Pediatric Sedation Research Consortium: Database Orientation and FAQs

Where do I find the new database?

You can access the new database at this website:

https://www.sac-cu.org/PSRC/

The original database that was housed at Dartmouth will be referred to hereon in as the **legacy database**.

What are some of the major changes in the new database?

Here are select examples of some of the more prominent changes that were made (note that this is not meant to be an exhaustive list of all changes that were made):

- The data collection tool is now on one single webpage.

- We have re-defined the primary and co-existing medical diagnoses to allow you to choose more specific diagnoses. For example, instead of only being able to choose "Metabolic" as your primary or co-existing diagnosis, you can now choose more specific diagnoses under the category of Metabolic such as Type 1 DM and hypothyroidism. Obesity has been made its own category/diagnosis.

- We have transitioned to an "**intervention-based**" model where we will only be documenting an event (e.g. hypoxia, vomiting) if it was associated with a clinically meaningful intervention. This means that if an event occurred but you did not do anything about it, then we do not consider the event to be clinically meaningful and will not document the event. This model has the new ability to link interventions with the events that prompted the intervention.

- We have created three main clinically-relevant phases within which we will capture medication administration and interventions performed: Pre-sedation, Induction, and Maintenance. This will allow us to attribute medications and interventions to specific phases of the sedation and procedure. There is a fourth **opt-in** recovery phase, which will be discussed in more detail later in this document.

- We will be collecting the dose of medications administered. During induction, we will collect the TOTAL induction dose. During maintenance, if an infusion is used, we will collect the HIGHEST infusion rate that was used; if boluses are used during maintenance, the TOTAL cumulative dose of boluses will be collected. If an infusion is used, and intermittent boluses are given, we will collect the HIGHEST infusion rate used, and simply document that additional

boluses were given (yes/no). We will not be collecting the number of boluses, or dose of boluses, that are given in addition to an ongoing infusion.

Are there any new interventions that were not in the legacy database?

Yes. The legacy database focused on airway interventions. The new database collects interventions related to the airway as well as other systems including cardiovascular (eg. chest compressions), non-sedative interventions that are medications (eg. epinephrine, isotonic fluid bolus), and non-pharmacologic interventions (eg. Child Life Specialists).

We have added other clinically-relevant interventions such as "Unanticipated pause in procedure (but procedure completed)" that can be documented in response to an event (e.g. vomiting).

What if I performed an intervention pre-emptively (as part of my usual practice), not in response to some event that occurred?

We created the ability to designate if the intervention was "pre-emptive" or "in response" to an event (e.g. hypoxia). For example, you can perform and document the use of a neck roll as a pre-emptive intervention if that is something you do for every patient during a sedation to prevent an event, but was not performed in response to an event. For pre-emptive interventions, you can also indicate the duration for which it was used, so you do not have to enter it every time for every single phase. This is useful if you started the intervention in the pre-sedation phase and use it all the way through the maintenance phase.

When we document the sedative dose administered, are we supposed to record the total or highest dose given?

For the induction phase, record the TOTAL dose administered. For the maintenance phase, record the HIGHEST infusion rate administered if an infusion was given. If boluses are used during maintenance, the TOTAL cumulative dose of boluses will be collected. If an infusion is used, and intermittent boluses are given, we will collect the HIGHEST infusion rate used, and simply document that additional boluses were given (yes/no). We will not be collecting the number of boluses, or dose of boluses, that are given during an ongoing infusion. We recognize that we will not be able to capture exactly what was given during the maintenance phase if an infusion was used, and if an infusion was used with additional concurrent boluses. However, collecting these variables was decided to be the best balance between feasibility of collecting accurate data and collecting data that was still clinically meaningful and informative.

How will we know if we entered a variable incorrectly or if we are forgot to complete a field?

When you click "Submit (Complete)", variables that are missing or some predefined errors will be flagged for your review. These flags must be addressed before the form can be submitted for review.

Are there any new features to help reduce the amount of data we have to enter for every new patient?

Yes. We have created "templates" that each user can customize to allow a limited number of variables to always be pre-selected. For example, if you are an NP that always works in radiology and almost exclusively sedates for MRIs with dexmedetomidine, you can create a template that has all of those variables pre-checked. You will be able to create different templates to account for the most common scenarios specific to your individual practice.

The variables which can be pre-selected include:

- Procedure(s) performed
- Responsible provider
- Sedation location(s)
- Monitors
- Medication Type, Route, and Dose (units) for the pre-sedation, induction and maintenance phases

These are labelled with a blue T circle icon to indicate they are selectable for templates.

All other variables will not be able to be pre-selected, and will still need to be entered for every patient (e.g. interventions, drug dose used during maintenance).

In order to create, load, update, or delete the templates, use the "Manage Templates" button in the top right-hand corner. To create a new template, first you have to select the variables you wish to make up your template. After you have made your selections, go to "Manage Templates", check "Save as new template", give your template a name, and click "Save".

Can we still generate reports? Are there any changes?

The ability to generate reports is under development at this time. This functionality will be available June 2020.

Yes. You can still generate reports that include data from your own site that you have entered. You will now automatically see three columns of data: data from your own site, your peer group, and all other sites in the PSRC.

A reminder that the data from these reports are **not intended for conducting research or peer-reviewed publication**. If you wish to conduct a research study using the database, please refer to ***Guidelines for PSRC Research Study Proposals*** on the SPS website.

There have been a number of changes made to increase functionality. To generate reports, go to the Menu and select "Data Summaries". You will see that you have the ability to filter your reports based on multiple variables using multiple logic functions. If you wish to query data for a certain range of dates, filter using the "Procedure Date" variable. If you do not filter your reports using any of the variables, you will create a report using all data in the database.

Will we collect information for a recovery or post-sedation phase?

We will have the ability to collect data for a recovery or post-sedation phase. However, we recognize that not all PSRC sites have the resources or workflow to reliably collect this information. As a result, sites must **opt-in** to collect recovery phase data. This will allow us to more accurately assess and report on interventions and events that occur during this phase.

Practically speaking, this means that the default view is for the pre-sedation, induction, and maintenance phases to be visible to all sites. Only sites that have opted-in to collect recovery phase data will be able to see the recovery phase.

To opt-in to collect recovery phase data, email your request to the Research Committee Chair, Daniel Tsze (dst2141@cumc.columbia.edu).

Should our site collect recovery phase data?

It depends on your existing resources and workflow. If you wish to collect data for the recovery phase, you must be able to collect all relevant and required data uniformly and consistently for every patient that is sedated.

Is there anything different about how data is submitted and reviewed?

Yes, there have been a number of changes made in this process. You will see that the three main actions are to "Save (Incomplete)", "Submit (Complete)", and "Delete". When you click on "Save (Incomplete)", that allows you to leave the form partially completed and return at a later time to finish entering data.

"Submit (Complete)" means that you have entered all the data and are now submitting it for your designated site reviewer to approve for submission into the database. When you click this button, you have NOT submitted your data into the database. Data can only be submitted to the database by the reviewer once they have approved that entry. Clicking this button is also when you will receive flags that warn you of incomplete fields or potential errors in data entry for a certain number of fields. We currently have not implemented age-specific error flags for weight and height entries, but this functionality is under development.

Last updated June 3rd, 2020

Wait – are you telling me that the designated site reviewer has to review every single case?

No, the designated site reviewer does not have to review every single case. The site reviewer does, however, need to *approve* every single case for submission into the database.

As part of our ongoing process to refine our data auditing procedures, our first step was to create some degree of uniformity in when (and eventually how) cases are selected for auditing as part of our data integrity assurance. This meant that all cases will be submitted to the site's designated reviewer before it is submitted to the database, and the selection of which cases will be audited will occur at that stage, rather than at the user stage. The designated site reviewer, at this time, will still be able to select which cases to be reviewed and audited, and may submit other cases to the database without a review or audit – these cases (that are not reviewed) are the ones that receive a simple "approval" by the site reviewer and are submitted into the database without a review. We recognize that this will require some adjustment to how you have currently been auditing your data, and we appreciate your understanding. The auditing process will continue to evolve over time, but this change will allow us to set the foundation for further development.

If my patient was born premature but currently does not have any active prematurity-related issues, how do I document that?

In "Primary reason for procedure" or "Co-existing medical problem", select "Born <37 weeks" and use the dropdown menu to select the patient's gestational age. Since your patient does not have any active prematurity-related issues, you do not have to document anything else.

If my patient was born premature but does have active prematurity-related co-morbidities, how do I document that?

When you select "prematurity" as a primary reason for procedure or co-existing medical problem, you will see that prematurity is defined as <37wk GA and you will have the opportunity to indicate how weeks GA the patient was in the drop down menu that appears when you select "Born <37 weeks GA". You will notice that unlike the legacy database, however, we do not list prematurity-associated co-morbidities in the Prematurity section. Instead, we ask that if the patient has an active or currently treated prematurity-related problem, you document it in the section corresponding to the problem. For example, if your patient has active CLD/BPD, you would indicate that in the "Respiratory, lower" section. If your patient has a prematurity-related problem that has resolved, does not require treatment, or does not have any clinically-relevant sequelae, you do not have to document this problem at all. These instructions can also be found in the hover text for "Prematurity".

Should I document sedatives or analgesics that were given before a procedure performed, but not necessarily in preparation (or in direct relation) to the actual procedure? For example, should I document a dose of morphine given for analgesia to a patient with a fracture, even though it was not given as part of the sedation plan?

Sedatives or analgesics that are given before induction should be documented in the pre-sedation phase if you think that induction will occur during the sedative or analgesic's expected duration of action, or if you think the medication is still having a clinical effect on the patient. For example, you should document a dose of intranasal fentanyl in the pre-sedation phase if it was given 30 minutes before induction for a closed fracture reduction. However, you should not document the intranasal fentanyl if it was given 3 hours before induction for the procedure.

Is there a way to flag cases in which an event requiring an intervention occurred?

Cases in which an intervention was performed in response to an event will be automatically flagged as "Y" in the "Event" column in the designated site reviewer's list of cases pending approval/review. Only the designated site reviewer will be able to see this flag. You, as the user, do not have to do anything to trigger this flag.

How do I document the discontinuation of a procedure because an IV infiltrated and a parent will not let us place another IV?

Choose "Discontinued procedure" as the intervention, and indicate that is was performed "in response". In the events section, there are "IV-related event" and "Parenteral preference", which are meant to capture events such as IV infiltration or inability to obtain IV access and parental refusal, respectively.

Do I have to repeatedly enter a pre-emptive intervention that is being used from pre-sedation through maintenance in every one of those phases (i.e. pre-sedation, induction, and maintenance)?

No, you do not have to enter the same pre-emptive intervention in every phase that it is used (e.g. supplemental oxygen that is placed during pre-sedation and kept on until the end of maintenance phase). You only have to enter it once in the phase in which it was initiated, and use the "Duration" drop-down menu to indicate which subsequent phases also used the same pre-emptive intervention.

If you have indicated that a pre-emptive intervention was used in an earlier phase, do not enter the same intervention in a subsequent phase – leave that specific intervention blank in the subsequent phase. If you do not leave it blank, the system will recognize this as an error and prompt you to remove it before you are allowed to submit your entry.

Why does it appear like I have to keep entering pre-emptive interventions in every phase when I already said the duration of when I would be using it in the pre-sedation phase?

To allow users to be able to enter data in any phase in whatever order they like, or change data entered at any stage without affecting previously entered data, the system cannot prefill other variables based on what may have been entered in another phase.

This means if you enter a pre-emptive intervention in one phase and indicate that it will be performed for the duration of a certain number of subsequent phases, you just need to remember NOT to enter the same intervention in those subsequent phases. For example, if you document in the pre-sedation phase that you are using supplemental oxygen pre-emptively all the way through the maintenance phase, do not enter supplemental oxygen as an intervention in the induction and maintenance phases. You can enter other interventions, but you would not need to enter supplemental oxygen as a pre-emptive intervention in the induction and maintenance phases.

How do I document the dose of a sedative if multiple small boluses are given serially to maintain sedation?

If you are giving multiple boluses during the maintenance phase to provide sedation, document the total dose that was administered (i.e. add up all of the boluses that were given).

However, if you are using an infusion during the maintenance phase and you are giving additional supplemental boluses while the infusion is running, document the highest infusion rate administered and then check off the box "+ bolus(es)" to indicate that supplemental boluses were given. You do not need to document the dose of boluses given nor the number of boluses that were given during the infusion.

If I give lidocaine with propofol to decrease the pain associated with propofol injection, how do I document that?

Document the use of lidocaine for propofol injection pain in the "Interventions/other medications" section. In the "Medications" category, check the option "Liodcaine for propofol injection pain" and indicate that it was pre-emptive.

If Child Life was present to access a port prior to the sedation, should their involvement be documented in the pre-sedation phase?

If accessing the port is part of the overall sedation/procedure (e.g. starting an IV to obtain access for sedative administration), then yes, you should document Child Life as a pre-emptive intervention in the pre-sedation phase.

If my patient is already on pre-emptive supplemental oxygen, but something happens later on and I have to either increase the amount of oxygen being given or change to a different form of oxygen delivery (e.g. change from nasal cannula to face mask), how do I document that?

In "Interventions/Other Medications" under "Airway/Breathing", there is an intervention called "Increased supplemental oxygen support" that you should check off in this and other similar circumstances.

How do we differentiate between a topical anesthetic (e.g. LMX) that is placed for an IV versus a topical anesthetic that is placed for the procedure itself (e.g. LP)?

In "Interventions/Other Medications" under "Medications", when you click on "Topical anesthetic, lidocaine based" or "Other local/topical anesthetic…", there will be a drop-down menu that allows you to indicate whether the topical anesthetic was placed for the IV cannulation, the procedure, or for both.

If a patient recovers in an area that is different from where the sedation/procedure was performed, should both locations be documented in sedation location(s)?

No. Only document the location where the sedation/procedure was performed. However, if the sedation/procedure was conducted in two different places (i.e. two different procedures were completed in two different locations during the same sedation event), you should document both locations.

If we document an intervention that is in response to an event during induction (e.g. oral airway in response to airway obstruction), and we keep the oral airway in place through maintenance, how should we document this?

In the induction phase, document the intervention (oral airway) in response to an event (airway obstruction). Then in any subsequent phase in which you continue to use this same intervention (e.g. maintenance), enter it again as the same intervention (oral airway) in response to the same event (airway obstruction). Do not enter it as a pre-emptive intervention in the subsequent phase (e.g. maintenance).

How do I report a bug?

When you encounter a bug or error in the system, email the Research Committee Chair (Daniel Tsze, dst2141@cumc.columbia.edu) with the following three things:

1. A description of the error and (as best you can) all the steps leading up to the error. An important part of diagnosing the error is to be able to reproduce it.
2. The procedure number for the case(s) in which the bug or error occurred.
3. Screenshots of any errors or error messages.

Is there a video that provides a walk-through of the new database?

Yes, we have an orientation video that walks you through the new database and some of the most pertinent changes. The video can be accessed at the following link;

https://youtu.be/uKZGerMUamU

Feel free to share this link with any of your colleagues who will be using the new PSRC database.

Help, I still have questions!

If you still have questions, it is more than likely that others have the same questions as well. Please reach out to the Chair and Vice Chair of the Research Committee, Daniel Tsze (dst2141@cumc.columbia.edu) and Kevin Couloures (kcouloures@stanford.edu), with your questions We will address them and add frequently-asked questions to this document on an ongoing basis.