Author's response to reviews

Title: Scandinavian guidelines for initial management of minimal, mild and moderate head injuries in adults - an evidence and consensus based update.

Authors:

Johan Unden (dr.johan.unden@gmail.com)
Tor Ingebrigtsen (tor.Ingebrigtsen@unn.no)
Bertil Romner (bertil.Romner@med.lu.se)

Version: 2 Date: 10 December 2012

Author's response to reviews: see over
Dear Editor,

We would like to thank the reviewers for a constructive and thorough review of our work. Below follow our comments and manuscript alterations with respect to the points raised.

Reviewer 1

Have the guidelines been presented and explained in a way that the community can fully understand and implement?

The guidelines are presented in both written form and flowsheet. They are well written and easy to understand. On the discharge form I think it would be useful to include monitoring advice (for example, being checked on once in the night). There is very little evidence regarding discharge advice but we do agree with your suggestion. Our general idea was to keep this sheet as simple as possible and to assure patients that they are "safe" (since we are after all discharging them) but at the same time having some sort of simple home monitoring. We have included your suggestion in the advice form.

Have similar guidelines been published previously? If so, are these proposed guidelines an improvement over existing guidelines?

The article presents new CT head guidelines, which are partially evidence based and partially consensus based. The authors should be commended on their thorough literature search and presentation of this data. These guidelines as a set have not been validated clinically, as the authors have stated, so we do not know their sensitivity and specificity. Until this has been established, I do not think they will replace well-established guidelines with known sensitivities and specificities, such as the Canadian CT Head Rule and the New Orleans criteria. We agree. External validation (at least concerning the CT selection part of the guidelines) is essential before widespread implementation can be suggested. This is further emphasised in the text and abstract.

How useful will these guidelines be to clinicians?

From a Canadian perspective, we have concerns with three of the recommendations. First, the admission guidelines are not feasible in our health care system and I believe are excessive for mild head injury patients, even in the setting of an abnormal CT scan. Such close monitoring would not even be available in our intensive care unit and almost all mild head injury patients are admitted to ward beds. We understand the concerns and have discussed this at length during the work process since it is an area lacking in good evidence. With respect to admission instead of doing a CT, we feel it is important to have very close observation on patients where a CT is indicated but, for whatever reason, not done. Although rare, we have all seen or heard of patients who rapidly deteriorate and these patients need prompt treatment. These routines were also chosen to ensure close monitoring whilst still in the ED, for instance when waiting for a CT scan. Please note that the monitoring routines are set from time after trauma, not after admission. Hence, most patients will have already passed the “15-minute” time period when actually arriving to a ward (4 hours after the trauma event). Our goal is that only a small minority of patients will be admitted (Moderate and high-risk Mild are relatively uncommon patients and the rest should preferably have a CT). We have added text...
concerning these aspects in the results section.

Second, there is no evidence to support CT scanning all patients with intraventricular shunts after minimal or mild head injury with GCS 15 and no other risk factors. These patients are already exposed to excessive radiation as shunt dysfunction is often suspected any time these patients seek medical attention for any symptom. In addition, it seems excessive that, even if the CT scan is normal and the patient is neurologically intact, that the patient be admitted for 24 hours. Although we understand that the number of patients presenting with shunts and head injury will be a very small proportion of patients and use minimal resources overall, it is not an evidence based recommendation.

Furthermore, it encourages unnecessary CT scanning of patients with shunts and increases physician discomfort with these patients, both of which are already a problem in emergency rooms.

Lastly, the use of S100B, while well validated, is not widely available in Canada and so limits the application of these guidelines.

Are all claims and statements fully supported with either new data or references to previous publications?

The evidence for using age greater than 65 combined with anti-platelet medication use and the presence of an intraventricular shunt as risk factors for neurosurgical intervention is very weak and the authors admit to this. In addition, there is no evidence that the observation regimens need to be so extensive and it would be useful to know how the authors came to a consensus on this issue. Regarding monitoring, please see above. The combination of age and anti-platelet medication was chosen through consensus since these risk factors only had moderate individual predictive properties and are very common in the population. As stand-alone risk factors, they would not be accepted in Scandinavia due to the large increase in CT scanning (especially in relation to a relatively low clinical impact of these CT scans). There is some weak/extrapolative evidence for the combination but not good enough to be included in the work process and so the final inclusion was through consensus only. The reasoning is that these groups already heavily overlap (most patients taking anti-platelet medication are over 65 and many patients over 65 take anti-platelet medication). It is theoretically reasonable to assume that the combination of these risk factors should be more predictive of intracranial injury/neurosurgery or that the presence of anti-platelet medication is in fact an important confounder in the older age groups for intracranial injury/neurosurgery after TBI (Fabbri et al 2010). Shunts are, and have been, an issue since the SNC guidelines from 2000. Unfortunately, no evidence has emerged since these were published and so this is still based upon consensus in the group. Primarily the neurosurgeons (who make up most of the SNC working group) defended this choice and many seem to have had cases with devastating consequences (for instance, normal CT scan followed by rapid deterioration). We are fully aware that this refers to the lowest form of evidence but we cannot ignore the consensus in the group concerning areas without good evidence. We wanted the guidelines to be applicable to all patients, even those with shunts. In Scandinavia, all neurosurgeons would recommend a CT in such a patient and few would approve direct discharge, even after a normal CT scan. Since these patients are very uncommon, we do not feel it will impact the overall guideline in a
major way. However, as you correctly mention, the impact on the individual patient with a shunt is significant. However, radiation dosing to adults, although potential harmful must be weighed considering the potential consequences of a rapidly progressive intracranial mass lesion. We are presently working on paediatric guidelines using the same methodology and here this aspect (among many others) is much more complicated considering potentially harmful radiation doses. Regarding adults, however, I fear that it is unlikely that future studies will help us. We have some study cohorts, recently a series of 700 patients with non-severe TBI and not one of these had a shunt.

With regard to S100B, if this is unavailable a CT should be done (as with medium-risk patients), see Figure 4. The function of S100B in our guidelines is to reduce CT scanning and resource use in a subgroup of patients with low-risk TBI. In Scandinavia, almost all centres have capability to easily introduce S100B analysis in existing diagnostic apparatus (only the S100B kit is needed). As we understand, this is similar in most other European countries. We are unsure concerning the status of S100B in the US and Canada. As there are centres where S100B may be unavailable, we included the CT option for these patients.

We have added some clarification in the text.

Grammar suggestion

In the results section, paragraphs numbered 1 and 2, the word minimal should be removed, because by definition minimal head injury cannot have a GCS of 14 or less or have any of the stated risk factors. In the paragraph numbered 3, moderate should be removed as moderate head injuries cannot be GCS 15. We agree, we missed this. Thank you.

Quality of written English: Needs some language corrections before being published. We agree. We have made corrections.

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

We declare that we have no competing interests

Reviewer 2

Have the guidelines been presented and explained in a way that the community can fully understand and implement these?

To improve clarity, the following are recommended: Explicitly define minimal, mild and moderate TBI in text (only place I see definitions are in a figure labelled ‘help sheet’). We agree. This definition tends to “glide” somewhat in the literature and, in may view, there are still problems with this definition. Our pre-review definition, as in the 2000 guidelines, is based upon GCS according to the HISS classification from Stein and Spettell (Stein et al 1995). Our review includes all "non-severe" head injuries, i.e. GCS >8. The classification in the final guidelines is the same with respect to GCS but Mild has
been risk stratified according to the different risk factors. We have added the definition in the Methods section including the reference to Stein et al. There are 3 that are unlabeled (I assume they are figures 3, 4 and 5). Please label all figures. Sorry, missed this. They are now labelled. On table 3, please make clear that the evidence level was determined via CEBM. Thank you, this had been added. I found the Methods section quite confusing. Recommend adding a flow diagram, such as the one below, to assist the reader. Great suggestion! This has been added, see Figure 1.

With regards to Table 5, how were clinical predictors selected for inclusion in your recommendations? This should be described in the text. We have added some text concerning this. Basically we used the GRADE methodology. More specifically, risk factors were chosen based upon the results in Table 5, i.e. the likelihood ratios but also considering other aspects. Need for neurosurgery was judged the most important outcome variable but ICI and CT findings were also considered, especially when evidence for neurosurgery was poor or inconsistent. Consideration was also made regarding the prevalence of the risk factors. Very common risk factors, such as headache, would have to show very high predictive values in order to be included in the recommendations in order to avoid unnecessary CT scanning. With regards to Tables 8 and 9, what do Delphi points 1-9 refer to? We have added this information in the tables. What happened between Round 1 and Round 2? This should be described in the text. This has been explained in the text. The decision to recommend as risk factors the combination of age>65 and anti-platelet medication, and shut-treated hydrocephalus clearly sticks out as not really being evidence-based. Readers may want to know why you felt there was “little doubt” these would be predictive of complications. We agree with the concerns, see comments to Reviewer 1. We have added some discussion concerning this and re-worded some aspects for clarification. In the Results section, I found Recommendations 1 and 2 for Clinical Question 1 to be a bit confusing. In Rec1, for a LOC or vomiting >2 x, you recommend head CT scan, but in Rec 2 for a LOC or vomiting>2x (associated with GCS 15), you recommend S100B. Please clarify. We agree this may be confusing and we have tried to clarify this in the text. These formulations were chosen to accommodate centres without the possibility of S100B analysis. S100B sampling should be done in the subpopulation of low-risk mild head injury where a CT is normally recommended. If S100B is unavailable, a CT should be done according to recommendation 1.

How well have reporting standards been adhered to?

No problems

How useful will these guidelines be to clinicians?

This remains to be seen. The final recommendations are a bit cumbersome to remember and clinicians will likely need some type of visual aid to remember them. See comments to Reviewer 1. We agree that a visual aid will be helpful or even necessary and this will be implemented in Sweden, Norway and Denmark after the guidelines have been
translated, published and disseminated on a national level. More importantly, clinicians in countries without access to S100B may not find these guidelines helpful. According to Figure 4, a CT should be done if S100B is unavailable. In Scandinavia, this is not a significant problem but our guidelines are fully applicable to centres without S100B availability.

Are all claims and statements fully supported with either new data or references to previous publications?

Yes, with the exception of the decision to recommend as risk factors the combination of age>65 and anti-platelet medication and shut-treated hydrocephalus. We agree with the concerns and these points are heavily consensus-based, see comments to Reviewer 1.

Have similar guidelines been published previously? If so, are these proposed guidelines an improvement over existing guidelines?

I think these are comprehensive and unique guidelines

Do the authors have the required expertise and knowledge to design these guidelines?

Yes

We would again like to thank the reviewers for their comments. We believe the changes made have significantly improved our manuscript.

It is important to stress that S100B sampling is an option for centres with this possibility. The guidelines are just as applicable to centres that, for whatever reason, do not have S100B analysis. If this is not clear from the guidelines, please give feedback again since this point is important.

As expected, the two consensus points (shunts and the combination of age/anti-platelet medication) raise some concern. We do believe they both have sound theoretical background and are supported by the expertise in the working group. However, the clinical impact remains from these risk factors and the guideline as a whole remains to be seen.

Warm regards,

Johan Undén, Tor Ingebrigtsen and Bertil Romner