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)

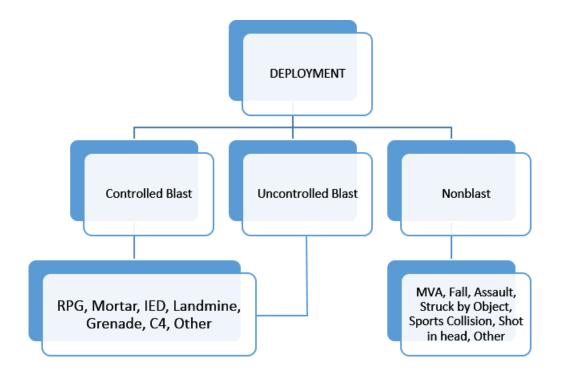
c. Alternative embedded screening questions where full CDI may be deferred. The embedded screening questions are limited to the first incident for each PCE Mapping category-Cue PCE (i.e. specific scenerios such as motor vehicle accident). The PCE Table must be used for any additional incident(s) in that category.

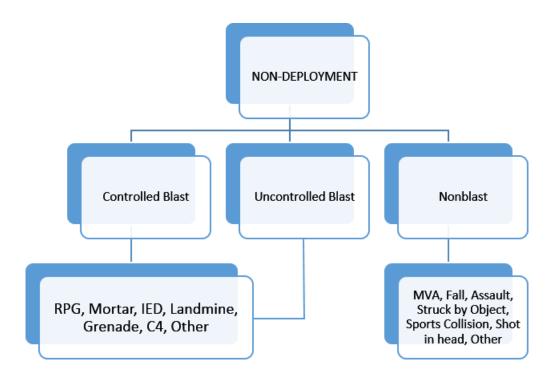
The purpose of the CDI-Blast and CDI-General forms is to gather the most detail about the key PCEs. Other potential concussive events beyond the key events will be captured in the embedded screening questions and if needed the PCE Table. The purpose of the screening questions is to document these non-key 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 catergory-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 <u>two</u> events in this category can be captured in the embeded 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 a subcategories for a control of the above. Examples of the PCE cause subcategories for None of the above.

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. <u>Free-Recall PCEs</u>: 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. <u>Category-Cue PCEs</u>: 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 catergory, 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 <u>two</u> incidents. <u>A</u> **Category-Cue PCE may be key and need a CDI**. Whether a **Category-Cue PCE** in either 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. <u>Controlled Blast PCEs</u>: 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 interogatted**. 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. <u>When in doubt</u>: . 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.

<u>1.5.</u> <u>PCE dates:</u> 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</p>

where all embedded screening responses are "No" The total number, and date ranges (first and most recent) for these exposures are also collected. After interogatting 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 <u>key</u> 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 <u>key</u> 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 enteries 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.



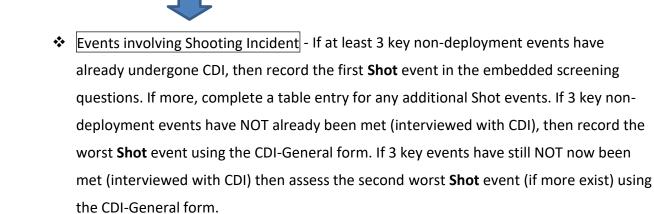
Events involving MVA (e.g. bicycle, motorcycle, ATV, car) - If at least 3 key nondeployment events have already undergone CDI, then record the first MVA event in the embedded screening questions. If more, complete a table entry for any additional MVA events. If 3 key non-deployment events have NOT already 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 nondeployment 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.





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, <u>if the worst controlled detonation screens positive for TBI</u> (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.</p>



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 Needed" field/column for that event, and assess it with a subsequent non-deployment embedded screening questions and table entries (or the worst event from the earliest embedded screening questions and table entries (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 nondeployment 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.]

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

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

File Edit View Action Options Tools Help	
CHDRZZZTESTPATIENT, CHDRTWO (OUTPATIENT) Visit No 666-00-0002 Mar 03,1 961 (53) Provider:	
Last 100 Signed Notes (Total: 8)	Visit 03/21/13 PM&R INPAT
Ar signed holes May 29,14 PM&R INPATIENT ATTENDING NOTE, RIC/PMR/RM	LOCAL TITLE: PM&R INPAT STANDARD TITLE: PHYSICAL
B Aug 26.13 PM&R OUTPATIENT ATTENDING NOTE, ZZ//OT/BAI B Jun 04.13 NURSING IMMUNIZATION NOTE (SR), ZZ//RIC/PHYSI B May 09.13 SPEECH PATHOLOGY PROGRESS NOTE, ZZ//RIC/PHYSICA B May 09.13 ADDIOLOGY CONSULT, ZZ//RIC/PHYSICA, THEF May 09.13 AUDIOLOGY CONSULT (T), ZZ//RIC/PHYSICA, THEF	AUTHOR: MCNAMEE, SH URGENCY:
 ・ 圏 May 09,13 AUDIOLOGY HEARING AID NOTE, ZZ//RIC/PHYSICA ・ ・ Jan 31,13 PM&R OT OUTPT NOTE, RIC/PMR/OT/OUTPATIENT ・ 	Generated from TBI Toolb Visit - 5/29/2014 10:27:
	SUMMARY OF CONTENTS
	Included Instruments + Coma/Near-Coma Scale
	INSTRUMENT DATA
	Instrument - Coma/Near-C Total CNC Score (add s Coma/Near-Coma Level (or COMA/NEAR-COMA CATEGON Level 0.00-0.85 stimulation trats # plus 1 0.90-2.00 sensory modalities and/c commands. 2 or 3 sensory modality 3 2.90-3.49 one sensory modality and 4 3.50-4.00 response to simple comma /es/ SHANE MCNAMEE, MD ACOS, Clinical Informati Signed: 05/29/2014 10:30
۰ ا	
√ Templates	
Encounter	
New Note	
Cover Sheet Problems Meds Orders Notes Consults Surgery D/C	Summ Labs 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

e Edit View Tools Help					
CHDR222TESTPATIENT,CF 666-00-0002	HDRTWO (OUTPATIENT) Visit N Mar 03,1961 (53) Provide		Primary Care Team Unassigned NE		Flag VistaWeb Post
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- Alergies	CENTRAL ARKANSAS HCS		Adverse React/Allergy	MATTHEWE GOODWIN [
Patient Information	CENTRAL ARKANSASHCS	05/10/2013 14		MATTHEWE GOODWIN [
E Visits / Admissions	CENTRAL ARKANSASHCS	05/10/201314_		MATTHEWE GOODWIN [
- Comp & Pen Exams	CENTRAL ARKANSASHCS		PMRS PHYSICIAN CONSULT RESULTS	MATTHEWE GOODWIN [
-Discharge Summar	CENTRAL ARKANSAS HCS BROOKE AMC+T. SAM HOU		PMRS OT CONSULT RESULTS BEH HEALTH CLINICAL HEALTH	MATTHEWE GOODWIN [000FERGUSONNANCY [
-Discharge Summar	BROOKE AMC+T: SAM HOU	05/30/2013 14		QODFERGUSONNANCY [
R Medicine/CP	EL PASO VA HCS		CHEST CONSULT RESULTS	SANDRA RIOS RN MBA	
e Orders	HAMPTON (VAMC)		CARDIOLOGY-GENERAL NOTE	RICKHINES [
Outpatient Encounters / GAF S	HAMPTON (VAMC)		HISTORY AND PHYSICAL (PART 1)	JAMER BENNETT [
e Phamacy	MINIEAPOLIS VAIHOS	05/14/2013 12	REHAB MEDICINE CONSULT	MCHAELARMSTRONG [
Problem List	MINIEAPOLIS VA HCS	05/14/201312_		MCHAELARMSTRONG [
B Progress Notes	MINIEAPOLIS VA HCS		Adverse Read/Allergy	MEUSSA E ALLARD, RN, [
-Progress Notes	MINIEAPOLIS VA HCS		NEUROLOGY CLINIC NURSING NOTE	MELISSA E ALLARD, RN, [
-Advance Directive	MINIEAPOLIS VA HCS		CARDIOLOGY CLINIC STAFF NOTE	MEUSSAE ALLARD, RN	
-Clinical Warnings	SAN DIEGO HCS SAN DIEGO HCS		Pulmonary Nurse Case Manager Progress Note Pulmonary Nurse Case Manager Progress Note	WILLIAM DAVE EASTER [WILLIAM DAVE EASTER [
-Crisis Notes	SAN DIEGO HCS		+ Pulmonary Nurse Case Manager Progress Note + Pulmonary Nurse Case Manager Progress Note	WILLIAM DAVE EASTER [
Radiology	SANDIEGO HCS		NUTRITION CALORIE COUNT	Melinda Lee, MSRD [
-Surgery Reports	SANDIEGO HCS		VLER HEALTH OPT IN OUT	APRILBRENNER, RN.M. [
Vital Signs	SAN DIEGO HCS		NOTICE OF CERTIFICATION (5250)	JO-ANNE TOOMEY [
-Anticoagulation Flowsheet	SAN DECO HOS	10/07/2011 09	Ni voa Drarttinnar Haalth áceacomant Ninta	ID-ANNETTOONEY I	
Daily Order Summary					
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wer Sneet Problems Meds On	ders Notes Consults Surgery D	U Summ Labs	Reports		

iii. Under Meds tab for current and expired medications

- 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

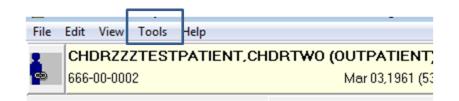
- Change Date Range (*located TOP of screen*) to "All Results"
- 3. Click on <u>Date/Time title...</u> (*located above dates of the notes*) to arrange notes in order by date
- iii. Click Discharge Summary
 - Change Date Range (*located TOP screen*) to "All Results"
 - 2. Click on <u>Date/Time title...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

File Edit View Tools Help							
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Anatomic Pathology Blood Bank Report		Date/Time of	Type of Note	Author of Note		Captn James Lovell Fed Hit Or	Ň
- Chart Copy Summary	RICHMOND VAMC			SHANE MONAMEE, MD		Central Arkansas Hos	k,
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E Dept. of Defense Reports	RICHMOND VAMC		AUDIOLOGY CONSULT (T)	SHANE MONAMEE, MD			
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e-Laboratory	CENTRAL ARKANSAS HCS		Adverse React/Allergy	MATTHEW E GOOD WIN	k f		
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-Questionnaires (DOD Remote de	EL PASO VA HCS		CHEST CONSULT RESULTS	SANDRA RIOS RN, MBA	 [
-Radiology Report - Vital Signs	HAMPTON (VAMC)			RICKHINES	[- 1
-Dietetics Profile	HAMPTON (VAMC)		HISTORY AND PHYSICAL (PAR		r -		
-Graphing (local only)	MINIEAPOLIS VA HCS MINIEAPOLIS VA HCS		REHAB MEDICINE CONSULT TBI CONSULT	MCHAELARMSTRON.			
E HDR Reports	MINNEAPOUS VAHCS		Adverse React/Allergy	MELISSA E ALLARD, R.			
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-Med Admin Log (BOMA)							
-Nutritional Assessment							
-Order Summary for a Date Range							
-Outpatient RX Profile							
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Cover Sheet Problems Meds Orde	ers wores Consuits Surgery D/	u summ j Labs	Reports				_

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

iii. Click Discharge Summary

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



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- 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"

			0.0
- The https://jic.med.va.gov/ILV/applindex	,D + B C 🔣 JLV - (hosted at AITC) ×		6 ↔ Θ
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		Jan 27, 2016 149.3 VENTRICULAR PR. ACTIVE HON	
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Encounter V Clinic Provider Diagnosis Site		Oct 02, 2015 084.1 Vivax malaria (SCT ACTIVE HON	
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Dectails tixts		May 14, 2013 346.90 Nov 11, 2011 Marsine, unspecifie ACTIVE	
Aug 14, 2007 15.46 LSL Emergency Room JONES, MICHAEL D ATYPICAL CHEST PAIN B DOD		May 13, 2013 327.23 May 01, 2012 Statustics.Siess.A. ACTIVE STX	
Dec 29, 2006 14:28 ZZELP-756WBAMO-A		May 13, 2013 736.89 Apr 01, 2012 Ingainment of Knee. ACTIVE STX	×
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		K 1 2 Displaying 1-25 of 28	<u>M018.22</u>
		Lab Panel Results (0)	X II C C C X
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Allergies (55) 0 📋 🖶 🗢 🖽 🗙			
Allergies from Theater Data Sources are not displayed at this time.			
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May 14, 2013 TOPAMAX May 14, 2013			
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Summaries - VA Encounters	Wedcetons Burmaries Results	Encounters Medications De	ployment Forms Ct

(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
 - 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

ter by Local Note Title elect a Local Note		18, 2014 Aug 18, 2014 Apply Fitter by Standard Note Title Select a Standard Note Title	Filter by Provider Select a provider	~	
ose Filter	Local Note Title	Standardized Note Title	Provider	Clinic	Site
ul 30, 2014 14:45	CARDIOLOGY-GENERAL NO		HINES, RICK	ALBEMARLE CBOC	HAM
May 29, 2014 10:29	PM&R INPATIENT ATTENDING	and the second se	MCNAMEE, SHANE	RICHMOND VAMC	RIC

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.richmon				
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		· · · · · · · · · · · · · · · · · · ·	THESIOLOGY INPT Cons Con	sult #: 2977
All consults All consults	is Consult #: 2977133 P CARDIOLOGY ELECTROPHYSIOI P CARDIOLOGY ELECTROPHYSIOI P CARDIOLOGY ELECTROPHYSIOI	Order Information To Service:	NSC (VERIFIED) NSC VETERAN NO ANESTHESIOLOGY INPT	
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-		Consult: Reason For Request: needs to be seen for : Inter-facility Inform This is not an inter-:	Consult Request surgery ation	est.
		Status: Last Action: Facility	CANCELLED CANCELLED	
		Activity	Date/Time/Zone	Respo
< III	•	CPRS RELEASED ORDER PRINTED TO CYSTO	08/22/14 07:58 08/22/14 07:58	ROSS,
Edit/Resubmit		CANCELLED Test patient only	08/22/14 14:21	WATKI
New Consult		lest patient only		
New Procedure		Note: TIME ZONE is lo	cal if not indicated	
Para and a second s		No local TIU results (

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 S	elected P	Primary Care Team Unassigned				
2000-00-3212 Jun 20,1965 (49) Current Prov	Patient Inquiry					
All Consults		ible and provision of hospital care is mandatory				
All consults Aug 22,14 (a) ANESTHESIOLOGY INPT Cons Consult # Aug 22,14 (a) ANESTHESIOLOGY INPT Cons Consult # Aug 11,14 (c) CP ELECTROPHYSIOLOGY CP CARDIOL Aug 11,14 (c) CP ELECTROPHYSIOLOGY CP CARDIOL Aug 11,14 (c) CP ELECTROPHYSIOLOGY CP CARDIOL Aug 01,14 (c) MENTAL HEALTH INPT ROUTINE Cons C Jul 31,14 (c) MENTAL HEALTH INPT ROUTINE Cons C Jul 31,14 (c) MENTAL HEALTH INPT ROUTINE Cons C Jul 31,14 (c) MENTAL HEALTH INPT ROUTINE Cons C Jul 31,14 (d) MENTAL HEALTH INPT ROUTINE Cons C Jul 32,14 (do) MENTAL HEALTH INPT ROUTINE Cons C Jul 25,14 (do) MENTAL HEALTH INDT ROUTINE Cons C Jun 20,14 (do) MENTAL HEALTH INDIVIDUAL COUNSE	Primary Means Te Medication Copay Patient's income Last Rx Copay Ex Status : PA Future Appointme Remarks: Date of Death In Date of Death In	est Last Applied 'DEC 12,2013' (COMPLETED: DEC 12,2013@20:14) ment Exemption Status: NON-EXEMPT a is greater than Copay Income Threshold xemption date: DEC 12, 2013 ATIENT HAS NO INPATIENT OR LODGER ACTIVITY IN THE COMPUTER ents: NONE nformation ath: Notification: to/Time:				
		e Information: COS Subscriber ID Group Holder Effective Expires 				
۲	Service Connec	ion/Rated Disabilities: cted: NO ties: NONE STATED				
Edit/Resubmit	[
New Consult	Select New Patient	Print Close				
New Procedure						
- 🏦 No related documents found		Note: TIME ZONE is local if not indicated No local TIU results or Medicine results available for this consult				

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

<u>Notes</u>

🖉 VistA C	PRS in use by: Shin,Robert (vista.richmond.med.vi	a.gov)			- 6
File Ed :	View Action Options Tools Help				
	Chart Tab Information	 lected er Not Selected 	Primary Care Team Unassigned FI	ng VistaWeb Remote Data	Postings WA
Last 100 Sigr			rait: 09/16/14 ANESTHESIA NOTE, RIC/ANESTHESIA-OUT OF OR EP, MARIE A WILBORN (Sep 16,14@08:46)		
E S All si	Signed Notes (All)		LOCAL TITLE: ANESTHESIA NOTE		
- 8	Signed Notes by Author		STANDARD TITLE: ANESTHESIOLOGY NOTE		
	Signed Notes by Date Range	N, RIC/PRE-AN OUT OF OR IR,	DATE OF NOTE: SEP 16, 2014@08:46 ENTRY DATE: SEP 16, 2014@08:46:29 AUTHOR: WILBORN, MARIE A EXP COSIGNER:		
	Uncosigned Notes	IN , RIC/PRE-AN	URGENCY: STATUS: COMPLETED		
		, TRACY LIMEY	see scannes anesthesia record in vista		
E	Custom View	ISH), HIC/ANES			
	Search for Text (Within Current View)		(es/ MARIE A WILBORN NURSE ANESTHETIST		
- 1	Save as Default View	OUT OF OR GI,	Signed: 09/16/2014 08:49		
	Return to Default View	EST CLINIC-X, 2 RE-ANESTHESI			
		IN , RIC/PRE-AN			
	Details	T OF OR GI, DE.			
	Icon Legend	N MGMT, RACH E (S), RIC/PC/E			
	Aug 11,14 SCI&D ACUPUNCTURE CONSULT, RIC				
E Fi	Jul 14,14 Adverse React/Allergy, ** No Location **, 1 Jul 11,14 NEUROLOGY LAB LETTER (S), CHA/PC.	CHRISTINE M TURD			
🞴 🗎					
E	May 29,14 GI NURSING NOTE, CHA/ANTICDAGU	LATION MGMT, RAC			
	/ Templates				
-	Encounter		Diagnoses:		
	Encounter		adjust Pacemaker - Fitting & adjustment of cardiac pacemaker (ICD-9-CM V53.31) (Primary)		Ĵ.
Cover Sheet		rgery D/C Summ Lai	ne Bennits		
	Notes Tours of the Notes Tours of the	La Contraction Carl			
				~ ~ ~ ~	2:22 PM
			EN EN	- 😼 🔂 🌖	9/16/2014

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

77 1661	THEREFORE (OUTPATIENT)	Visit Not Selected	Primary Care Team Unassigned
			Primary Care Team Unassigned
000-00-321	2 Juh 20, 1965 (49)	Current Provider Not Selected	
t 100 Signed No		V	isit: 09/16/14 ANESTHESIA NOTE, RIC/ANESTHESIA-OUT OF OR EP, MAI
All signed n			LOCAL TITLE: ANESTHESIA NOTE
	16,14 ANESTHESIA NOTE, RIC/AN		TANDARD TITLE: ANESTHESIOLOGY NOTE
	16,14 ANESTHESIA PRE-OPERATI		ATE OF NOTE: SEP 16, 2014@08:46 ENTRY DATE: SEP 1
	16,14 ANESTHESIA RECORD , RIC		AUTHOR: WILBORN, MARIE A EXP COSIGNER: URGENCY: STATUS: COMPL
	16,14 ANESTHESIA PRE-OPERATI		OKGENCI. SIRIUS. COMPL
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	29,14 ANESTHESIA RECORD , RIC		
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	22,14 ANESTHESIA PRE-OPERATI 22,14 ANESTHESIA NOTE, RIC/AN		
	12,14 IV CARE NOTE (S), CHA/ANT		
	11,14 PAIN ASSESSMENT/REASS		
	11,14 SCI&D ACUPUNCTURE CON		
	01,14 GI NURSING NOTE, CHA/PC		
	01,14 GI TELEPHONE NOTE, CHA/		
	4,14 IV CARE NOTE (S), CHA/PC/T		
	1,14 EYE CLINIC NOTE, CHA/PC/T		
	4,14 Adverse React/Allergy, ** No Li		Search for Text (Within Current View)
	4,14 Adverse React/Allergy, ** No L		Search string:
	1,14 NEUROLOGY LAB LETTER (S		
	9,14 NURSING IMMUNIZATION NO		seizure OK
- 🗐 Jul C	9,14 PRIMARY CARE CBOC NURSI	ING NOTE, CHA/PC/TEAM 1 TI	Your current view of notes will be searched for Cancel
- 🗐 Jul (9,14 PRIMARY CARE TELEPHONE	NOTE, CHA/PC/TEAM 1 TELE	the specified string. If you want to search a
- 🗐 Jun	20,14 PRIMARY CARE CBOC NURS	SING NOTE, CHA/ANTICOAGUL	larger range of notes, you need to pull up that
— 🗒 Jun	20,14 PRIMARY CARE CBOC NURS	SING NOTE, CHA/ANTICOAGUL	view prior to searching.
- 🞴 🗒 Jun	13,14 CONSENT FOR LONG-TERM	OPIOIDS FOR PAIN, ** No Loc-	
🖾 Mau	29,14 GI NURSING NOTE, CHA/AN	ITICOAGULATION MGMT, BAC	

- 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)

<u>Problems</u>

ſ	Z VistA CPRS in use by: Shin,Robert (vista.richmond.med.va.gov)						
	File Edit View Action Tools Hel	elp					
	ZZ TEST,THEREFORE (OUTP) 000-00-3212 Jun 20	PATIENT) Visit Not Selected 20,1965 (49) Current Provider Not Selected	Primary Care Team Unassigned F	lag VistaWeb Remote Data	Postings		
	View options Active Stat.	ive and Inactive Problems (1 of 1) at Description	0nset D	ate Last Upda L	ocation		
	Both active and inactive	Moderate depression (SCT 310496002)	Jun 20 2		ha/Anticoagulatic		
	Numeridan						
	New problem						
	Cover Sheet Brobleme Meds Orders	Notes Consults Surgery D/C Summ Labs	Reports				
I							

- 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

<u>Consults</u>

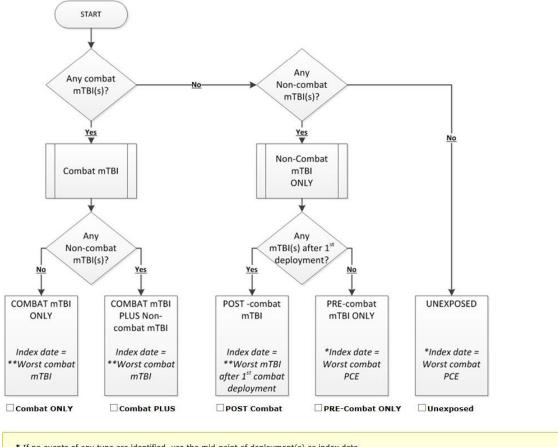
e Edit View Action Options Tools Help				
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New Consult		Inter-facility Inform	ation	
New Procedure		This is not an inter-	facility consult request	t.
State of the second sec		Status: Last Action:	CANCELLED CANCELLED	
		Facility Activity	Date/Time/Zone	Responsibl
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		Note: TIME ZONE is lo		
		No local TIU results	or Medicine results avai	ilable for ♪
ver Sheet Problems Meds Orders Notes Consults	Surgerv D/C Summ Labs	Beports		

- 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 P1 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 <u>leave the</u> <u>day field blank</u>. The <u>day</u> 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.

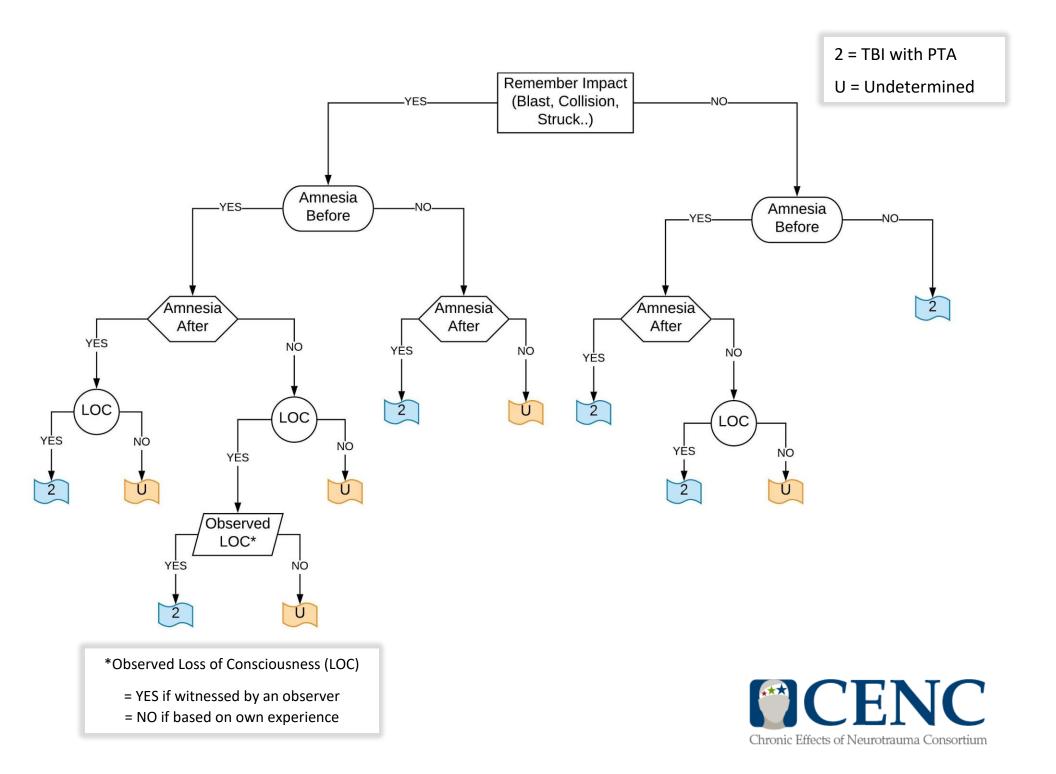


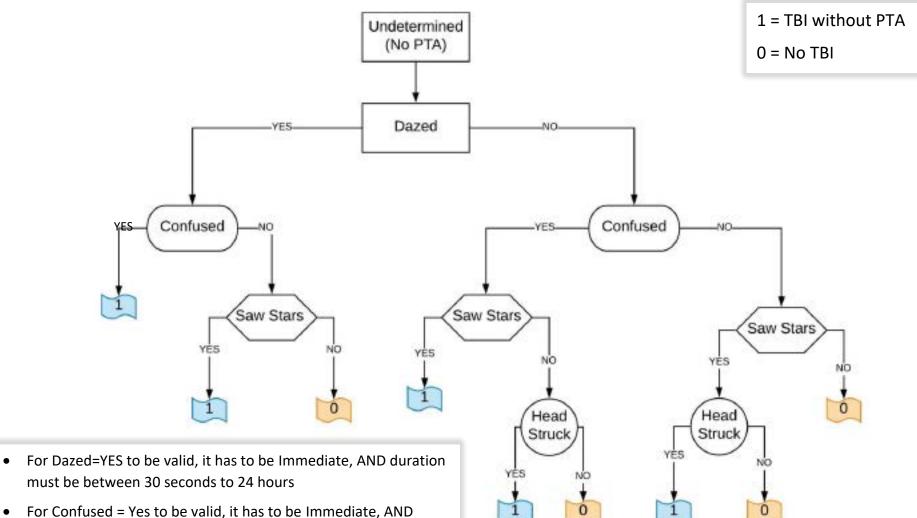
START Any combat Any Non-combat mTBI(s)? mTBI(s)? Yės Yės Non-combat Combat mTBI mTBI ONLY No Any Combat Any mTBI(s) after 1st Non-combat deployment? mTBI(s)? Yes Yes No No COMBAT COMBAT **POST Combat** Pre-combat **UNEXPOSED** mTBI ONLY mTBI PLUS mTBI **mTBI ONLY** Non-combat mTBI Index date = *Index date = **Worst mTBI Worst combat Index date = Index date = Index date = **Worst combat **Worst combat after 1st combat **Worst combat PCEmTBI mTBI deployment PCE POST Combat Combat ONLY Combat PLUS PRE-Combat ONLY Unexposed

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. wort 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.]





- For Confused = Yes to be valid, it has to be Immediate, AN 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.

