

A Clinical Decision Rule to Identify Children with Intra-abdominal Injuries [Intra-abdominal Injury (IAI) Project] Overview of Public Use Datasets

This document overviews the study and the general principles used in creating the public use datasets for the Pediatric Emergency Care Applied Research Network (PECARN) Intra-abdominal Injury (IAI) Project. See the protocol for additional details of the study.

Introduction: The intra-abdominal injury (IAI) public use dataset is the data produced from a prospective cohort study of patients younger than 18 years with blunt torso trauma presenting to one of 20 participating emergency departments. The study was approved by the Human Subjects Research Committee at each site with waiver of consent at some sites and verbal consent for telephone follow-up at others. The subject population was enrolled from May 2007 through January 2010. A total of 12,044 subjects were enrolled.

Data Collection: Trained site investigators and other emergency department physicians recorded patient history, injury mechanism, and symptoms and signs on a standardized data form before knowing imaging results (if imaging was done).

Patients were admitted to the hospital at emergency department physician discretion.

Outcomes: We defined our main study outcome as ***intra-abdominal injury in need of acute intervention*** (IAI^{AI}) which was defined a priori as follows:

- Death secondary to an IAI
- Therapeutic intervention at laparotomy (i.e. necessary abdominal surgery)
- Angiographic embolization of an actively bleeding abdominal organ or other abdominal vascular structure
- Blood transfusion for anemia secondary to intra-abdominal hemorrhage from IAI
- Administration of IV fluids for greater than or equal to two nights to maintain hydration in patients unable to eat or drink because of their IAI (e.g. pancreatic or duodenal injury)

Note 1: Form 6b (Site PI Clinical Outcome form) and Form 6c (Clinical Outcome-Surgeon Data Collection form) collected the data that identified those patients with an intra-abdominal injury (IAI) and those patients with an intra-abdominal injury in need of acute intervention (IAI^{AI}), the main study outcome. It is important to differentiate this from data collected on form 4b (Imaging results Data Collection form –Study PI abstraction) where subjects with an *abdominal CT positive for IAI* were recorded.

Note2: Data on urine dipstick and urinalysis variables were dropped due to inconsistency and unreliability in the way that sites captured and reported urine results.

Note 3: Lactate data were only collected at one site.

There are a total of 68 public use datasets available as both CSV and SAS files (with formats and labels). Accompanying documentation and resources provided include the study protocol, the annotated eCRF, and, for each dataset, a PDF document summarizing variables in that dataset (i.e., frequency distributions or descriptive statistics). For SAS users, an example script to set up the SAS library and apply SAS formats is also provided. The annotated eCRF should be referenced frequently during analysis as this is the most complete reference of all variables included in each dataset. Please see the Research Data Use Agreement (RDUA) for a description of intended use and disclaimer.

GENERAL PRINCIPLES FOR CREATION OF DATASET

1. The population for the public use dataset is all enrolled patients. Screening information is not included. See the protocol for a detailed list of inclusion/exclusion criteria and for additional details of study conduct.
2. The datasets are primarily based on raw data as collected by the clinical sites. All variables are described in the annotated eCRF.
3. Sensitive or identifying information has been removed throughout the dataset as follows:
 - Dates have been recoded to reflect the number of calendar days from ED triage.
 - Limited open text fields are included. When included, these fields were reviewed in detail and any sensitive or identifying information was removed (i.e., entry redacted).
 - Identifying information such as date of birth, physician name, and site name have been removed.
4. If variables were collected in multiple locations within the CRF, the public use dataset only includes the final data source utilized for study analyses. In addition, variables collected for study purposes only, which would not be relevant to clinical research, are not included. Variables not included in the public use dataset do not appear on the annotated eCRF or are identified as *Not included*.
5. Many of the available datasets include only one record per patient (unique identifier *subjectID*). Other datasets are relational, that is, may have more than one record per patient. The annotated eCRF provides information as to the structure of each dataset and the unique identifier for each record.

LIST OF PUBLIC USE DATASETS AVAILABLE

- **demographics:** Demographics
- **form1:** Form 1 ED Visit
- **form1_abdabnormalities:** Form 1 ED Visit – abdomen abnormalities
- **form1_indicforabdct:** Form 1 ED Visit – factors used for obtaining abdominal CT
- **form1_mvccollision:** Form 1 ED Visit – motor vehicle collision
- **form1_pelvtenderloc:** Form 1 ED Visit – pelvic locations that are tender
- **form1_thoracicabnormalities:** Form 1 ED Visit – thoracic abnormalities
- **form2:** Form 2 ED Visit Kappa
- **form4a:** Form 4A Imaging Data
- **form4a_abdct:** Form 4A Imaging Data – abdominal CT imaging
- **form4a_abdothor:** Form 4A Imaging Data – other abdominal imaging
- **form4a_traumaticinj:** Form 4A Imaging Data – traumatic injuries on chest radiograph
- **form4a_us:** Form 4A Imaging Data – abdominal ultrasound imaging
- **form4bct:** Form 4B CT Findings
- **form4bct_ctfindings:** Form 4B CT Findings - injuries
- **form4bother_abdangio:** Form 4B Abdominal Angiography
- **form4bother_abdmri:** Form 4B Abdominal MRI
- **form4bother_bladder:** Form 4B Cystogram
- **form4bother_pelangio:** Form 4B Pelvic Angiography
- **form4bother_uppergi:** Form 4B Upper Gastrointestinal
- **form4bus:** Form 4B Abdominal Ultrasound
- **form4bus_iaiorgansinj:** Form 4B Abdominal Ultrasound - injuries
- **form4bus_ipfluidloc:** Form 4B Abdominal Ultrasound – intraperitoneal fluid location
- **form5:** Form 5 Laboratory Data
- **form5_alt:** Form 5 Laboratory Data – serum alt
- **form5_amylase:** Form 5 Laboratory Data – serum amylase
- **form5_ast:** Form 5 Laboratory Data – serum ast
- **form5_bicarb:** Form 5 Laboratory Data - bicarbonate
- **form5_bun:** Form 5 Laboratory Data – serum bun
- **form5_creatinine:** Form 5 Laboratory Data – serum creatinine
- **form5_hematocrit:** Form 5 Laboratory Data - hematocrit
- **form5_lipase:** Form 5 Laboratory Data – serum lipase
- **form5_wbc:** Form 5 Laboratory Data – white blood cells
- **form6a:** Form 6A Clinical Outcome RA
- **form6a_nonabdsurgery:** Form 6A Clinical Outcome RA – surgical procedures
- **form6b:** Form 6B Clinical Outcome PI
- **form6b_aortinjinterv:** Form 6B Clinical Outcome PI – aortic injury interventions
- **form6b_bonesfractured:** Form 6B Clinical Outcome PI – pelvic bone fractures
- **form6b_lgbowelinjury:** Form 6B Clinical Outcome PI – large bowel injury
- **form6b_smbowelinjury:** Form 6B Clinical Outcome PI – small bowel injury

- **form6b_thoracinj:** Form 6B Clinical Outcome PI – thoracic injury
- **form6c:** Form 6C Clinical Outcome Surgeon
- **form6c_fascialinterv:** Form 6C Clinical Outcome Surgeon – fascial injury interventions
- **form6c_gallbladinterv:** Form 6C Clinical Outcome Surgeon – gallbladder injury interventions
- **form6c_kidneyinterv:** Form 6C Clinical Outcome Surgeon – kidney injury interventions
- **form6c_lgintesinterv:** Form 6C Clinical Outcome Surgeon – large intestine injury interventions
- **form6c_liverinterv:** Form 6C Clinical Outcome Surgeon – liver injury interventions
- **form6c_pancreasinterv:** Form 6C Clinical Outcome Surgeon – pancreas injury interventions
- **form6c_smintesinterv:** Form 6C Clinical Outcome Surgeon – small intestine injury interventions
- **form6c_spleeninterv:** Form 6C Clinical Outcome Surgeon – spleen injury interventions
- **form6c_stomachinterv:** Form 6C Clinical Outcome Surgeon – stomach injury interventions
- **form6c_urinaryinterv:** Form 6C Clinical Outcome Surgeon – urinary bladder injury interventions
- **form7apancinj_comp:** Form 7A Pancreatic Injury – pancreatic injury complications
- **form7apancinj_spec:** Form 7A Pancreatic Injury
- **form7bgiinj:** Form 7B Gastrointestinal Injury – injury identification methods
- **form7bgiinj_colon:** Form 7B Gastrointestinal Injury – colon injury location
- **form7bgiinj_comp:** Form 7B Gastrointestinal Injury – GI injury complications
- **form7bgiinj_duod:** Form 7B Gastrointestinal Injury – type of duodenum injury
- **form7bgiinj_mes:** Form 7B Gastrointestinal Injury – mesenteric injury location
- **form7bgiinj_meth:** Form 7B Gastrointestinal Injury – small intestine injury identification method
- **form7bgiinj_phys:** Form 7B Gastrointestinal Injury – physicians’ suspicion
- **form7bgiinj_smint:** Form 7B Gastrointestinal Injury – small intestine injury location
- **form7bgiinj_spec:** Form 7B Gastrointestinal Injury
- **form7bgiinj_stom:** Form 7B Gastrointestinal Injury – type of stomach injury
- **form7cbladinj:** Form 7C Urinary Bladder Injury – injury identification methods
- **form7cbladinj_comp:** Form 7C Urinary Bladder Injury – bladder injury complications
- **form7cbladinj_spec:** Form 7C Urinary Bladder Injury
- **form7cbladinj_type:** Form 7C Urinary Bladder Injury – type of bladder injury