IHAST2 Update

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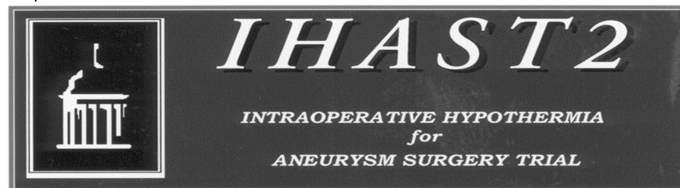

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Effective Immediately!

NEW IE FORMS AND CODES

Effective Immediately

1) Stop using the old IE code 632 (intracranial hypertension or brain swelling).

   Start using the new codes, 636 (intracranial hypertension) or 637 (brain swelling).

2) IE codes 636 (intracranial hypertension), 637 (brain swelling), and 633 (cerebral infarction) are now classified as "indicator events". They must be faxed to the CCC (319-384-8072) within 24 hours of onset.

3) Stop using the old IHAST2 IE and IE SUPPLEMENT forms and, with your next new patient, start using the new IE forms included in this mailing.

Why? What's Up?

Patient safety is paramount. Outcomes and IEs are continuously reviewed for indications of unwarranted or unexpected hazards. Monitoring is conducted by the CCC, by the Physician Safety Monitor (Dr. Hal Adams), and by the NIH-appointed PSMB Committee. The most important source of information for these individuals and groups is the INTERCURRENT EVENTS (IE) form.

Dr. Adams and the PSMB have requested that a change in format be made to better characterize all IEs listed on the form. The three main changes are:

1) You must record the date of onset of **each** related/concurrent event.

2) You must provide a maximum severity rating for **each** related/concurrent event.

3) You must indicate resolution (yes/no) for **each** related/concurrent event.

However, IE codes for procedures (*e.g.*, CT scan-694, electrocardiogram-296) do not need either a severity rating or indication of resolution.

In addition, intracranial hypertension and brain swelling will no longer be combined into a single IE code (632). There have been too many cases in which intracranial hypertension has occurred in the absence of documented brain swelling (e.g. hydrocephalus); and too many cases of brain swelling where intracranial hypertension was not confirmed. To stop this confusion, we are **eliminating** IE code 632. Each specific condition now has its own code.

1) Intracranial hypertension is now IE code 636. The definition for intracranial hypertension has not changed [measured intracranial pressure greater than 25 mmHg (3.3 kPa) for 15 consecutive minutes or longer]. *(continued on page 2)*

Please File Your *IHAST2 Updates*

Please file one copy of each edition of the ***IHAST2 Update*** in your Site Regulatory Binder. (See Chapter VII.A.5 of the Operations Manual)

2) Brain swelling is now IE code 637. The definition for brain swelling has not changed [when either direct surgical observation or imaging studies (CT or MRI) indicate brain volume and/or water content ("brain edema") are greater than normal, either focally or globally. On imaging studies, brain swelling will often be associated with effacement of the cortical sulci and/or shift of intracranial structures…].

In addition, our safety monitors indicated that because patients with intracranial hypertension and/or brain swelling tend to have poor outcomes, these events should be reported promptly to the CCC. Therefore, codes 636 (intracranial hypertension) and 637 (brain swelling) are now designated as "indicator events". This means that any IE form involving such codes must be reported to the CCC (by fax) within 24 hours of onset, regardless of their actual clinical severity. For example, if the ICP was 26 mmHg for 16 minutes, but the patient was otherwise well and had no adverse response; you would rate it as "mild". Nevertheless, this meets criteria for intracranial hypertension (636) and should be reported to the CCC.

Of course, intracranial hypertension (636) and brain swelling (637) can both be present in the same patient. If so, please record both codes.

Finally, just as intracranial hypertension (636) and brain swelling (637) appear to be associated with poor outcomes, the safety monitors feel that this seems to be true with respect to cerebral infarction (IE code 633). Therefore, they have also asked us to now make cerebral infarction (633) an "indicator event".

Okay, so what do I do now?

First, starting using the new IE codes 636 and 637 immediately, and remember, these events, as well as 633 (cerebral infarction) must be reported to the CCC within 24 hours of onset (by fax 319-384-8072).

Second, replace the old IE code lists located in each of the unused Patient Notebooks with the new lists included in this mailing.

Third, revise your IE pocket notebooks (the 4 x 6 inch spiral bound books with the pretty blue, white, and red "IHAST2" title). To do this use the 2 small adhesive stickers that have the new IE codes printed on them. Place the larger sticker on page 18 of the notebook. This sticker should ONLY cover up old code 632 and code 633. This sticker will provide definitions for codes 636 and 637 as well as indicate that 636, 637, and 633 are all now "indicator events". Place the smaller sticker on page 19 over the definition and code for 691 (Craniotomy Wound or Bone Debridement or Removal). This is revised only because there is a reference to old code 632.

Fourth, replace the pages in the Operations Manual with the new ones that are also included in this package and discard/recycle the old pages. These new pages pertain entirely to the new INTERCURRENT EVENTS form(s) and the new IE codes. (Please don't forget to place the cover page to the Operations Manual Update in your Regulatory Binder).

Fifth, beginning with the NEXT patient, start using the new INTERCURRENT EVENTS and IE SUPPPLEMENT forms. We are providing you with these new forms in this mailing.

NOTE

Do not revise IE forms that include code 632 if the form has already been submitted to the DMC.

If you have an IE started on the old form, but the patient is still in the hospital, you do not need to redo it. However, start using the new IE forms on the next patient.

If you have a patient that is currently in the hospital and have used code 632 please do revise the IE code to either 636 and/or 637. (You don't need to redo the whole IE on a new form though.)

Re-emphasis of the Difference Between Primary and Secondary IEs

"Primary IEs" are those which are considered to be the principal, underlying or initiating event of the medical problem of interest. Most of the time, only a single IE code should be entered as the primary IE. It is understood that when multiple IEs occur within a short time period, it may be difficult to know which IE was the primary IE. Use your best judgment. If you are certain there are more than two primary IEs occurring simultaneously, please complete additional IE forms for all other Primary IEs. Remember to adjust the "Time of Onset" in the header by :01 on each additional IE form.

"Clearly related and/or concurrent IEs" are events and/or procedures occurring either as a result of the primary IE, or occurring in such close association with the primary IE that they cannot be separated from it. To use the "chicken and the egg" analogy, "Primary IEs" are the chicken, and "related/concurrent IEs" are the egg. Hmm? Because sorting this out can often be difficult, we want to again encourage the very active participation of the local PI and Co-PI in this determination. Local Study Coordinators should seek the advice and council of the local PI and Co-PI in these matters.

Request to the Local PI/Co-PI:

Finally, at the request of our safety monitors we remind local PIs and Co-PIs to be fully aware of adverse outcomes in IHAST2 patients. Whenever a severe or "indicator" event occurs and is reported to the CCC, the local PI and/or Co-PI must be aware of the event.

CASE REPORT FORMS: Check Version Dates

Please review your unused Patient Notebooks to ensure that your center is using current IHAST2 Case Report Forms. For those centers that send an advance supply of Neuropsychology Packets to their Neuropsychology Examiners, please also make sure that they too have updated their forms. Following is a list of forms and the corresponding version date that should appear in the lower right hand corner of the form. Please review all unused Patient Notebooks (including unused Neuropsychology Packets that have been sent to your Neuropsychologist already) to make sure that the following dates appear on the forms.

FORM NAME	FORM DATE
SCREENING	021800
ELIGIBILITY (page 1)	040901
ELIGIBILITY (page 2 & 3)	032400
NOMOGRAM	092099 or 031600
CONTACT	091599
NIH STROKE SCALE	010801
PRE-SAH HISTORY	091599
POST-ADMIT SCREEN	092999
ANESTHESIOLOGIST (pages 1,2,3,5,6)	040600
ANESTHESIOLOGIST (page 4)	041301
NEUROSURGEON (page 1)	030201
NEUROSURGEON (pages 2 & 3)	021800
MEDICATIONS	101100
DAILY POST-OP SCREEN	100300
DPS SUPPLEMENT	101900
INTERCURRENT EVENTS	062601 (new)
IE SUPPLEMENT	062601 (new)
CONTACT FOLLOW-UP	070300
OUTCOME FOLLOW-UP	021800
DEATH/PATIENT WITHDRAWAL	032300

Neuropsych Battery

CHECKLIST	100400
BENTON VISUAL RETENTION	091599
ORAL WORD	091599
COMPLEX FIGURE TEST	091599
GP/TMT	110100
TRAIL MAKING A & B	No dates
MMSE	092099
MMSE FIGURE	091599

Thank you for taking time to check the forms as it is crucial for obtaining complete and accurate data sets.