuesday and continues through to the following Tuesday, and so on. There are 46 8-day cycles in 1 year, and the program requires 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.

Case Inclusion Criteria

The following inclusion criteria were applied to cases collected in 2015. 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 2015. 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 and older
- Cases involving Hyperthermic Intraperitoneal Chemotherapy (HIPEC), regardless of whether or not the procedure performed has an included CPT code(s).
- ASA 6 (Declared brain-dead patients whose organs are being removed for donor purposes).
- A return to the operating room/ICU setting as the principal operative 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.
- Multiple cases within 30 days Multiple cases for the same patient within 30 days are excluded.
- Trauma Cases Specifically: Any injury with a principal ICD-9 diagnostic code within the range of 800-959.9. Additionally, excludes 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 met NSQIP Pediatric program inclusion criteria. Any suspected abuse/neglect with ICD-9 code within the range of 959.50-995.59 will be excluded.
 - Exception to Trauma Criteria: Include cases where there is an isolated limb section fracture and included CPT code.
- Transplant Cases Specifically: A patient who is admitted to the hospital for organ transplant surgery, and has additional surgical procedures performed during the same hospital stay, will be excluded. Any

operation performed after the patient has been discharged from the transplant stay will be included.

- Concurrent Cases An additional operative procedure performed by a different surgical team under the same anesthetic.
- CPT code different from that of the Principal Operative Procedure: an additional operative procedure performed by a different surgical team under the same anesthetic is not included as a separate case, but is listed as a concurrent procedure.
- Cases with CPT codes not on the CPT Code Inclusion List
- Procedures performed by a surgical service not reviewed in NSQIP Pediatric.
- SCR on vacation Each site is allowed to assign 6 of the 8-day cycles as vacation cycles and therefore does not need to collect cases during those cycles.

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. A site is excluded from the odds ratio calculations and the PUF if it fits any of the following criteria:

- 30-day follow-up rate is under 80%
- Inter-Rater Reliability Audit disagreement rate is over 5%

Case Selection

Step 1: "Essential 10" cases: ACS NSQIP Pediatric Full CPT code inclusion list.

- The first 10 "Essentials" cases are collected per 8-day cycle by applying all inclusion/exclusion criteria and collecting cases in consecutive order utilizing the ACS NSQIP Pediatric Full CPT Code inclusion list.
- If a targeted procedure (a CPT code that is on the Subspecialty inclusion list) comes up naturally in the "Essentials 10" systematic sampling process, it is counted as an "Essentials" case.

Step 2: Procedure Targeted Cases: Procedure Targeted (subspecialty) CPT Code Inclusion List

- Sampling numbers for each subspecialty area are based on each site's total annual volume in each subspecialty area and are provided by ACS in a worksheet.
- Hospitals use the volumes designated for each subspecialty area in their worksheet to collect the 25 procedure targeted cases.

- Hospitals must sample from all the CPT Codes for the subspecialty areas. A hospital cannot pick and choose a procedure or certain codes within a selected subspecialty.
- For each subspecialty, cases are selected in consecutive order by utilizing systematic sampling.

Step 3: Rounding Out to Achieve 35 Cases per Cycle

- If less than 35 cases are abstracted for a cycle, 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."
 - Start back where they left off on the operative log with the first "10 Essential" cases and collect additional cases from the Procedure Targeted CPT Code inclusion list using systematic sampling.
 - If 35 cases are not collected utilizing additional subspecialty procedures, additional cases may be collected by starting back where they left off with their first "10 Essential" cases and abstracting additional cases from the full CPT Code list using systematic sampling.
 - If 35 cases have not been collected after following the two previous steps, cases of the "limited procedures" (Appendectomy, Laparoscopic Cholecystectomy, and Gastrostomy) may be captured using the current sampling methodology.

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 indepth 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 (59% to 89%, 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 Procedure Targeted User Guide or PUF, as well as comments and suggestions for improvements are welcome and may be directed to Brian Matel, ACS NSQIP Statistical Report Manager, via email at <u>bmatel@facs.org</u>.

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 PUFbased 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) deidentified data from sites participating in the ACS NSQIP Pediatric that received odds ratios in 2015. The variable name, variable label, data definition, and other pertinent information are provided in Section 10: Data Variables and Definitions.
- Q: Are other Pediatric Procedure Targeted PUF data sets available?
- A: No, this is the first Pediatric Procedure Targeted PUF available.
- Q: Where can I find the Procedure Targeted variables and definitions?
- A: You can contact your site's SCR for the Procedure Targeted Variables and Definitions.
- 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.

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- 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 PUF exclude specific dates?
- A: In order to release the 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: <u>http://privacyruleandresearch.nih.gov/</u>

http://privacyruleandresearch.nih.gov/pdf/HIPAA_Booklet_4-14-2003.pdf.

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 5 digit CPT code but a CPT description set to NULL?
- A: If the case has a valid 5 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 file, an SPSS file, and a SAS file.

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Position #	Variable Name	Data Type	Variable Label	Variable Definition	Variable Options at Entry	Comments
1	CaseID	Num	Case Identification Number	Each case or record in the database has a unique CaseID number.		
2	PED_APP_APPENDECTOMY	Char	Acute appendectomy	Appendectomy performed for acute abdominal pain with a diagnosis of appendicitis made <= 7 days prior to hospitalization for operation.	Acute abdominal pain/acute or perforated appendicits	NULL = Unknown
				(Interval appendectomy : >7 days from initial hospital addmission for appendicitis.)	Interval appendectomy	
				(Other: chronic abdominal pain, incidental appendectomy, Ladd procedure, other)	Other	
3	PED_APP_PRE_CTOTHER	Char	Preoperative CT scan at another institution	Any preoperative CT scan of the abdomen and/or pelvis obtained at another/referring facility within 72 hours prior to hospital admission associated with appendectomy regardless of ordering physician, stated purpose, findings, impression, or control used.	Yes; No	NULL = Unknown
4	PED_APP_PRE_CT	Char	Preoperative CT scan at surgical institution	Any preoperative CT scan of the abdomen and/or pelvis obtained at the hospital where the surgery was performed within 72 hours prior to the hospital admission associated with the appedectomy regardless of ordering physician, stated purpose, findings, impression, or contrast used.		NULL = Unknown
5	PED_APP_PRE_ULTRAOTHER	Char	Preoperative ultrasound at another institution	Any preoperative ultrasound of the abdomen and/or pelvis obtained as a formal radiologic study at another/referring facility within 72 hours prior to hospital admission associated with appendectomy regardless of ordering physician, stated purpose, or impression.	Yes; No	NULL = Unknown
6	PED_APP_PRE_ULTRA	Char	Preoperative ultrasound at surgical institution	Any preoperative ultrasound of the abdomen and/or pelvis obtained as a formal radiologic study at the hospital where the surgery was performed within 72 hours prior to hospital admission associated with appendectomy regardless of ordering physician, stated purpose, findings, or impression.	Yes; No	NULL = Unknown
7	PED_APP_PRE_MRIOTHER	Char	Preoperative MRI at another institution	Any preoperative MRI of the abdomen and/or pelvis obtained at another/referring facility within 72 hours prior to hospital admission associated with appendectomy regardless of ordering physician, stated purpose, findings, or impression.	Yes; No	NULL = Unknown
8	PED_APP_PRE_MRI	Char	Preoperative MRI at surgical institution	Any preoperative MRI of the abdomen and/or pelvis obtained at the hospital where the surgery was performed within 72 hours prior to hospital admission associated with appendectomy regardless of ordering physician, stated purpose, findings, or impression.	Yes; No	NULL = Unknown
9	PED_APP_OPFINDING	Char	Definitive operative finding of complicated appendicitis	Documentation of operative findings noted in the immediate or formal operative report of complicated appendicits with the observation of a visible hole in appendix, fecalith in peritoneal cavity outside of the appendix, abscess, and/or diffuse fibrinopurulent exudate in peritoneal cavity.	Yes; No	NULL = Unknown
10	PED_APP_PATHDIAG	Char	Pathologic diagnosis	The final diagnosis of appendix by the pathologist as indicated on pathology report.	Normal appendix	NULL = Unknown
					Appendicitis	
					Other appendiceal pathology	4
		Char	Derevitere even direite ere	Any amination (during the second tension between a station of the second s	Not available	NUUL Labor
11	PED_APP_PERCDRAIN	Char	Percutaneous drainage	Any aspiration/drain placement for abdominal and/or pelvic fluid collection performed within 30 days following appendectomy regardless of ordering physician, stated purpose, findings, or impression.	Yes; No	NULL = Unknown
12	PED_APP_PICC	Char	Placement of PICC	PICC (percutaneously-inserted central catheter) or other central venous catheter was placed during the same hospitalization as appendectomy.	Yes; No	NULL = Unknown
	PED_APP_PAR_NUTRITION	Char	Parenteral nutrition after diagnosis	Total or partial parenteral nutrition (PN) initiated during the same hospitalization as appendectomy	Yes; No	NULL = Unknown
14	PED_APP_TEMP_POSTOP	Char	Postoperative temperature	Patient had a temperature greater than or equal to 38.5°C recorded on postoperative day 3 or 4 by an route.	Yes; No	NULL = Unknown

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Position #	Variable Name	Data Type	Variable Label	Variable Definition	Variable Options at Entry	Comments
15	PED_APP_POST_CTANY	Char		Any postoperative CT scan of the abdomen and/or pelvis obtained at any facility within 30 days following appendectomy regardless of ordering physician, stated purpose, findings, impression, or contrast used.	Yes; No	NULL = Unknown
16	PED_APP_POST_UTLRAANY	Char		Any postoperative ultrasound of the abdomen and/or pelvis obtained as a formal radiologic study at any facility within 30 days following appendectomy regardless of ordering physician, stated purpose, findings, or impression.	Yes; No	NULL = Unknown
17	PED_APP_POST_MRIANY	Char		Any postoperative MRI of the abdomen and/or pelvis obtained at any facility within 30 days following appendectomy regardless of ordering physician, stated purpose, findings, impression, or contrast used.	Yes; No	NULL = Unknown
18	PED_APP_PAR_ANTIBIO_DISCH	Char		Child is prescribed outpatient intravenous and/or intramuscular antibiotics to be administered following hospital discharge.	Yes; No	NULL = Unknown
19	PED_APP_ORAL_ANTIBIO_DISCH	Char	0	Child is prescribed outpatient oral antibiotics at hospital discharge following appendectomy for continued treatment.	Yes; No	NULL = Unknown
20	PED_APP_POST_ED	Char	Postoperative Emergency Department visit	Child had an ED visit within 30 days following appendectomy to any facility.		NULL = Unknown



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