

Prospective Longitudinal Study

**Mapping of Lifetime Potential Concussive
Events (PCEs) Structured Interview for
Potential Concussive Event (PCE) Mapping**

STUDY ASSESSMENTS

Mapping of Lifetime Potential Concussive Events (PCEs) Structured Interview for Potential Concussive Event (PCE) Mapping

1.1 PCE Mapping Overview

Potential concussive events (PCEs) are past events in which possible injury to the head (or neck) occurred that may or may not have resulted in a TBI. The PCE mapping interview (derived from the OSU-TBI-ID interview), associated concussion diagnostic interview(s) (CDIs) and subsequent determination of index date are critical components of the Prospective Longitudinal Cohort Study. The interviewer should use the Web Interview System to guide the interview and enter data directly as he/she interviews the participant. Note that interview terminology for PCEs is “incidents” or “injuries.”

The PCE mapping interview is conducted in two separate but nearly identical parts. In **Part-1** PCEs are sought for during all combat deployment(s), and in **Part-2** they are sought for outside of combat deployment (i.e., during any other part of military career or civilian life). In both parts, as each PCE is identified, further information is gathered to help determine if it resulted in a clinical TBI, and if so how severe. This is done for every PCE by way of either a full concussion diagnostic interview (CDI), or a few screening questions (cause?, dazed?, memory gap?, LOC?), or in some cases both screening and full CDI. Ideally, all PCEs would undergo full CDI; but in recognition this may be impractical in some heavily exposed participants there is a soft cap on the number of mandated CDIs in **Part-1** and separate cap in **Part-2** (after which the screening questions may be substituted for further PCEs). The objective is to capture with a CDI all “key” PCEs from all combat deployments combined plus all “key” PCEs from non-combat deployment periods of life. MOP section 3.14 details whether a PCE is key and requires a full CDI. Discretion of the site PI will be used to determine which, if any, extra CDIs will be completed beyond the mandatory minimum.

Importantly, both the CDIs and screening questions are designed for only a single event. In cases where a series of PCEs occurred within the same day (for example, four very close explosions during a combat engagement), they should not be grouped together; instead it is necessary to isolate one or more individual PCE(s).

1.2 Form structure

The first form used first during the interview process is the parent form, the PCE Mapping Form. This form guides the interview and is thus divided into two parts, Part-1 Deployment PCEs and Part-2 NON-deployment PCEs. As the participant answers PCE identification questions on this form, the interviewer will be further directed into 3 potential data collection locations (separate embedded form structures) for supplemental interview depending on the type of PCE identified. These embedded form structures are:

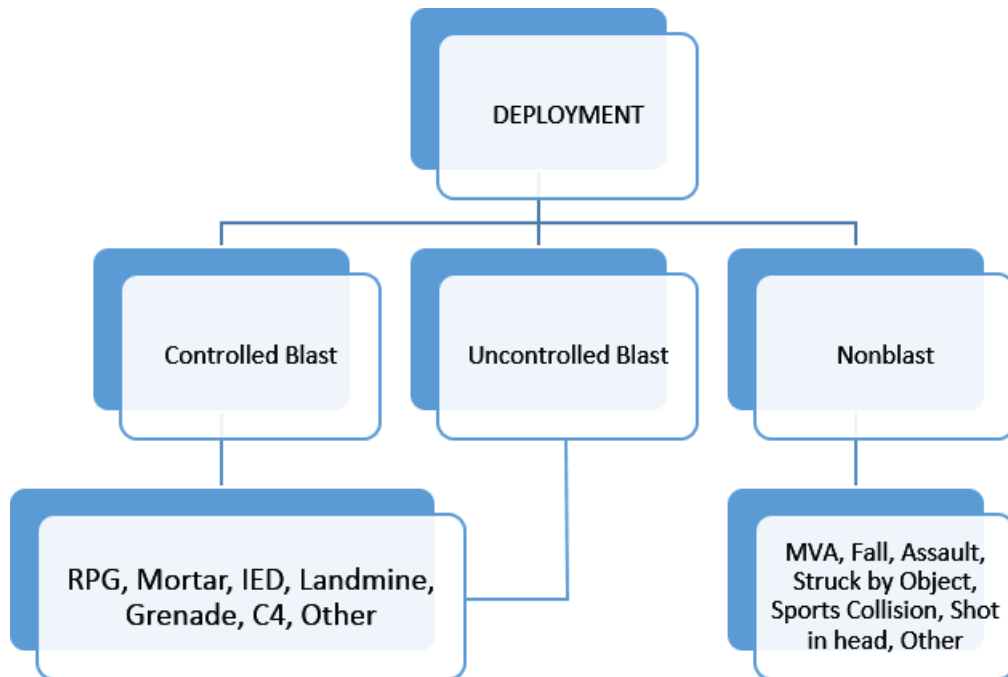
- a. CDI-Blast (full TBI interview used for injuries related to a blast/explosion)
- b. CDI-General (full TBI interview used for injuries related to a nonblast cause)
- c. Alternative embedded screening questions where full CDI may be deferred. The embedded screening questions are limited to the first incident for each PCE Mapping category-Cue PCE (i.e. specific scenerios such as motor vehicle accident). The PCE Table must be used for any additional incident(s) in that category.

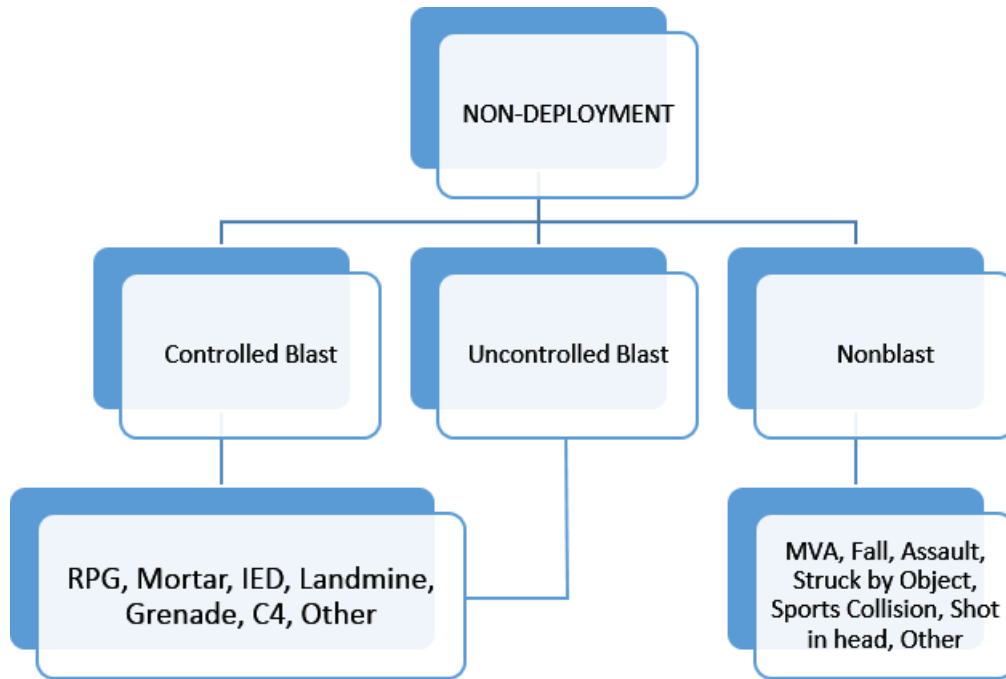
The purpose of the CDI-Blast and CDI-General forms is to gather the most detail about the key PCEs. Other potential concussive events beyond the key events will be captured in the embedded screening questions and if needed the PCE Table. The purpose of the screening questions is to document these non-key PCEs, but in less detail than the pre-specified key events. The embedded screening questions should be completed to capture the first incident for each category-Cue PCEs (i.e. MVA, Fall, Assault, Treated/Evacuated, Shooting, Controlled Blast, etc) and every additional incident for that category must be entered in the PCE Table. Since uncontrolled blast incidents are the most common category-Cue PCE during deployment, the first two events in this category can be captured in the embedded screening questions and the PCE Table must be used for any additional deployment uncontrolled blast events.

1.3 PCE causes

Both CDIs, embedded screening questions and the PCE Table capture the cause of the PCE. PCE causes are divided into three main categories: controlled blast, uncontrolled blast, and nonblast. Examples of the PCE cause subcategories for a controlled or uncontrolled blast are Mortar, IED, Land mine, Grenade (includes RPG), C4, or None of the above. Examples of the PCE cause subcategories for nonblast injury are MVA, Fall, Assault, being struck by an object, Sports

collision, being Shot in the head, or None of the above. If the specific cause does not match one of the response options, the coordinator will have a free text field within the web system to type the entry. Note that the main category of controlled blast has unique features during mapping that are described in MOP section 1.4.3.





1.4 Free-Recall versus Category-Cue PCEs and how to determine if a PCE must undergo CDI versus embedded screening questions and PCE Table form structure assessment.

1.4.1. Free-Recall PCEs: Both parts of the PCE mapping interview and form begin by asking the participant to report up to 3 freely recalled PCEs starting with the “worst” one. **All Free-Recall PCEs are automatically designated as “key” PCEs and a full CDI is required for each one.** In Medidata, the Free-Recall PCEs are programmed to present a blank CDI when present once the PCE Mapping form has been saved.

Part-1 Default Key PCEs; full CDI must be administered for each:

1. Participant identified “Worst” deployment related PCE
2. Participant identified 2nd worst deployment related PCE
3. The first deployment related PCE

Part-2 Default Key PCEs; full CDI must be administered for each:

1. Participant identified “Worst” NON-deployment related PCE
2. Participant identified 2nd worst NON-deployment related PCE

3. The first NON-deployment related PCE

1.4.2. Category-Cue PCEs: In both Part-1 and Part-2 of PCE mapping, after the Free-Recall PCEs are queried the interviewer then asks about specific types (categories) of events in hopes of triggering further recall and reporting of past PCEs. Incidents found in this series of questions are the Category-Cue PCEs. **Category-Cue PCEs are generally considered non-key** for the purpose of collecting CDIs; **In Medidata** they are programmed to present embedded screening questions for only the first incident in each category type when endorsed “Yes”. If there are more than one incident for one category, then the “Additional Incidents” question must be answered “yes” and the additional events must be entered in the PCE Table. The one exception is the deployment uncontrolled blast category, which is programmed to present embedded screening questions for the first **two** incidents. **A Category-Cue PCE may be key and need a CDI.** **Whether a Category-Cue PCE in either Part-1 or Part-2 is key depends on how many Free Recall PCEs were found and underwent full CDI in Part-1 or Part-2 respectively.** See below for when Category-Cue PCEs are considered key, in which case the default embedded screening questions and table form structure do not suffice, and a CDI must be administered:

Exception #1 to default non-key designation; a Category-Cue PCE becomes key:

- When fewer than 3 Free-Recall CDIs were completed in that part of mapping.
 - **If only 2 Free-Recall CDIs were done in one part**, then **the first Category-Cue PCE** (other than a controlled blast) found in that part **must undergo CDI**.
 - **If only 1 Free-Recall CDI was done in one part**, then **the first 2 Category-Cue PCE** (other than a controlled blast) found in that part **must undergo CDI**.
 - **If no Free-Recall CDI was done in one part**, then **the first 3 Category-Cue PCEs** (other than controlled blast) found in that part **must undergo CDI**. Additionally, **if the only Category-Cue PCE(s) found in this part are of the controlled blast type, then the worst controlled blast must undergo CDI**. To do so in Medidata, enter the event date in the default screening question and/or the table form, click on “yes” in the “CDI needed?” field/column, if applicable select the appropriate event type in “Specify type” field/column, and save the PCE form; a

CDI form will then be presented as a form below the “PCE Mapping Form” once the page has been saved.

Exception #2 to default non-key designation; a Category-Cue PCE becomes key:

- If in either part of the mapping (i.e. Part-1 or Part-2 separately) **all CDIs done so far have been negative for TBI** then **a CDI is necessary for any embedded screening questions and/or table entry that screens positive for TBI** (e.g. either Dazed?, Memory gap? Or LOC? has a yes response). To do so in Medidata, enter the event date in the default screening question and/or the table form, click on “yes” in the “CDI needed?” field/column, if applicable select the appropriate event type in “Specify type” field/column, and save the PCE form; a CDI form will then be presented as a form below the “PCE Mapping Form” once the page has been saved.

Using this prioritization, there will typically be a maximum of 3 deployment CDIs completed in Part-1, beyond which additional Part-1 deployment PCEs identified will undergo screening only with the modified OSU-TBI-ID query (Dazed?, Memory gap?, LOC?). Similarly, there will typically be a maximum of 3 NON-deployment CDIs completed in Part-2, beyond which additional NON-deployment PCEs identified in Part-2 will undergo screening only. However, in some cases additional CDIs may be done under the discretion of site investigators (e.g. if the screening process indicates another PCE may be the worst or earliest).

Note that controlled blast, a special type of Category-Cue PCEs, are discussed further below.

1.4.3. Controlled Blast PCEs: If controlled blast PCEs present, mapping asks for the worst, first, and estimate of total number of these exposures. Like the other Category-Cue PCEs, Controlled Blast PCEs are typically non-key PCEs, but instead of interrogating every controlled blast with embedded screening questions or with the Table form structure, **only the worst and first controlled blast PCE are interrogated**. Thus, use the embedded screening questions to ask for additional details of the worst controlled blast event. If the first controlled blast is not the same as the worst one then click “yes” to the “additional incident?” question and capture the first controlled blast event in the PCE Table.

Importantly, by definition a Controlled Blast properly carried out will not cause a clinical TBI.

Thus, **any Controlled Blast captured in the follow-up questions or in the table entry that**

screens positive for TBI (e.g. either Dazed?, Memory gap? Or LOC? has a yes response) **should be entered as Uncontrolled type in the embedded screening questions and the PCE Table** (i.e. it was not adequately controlled). It **then becomes a typical Category-Cue PCE and is managed as noted above in MOP section 1.4.2** (i.e. subject to being key PCE and needing CDI if less than 3 key PCEs were done in that part and/or if all CDIs in that part have been negative for TBI). **If this happens, the interviewer should also ask for the next worst controlled blast and capture in the PCE Table** and continue this process until entering one that screens negative for TBI.

As long as the Worst Controlled Blast screens negative for TBI, there is only one scenario where it becomes a key PCE (and needs CDI) [This scenario was explained in MOP section 1.4.2, Category-Cue Exception #1, second bullet point.]: **If in either part of the mapping** (i.e. Part-1 or Part-2 separately) **Controlled Blast is the only type of PCE found** (i.e. no other PCEs whatsoever found in that part of mapping and thus no CDIs completed). **If this happens, then the Worst Controlled Blast PCE is considered key and must undergo full CDI.** Additionally, if that CDI is positive for TBI, the interviewer should ask for the next worst controlled blast and capture the event in the PCE Table and continue this process until entering one that screens negative for TBI.

1.4.4. When in doubt: . It is important to note that there is a constant assessment as the participant describes the PCEs as to whether it meets the criteria to gather more detail (CDI blast and general forms) or less detail (embedded screening questions and PCE Table). This assessment process is described in the MOP sections below. To be safe, a CDI should be performed for any event when there is any question whether or not it is a Key PCE.

1.5. PCE dates: The PCE Form only requires a month and year of injury. *If a participant cannot recall an exact date, please use the method below to determine a month. Ask the participant if he/she is able to remember the season. For each season, use the corresponding month below.*

Spring = April

Summer = July

Fall = October

Winter: confirm year with participant and ask if it was early winter or mid-late winter

Early winter = December

Mid/late winter = January

If the participant remains unable to give a date, explain that it is okay to guess and that their guess will be better than ours. In particular, it is crucial to document a date for the key PCEs.

1.6. Part-1 Mapping Details:

PCE Part-1. Deployment Potential Concussive Events (PCEs)

Collect the greatest detail, via the CDI-General or CDI-Blast (depending on source) form, on these 3 Deployment Free-Recall PCEs:

- Worst
- 2nd Worst
- First



Proceed with collecting information on the following types of Category-Cue PCEs during deployment.

- **Controlled detonation** (e.g. breaching tactics) – Record the worst **controlled detonation** (or first if participant cannot classify an event as “worst”) by completing all the embedded screening questions or all the columns in a row on the PCE Table. Usually mark “No” in “CDI needed” field/column [Remember that if no deployment CDIs get done once through entirety of Part 1, then must come back, change “CDI needed” mark from “No” to “Yes”, and do full Blast-CDI on this event.] Additionally, if the worst controlled detonation screens positive for TBI (e.g. either Dazed?, Memory gap? Or LOC? has a yes response) then 1) enter or change entry to “Uncontrolled” in the Controlled/Uncontrolled field/column, 2) If < 3 CDIs have been performed so far in Part-1 then mark “Yes” for “CDI Needed” field/column and do full CDI on this event, and 3) if multiple controlled detonations exposures during deployment, click on “yes” in the “additional incident” field in the embedded screening questions and enter the next worst **controlled blast event in the PCE Table** and repeat above steps until one entered

where all embedded screening responses are “No” The total number, and date ranges (first and most recent) for these exposures are also collected. After interrogating the worst controlled blast, ask for the date of their first and most recent controlled blast exposure and query the first event using the PCE Table



- **Uncontrolled explosion/blast** – If at least 3 key deployment events have already undergone CDI, then record the first two **uncontrolled blast** events in the embedded screening questions . **If more, complete a table entry for any additional uncontrolled blast.** If 3 key deployment events have NOT already been met (interviewed with CDI), then record the worst **uncontrolled blast** using the CDI-Blast form. If 3 key events have still NOT now been met (interviewed with CDI) then assess the second worst **uncontrolled blast** (if more exist) using the CDI-Blast form.



- **Events requiring medical evacuation or medic treatment** - If at least 3 key deployment events have already undergone CDI, then record the first **evacuation/medic** event in the embedded screening questions. If more, complete a table entry for any additional evacuation/medic events. If 3 key deployment events have NOT already been met (interviewed with CDI), then record the worst **evacuation/medic** event using the CDI form. If 3 key events have still NOT now been met (interviewed with CDI) then assess the second worst **evacuation/medic** event (if more exist) using the CDI form.



- **Events involving moving vehicle accident (MVA)** (E.g. bicycle, motorcycle, ATV, car) – If at least 3 key deployment events have already undergone CDI, then record the first **MVA** event in the embedded screening questions. If more, complete a table entry for any additional MVA events. If 3 key deployment events have NOT already been met (interviewed with CDI), then record the worst **MVA** event using the CDI-General form. If 3 key events have still NOT now been met (interviewed with CDI) then assess the second worst **MVA** event (if more exist) using the CDI-General form.



- **Events involving Fall or Head Strike** (Struck by Object) - If at least 3 key deployment events have already undergone CDI, then record the first **Fall/Strike** event in the embedded screening questions. If more, complete a table entry for any additional Fall/Strike events. If 3 key deployment events have NOT already been met (interviewed with CDI), then record the worst **Fall/Strike** event using the CDI-General form. If 3 key events have still NOT now been met (interviewed with CDI) then assess the second worst **Fall/Strike** event (if more exist) using the CDI-General form.



- **Events involving Assault** - If at least 3 key deployment events have already undergone CDI, then record the first **Assault** event in the embedded screening questions. If more, complete a table entry for any additional Assault events. If 3 key deployment events have NOT already been met (interviewed with CDI), then record the worst **Assault** event using the CDI-General form. If 3 key events have still NOT now been met (interviewed with CDI) then assess the second worst **Assault** event (if more exist) using the CDI-General form.



- **Events involving Shooting Incident** - If at least 3 key deployment events have already undergone CDI, then record the first **Shot** events in the embedded screening questions. If more, complete a table entry for any additional Shot events. If 3 key deployment events have NOT already been met (interviewed with CDI), then record the worst **Shot** event using the CDI-General form. If 3 key events have still NOT now been met (interviewed with CDI) then assess the second worst **Shot** event (if more exist) using the CDI-General form.



Stop and Review

- **Were fewer than 3 deployment CDIs completed?** – If less than three completed, then one or more event(s) (except controlled blast type) existing in the embedded screening questions or in the PCE Table must undergo full CDI. Go back into the earliest embedded screening questions and table entries that has any events that are not controlled blast type, ask which was the worst, enter “Yes” in the “CDI Needed” field/column for that event, and assess it with a full CDI. If this was the only deployment CDI done, then two other events (except controlled blast type) existing in the embedded screening questions or table must also undergo CDI. Not counting controlled blast events, ask for the second worst event from the earliest embedded screening questions or table (or the worst event from a subsequent deployment embedded screening questions or table), enter “Yes” in the “CDI Needed” field/column for that event, and assess it with a full CDI.

- **Even after above step, were zero deployment CDIs completed?** – If no deployment CDIs whatsoever have been done, then the worst controlled blast must undergo CDI. If any controlled blasts exposures were endorsed, go back to the embedded screening questions, enter “Yes” in the “CDI Needed” field for the worst controlled detonation, and assess it with a full CDI.

- **Are any deployment CDIs missing an auto-populated preliminary TBI diagnosis?**
[Review the last page of each one to determine. If data entry was complete the algorithm (Appendix D) should have marked either “TBI with PTA”, “TBI without PTA” or “Not TBI”. Pay attention to the diagnosis generated which pertains to the next step] – If any are missing then CDI data entry is incomplete; complete data entry and ask any questions that were missed.

- **Does every single deployment CDI have “Not TBI” as the preliminary TBI diagnosis?** [If you did not pay close attention during CDI review in above step and are not sure then review the last page of every one again to determine.] – If every deployment CDI is negative for TBI, then all the embedded screening questions and table entries must also be reviewed here. A CDI is necessary for any embedded screening questions and table

entry that screens positive for TBI (e.g. either Dazed? Memory gap? Or LOC? has a yes response). To do so in Medidata, enter the event date in the default embedded screening question and/or the table form, click on “yes” in the “CDI needed?” field/column, if applicable select the appropriate event type in “Specify type” field/column, and save the PCE form; a CDI form will then be presented as a form below the “PCE Mapping Form” once the page has been saved.

The total concussion diagnostic interviews at the end of this deployment session should generally equal up to 3. All additional deployment PCEs should generally be captured in the embedded screening questions and entered into the PCE Table if needed. Now proceed to Part-2. Because exceptions exist, conduct a full CDI whenever in doubt.

1.7. Part-2 Mapping Details:

PCE Part-2. Non-Deployment Potential Concussive Events (PCEs)

Collect the greatest detail, via the CDI-General or CDI-Blast (depending on source) form, on these 3 Non-deployment Free-Recall PCEs:

1. Worst
2. 2nd Worst
3. First



Proceed with collecting information on the following types of Category-Cue PCEs during non-deployment periods (includes civilian life as well as military life outside of deployment).

- ❖ Events involving Hospitalization or ER - If at least 3 key non-deployment events have already undergone CDI, then record the first **hospital/ER** event in the embedded screening questions. If more, complete a table entry for any additional Hospitalization/ER events. If 3 key non-deployment events have NOT already been met

(interviewed with CDI), then record the worst **hospital/ER** event using the CDI-General form. If 3 key events have still NOT now been met (interviewed with CDI) then assess the second worst **hospital/ER** event (if more exist) using the CDI-General form.



- ❖ **Events involving MVA** (e.g. bicycle, motorcycle, ATV, car) - If at least 3 key non-deployment events have already undergone CDI, then record the first **MVA** event in the embedded screening questions. If more, complete a table entry for any additional MVA events. If 3 key non-deployment events have NOT already been met (interviewed with CDI), then record the worst **MVA** event using the CDI-General form. If 3 key events have still NOT now been met (interviewed with CDI) then assess the second worst **MVA** event (if more exist) using the CDI-General form.



- ❖ **Events involving Fall or Head Strike** (also Struck by Object) - If at least 3 key non-deployment events have already undergone CDI, then record the first **Fall/Strike** event in the embedded screening questions. If more, complete a table entry for any additional Fall/Strike events. If 3 key non-deployment events have NOT already been met (interviewed with CDI), then record the worst **Fall/Strike** event using the CDI-General form. If 3 key events have still NOT now been met (interviewed with CDI) then assess the second worst **Fall/Strike** event (if more exist) using the CDI-General form.



- ❖ **Events involving Sports Collision** (e.g. playing sports or on playground) - If at least 3 key non-deployment events have already undergone CDI, then record the first **Sport Collision** event in the embedded screening questions. If more, complete a table entry for any additional Sport Collision events. If 3 key non-deployment events have NOT already been met (interviewed with CDI), then record the worst **Sport Collision** event using the CDI-General form. If 3 key events have still NOT now been met (interviewed with CDI) then assess the second worst **Sport Collision** event (if more exist) using the CDI-General form.



- ❖ **Events involving Shooting Incident** - If at least 3 key non-deployment events have already undergone CDI, then record the first **Shot** event in the embedded screening questions. If more, complete a table entry for any additional Shot events. If 3 key non-deployment events have NOT already been met (interviewed with CDI), then record the worst **Shot** event using the CDI-General form. If 3 key events have still NOT now been met (interviewed with CDI) then assess the second worst **Shot** event (if more exist) using the CDI-General form.



- ❖ **Controlled detonation** (breaching tactics) – Record the worst non-deployment **controlled detonation** (or first if participant cannot classify an event as “worst”) by completing all fields in the embedded screening questions. [Remember that if no non-deployment CDIs get done once through entirety of Part 2, then must come back, change mark to “Yes”, and do full Blast-CDI on this event.] Additionally, if the worst controlled detonation screens positive for TBI (e.g. either Dazed?, Memory gap? Or LOC? has a yes response) then 1) enter or change entry to “Uncontrolled” in the Controlled/Uncontrolled field/column, 2) If < 3 CDIs have been performed so far in Part-2 then mark “Yes” for “CDI Needed” field/column and do full CDI on this event, and 3)) if multiple controlled detonations exposures outside deployment, click on “yes” in the “additional incident” field in the embedded screening questions and enter the next worst controlled blast in the PCE Table and repeat above steps until one entered where all screening responses are “No”. The total number, and date ranges (first and most recent) for these exposures are also collected.



- ❖ **Uncontrolled explosion/blast** – If at least 3 key non-deployment events have already undergone CDI, then record the first **Uncontrolled Blast** event in the embedded screening questions. If more, complete a table entry for any additional uncontrolled Blast event. If 3 key non-deployment events have NOT already been met (interviewed

with CDI), then record the worst **Uncontrolled Blast** event using the CDI-General form. If 3 key events have still NOT now been met (interviewed with CDI) then assess the second worst **Uncontrolled Blast** event (if more exist) using the CDI-General form.

Stop and Review

- **Were fewer than 3 non-deployment CDIs completed?** – If less than three completed, then an existing event(s) in the embedded screening questions or PCE Table (except controlled blast type) must undergo full CDI. Go back into the earliest follow-up questions and table entries that has any events that are not of the controlled blast type, ask which was the worst, enter “Yes” in the “CDI Needed” field/column for that event, and assess it with a full CDI. If this was the only non-deployment CDI done, then two other events other than controlled blast type in the embedded screening questions or PCE Table, must also undergo CDI. Not counting controlled blast events, ask for the second worst event from the earliest embedded screening questions and table entries (or the worst event from a subsequent non-deployment embedded screening questions or table), enter “Yes” in the “CDI Needed” field/column for that event, and assess it with a full CDI
- **Even after above step, were zero non-deployment CDIs completed?** – If no non-deployment CDIs whatsoever have been done, then the worst controlled blast must undergo CDI. If any controlled blasts exposures were endorsed, go back to the embedded screening questions and table entries for the controlled blast events, enter “Yes” in the “CDI Needed” field/column for the worst controlled detonation, and assess it with a full CDI.
- **Are any non-deployment CDIs missing an auto-populated preliminary TBI diagnosis?**
[Review the last page of each one to determine. If data entry was complete the algorithm (Appendix D) should have marked either “TBI with PTA”, “TBI without PTA” or “Not TBI”. Pay attention to the diagnosis generated which pertains to the next step] – If

any are missing then CDI data entry is incomplete; complete data entry and ask any questions that were missed.

- **Does every single non-deployment CDI have “Not TBI” as the preliminary TBI diagnosis?** [If you did not pay close attention during CDI review in last step and are not sure then review the last page of every one again to determine.] – If every non-deployment CDI is negative for TBI, then all the embedded screening questions and table entries must also be reviewed here. A CDI is necessary for any embedded screening questions and table entry that screens positive for TBI (e.g. either Dazed? Memory gap? Or LOC? has a yes response). To do so in Medidata, enter the event date in the default embedded screening question and/or the table form, click on “yes” in the “CDI needed?” field/column, if applicable select the appropriate event type in “Specify type” field/column, and save the PCE form; a CDI form will then be presented as a form below the “PCE Mapping Form” once the page has been saved.

The total concussion diagnostic interviews at the end of this non-deployment session should generally equal up to 3. All additional deployment PCEs should be captured in the embedded screening questions and entered into the PCE Table if needed. You are now finished with the interview component of PCE mapping.

2 Abstraction of VA and DoD Records [Applicable only to VAMC CPRS and Joint Legacy Viewer (JLV).] [Note this section covers not only abstraction for PCE/TBI mapping and indexing, but also abstraction for Disability/%Service Connected figures entered onto the Abstraction of Service Connected Disabilities (ASCD) CRF, and seizure documentation findings entered onto the Epilepsy Documentation Form (EDF) CRF; it is most efficient to do them together.]

CPRS; TBI First Responder (EMS or medic) and Urgent Care (Emergency Department or in country medical clinic) Records Independent Review of PCEs

Step A. Search for all medical notes or military field reports related to all reported PCEs.

The screenshot shows a medical software window with a menu bar (File, Edit, View, Action, Options, Tools, Help) and a patient header section. The patient header includes the name 'CHDRZZZTESTPATIENT, CHDR TWO (OUTPATIENT)', ID '666-00-0002', date of birth 'Mar 03, 1961 (53)', and provider 'MCNAMEE, SHANE'. Below the header, there is a section titled 'Last 100 Signed Notes (Total: 8)' with a list of notes including 'PM&R INPATIENT ATTENDING NOTE', 'NURSING IMMUNIZATION NOTE', 'SPEECH PATHOLOGY PROGRESS NOTE', 'AUDIOLOGY CONSULT', and 'AUDIOLOGY HEARING AID NOTE'. To the right of the notes list, there is a section for 'Visit 03/21/13 PM&R INPAT' with details like 'LOCAL TITLE: PM&R INPAT', 'STANDARD TITLE: PHYSICAL', 'DATE OF NOTE: MAY 29, 2014', and 'AUTHOR: MCNAMEE, SHANE'. Below this, there is a 'SUMMARY OF CONTENTS' section and an 'INSTRUMENT DATA' section. At the bottom of the window, there is a tabbed interface with tabs for 'Cover Sheet', 'Problems', 'Meds', 'Orders', 'Notes', 'Consults', 'Surgery', 'D/C Summ', 'Labs', and 'Reports'.

Local VA records through CPRS

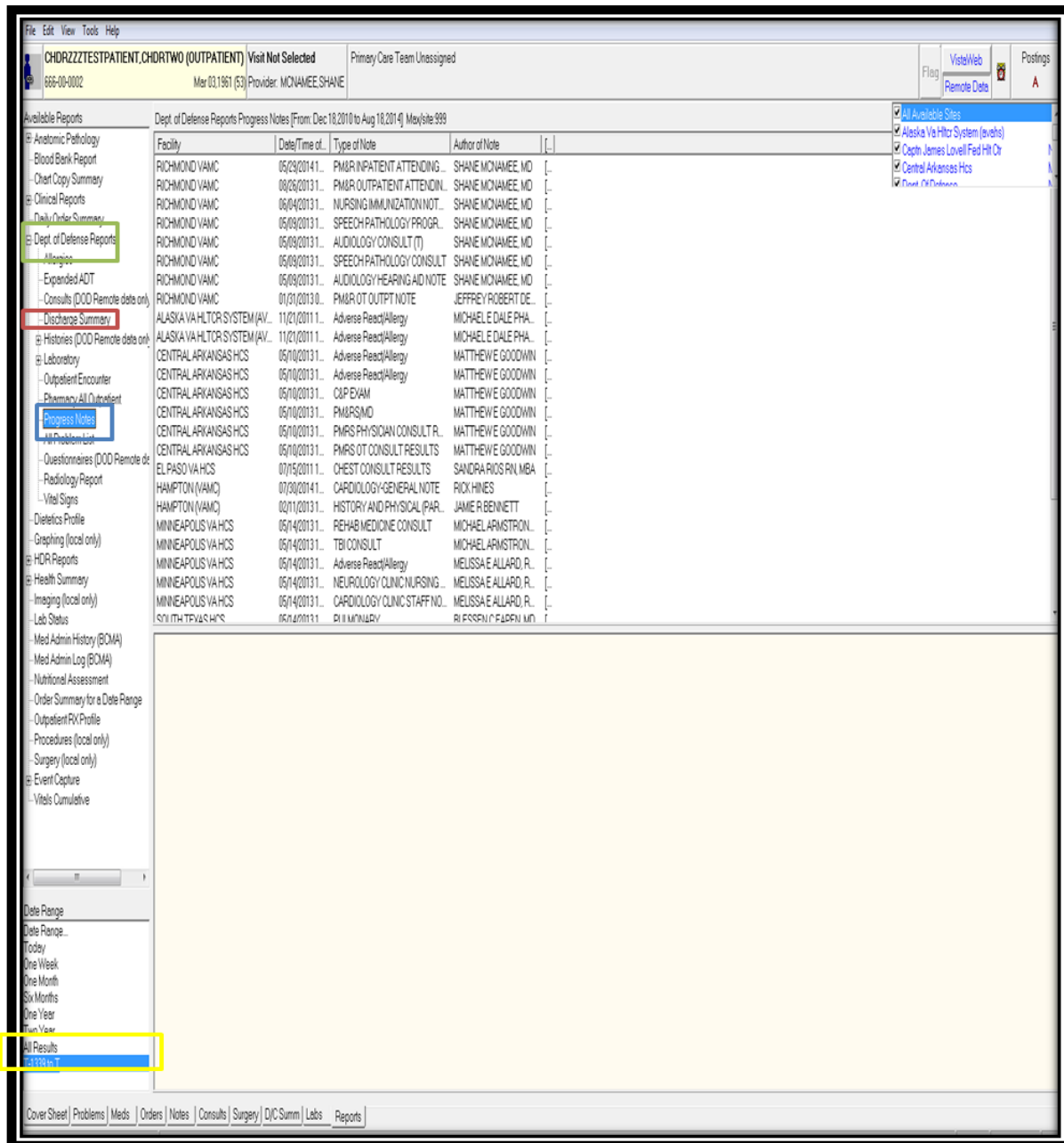
1. In CPRS search under **Notes** for:
 - all Polytrauma notes (PRC, PTRP, PNS)
 - the following clinics: PM&R, Neurology, Behavioral Health
2. Within each note search for information on any mTBI or PCEs with attention to references of medical evaluations close to time of PCEs
3. Unless Veteran presented to VAMC very soon after a PCE these notes will not be useful themselves; utility will be citing earlier documentation
4. Within each note search for information on epilepsy to complete the Epilepsy Medical Record Review Screening Form (if diagnosis was made locally, Neurology clinic notes should be helpful; if no local diagnosis was made, other notes may cite earlier documentation)
 - i. A keyword search of the following may also be helpful (within the **Notes** window or within the note itself): neurology, seizure
 - ii. Under **Active Problems** list on **Cover Sheet** tab:
 1. ICD-9 Code 345.XX

iii. Under **Meds** tab for current and expired medications

The screenshot shows a medical software interface for a patient named CHDRZZTESTPATIENT,CHDR2WO (OUTPATIENT). The patient's visit is not selected, and the primary care team is unassigned. The interface includes a top menu bar with File, Edit, View, Tools, and Help. Below the menu bar, there is a patient information section with fields for Patient ID (666-00-0002), Date of Birth (Mar 03 1961), and Provider (MONAHEE SHANE). The main area displays a list of reports, including Clinical Reports, Discharge Summary, and Progress Notes. The 'Clinical Reports' button is highlighted with a yellow box. The 'Progress Notes' button is highlighted with a green box. The 'Remote Data' button is highlighted with a red box. The 'All Results' button is highlighted with a blue box. The 'Meds' tab is selected at the bottom of the screen.

1. Remote Data documents (VA and DoD) through CPRS
 - a. Select patient in CPRS:
 - b. Click on **Report** tab (at the bottom of the screen)
 - c. Click **Remote Data** (at top right screen in blue font) – select “all available sites”
 - d. **VA Data** – from other facilities
 - i. Click (+) beside **Clinical Reports**
 - ii. Click (+) beside **Progress Notes**
 1. Click **Progress Notes**

2. Change Date Range (*located TOP of screen*) to **"All Results"**
 3. Click on Date/Time title... (*located above dates of the notes*) to arrange notes in order by date
- iii. Click **Discharge Summary**
1. Change Date Range (*located TOP screen*) to **"All Results"**
 2. Click on Date/Time title... (*located above dates of the notes*) to arrange notes in order by date

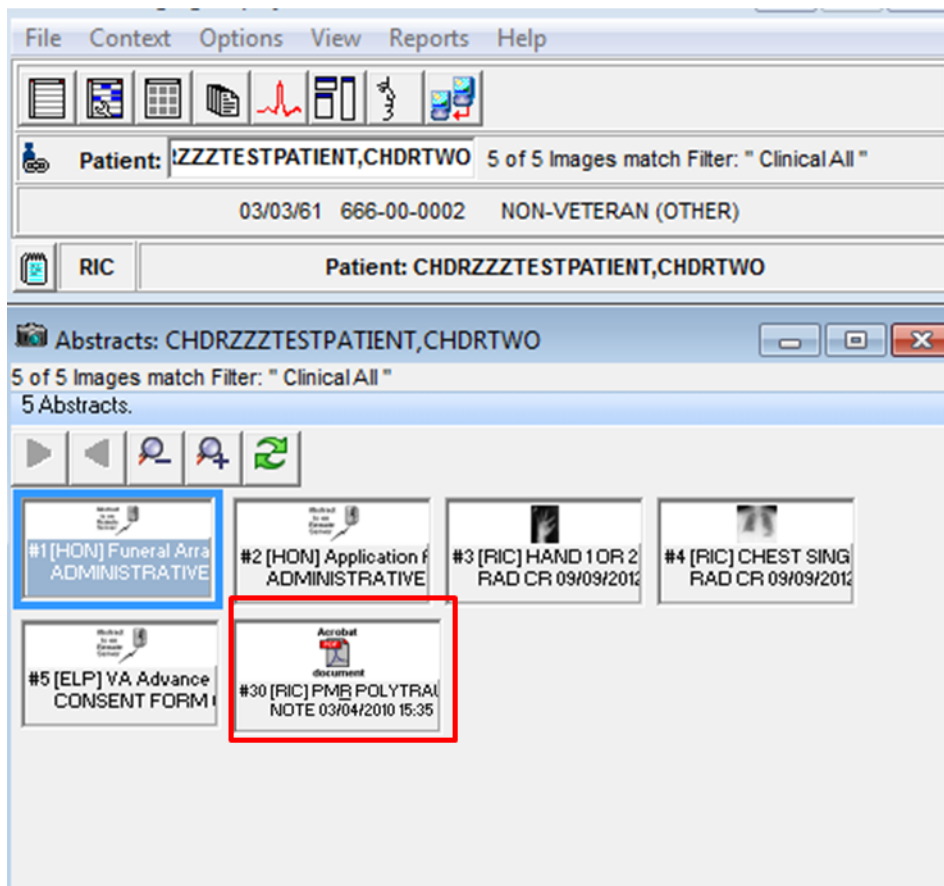
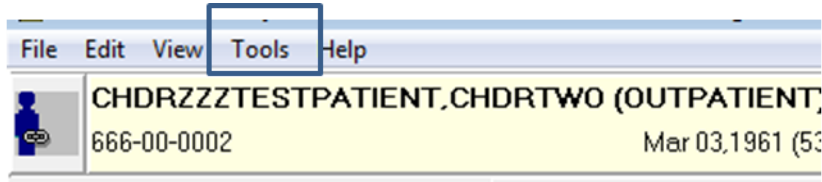


e. DoD Data through CPRS

- i. Click (+) beside **Dept. of Defense Reports** (to expand list, if needed)
 - ii. click **Progress Notes**
1. Change Date Range (located bottom, left of screen) to **"All Results"**
 2. Click on Date/Time title... (located above dates of the notes) to arrange notes in order by date

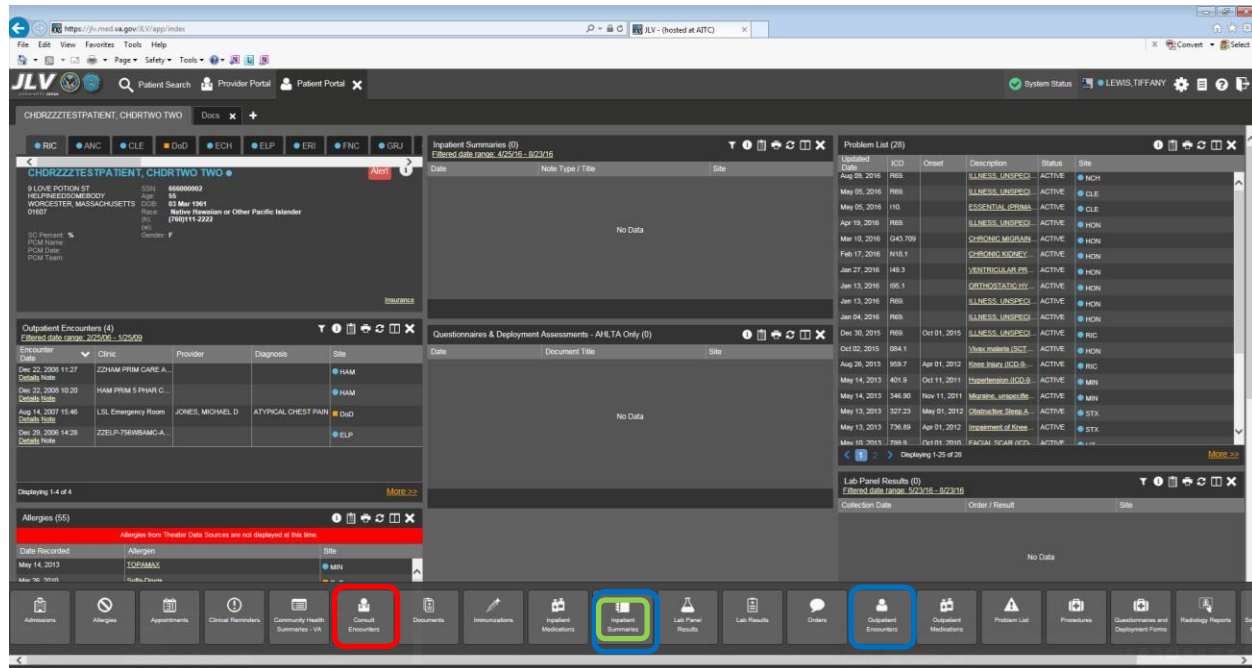
iii. Click **Discharge Summary**

1. Change Date Range (*located bottom, left of screen*) to **"All Results"**
2. Click on Date/Time title... (*located above dates of the notes*) to arrange notes in order by date



3. Scanned inpatient medical records from Bethesda or other MTFs:
 - a. Click on **Tools** (*at top of screen*)
 - b. Select **Vista Imaging Display**

- c. Select note titled **"PM&R Polytrauma scanned Med Record"**
(abstract icon will be a pdf file)



(Usually pts. transferred from Bethesda will have this in their record, but not all.)

4. Other VA-DoD documents from the Joint Legacy Viewer (JLV)
 - a. Log onto JLV and select appropriate patient
 - b. **Progress Notes** Widget - In above screenshot this is "Inpatient Summaries" and "Outpatient Encounters")
 - i. Click **More** at bottom of widget
 - ii. Set time frame to year before patients stated injury time frame
 - iii. **Filter by Local Title Name**
 - c. **Consults Encounters**
 - i. Click **More** at bottom of widget
 - ii. Set time frame to year before patients stated injury time frame
 - iii. **Filter by Local Title Name**
 - d. **Discharge Summary** Widget – Embedded within "Inpatient Summaries"
 - i. Click **More** at bottom of widget

- ii. **Set time frame** to year before patients stated injury time frame
- iii. **Filter by Local Title Name**

Step B. Print source document(s)

Note: If ED documentation found and the participant was admitted to the hospital then also print hospital discharge summary.

Step C. Provide the source document to the PI (or designee) who finalizes the eligibility and CDI discrepancy rating determinations. If the site PI requests summary information from the found document(s), the following format is recommended:

- a. Evaluation done by whom,
- b. Elapsed time of evaluation from incident,
- c. Observed or witness reported LOC,
- d. Mental status exam (GCS?, Oriented x 3?, confused?),
- e. Patient symptoms (unable to remember incident?, dazed?, confused?, seeing stars?)

Step D. Site Principal Investigator or trained designee review the completed PCE Map CRF and all CDI CRFs directly in Medidata (or paper format if preferred), as well as all associated source documentation; and then verify agreement (or disagreement) with each auto populated preliminary CDI algorithm diagnosis (see Appendix D): No TBI, TBI with PTA, versus TBI without PTA. The site PI should also determine if any of the TBIs found are of greater severity than mild;

if any are determined to be a moderate or severe TBI then the participant is not eligible for this study. It is strongly recommended for any eligibility or TBI diagnosis uncertainty that the Site PI (or clinically experienced designee) speak directly with the participant for supplementary interview to help make the final determination. The relevant content from the supplementary interview should be summarized and entered into an appropriate free-text entry area in Medidata.

VA Disability Status and % Service Connection for ASCD CRF

Vista CPRS in use by: Shin,Robert (vista.richmond.med.va.gov)

File Edit View Action Options Tools Help

ZZ TEST, THEREFORE (OUTPATIENT) Visit Not Selected Primary Care Team Unassigned
000-00-3212 Jun 20,1965 (49) Current Provider Not Selected

All Consults

Aug 22,14 (x) ANESTHESIOLOGY INPT Cons Consult #: 2977134
Aug 22,14 (x) ANESTHESIOLOGY INPT Cons Consult #: 2977133
Aug 11,14 (c) CP ELECTROPHYSIOLOGY CP CARDIOLOGY ELECTROPHYSIOL
Aug 11,14 (c) CP ELECTROPHYSIOLOGY CP CARDIOLOGY ELECTROPHYSIOL
Aug 11,14 (c) CP ELECTROPHYSIOLOGY CP CARDIOLOGY ELECTROPHYSIOL
Aug 08,14 (dc) MENTAL HEALTH INPT ROUTINE Cons Consult #: 2963941
Jul 31,14 (c) MENTAL HEALTH INPT ROUTINE Cons Consult #: 2956295
Jul 17,14 (dc) PHARMACY MEDICAL SUPPLY ORDER OUTPT Cons Consult #: 2
Jul 16,14 (dc) MENTAL HEALTH INPT ROUTINE Cons Consult #: 2942672
Jun 25,14 (dc) HEMATOLOGY/ONCOLOGY OUTPT Cons Consult #: 2925066
Jun 20,14 (dc) MENTAL HEALTH INDIVIDUAL COUNSELING OUTPT - CHARLO

Aug 22,14 (x) ANESTHESIOLOGY INPT Cons Consult #: 2977134

Current Pat. Status: Outpatient
Primary Eligibility: NSC (VERIFIED)
Patient Type: NSC VETERAN
OEF/OIF: NO

Order Information
To Service: ANESTHESIOLOGY INPT
From Service: RIC/PRE-ANESTHESIA
Requesting Provider: ROSS, REGINA H
Service is to be rendered on an INPATIENT basis
Place: Bedside
Urgency: Routine
Earliest Appr. Date: Aug 23, 2014
Orderable Item: ANESTHESIOLOGY INPT
Consult: Consult Request
Reason For Request: needs to be seen for surgery

Inter-facility Information
This is not an inter-facility consult request.

Status: CANCELLED
Last Action: CANCELLED

Facility	Activity	Date/Time/Zone	Respon
CPRS RELEASED ORDER		08/22/14 07:58	ROSS, R
PRINTED TO CYSTO		08/22/14 07:58	
CANCELLED		08/22/14 14:21	WATKIN

Test patient only

Note: TIME ZONE is local if not indicated

No local TIU results or Medicine results available

===== END =====

Edit/Resubmit
New Consult
New Procedure

No related documents found

Step A. Click Participant Information Box

Vista CPRS in use by: Shin,Robert (vista.richmond.med.va.gov)

File Edit View Action Options Tools Help

ZZ TEST,THEREFORE (OUTPATIENT) Visit Not Selected Primary Care Team Unassigned

000-00-3212 Jun 20,1965 (49) Current Prov

Patient Inquiry

Patient's status as an outpatient based on primary means test
 Veteran is eligible and provision of hospital care is mandatory
 Primary Means Test Last Applied 'DEC 12,2013' (COMPLETED: DEC 12,2013@20:14)
 Medication Copayment Exemption Status: NON-EXEMPT
 Patient's income is greater than Copay Income Threshold
 Last Rx Copay Exemption date: DEC 12, 2013

Status : PATIENT HAS NO INPATIENT OR LODGER ACTIVITY IN THE COMPUTER

Future Appointments: NONE

Remarks:

Date of Death Information
 Date of Death:
 Source of Notification:
 Updated Date/Time:
 Last Edited By:

Health Insurance Information:

Insurance	COB	Subscriber ID	Group	Holder	Effective	Expires
No Insurance Information						

Service Connection/Rated Disabilities:

Service Connected: NO
 Rated Disabilities: NONE STATED

Edit/Resubmit
 New Consult
 New Procedure

Select New Patient Print Close

Note: TIME ZONE is local if not indicated

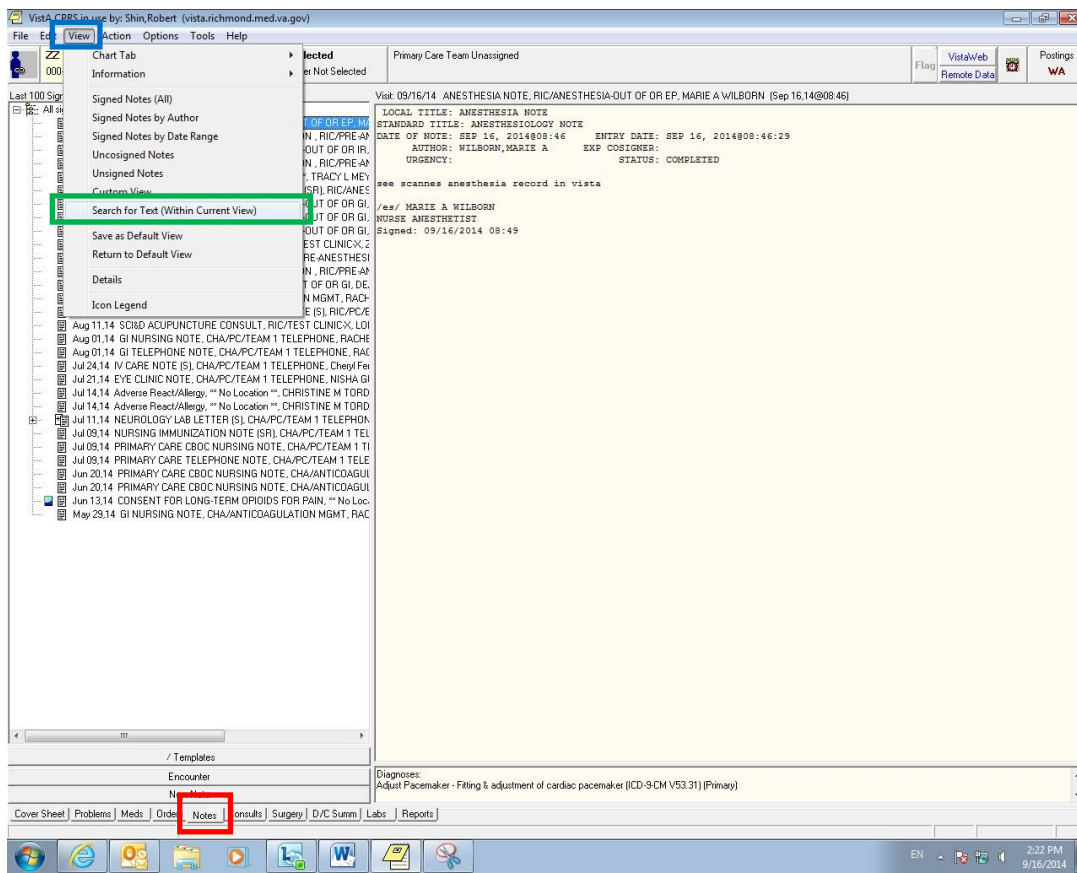
No local TIU results or Medicine results available for this consult
 ===== END =====

Step B. Scroll down and locate **"Service Connection/Rated Disabilities"** section

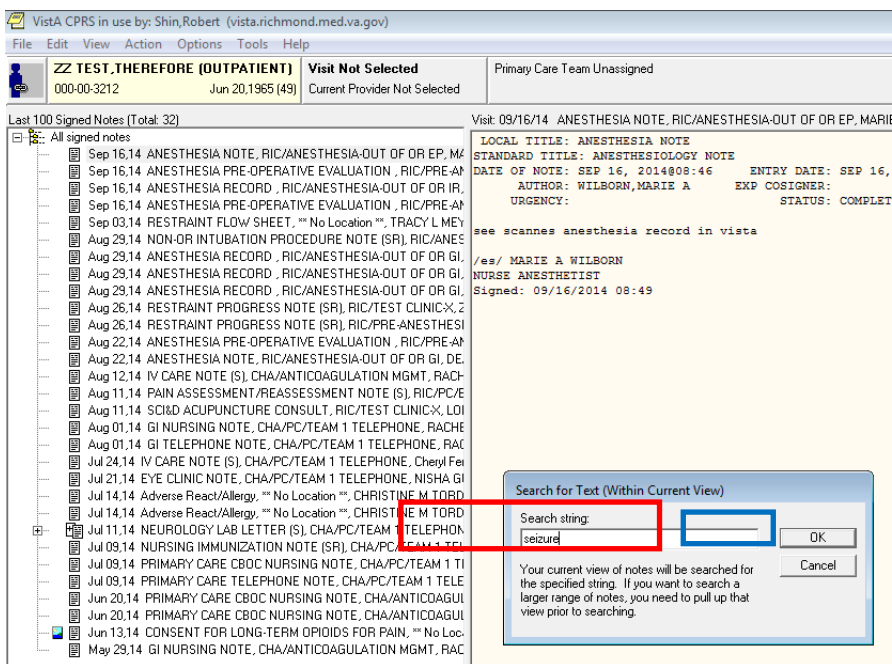
Documented Seizure, Seizure Diagnosis, and Seizure Treatment

Search Notes, Problems, and Consults tabs to find documented seizure, seizure diagnosis, and seizure treatment

- **Notes**

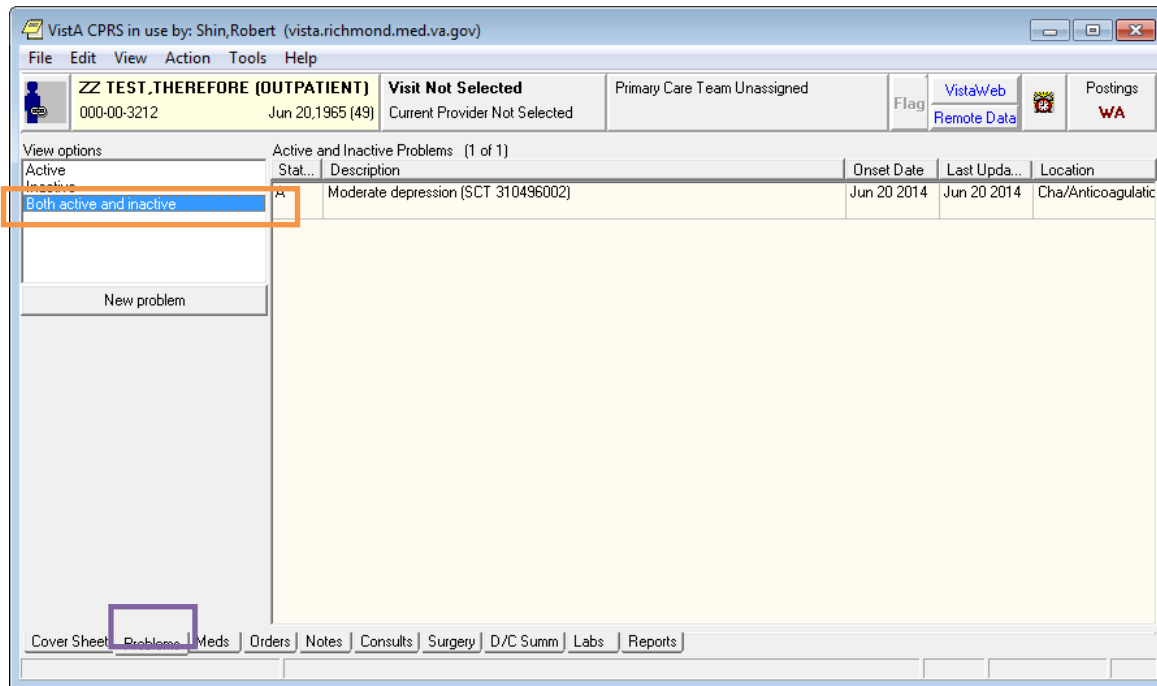


- Click on **Notes** tab
- Click **View** and **Search for Text (Within Current view)**



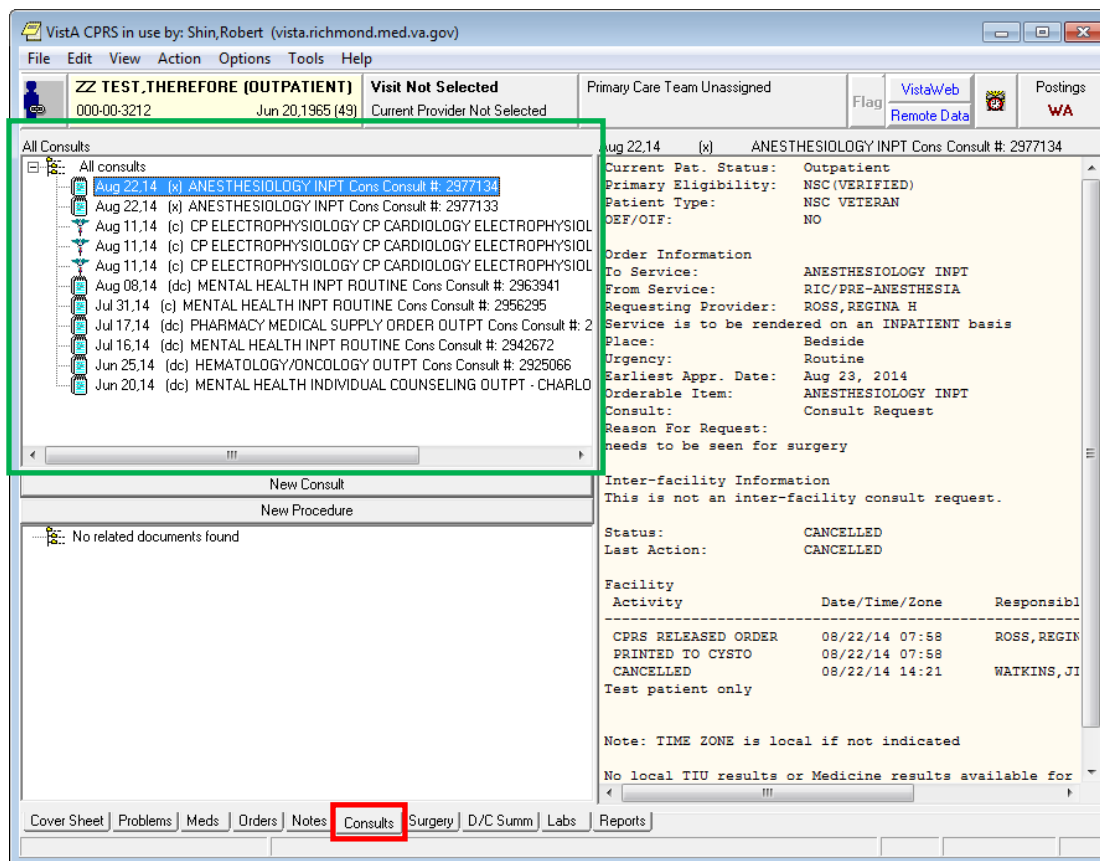
- Under **Search String**, type in 'Seizure' or 'Epilepsy' and click **'OK'**
- Look through each note (especially neurology notes) for relevant information (Note: Can highlight a particular keyword by right-clicking on the note window and using "Find in Selected Note" feature)

- **Problems**



- Click on **Problems** tab
- Under view options, click on **"Both active and inactive"**
- Look through the list of documents problems and find information relevant to seizures

- **Consults**

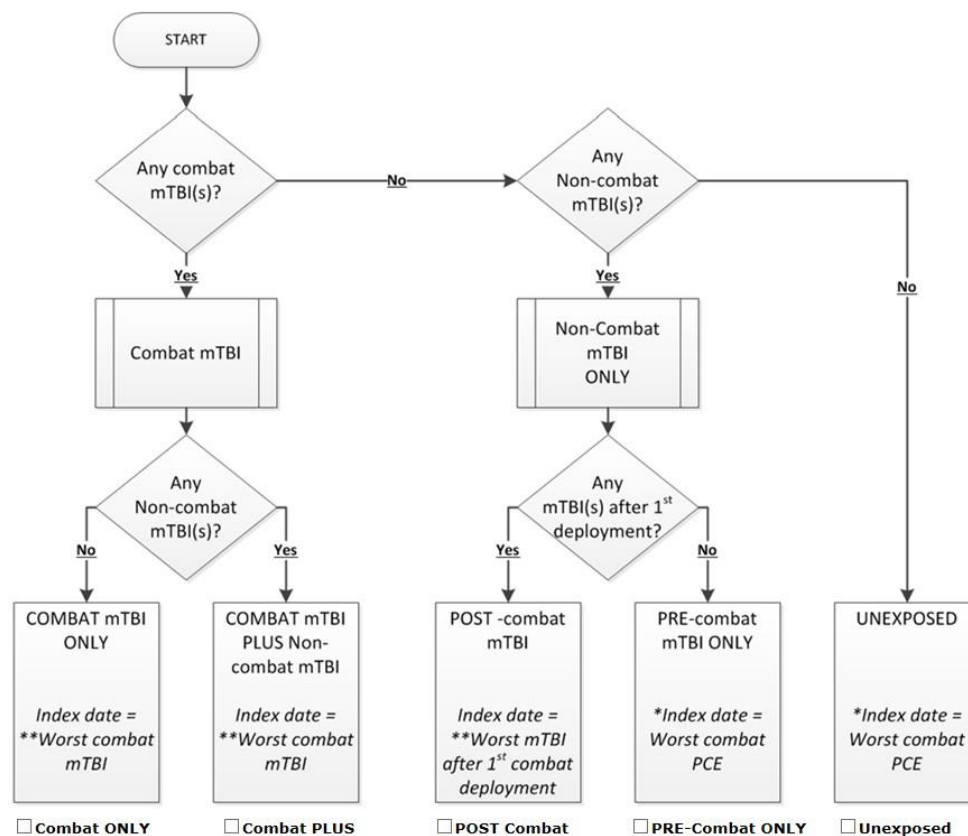


- Click on **Consults** tab
- Under **All Consults**, look for neurology consults for relevant seizure information

3 Establishing an Index Date [Baseline Assessment Only]

Once the TBI status of all applicable PCEs is determined and confirmed, the index date can be established. The TBI status for each applicable PCE should be confirmed by the site PI or designee after careful review of all the mapping data and all relevant medical records found. As noted previously, if the site PI has significant doubt regarding a determination, they should interview the participant further. Sometimes the site PI will refer to the Central TBI Diagnosis committee for further deliberation but it is strongly recommended the site PI first have conducted supplementary interview to better inform the determination. The diagram below should be used to determine the index date of both exposed and unexposed participants.

Concussion Groups & Index Date Assignments



* If no events of any type are identified, use the mid-point of deployment(s) as index date.
[eg 1/2 way in between first deployment departure date and last deployment return date]

** Study definition of "Worst mTBI" = participant's self-identified worst PCE unless that PCE is NOT TBI; then use 2nd worst PCE unless it is also NOT TBI; then (i.e. worst and 2nd worst PCE both NOT TBI) use the 1st TBI during deployment for Combat mTBI or 1st TBI after 1st deployment for POST-combat mTBI.
[Note: site PI may override if he/she determines that a different PCE is the worst mTBI, but must get concurrence from the central diagnosis committee.]

Once a participant's PCEs and TBIs have been assessed, reconciled with applicable medical records, and confirmed and an index date is established and entered in Medidata; he or she will be placed on a schedule of follow-up comprehensive in-person reassessments and telephone assessments. *Once the index date is established at baseline evaluation, the index date will not be changed during follow-up if sustaining a future mTBI. However if a new TBI during follow-up is discovered that changes their index TBI group, the TBI group label will be changed in the central database (e.g. TBI negative participant sustains a new TBI to become TBI positive, or Combat-TBI participant sustains new non-deployment TBI to become Combat Plus TBI group.*

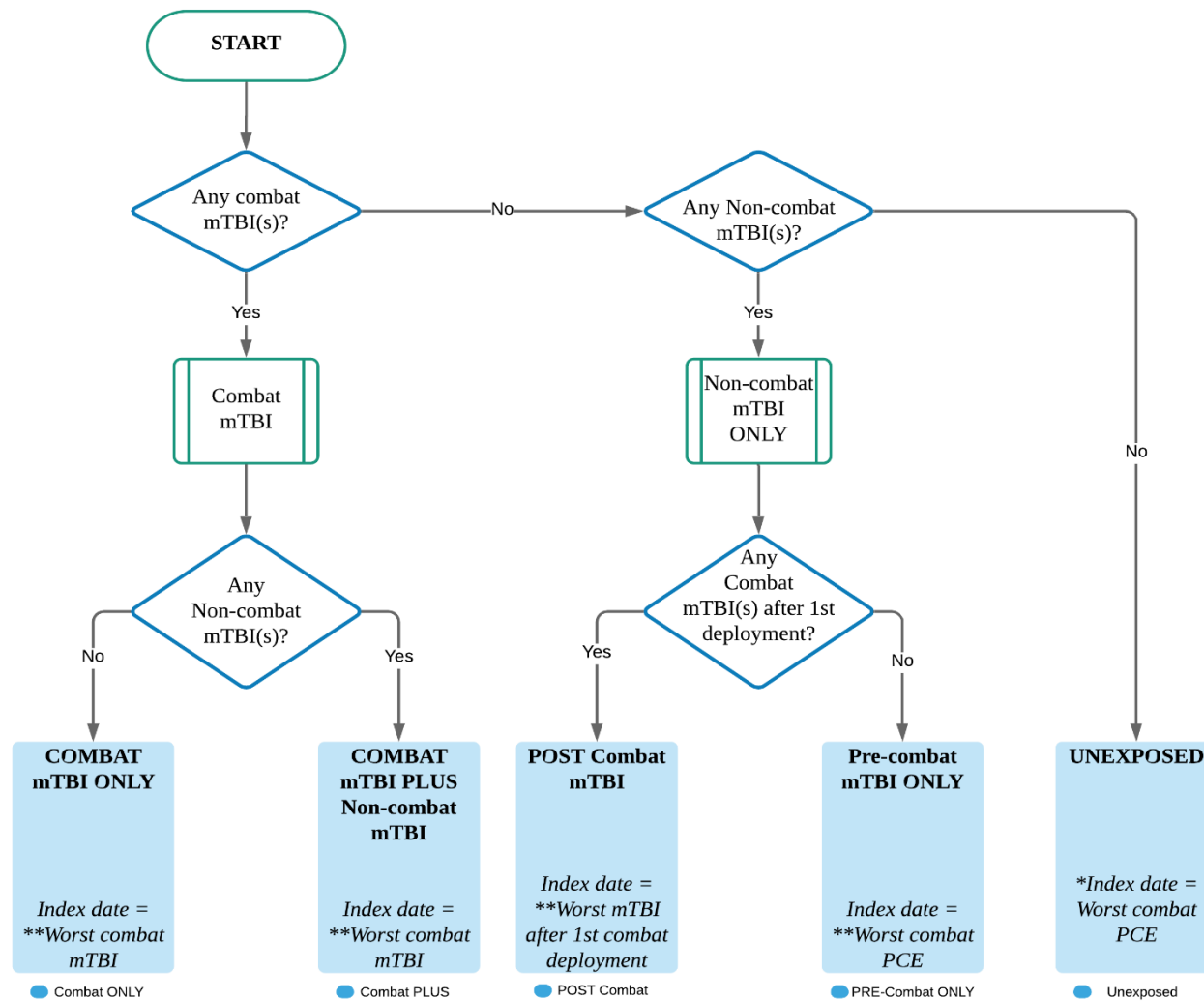
Note: In the first step of the algorithm (Appendix D), if someone endorses not remembering the impact (blast) then they automatically had TBI with PTA unless they then give an illogical

response of positive retrograde but no antegrade amnesia which then goes to a referee (LOC). Importantly, the algorithm rationale is confounded (polluted) in some atypical scenarios such as if person was asleep or extremely intoxicated at time of impact. Additional unstructured interview is recommended for such an event and the algorithm diagnosis should not be relied upon alone.

On the Index Date Form within the Medidata, just enter the year and the month and **leave the day field blank**. The **day** is randomly assigned by the system after the form is saved .

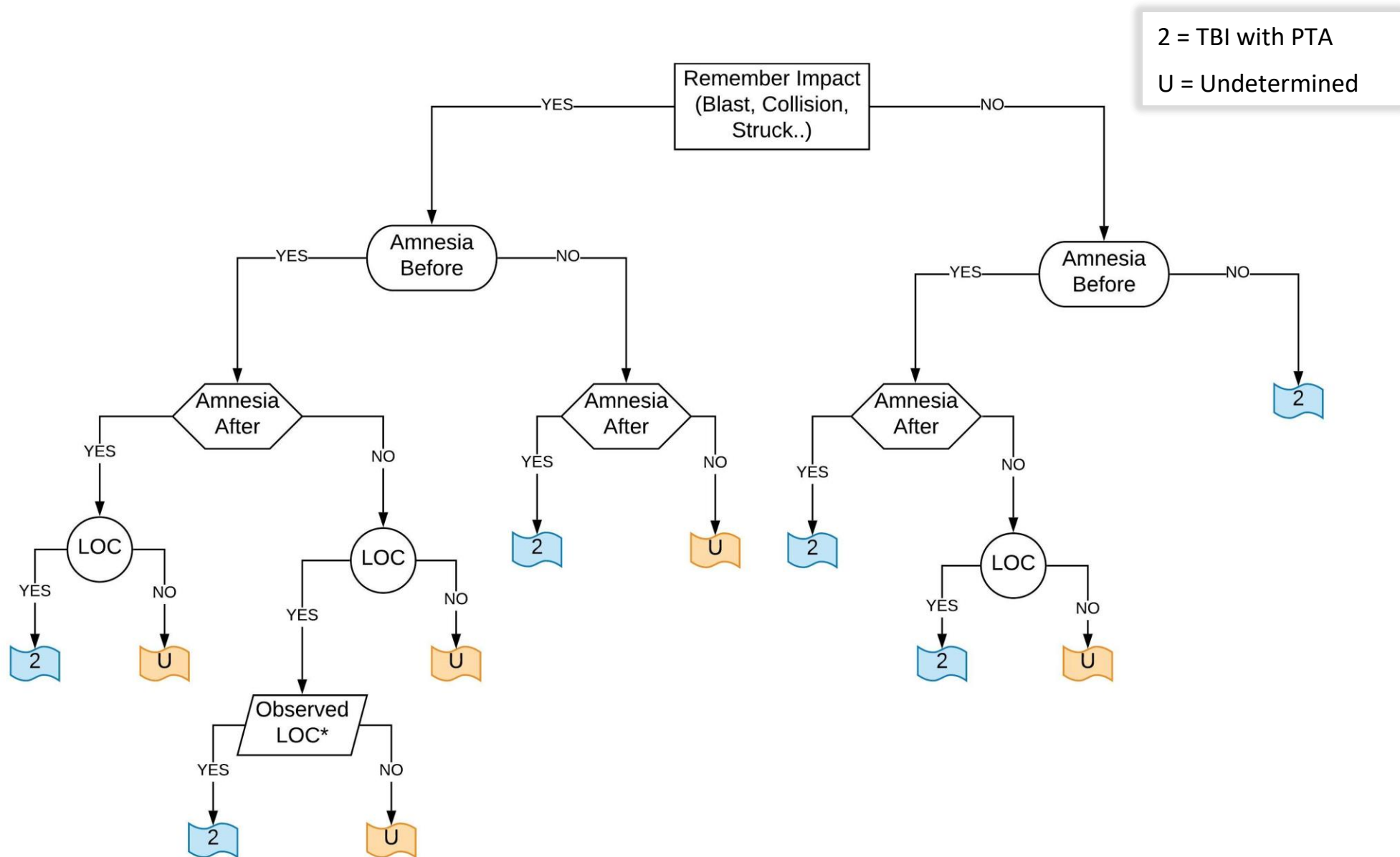
In the event that a site cannot confirm all TBI diagnoses in order to assign a group or index date to a participant, the site can refer the case to the TBI Diagnosis Committee. The Committee will meet quarterly, but will also meet to discuss cases on an as needed basis. Within the Medidata, the Site PI or designee can specify that a CDI should be referred to the committee. This action triggers a notification to be sent to a secure email address. A staff member from the DBC will contact the site for supporting documentation if needed and notify the Committee. The DBC will then notify the site of the Committee's determination and the site must then go and update the Medidata.

Index Date and Group



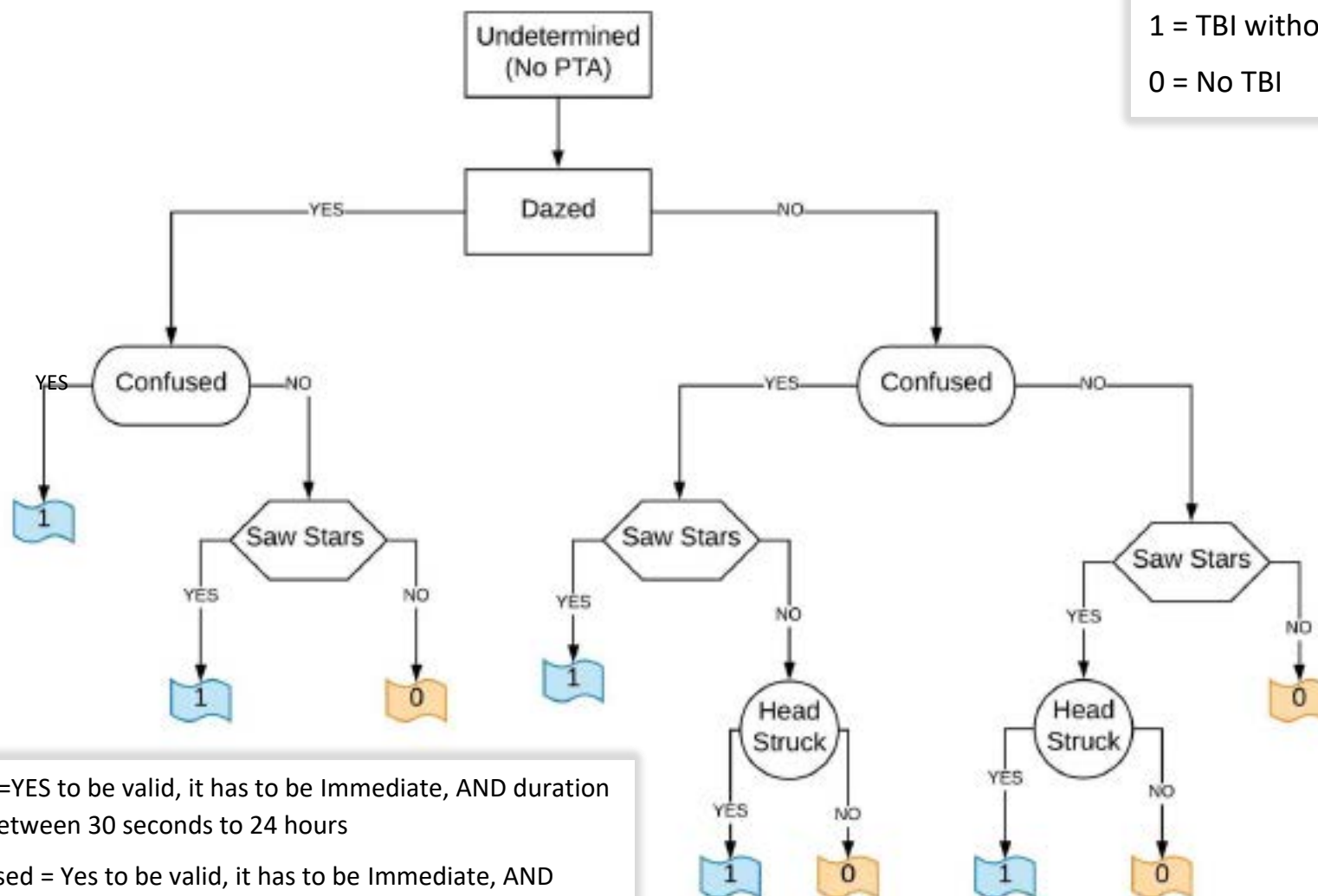
*If no events of any type are identified, use the mid-point of deployment(s) as Index date.
[eg ½ way in between first deployment departure date and last deployment return date]

**Study definition of “Worst mTBI” = participant’s self-identified worst PCE unless that PCE is NOT TBI; then use 2nd worst PCE unless it is also NOT TBI; then (i.e. worst and 2nd worst PCE both NOT TBI during deployment for Combat mTBI or 1st TBI after 1st deployment for POST-combat mTBI.
[Note: Site PI may override if he/she determines that a different PCE is the worst mTBI, but must get concurrence from the central diagnosis committee.]



*Observed Loss of Consciousness (LOC)

= YES if witnessed by an observer
= NO if based on own experience



- For Dazed=YES to be valid, it has to be Immediate, AND duration must be between 30 seconds to 24 hours
- For Confused = Yes to be valid, it has to be Immediate, AND duration must be between 30 seconds to 24 hours
- For Saw stars = Yes to be valid, it has to be Immediate, AND duration must be between 30 seconds to 24 hours
- For head struck = Yes, head was struck OR head hit something must be selected

Note: For interview coding of dazed and confused, less than 30 seconds is coded as 0 minutes; so valid duration is 1 minute to 24 hours.