

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------|-------------------|---------|---------|---|---|
| Abbott Laboratories | Evidence review G | 009 | 101 | <p>On page 9 line 101 of the Evidence Review G the committee stated that "Biomarker testing is the first stage of a two-step process, followed by CT/MRI if indicated by a positive test. The need for the index test to have a very few false negatives was considered to be important so as to avoid anyone with intracranial injury/lesion exiting at first stage prematurely. Specificity was considered to be important as false positives would mean people who do not have intracranial injury/lesion would receive unnecessary radiation (particularly for children)."</p> <p>The committee reviewed the ALERT-TBI study publications (Bazarian, Biberthaler et al. 2018, Bazarian, Welch et al. 2021) and agreed on their high quality, with the risk of bias and indirectness being indicated as none (see evidence review G, page 208, table section "ALERT-TBI studies").</p> <p>These studies demonstrated that the use of a combination of GFAP and UCH-L1 biomarkers</p> | <p>Thank you for your comment. Recommendations are based on the overall evidence; it is not based on one study. There were high sensitivity values for some biomarkers at certain thresholds; however, the specificity values were not high enough across the evidence; the committee agreed that this was equally important given the consequences of unnecessary radiation particularly in children. The accuracy of the biomarkers differed quite widely between different studies looking at the same biomarker test. Considering the limitations of the evidence the committee were unable to make recommendations.</p> <p>The committee therefore agreed that further prospective studies were required before biomarkers could be recommended as clinically and cost effective for informing the decision to conduct brain imaging (please see evidence review G, appendix J).</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--|----------------------|
| | | | | <p>as a single test can rule out intracranial lesions with a sensitivity of 95.8% and a specificity of 40.4%. Sensitivity reflects the rate of false negatives and the risk of anyone with intracranial injury/lesion exiting without imaging. This was demonstrated to be even higher (96.7%) in the pivotal study for the Alinity GFAP and UCH-L1 tandem test (see Alinity i TBI instructions for use), and confirmed that no life-threatening neurosurgically manageable cases were among the false negative results.</p> <p>As for the rate of false positives who would potentially receive unnecessary radiation without having an intracranial injury/lesion, the data indicates that clinical implementation of the test would reduce the number of CT scans by 40% among those who would otherwise have had a scan according to the current practice, as all patients in the study cohort have been scanned based on the decision of the treating physician. Thus, there is no evidence to suggest that the apparently low specificity of the test would result in an increase of scans being</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------|-------------------|---------|---------|--|--|
| | | | | conducted. On the contrary, a 40% reduction in the scans is expected based on the study results. | |
| Abbott Laboratories | Evidence Review G | 151 | 012 | <p>The thresholds for sensitivity and specificity for potential biomarker tests were set between 90% and 60% as stated on page 151 line 12. It is not entirely clear from the text of the review whether the same 60 to 90% thresholds apply to both sensitivity and specificity, or if 90% refers to sensitivity threshold to be included in recommendations, and 60% refers to specificity. We proceed on the assumption that the latter is true</p> <p>While it would be ideal to have a test with such high diagnostic performance, such high thresholds of recommendations are unrealistic and are likely to prevent innovation in the field of blood biomarker development for neurological conditions. Indeed, if such stringent criteria were used in other fields, it would prevent many widely used biomarkers such as troponin from being implemented in the clinic. The NICE DG40 "High Sensitivity troponin tests for the early rule out of NSTEMI" looked at a similar</p> | <p>Thank you for your comment. Sensitivity and specificity were identified by the committee as the primary measures in guiding decision-making. Sensitivity and specificity are the paramount measures as they tell us the most important information about how many people with the disorder will be missed, and how many without the disorder will be misdiagnosed.</p> <p>Clinical decision thresholds for both sensitivity and specificity were set by the committee at 90% (above which a test would be recommended) and 60% (below which a test is of no clinical use).</p> <p>Positive predictive value (PPV) and negative predictive value (NPV) were not considered as primary measures for decision making as PPV and NPV would only make sense if the prevalence of the condition in the study is the same as the prevalence in the population, as both values depend on the prevalence. The advantage of sensitivity and specificity (in addition to being the most relevant measures for clinical decision making) is that they are independent of the condition prevalence (as each is</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--|---|
| | | | | <p>biomarker approach for ruling out NSTEMI and found (see section 3.11 and subsequent) sensitivity of ~100% but specificity of 19 – 36%, and this performance was deemed adequate. NICE DG40 recommended hsTroponin for early rule out of NSTEMI. In the context of ruling out the need for head CT, the Abbott TBI biomarkers (GFAP and UCH-L1) would have a similar sensitivity and NPV as hsTroponin for NSTEMI, and their implementation would result in useful reduction in head CTs (~40%), which would have impact on reduction in radiation and possible operational benefits. For the rule out tests sensitivity and negative predictive values are the best measures of diagnostic performance. Specificity of rule out test does not reflect its safety and impact on particular patient, mostly it reflects its efficiency and health economic impact. We agree that more evidence is needed to be collected on the latter, however it is rarely possible to collect such data without the test being routinely used in the clinic. Hence lack of guideline recommendation will prevent</p> | <p>calculated within the separate classes of people with and people without the disorder).</p> <p>The committee were not able to make any recommendations as the evidence for biomarkers was insufficient and not consistent in both adults and children. There were high sensitivity values for some biomarkers at certain thresholds; however, the specificity values were not high enough across the evidence; the committee agreed that this was equally important given the consequences of unnecessary radiation particularly in children.</p> <p>Also, many biomarkers were tested in small samples leading to imprecise estimates. Alternatively, such estimates were from large but single studies. The accuracy differed quite widely between different studies looking at the same biomarker test. Considering the limitations of the evidence the committee were unable to make recommendations.</p> <p>The committee therefore agreed that further prospective studies were required before biomarkers could be recommended as clinically and cost effective for informing</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------|-------------------|---------|---------|--|---|
| | | | | many hospitals from being able to collect relevant data. | the decision to conduct brain imaging (please see the research recommendations in evidence review G, appendix J). |
| Abbott Laboratories | Evidence review G | 154 | 017 | <p>In Evidence review G, page 154, paragraph starting from line 17 the committee expressed the concern over the time it will take to obtain test results.</p> <p>The Abbott TBI test which combines GFAP and UCH-L1 measurements can be conducted within 18 minutes on the lab-based Alinity analyser or 15 minutes on the i-STAT point of care device. While this time does not take into account sample processing to plasma, from the experience of other emergency medicine tests such as troponin we have evidence to suggest that laboratories can provide results within 1 hour. Indeed, the ability to provide results within 1 hour from emergency department sample collection was included in the Royal College of Pathology Key Performance Indicators for pathology services in 2015 (see The Royal College of Pathologists Key Performance Indicators Proposals for implementation, 2013). With the current waiting times of the emergency</p> | <p>Thank you for your comment. Most studies in the review assessed lab-based biomarker testing (which would be available only after a few hours) and only one of them was point of care testing.</p> <p>As the study you refer to is yet to be published in full, we are unable to include it in this guideline. It will be considered for any future updates of the guideline. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------|-----------|---------|---------|---|--|
| | | | | departments this is very likely to be available before a CT scan report becomes available for the patient. Indeed, some trusts identified their waiting times for CT head scan for patients with GCS 15 to be up to 4 hours (unpublished). | |
| Abbott Laboratories | Guideline | General | General | <p>References</p> <p>"Alinity i TBI H22974R01. Instructions for use. Abbott Ireland Diagnostics Division. Sligo, Ireland; October 2021."</p> <p>"The Royal College of Pathologists Key Performance Indicators Proposals for implementation."</p> <p>Bazarian, J. J., P. Biberthaler, R. D. Welch, L. M. Lewis, P. Barzo, V. Bogner-Flatz, P. Gunnar Brolinson, A. Buki, J. Y. Chen, R. H. Christenson, D. Hack, J. S. Huff, S. Johar, J. D. Jordan, B. A. Leidel, T. Lindner, E. Ludington, D. O. Okonkwo, J. Ornato, W. F. Peacock, K. Schmidt, J. A. Tyndall, A. Vossough and A. S. Jagoda (2018). "Serum GFAP and UCH-L1 for prediction of absence of intracranial injuries on head CT (ALERT-TBI): a multicentre observational study." <i>Lancet Neurol</i> 17(9): 782-789.</p> | <p>Thank you for your references.</p> <p>Alinity i TBI H22974R01. Instructions for use. Abbott Ireland Diagnostics Division. Sligo, Ireland; October 2021."</p> <p>"The Royal College of Pathologists Key Performance Indicators Proposals for implementation."</p> <p><i>Not a diagnostic study. Does not meet review inclusion criteria.</i></p> <p>Bazarian, J. J., P. Biberthaler, R. D. Welch, L. M. Lewis, P. Barzo, V. Bogner-Flatz, P. Gunnar Brolinson, A. Buki, J. Y. Chen, R. H. Christenson, D. Hack, J. S. Huff, S. Johar, J. D. Jordan, B. A. Leidel, T. Lindner, E. Ludington, D. O. Okonkwo, J. Ornato, W. F. Peacock, K. Schmidt, J. A. Tyndall, A. Vossough and A. S. Jagoda (2018). "Serum GFAP and UCH-L1 for prediction of absence of intracranial injuries on head CT (ALERT-TBI): a</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--|---|
| | | | | <p>Bazarian, J. J., R. D. Welch, K. Caudle, C. A. Jeffrey, J. Y. Chen, R. Chandran, T. McCaw, S. A. Datwyler, H. Zhang and B. McQuiston (2021). "Accuracy of a rapid glial fibrillary acidic protein/ubiquitin carboxyl-terminal hydrolase L1 test for the prediction of intracranial injuries on head computed tomography after mild traumatic brain injury." Acad Emerg Med 28(11): 1308-1317.</p> <p>Foks, K. A., C. L. v. d. Brand, H. F. Lingsma, J. v. d. Naalt, B. Jacobs, E. d. Jong, H. F. d. Boogert, Ö. Sir, P. Patka, S. Polinder, M. I. Gaakeer, C. E. Schutte, K. E. Jie, H. F. Visee, M. G. M. Hunink, E. Reijners, M. Braaksma, G. G. Schoonman, E. W. Steyerberg, K. Jellema and D. W. J. Dippel (2018). "External validation of computed tomography decision rules for minor head injury: prospective, multicentre cohort study in the Netherlands."</p> <p>Lagares, A., A. M. Castaño-Leon, M. Richard, P. P. Tsitsopoulos, J. Morales, P. Mihai, V. Pavlov, O. Meján, J. de la Cruz and J. F. Payen (2022). "Variability in the indication of brain CT scan after mild traumatic brain injury. A</p> | <p>multicentre observational study." Lancet Neurol 17(9): 782-789.</p> <p><i>Study already included in biomarkers for post-injury complications review.</i></p> <p>Bazarian, J. J., R. D. Welch, K. Caudle, C. A. Jeffrey, J. Y. Chen, R. Chandran, T. McCaw, S. A. Datwyler, H. Zhang and B. McQuiston (2021). "Accuracy of a rapid glial fibrillary acidic protein/ubiquitin carboxyl-terminal hydrolase L1 test for the prediction of intracranial injuries on head computed tomography after mild traumatic brain injury." Acad Emerg Med 28(11): 1308-1317.</p> <p><i>Study already included in biomarkers for post-injury complications review.</i></p> <p>Foks, K. A., C. L. v. d. Brand, H. F. Lingsma, J. v. d. Naalt, B. Jacobs, E. d. Jong, H. F. d. Boogert, Ö. Sir, P. Patka, S. Polinder, M. I. Gaakeer, C. E. Schutte, K. E. Jie, H. F. Visee, M. G. M. Hunink, E. Reijners, M. Braaksma, G. G. Schoonman, E. W. Steyerberg, K. Jellema and D. W. J. Dippel (2018). "External validation of computed</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|---|--|
| | | | | <p>transnational survey." European journal of trauma and emergency surgery : official publication of the European Trauma Society. Papa, L., J. G. Ladde, J. F. O'Brien, J. G. Thundiyil, J. Tesar, S. Leech, D. D. Cassidy, J. Roa, C. Hunter, S. Miller, S. Baker, G. A. Parrish, J. Davison, C. Van Dillen, G. A. Ralls, J. Briscoe, J. L. Falk, K. Weber and P. A. Giordano (2022). "Evaluation of Glial and Neuronal Blood Biomarkers Compared With Clinical Decision Rules in Assessing the Need for Computed Tomography in Patients With Mild Traumatic Brain Injury." JAMA Network Open 5(3): e221302-e221302.</p> | <p>tomography decision rules for minor head injury: prospective, multicentre cohort study in the Netherlands."</p> <p><i>Study already included in evidence review on clinical decision rules selecting people with head injury for imaging</i></p> <p>Lagares, A., A. M. Castaño-Leon, M. Richard, P. P. Tsitsopoulos, J. Morales, P. Mihai, V. Pavlov, O. Mejan, J. de la Cruz and J. F. Payen (2022). "Variability in the indication of brain CT scan after mild traumatic brain injury. A transnational survey." European journal of trauma and emergency surgery : official publication of the European Trauma Society.</p> <p><i>Inappropriate study design- survey. Does not meet inclusion criteria for evidence review on clinical decision rules selecting people with head injury for imaging</i></p> <p>Papa, L., J. G. Ladde, J. F. O'Brien, J. G. Thundiyil, J. Tesar, S. Leech, D. D. Cassidy, J. Roa, C. Hunter, S. Miller, S. Baker, G. A. Parrish, J. Davison, C. Van Dillen, G. A. Ralls, J. Briscoe, J. L. Falk, K. Weber and P. A. Giordano (2022).</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------|-----------|---------|---------|---|---|
| | | | | | <p>"Evaluation of Glial and Neuronal Blood Biomarkers Compared With Clinical Decision Rules in Assessing the Need for Computed Tomography in Patients With Mild Traumatic Brain Injury." JAMA Network Open 5(3): e221302-e221302.</p> <p><i>Inappropriate comparison. We looked for diagnostic accuracy of clinical decision rules and biomarkers separately but did not look for studies comparing biomarkers and clinical decision rules with each other.</i></p> |
| Abbott Laboratories | Guideline | 18 | General | As a result of evidence review current NICE guidelines clinical decision rule (CDR) was selected as the criteria for doing a CT head scan. As stated on page 53 paragraph starting from line 11, "the evidence for the performance of the current CDRs is of poor quality and suggests low specificity". The committee noted that only 1 study so far assessed the performance of the 2014 update of NICE Head Injury guidelines (Foks, Brand et al. 2018), and demonstrated 73% sensitivity and 61% specificity. The committee also noted that this study had several limitations which might have | Thank you for your comment. The evidence on specificity from the systematic review and the experience of the committee is that considerably more than 10%-20% of people with head injury are excluded from a head CT scan using the Canadian head CT rule, as modified by NICE. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------|-----------|---------|---------|--|---|
| | | | | <p>affected the results of the diagnostic performance. This is likely to be true for both sensitivity and specificity measures. To the best of our knowledge, it is not known what the current rate of CT rule out is in mild head injury patients in the UK, with the Foks study providing little insight into what is the actual, not theoretical rule out rate of the current guidelines. Based on communications with several hospital sites across the UK this rate is very likely to be close to 10-20%. This is in line with many studies showing low rule out rate of many CDRs, and difficulties of implementing CDRs into clinical practice (Lagares, Castaño-Leon et al. 2022, Papa, Ladde et al. 2022). Moreover, several UK sites that analysed their rate of CT findings showed that only 5-10% of their CT head scans for trauma report any visible abnormalities (unpublished). Hence it is clear that the current practice is not effective in ruling out unnecessary CT scans.</p> | |
| Abbott Laboratories | Guideline | 044 | 017 | <p>We would like to suggest to the committee to be more specific in the research recommendations and indicate which biomarkers appeared to be</p> | <p>Thank you for your comment. The committee do not consider this as a reason to exclude some biomarkers, as the accuracy differed quite widely between different</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------|-----------|---------|---------|---|--|
| | | | | the most promising in the course of the review, for example as mentioned in Evidence review G Page 153 line 36 "There were high sensitivity values for some biomarkers at certain thresholds". This could help clinical researchers to focus their efforts on the markers mostly likely to be adapted in the clinic in the course of the next guideline review. | studies looking at the same biomarker test. They agreed that all biomarkers in the list had promise; hence, they have been included in the research recommendation. |
| Ageing Well NHS England | Guideline | General | General | <p>General: A personalised approach to the care of older people living with frailty is essential as they live with a complex combination of long term conditions, functional impairments and in some cases impaired cognition. Their homeostatic responses are less effective and any "insult" is liable to produce a disproportionate destabilisation in their physical, mental and functional status. They are at high risk of deterioration and adverse events if hospitalised.</p> <p>Falls and therefore head injuries are more common in patients living with frailty. They are therefore an important population to consider in this guidance.</p> | <p>Thank you for your comment. The committee agreed these are important factors to consider. The committee has made two additional recommendations 1.1.1 and 1.1.2 which refer to the NICE guidelines on shared decision making and decision making and mental capacity (including advance care plans). These recommendations have been cross referred to in recommendations 1.2.2-1.2.5. The committee discussed making further reference to advance care plans but agreed that the cross references to the relevant NICE guidelines covered the key points.</p> <p>The committee noted that the ability to assess someone with head injury (and to be able to take into consideration an advance care plan), who are often on anticoagulant or</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--|---|
| | | | | <p>The Head Injury guidance is often cited in clinical practice as a reason for emergency department attendance, admission and monitoring for all patients irrespective of their level of frailty. We would advocate for an assessment of frailty using a tool such as the validated and well-established Clinical Frailty Scale to assess severity.</p> <p>Many older adults living with severe frailty are aware that they are in the last phase of their life (a view with a robust research basis (eg Stow et al, 2018)) and welcome the opportunity to make an advance care plan (with evidence of a “better death” and better experience for the bereaved relatives of the deceased- again well evidenced eg Bischoff et al, 2013).</p> <p>Thus, a blanket statement that all patients with a head injury who are taking an anticoagulant must have a head CT within 8 hrs is inappropriately prescriptive. The wishes of the patient, whether expressed in an advance care</p> | <p>antiplatelet therapy medication, at the scene will depend on their training, and that a person may need to be referred to hospital for a variety of reasons -other than the risk of intracranial bleeding. For example, the commonest cause of head injury in older adults is a fall from a standing height and a person on the aforementioned therapies may require assessment to explore possible acute medical events or unstable co-morbid conditions as causes of the fall (see recommendation 1.10.13). The management of any bleeding scalp/ head wound and the wholistic assessment for extracranial injury also requires expertise that may not be available at scene. When to stop anticoagulant therapy was outside of the scope of the guideline but the recommendations for stopping therapy are covered in the NICE guideline on multimorbidity Overview Multimorbidity: clinical assessment and management Guidance NICE.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--|----------------------|
| | | | | <p>plan (ACP), by the individual at the time of the incident or by family or other proxy with LPA (Lasting Power of Attorney) should be respected.</p> <p>Where no ACP or proxy with LPA is in place or available, in those living with severe frailty a careful assessment of the balance of risk and benefit of conveyance must be made whenever appropriately skilled staff or family who know the patient are available to inform decision making.</p> <p>With the upscaling of Hospital At Home/Virtual Ward models together with the current national provision of Urgent Community Response 8 am– 8pm in England there is an opportunity for the guidance to expand on options available in the pre-hospital section. For patients who do not wish to have neurosurgical intervention or due to frailty severity are unlikely to benefit from intervention a shared decision making conversation with a clinician in their home environment is an appropriate response.</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--|----------------------|
| | | | | <p>Weighing up the risks and benefits in this population is important to delivering personalised care. This would reduce the need for conveyance to hospital and the likelihood of hospital associated harm which research has shown is more likely in patients living with frailty.</p> <p>There is growing evidence demonstrating significantly poorer outcomes for patients living with frailty which should be considered by the committee. Imam et al (2020) has showed those patients stratified as having severe frailty who between 2017-2018 had undergone emergency neurosurgery had much poorer outcomes than those with mild or moderate frailty. The guidance therefore needs to emphasise the need for shared decision making for patients living with frailty.</p> <p>Any head injury in a patient with severe frailty who is taking an anticoagulant indicates the need to reassess the appropriateness of</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------|-----------|---------|---------|---|--|
| | | | | continuing anticoagulation. | |
| Ageing Well NHS England | Guideline | 006 | 1.1.3 | The guideline instructs that everyone with head injury should be sent to ED regardless of their proximity or otherwise to the end of their life, their informed wishes and any Advance Care Plan. Currently this results in ambulance services across the country bring severely frail older people to the emergency department regardless of their wishes and of the potential to benefit for that individual. | Thank you for your comment. The committee agreed these are important factors to consider. The committee has made two additional recommendations 1.1.1 and 1.1.2 which refer to the NICE guidelines on shared decision making and decision making and mental capacity (including advance care plans). These recommendations have been cross referred to in recommendations 1.2.2-1.2.5. The committee discussed making further reference to advance care plans but agreed that the cross references to the relevant NICE guidelines covered the key points. |
| Ageing Well NHS England | Guideline | 007 | 1.1.4 | See above - The guideline instructs that everyone with head injury should be sent to ED regardless of their proximity or otherwise to the end of their life, their informed wishes and any Advance Care Plan. Currently this results in | Thank you for your comment. The committee agreed these are important factors to consider. The committee has made two additional recommendations 1.1.1 and 1.1.2 which refer to the NICE guidelines on shared decision making and decision making and mental |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------|-----------|---------|---------|--|---|
| | | | | ambulance services across the country bring severely frail older people to the emergency department regardless of their wishes and of the potential to benefit for that individual. | capacity (including advance care plans) . These recommendations have been cross referred to in recommendations 1.2.2-1.2.5. The committee discussed making further reference to advance care plans but agreed that the cross references to the relevant NICE guidelines covered the key points. |
| Ageing Well NHS England | Guideline | 009 | 001 | Immediate management at the scene: same reservations as above. | Thank you for your comment. This recommendation was not updated as part of this guideline update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| Ageing Well NHS England | Guideline | 009 | 1.2.5 | Here there is some recognition that some people who have sustained a head injury may be living with dementia, however there's a missed opportunity to recognise that for those with advanced dementia who would not be neurosurgical candidates any intervention may be unwanted, futile, distressing and harmful. | Thank you for your comment. The committee agreed these are important factors to consider. The committee has made two additional recommendations 1.1.1 and 1.1.2 which refer to the NICE guidelines on shared decision making and decision making and mental capacity (this includes information on advance care plans). These recommendations have been cross referred to in recommendations 1.2.2-1.2.5. The committee discussed making further reference to advance care plans but agreed that the cross references to the relevant NICE guidelines covered the key points. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------|-----------|---------|---------|---|---|
| Ageing Well NHS England | Guideline | 016 | 1.3.15 | Here again the problem is blanket advice with no regard for personalised care/ frailty assessment/ ACP wishes etc | Thank you for your comment. We have added two new recommendations about shared decision making and supporting people who lack capacity, including people with an advanced care plan (1.1.1 and 1.1.2). These recs apply to the whole guideline. |
| Ageing Well NHS England | Guideline | 017 | 1.4.5 | Advice regarding transfer for head CT offered with no advice to ascertain patients' wishes/ potential to benefit. We are especially concerned that a severely frail person in a community hospital (for example) would have to be transferred for a head CT by staff who consulted the guideline. I personally have been asked by an ambulance staff member "Oh, does an ACP trump NICE guidelines then?" | Thank you for your comment. We have added two new recommendations about shared decision making and supporting people who lack capacity, including people with an advanced care plan (1.1.1 and 1.1.2). These recs apply to the whole guideline. |
| Ageing Well NHS England | Guideline | 018 | 1.4.8 | Lack of reference to frailty assessment, regard for patients wishes and personalised care | Thank you for your comment. We have added two new recommendations about shared decision making and supporting people who lack capacity, including people with an advanced care plan (1.1.1 and 1.1.2). These recs apply to the whole guideline. |
| Ageing Well NHS England | Guideline | 018 | 1.4.9 | Lack of reference to frailty assessment, regard for patients wishes and personalised care | Thank you for your comment. We have added two new recommendations about shared decision making and supporting people who lack capacity, including people with an advanced care plan (1.1.1 and 1.1.2). These recs apply to the whole guideline. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------|-----------|---------|---------|---|---|
| Ageing Well NHS England | Guideline | 020 | 1.4.13 | Lack of reference to frailty assessment, regard for patients wishes and personalised care | Thank you for your comment. The review findings suggested that people on anticoagulants (including warfarin and direct-acting oral anticoagulants) or antiplatelets (excluding people on aspirin monotherapy) with low-risk factors (no loss of consciousness, amnesia, a GCS score of 15 and no other indications for CT brain scan) can be risk assessed (including for other injuries, supervision at home, cause of incident and risk of further falls). Then, if there are no risk factors and after shared decision making, they could be discharged safely without a CT scan, with the usual discharge advice (see the recommendations in section 1.10). A new recommendation has been made to highlight the importance of shared decision making (1.1.1). |
| Airedale NHS Trust | Guideline | General | General | There is no reference to remote or virtual assessments carried out by video rather than telephone. This is a crucial addition as the patient and the injury (or lack of) can be clearly seen. | Thank you for your comment. The evidence for this recommendation was not updated as part of this guideline update. However the committee agreed that the recs 1.2.2 and 1.2.3 should apply to all remote modes of consultation and amended the wording to reflect this. |
| Airedale NHS Trust | Guideline | 006 | 026 | We are concerned that this recommendation often means care home residents are sent to ED unnecessarily | Thank you for your comment. The committee agreed these are important factors to consider. The committee has made two additional recommendations 1.1.1 and 1.1.2 which refer to the NICE guidelines on shared decision making and decision making and mental |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------|-----------|---------|---------|--|--|
| | | | | | capacity (including advance care plans) . These recommendations have been cross referred to in recommendations 1.2.2-1.2.5. The committee discussed making further reference to advance care plans but agreed that the cross references to the relevant NICE guidelines covered the key points. |
| Airedale NHS Trust | Guideline | 007 | 012 | We are concerned that if a low GCS is normal for people with dementia or in care homes, they will be sent to ED unnecessarily. Link this section to page 9, line 24. | Thank you for your comment. The committee agreed these are important factors to consider. The committee has made two additional recommendations 1.1.1 and 1.1.2 which refer to the NICE guidelines on shared decision making and decision making and mental capacity (including advance care plans). These recommendations have been cross referred to in recommendations 1.2.2-1.2.5. The committee discussed making further reference to advance care plans but agreed that the cross references to the relevant NICE guidelines covered the key points. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------------|-----------|---------|---------|---|---|
| Airedale NHS Trust | Guideline | 007 | 029 | We are concerned that this recommendation often means care home residents are sent to ED unnecessarily | Thank you for your comment. The committee agreed these are important factors to consider. The committee has made two additional recommendations 1.1.1 and 1.1.2 which refer to the NICE guidelines on shared decision making and decision making and mental capacity (including advance care plans) . These recommendations have been cross referred to in recommendations 1.2.2-1.2.5. The committee discussed making further reference to advance care plans but agreed that the cross references to the relevant NICE guidelines covered the key points. |
| Association of British Neurologists | Guideline | 011 | 019 | 1.2.13. Will the guideline about transport directly to a major trauma centre comment upon the severity of head injury necessary for transport to a MTC rather than trauma unit/local hospital? If so, what would the severity be that suggested that? | Thank you for your comment. This is covered in recommendation 1.3.14 referring to major trauma service delivery which recommends the use of a triage tool. |
| Association of British Neurologists | Guideline | 013 | 011 | 1.3.2. Intoxication is to be considered as a cause for depressed consciousness once 'an important traumatic brain injury has been excluded'. Will guidance be provided on how such brain injury is excluded? Many | Thank you for your comment. This recommendation was not updated as part of this guideline update. However, we believe these concerns are addressed in recommendation 1.9.1, where post "normal CT" patients are admitted for observation if their GCS is not back to |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------------|-----------|---------|---------|--|---|
| | | | | practitioners may consider that a normal CT scan rules out TBI as a cause for depressed consciousness, but diffuse axonal injury, which is invisible to CT, is as likely, or more likely, to cause depressed consciousness than a haemorrhagic injury. There is a danger that people will be assumed to be intoxicated because of a negative CT, even though significant TBI is actually present. | baseline or if there are other concerns. The recommendation does not preclude further imaging post admission and in practice CT or MRI is done if the patient does not return to baseline GCS. |
| Association of British Neurologists | Guideline | 016 | 014 | <p>1.3.15. In instances where imaging is normal, it may be better or complementary for the treating team to seek assistance from neurology where persisting coma, unexplained confusion, focal deficits, imbalance, and/or seizures without full recovery are identified.</p> <p>Involvement of neurology in the acute care of trauma patients has recently been shown to reduce length of stay in hospital (Harris et al. Clinical Medical Journal 22 DOI: https://doi.org/10.7861/clinmed.2022-0290)</p> | Thank you for your comment. This recommendation was not updated as part of this guideline update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------------|-----------|---------|---------|---|--|
| | | | | We recommend that early involvement of neurology is considered for TBI patients, to assist with diagnoses and management. This can bring benefits throughout the trauma system, for example by reducing length of stay and readmission rate. | |
| Association of British Neurologists | Guideline | 017 | 006 | 1.4.2 MRI often provides important diagnostic information, which is complementary to CT. CT imaging remains the primary investigation of choice for the initial assessment of TBI, as it will identify large haemorrhage and skull fractures. However, MRI provides important additional information about the presence of key pathologies such as diffuse axonal injury and diffuse vascular injury. The guidelines should acknowledge this and recommend the use MRI for the assessment of TBI in the subacute and chronic phase where there is any diagnostic uncertainty. | Thank you for your comment. This recommendation was not updated as part of this guideline update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. The recommendation does not preclude post admission MRI. |
| Association of British | Guideline | 018 | 017 | 1.4.9 We are concerned that by recommending CT scanning in this group within 8 hours, this time limit may become the timing to aim for, rather than the slowest scanning that is | Thank you for your comment. This time limit has not changed since the last update of the guideline and in the experience and opinion of the committee people are being scanned as soon as possible. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------------|-----------|---------|---------|---|---|
| Neurologists | | | | acceptable. The guideline could be updated to state that this group should be scanned as soon as possible following hospital attendance, with the slowest acceptable scanning being 8 hours. | |
| Association of British Neurologists | Guideline | 021 | 004 | <p>1.4.15 The guideline uses the term post-concussion syndrome despite its removal from the two main diagnostic manuals (i.e. DSMV and ICD11). We advise that this term is not used in the guideline for similar reasons to its removal from the diagnostic manual. For similar reasons we would advise against the use of concussion, as this is also a syndromic label.</p> <p>These issues are reviewed in Sharp et al. Practical Neurology 2015 http://dx.doi.org/10.1136/practneurol-2015-001087.</p> <p>Attempting to manage the long-term complications of TBI using a syndromic label rather than a diagnosis is unhelpful from a neurological perspective. This promotes a focus on non-specific symptoms under a single label without consideration of their cause. By doing</p> | Thank you for your comment. This term was used in the scope and in the review. In the experience of the committee it is used clinically. Recommendation 1.10.14 covers referral for symptoms which would include determining if they are related to the head injury and a specific management plan. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------------|-----------|---------|---------|---|---|
| | | | | this it attributes symptoms to head injury when this may not be the case and it hinders diagnostic work up for the cause of persistent symptoms. We would recommend the use of diagnostic labels such as TBI of different severity, BPPV, migraine etc., which would lead to a specific set of diagnostic and treatment recommendations. | |
| Association of British Neurologists | Guideline | 030 | 022 | Rec 1.8.1 The guideline should recommend specific assessment for post-traumatic amnesia (PTA) and BPPV at particular time points and using specific assessment tools. PTA is a very useful marker of injury severity and has important diagnostic and prognostic value. Additionally, recent data show that BPPV is more likely the more severe the head injury – and by analogy is a useful marker of injury severity. Furthermore, BPPV can be treated and should be screened for given that over half 50% of acute TBI in-patients have BPPV, that it may not provoke vertigo in around a third of in- | Thank you for your comment. The scope of this guideline is the initial assessment and management. In the experience of the committee it is not practical to assess BPPV during this acute phase but agree it could form part of an assessment on a ward. The evidence review did not include how to assess PTA or how frequently (see Appendix A, evidence review J). |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--|----------------------|
| | | | | <p>patients, and finally, it is curable with a physical manoeuvre.</p> <p>It would thus be helpful to have clear operational guidance about how and when to assess PTA and BPPV post-TBI. For PTA, one good option would be to use a validated test such as the Abbreviated Westmead PTA scale. For BPPV, the screening test is a Dix-Hallpike manoeuvre by an experienced practitioner such as a vestibular therapist or neurologist.</p> <p>We recommend that every single patient with a TBI is assessed daily for PTA, and that this assessment is continued until patient is out of PTA, as this is easily missed and has major implications for functional recovery. TBI severity should not simply be assessed using GCS. Only a minority of patients with TBI will actually present with a low GCS. A higher GCS along does not predict functional outcome well and often misses significant intracranial injury. There is now plenty of evidence that PTA is a much better indicator of injury severity and therefore</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------------|-----------|---------|---------|--|--|
| | | | | <p>how likely a patient is to have persisting problems.</p> <p>REFS: Yuh et al 2021 JAMA Neurology - doi: 10.1001/jamaneurol.2021.2120 Malec et al 2017 J Neurotrauma - doi: 10.1089/neu.2006.0245. Ponsford et al 2014 J Neurotrauma - doi: 10.1089/neu.2015.4025</p> | |
| Association of British Neurologists | Guideline | 037 | 012 | <p>1.9.4 We would recommend adding a clause stipulating that people should not be discharged if there is evidence of post-traumatic amnesia (PTA), or at least that they not be discharged unless a) being discharged with a competent adult, and b) with acute follow up offered. The emergence from PTA is an important marker that clinicians can use to identify when a patient is fully oriented and can form continuous memories. This has been shown to be an important predictor of long-term recovery, and a means for identifying patients appropriate for</p> | <p>Thank you for your comment. This is addressed by recommendation 1.10.7. In practice people with ongoing post-traumatic amnesia (PTA) are not discharged from ED observation wards and would always be referred to specialist neuroscience care.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------------|-----------|---------|---------|--|---|
| | | | | neurorehabilitation service. Discharging people from hospital who remain in PTA increases the risk of poor outcomes because the early effects of the injury on cognition are still prominent, patients are vulnerable because of their cognitive impairment and the injury may be more severe and long-lasting than has been appreciated by the treating team. | |
| Association of British Neurologists | Guideline | 039 | 021 | We recommend stipulating the severity of brain injury necessitating an endocrinology review. In our experience moderate or severe TBI is relatively commonly associated with hypothalamo-pituitary dysfunction, whereas this is much less common in mild TBI. | Thank you for your comment. The evidence review did not clearly identify the severity of injury necessitating an endocrinology review so the committee are unable to make a recommendation on this (see Appendix A, evidence review M). |
| Association of British Neurologists | Guideline | 040 | 015 | Concerning 'Focal neurological deficit', the examples given are suboptimal. (a) General weakness is not a focal sign and could amended to 'weakness'. (b) Consider adding in memory impairments (PTA); (c) nystagmus (spontaneous or positional) should be added as any type of nystagmus irrespective of the origin | Thank you for your comment. We have incorporated your suggestions into the section on focal neurological deficit. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------------|-----------|---------|---------|--|---|
| | | | | (i.e. central or peripheral), is a marker for skull fracture and more severe brain injury. | |
| Association of British Neurologists | Guideline | 042 | 019 | <p>If post-concussion syndrome is retained in the guidance, we strongly recommend that it is made clear that this label is not a diagnosis but simply a collection of symptoms and signs that are observed after a head injury.</p> <p>The use of post-concussion syndrome as a label should lead to a further diagnostic process aimed at providing a specific diagnosis. This would often require detailed clinical assessment and investigations, including the involvement of neurology.</p> <p>We feel that this is a very important point because patients are inappropriately managed because the diagnostic process if curtailed post-concussion syndrome is considered a diagnosis that explains their symptoms (when it does nothing of the sort). Additional research is ongoing to predict which patients will develop a chronic post-concussion syndrome.</p> | Thank you for your comment. In the experience and opinion of the committee this term is used. We have made it clear in the 'terms used' section that this is the term used in the evidence review. Recommendation 1.10.14 covers the referral of people with persisting symptoms. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------------|-----------|---------|---------|--|--|
| Association of British Neurologists | Guideline | 042 | 042 | Calling headache, dizziness, nausea and fatigue "physical" symptoms is not appropriate. These are sensory symptoms and should be included under that heading. Given that headache and dizziness are the most common features of a post-concussion syndrome, then the sensory section should be moved to the top and perhaps the physical heading should be removed entirely. | Thank you for your comment. This has been amended. Headache, dizziness and nausea are now in the category of sensory symptoms. We have also combined the categories of sensory and motor symptoms as there may be both sensory and motor components to the symptoms. |
| Association of British Neurologists | Guideline | 042 | 042 | We recommend adding vertigo to list of symptoms in the sensory category. This is an extremely common feature of head injury of all severities. | Thank you for your comment. This list is not exhaustive, and the committee have provided a few examples. Dizziness in sensory symptoms and poor coordination in motor symptoms would cover this. We have also combined the categories of sensory and motor symptoms as there may be both sensory and motor components to the symptoms. |
| Association of British | Guideline | 039 | 013 | Section 1.9.13 Follow Up: The Guideline provides very little detail on what follow-up should be provided to the large | Thank you for your comment. Detailed follow-up recommendations are outside of the scope of this guideline which refers to the initial assessment and |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------|----------|---------|---------|---|--|
| Neurologists | | | | <p>number of patients, with injuries of all severities, who have persistent symptoms and functional problems. This is a major limitation of the document and we recommend that more detail is provided.</p> <p>Simply saying that primary care can refer “to outpatient care for an appointment with a professional trained in assessing and managing the consequences of a traumatic brain injury” is not helpful when there are no formal pathways that currently exist in most parts of the country.</p> <p>In the current system, primary care teams are unlikely to actually know who best to refer to for patients with ongoing problems. Additionally, in the majority of cases, primary care teams are not trained or experienced in TBI, so relying on primary care to identify symptoms which need specialist investigation and management is inadequate.</p> <p>We suggest that this statement is revised to be more specific. In our view, in addition to early</p> | <p>management of people with head injury. This is being covered by the NICE guideline on rehabilitation after chronic neurological disorders (including acquired brain injury) (in development).</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--|----------------------|
| | | | | <p>inpatient involvement of specialist TBI teams (as noted above), all patients should be proactively reviewed in the initial weeks after discharge by a multi-disciplinary team with sufficient clinical expertise to manage the complex problems that are common in the subacute period after injury. These teams should be based within Major Trauma Centres but can provide outreach services to non-trauma centres. These teams will typically require neurological, neuropsychiatric, neuro-rehabilitation, neuropsychological and potentially neurosurgical input. There are often diagnostic uncertainties that need to be resolved before a clear management plan is defined. This will help guide therapy delivery, to optimise its benefits.</p> <p>It would be unimaginable that patients admitted with heart attacks are never seen or have their care consulted by cardiology, and that they are discharged without proactive further medical input in addition to rehabilitation. However, this is what happens to a large majority of TBI patients, even though daily admissions for</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------|---|-----------------------------|
| | | | | <p>patients with head injury almost double the number of daily admissions for heart attacks. We have proposed clear pathways of how current care structures can be organised to deliver the specialist multidisciplinary care required, and we recommend that work is done towards this on a national level.</p> <p>REF: Li et al 2021 Clin Med - doi: 10.7861/clinmed.2020-0336.</p> | |
| Association of Paediatric Emergency Medicine (APEM) | Guideline | General | General | Question 1 - None that any APEM member identified | Thank you for your comment. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|-----------|---|---|
| Association of Paediatric Emergency Medicine (APEM) | Guideline | General | General | Question 2 - None that any APEM members identified | Thank you for your comment. |
| Association of Paediatric Emergency Medicine (APEM) | Guideline | 18 - 19 | 16 and 21 | Rec 1.4.8 and 1.4.11 We were disappointed to see that the guidance for isolated vomiting as a risk factor has not changed. We feel that this is not in line with emerging evidence from Australia and Canada and in practice many departments will use prolonged observation rather than CT imaging, particularly in children, to avoid CT scanning and associated radiation risks. | Thank you for your comment. Three or more discrete episodes of vomiting is the risk factor identified in recommendation 1.5.11 and further vomiting in recommendation 1.5.12. These criteria are derived from the CHALICE tool. Updated evidence identified for this decision rule showed that it had good sensitivity when considering clinically important injuries or neurosurgical outcomes. It had much better specificity than the other tools (see evidence review D). The criteria to CT is 3 or more discrete episodes of vomiting to generate 4 hours post injury observation (1.5.12) rather than CT - unless further concerns arise during this brief observation (by and large completed in the Emergency Department).It is therefore unlikely that admitting children with isolated |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------|--|---|
| | | | | | vomiting is driving the majority of child head injury hospital admissions. Research suggests that less than 3 percent of child head injury ED attenders require CT with NICE Guidance Ramjeeawon, Nataliaea; Lecky, Fionab; Burke, Derek P.c; Ramlakhan, Shammic. Implementing the National Institute for Health and Clinical Excellence Head Injury 2014 Guidelines in a major children's hospital emergency department. European Journal of Emergency Medicine: June 2019 - Volume 26 - Issue 3 - p 158-162 doi: 10.1097/MEJ.0000000000000512 |
| Association of Paediatric Emergency Medicine (APEM) | Guideline | 011 | 019 | Rec 1.2.3 advises "Transport people who have sustained a head injury directly to a major trauma centre or trauma unit that has the age-appropriate resources to further resuscitate them, and to investigate and initially manage multiple injuries". We felt that this may need clarification as presumably the recommendation does not include minor head injuries which can be appropriately and safely managed at local emergency hospitals and urgent treatment centres / minor injury units? | Thank you for your comment. Recommendations 1.2.2 to 1.2.5 indicate which patients with head injury will need assessment in the hospital. |
| Association of Paediatric | Guideline | 012 | 013 | Rec 1.2.17 advises tranexamic acid dose of 15-30mg/kg bolus in people under 16. | Thank you for your comment. The committee agreed that they would like to keep the TXA dose range unchanged in |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------|----------|---------|---------|--|---|
| Acute Emergency Medicine (AEM) | | | | As stated in the explanation there is no evidence for this population and we understand the committee are trying to extrapolate from adult data and CRASH 3, however we felt that the recommended dose should not be left open as a range, rather should be given as either 15 mg/kg (current practice in many AEM units) or 30 mg/kg. | <p>the recommendation [15-30 mg/kg (up to maximum of 2g)].</p> <p>TXA is currently used (at a dose of 15 mg/kg) in all age groups in children in clinical practice, where life-threatening bleeding is a clinical concern. TXA dose 30 mg/kg is currently not used very often in clinical practice.</p> <p>The committee discussed that TXA dose in children is open to clinicians' discretion as there are scenarios where higher dose may be required, for example in skull fractures in neonates and infants. The amount of blood volume that can be lost due to isolated head trauma is greater in neonates and infants for two reasons. One, their skull sutures (the lines between the skull bones) have not yet fused, allowing for expansion of the intracranial space - this means that per kilo body weight, occult bleeds into the skull vault can be much more significant than in older children, as older children have a fixed volume into which blood can expand. Two, neonates and infants may experience profound blood loss into a subgaleal haematoma - this type of bleed is on the scalp, though strictly speaking extracranial, and can be life threatening in this age group.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------|---|---|
| | | | | | The committee are aware of an ongoing TXA trial in children younger than 18 years with haemorrhagic injuries to the torso and/or brain to evaluate the efficacy of TXA (TIC-TOC- Traumatic Injury Clinical Trial Evaluating Tranexamic Acid in Children). The trial compares 2 doses of TXA (15 mg/kg and 30 mg/kg) with placebo. The feasibility trial results did not show any evidence of harm with the higher dose. |
| Association of Paediatric Emergency Medicine (APEM) | Guideline | 014 | 024 | Rec 1.3.8 There are units which discharge low-risk patients at triage according to NICE guidelines. We feel that the inference here is that this will no longer be possible. We wondered if there is evidence to suggest this isn't considered safe practice? | Thank you for your comment. The meaning of this recommendation has not changed since it was last updated with the exception of the time frame which was removed because it does not reflect current clinical practice. The original wording was: 'Patients who, on initial assessment, are considered to be at low risk for clinically important brain injury and/or cervical spine injury should be re-examined within a further hour by an emergency department clinician.' |
| Association of Paediatric Emergency | Guideline | 019 | 020 | Rec 1.4.11 We wondered if this was a good opportunity to clarify "abnormal drowsiness", which we feel may be subjective and could be better described by Glasgow Coma Score, as in recommendations 1.4.10. | Thank you for your comment. The wording reflects that of the CHALICE clinical decision rule which is the evidence base for this recommendations. It is separate from the |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------|---|---|
| Emergency Medicine (APEM) | | | | | assessment of GCS and indicates a feature in the clinical history from a parent. |
| Association of Paediatric Emergency Medicine (APEM) | Guideline | 019 | 029 | Rec 1.4.11 Addition of current bleeding or clotting disorder as a risk factor seems reasonable but we feel additional advice such as "seek opinion from a paediatric haematology specialist if there is uncertainty regarding level of bleeding risk from specific disorders" could be considered, as level of bleeding risk will differ between disorders. | Thank you for your comment. The committee highlighted that it would not be possible to seek the opinion of a paediatric haematology specialist within the time frame of 1 hour specified in the recommendation. |
| Association of Paediatric Emergency Medicine | Guideline | 022 | 006 | We wonder if this is an opportunity to highlight the possibility of Spinal Cord Injury Without Radiological Abnormality (SCIWORA) in children. | Thank you for your comment. This is covered in recommendation 1.6.9. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------|---|--|
| (APEM) | | | | | |
| Association of Paediatric Emergency Medicine (APEM) | Guideline | 023 | 025 | We wish to highlight that the cervical spine imaging guidance is still largely based on Canadian C-spine rules which have not been validated in children. | Thank you for your comment. The committee agree but the rate of cervical spine injuries in children is so small that a prospectively validated study is unlikely to ever be possible. We therefore extrapolated from the adult population. |
| Association of Paediatric Emergency Medicine (APEM) | Guideline | 029 | 009 | Rec 1.7.12 states apply recommendations 1.7.1 to 1.7.9 to the under 16s population however we feel that differences in adult and child ventilatory insufficiency as judged by blood gases criteria for intubation should be highlighted or provided, rather than just stating values used for adults. We appreciate that this is in a section that has not been updated in the 2022 update, however relates to new recommendations. | Thank you for your comment. This recommendation was not updated as part of this guideline update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| Association of | Guideline | 029 | 012 | Rec 1.7.12 The statement "ventilate people under 16 according to age-appropriate level of | Thank you for your comment. We did not review the evidence; hence, we are unable to amend the |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------|--|--|
| Paediatric Emergency Medicine (APEM) | | | | oxygen saturation” requires clarification in our opinion. Usual practice for ventilation in children with severe traumatic brain injuries is to aim for PaO ₂ > 10 - 13kPa and to maintain oxygen saturations in the high 90s. The recommendation could be more prescriptive and reflect usual practice. | recommendation. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date |
| Association of Paediatric Emergency Medicine (APEM) | Guideline | 030 | 007 | <p>Rec 1.8.1 states “use these criteria for admitting people to hospital after a head injury but with the caveat that an isolated simple linear non-displaced skull fracture is unlikely to be a clinically important abnormality unless they are taking anticoagulant or antiplatelet medication”.</p> <p>We understand that the evidence on isolated skull fractures in children is reassuring, however we note that there is a higher risk of seizures at presentation and evaluation for non-accidental injury and are concerned that the recommendation may lead to children being discharged without consideration of these risks. We wonder if these two risks could therefore be highlighted in the paragraph beginning on line 7.</p> | Thank you for your comment. Children with head injury and suspected non-accidental injury and/ or seizures are covered in the same recommendation (now 1.9.1) as separate indications for admission. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-------------------|---------|---------|---|--|
| Association of Paediatric Emergency Medicine (APEM) | Guideline | 038 | 007 | Rec 1.9.8 states "give verbal and printed discharge advice". Some of our centres are moving towards online leaflets via QR codes. We wonder if this could be reflected in the recommendation. | Thank you for your comment. This is covered by the patient experience guideline. |
| bioMérieux UK Ltd | Evidence review G | 148 | 013 | We would like to inform you of the following publication Cost-Effectiveness of Blood-Based Brain Biomarkers for Screening Adults With Mild Traumatic Brain Injury in the French Healthcare Setting - PubMed (nih.gov) J Neurotrauma. 2022 Oct 20. doi: 10.1089/neu.2022.0270. Online ahead of print. | Thank you for guiding us to this paper. The study would have been includable had it been published before the search cut-off. The study compares the use of biomarkers compared with CT for people with GCS 14-15. The guideline do not currently recommend CT to everyone in this population. So, the relevant comparator for the committee would be the Canadian CT head rule, as modified by NICE. Therefore, the paper is of limited use for this guideline. |
| bioMérieux UK Ltd | Evidence review G | 151 | 002 | In a recent Cost-Effectiveness of Blood-Based Brain Biomarkers for Screening Adults With Mild Traumatic Brain Injury in the French Healthcare Setting - PubMed (nih.gov) analysis it was demonstrated that GFAP+UCH-L1 use was | Thank you for your comment. The study compares the use of biomarkers compared with CT for people with GCS 13-15. The guideline does not currently recommend CT to everyone in this population. So, the relevant comparator for the committee would be the Canadian CT head rule, |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------|-------------------|---------|-----------|--|--|
| | | | | <p>associated with an overall decrease in CT scans when compared with CT screening or S100B use in the French health care environment and resulted in cost savings.</p> <p>One of the main costs in the published model was the cost of a CT scan, which is about 88£ (=102.6€) for adults. In the Evidence Review G the relevant unit costs to be considered for cost effectiveness analysis within the NHS is also 88£ (88.06). Therefore, it cannot be excluded that the use of the examined biomarkers (GFAP and UCH-L1) could also be cost-effective in the United Kingdom.</p> | as modified by NICE. Therefore, the paper is of limited use for this guideline. We agree that it cannot be excluded but whether it is cost effective is uncertain. |
| bioMérieux UK Ltd | Evidence review G | 154 | 046 - 048 | <p>We agree that research on combined use of current prediction rules and biomarkers for CT decision-making is warranted. In a recent study (Papa L, et al. JAMA Network Open. 2022;5(3):e221302) it was indeed a combination of Canadian CT Head Rule (CCHR) and GFAP, which had the highest diagnostic performance for detecting traumatic intracranial lesions on computed tomography (CT) in patients with mild TBI. In addition to clinical efficacy, an economic</p> | Thank you for your comment. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------|-----------|---------|---------|--|-----------------------------|
| | | | | evaluation of such combined approach will be very helpful. | |
| bioMérieux UK Ltd | Guideline | 044 | 17-18 | We agree that this is a key recommendation for research. In patients with mild traumatic brain injury (mTBI), biomarkers have the potential to reduce the number of unnecessary head CT-scans. Based on current evidence, the following biomarkers are suggested in the recently released 2022 Joint Guidelines of the French Society of Emergency Medicine (SFMU) & French Society of Intensive Care Medicine (SFAR) to limit head CT-scans in adult mTBI patients at INTERMEDIATE risk of intracranial lesions: S100B for patients presenting within 3 hours of injury or the combination of GFAP and UCH-L1 for patients presenting within 12 hours of injury (Expert Opinion, p. 14, in French, translation in progress). www.sfmu.org/upload/consensus/RPP-TCL-2022.pdf Ongoing BRAINI-2 project, funded by the European Institute of Technology, EIT-Health (https://eithealth.eu/product-service/braini2/), | Thank you for your comment. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------|-----------|---------|-----------|---|-----------------------------|
| | | | | will additionally evaluate predictive performances of GFAP and UCH-L1 combination for acute post-traumatic complications in vulnerable patients, children and elderly, in two separate trials: https://clinicaltrials.gov/ct2/show/NCT05413499 and https://clinicaltrials.gov/ct2/show/NCT05425251 | |
| bioMérieux UK Ltd | Guideline | 047 | 007 - 008 | We agree that more research is needed on the prognostic accuracy of brain injury biomarkers for the prediction of post-concussion syndrome. This will be assessed as a secondary outcome in general adult mTBI population for the combination of GFAP and UCH-L1 in the European BRAINI study (Richard et al., 2021, https://bmjopen.bmj.com/content/11/2/e043635), funded by the European Institute of Technology, EIT-Health, (https://eithealth.eu/product-service/braini/), as well as in BRAINI-2 studies in children and elderly (https://eithealth.eu/product-service/braini2/). | Thank you for your comment. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------|-----------|---------|-----------|--|--|
| bioMérieux UK Ltd | Guideline | 060 | 014 - 018 | Indeed, recent Joint Guidelines of the French Society of Emergency Medicine (SFMU) & French Society of Intensive Care Medicine (SFAR) 2022 www.sfm.org/upload/consensus/RPP-TCL-2022.pdf have suggested the use of S100B for patients presenting within 3 hours of injury or the combination of GFAP and UCH-L1 for patients presenting within 12 hours of injury to limit head CT-scans in adult mTBI patients at INTERMEDIATE risk of intracranial lesions. | Thank you for your comment. The committee thought that the evidence included in the review was too limited to make recommendations. The committee therefore made a research recommendation on 'what is the diagnostic accuracy of brain injury biomarkers for predicting acute complications after a traumatic brain injury?' See appendix J in evidence report G. |
| bioMérieux UK Ltd | Guideline | 060 | 012 - 014 | We believe that one of possible reasons of observed differences in biomarkers accuracy between studies may be due to the use of different reagents and technologies to measure the same protein (biomarker). In this light we humbly suggest additional precision for the statement used for more clarity: "The committee noted that accuracy differed quite widely between different studies looking at the same protein biomarker, measured with different assays on different platforms". | Thank you. The suggested text has been added to the rationale and committee discussion section of evidence review G. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------|-----------|---------|-----------|---|--|
| | | | | Thank you. | |
| BNF Publications | Guideline | 012 | 008 - 019 | What is the rationale for using a 2g IV bolus dose instead of 1g IV bolus followed by 1g infusion over 8 hours? In the CRASH-3 study they used 1g IV bolus followed by 1g infusion over 8 hours. Rowell 2020 used a 2g bolus IV in one arm of the study and 1g IV bolus followed by 1g infusion in another arm but did not show benefit for either regimen. We also note that the split regimen (1g bolus followed by 1g infusion) was used in CRASH-2 for general trauma and is the dosing regimen currently recommended in the BNF for that indication. Could 2 different dosing regimens for tranexamic acid have potential for confusion in practice? | <p>Thank you for your comment. The recommendations for TXA dose were based on Rowell trial 2020. The evidence suggested that dosing protocol of a single TXA 2g bolus was effective in reducing in all-cause mortality at 28 days and 6 months in a pre-hospital/out of setting. For 1 g bolus, the evidence suggested there was increased all-cause mortality at 28 days and 6 months with TXA compared to placebo, but there was uncertainty around the evidence.</p> <p>The evidence suggested that isolated TBI patients have a different response to TXA than that observed in CRASH - 2 and therefore that bleeding and clotting in these different injury scenarios may respond differently to TXA. This is thought to result from breaching of the blood brain barrier and also high rates of pre-injury anticoagulation in isolated TBI patients</p> <p>There is no directive in the NICE Major Trauma Guidance for the TXA dosage that should be used in patients with</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------|-----------|---------|-----------|--|---|
| | | | | | <p>suspected extracranial bleeding. The BNF have published a recommended dose for people with significant haemorrhage following trauma.</p> |
| BNF Publications | Guideline | 012 | 008 - 009 | <p>We note that the SPCs for tranexamic acid detail dose reductions for patient with renal impairment due to a risk of accumulation. Are there any considerations when using this dosing regimen in patients with renal impairment?</p> | <p>Thank you for your comment. The committee do not think TXA dose needs to be adjusted in people with severe renal impairment or those on renal dialysis. TXA recommended in traumatic brain injury is a one -off dose hence there is less chance of accumulation.</p> |
| BNF Publications | Guideline | 012 | 006 - 009 | <p>What is the rationale for the time frame within which tranexamic acid should be given? This is stated in the draft guideline as within 2 hours and before imaging. However, the CRASH-3 study administered tranexamic acid within 3 hours of injury. Additionally, NICE guideline NG39 on major trauma recommends use of tranexamic acid as soon as possible in patients with major trauma and active or suspected active bleeding, within 3 hours of injury, unless there is evidence of hyperfibrinolysis (based on the CRASH-2 study). We wonder if this</p> | <p>Thank you for your comment. The time frame of 2 hours was based on evidence from Rowell trial which suggested benefit of 2g TXA administered within 2 hours of injury for reducing all-cause mortality (at 28 days and 6 months) with no evidence of negative effects. Major trauma guideline recommendation is used when head injury is associated with extra cranial bleeding on the basis of CRASH-2 trial.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------|-----------|---------|-----------|---|---|
| | | | | difference in the timeframe for giving tranexamic acid (within 2 hours for head injury or within 3 hours for general trauma) is necessary, or could the timeframes be aligned? | |
| BNF Publications | Guideline | 012 | 011 - 014 | Over what time would this bolus IV injection be given, in adults? And in children? Is there a minimum time that the bolus should be administered over? In the CRASH-3 study, a 1g IV bolus was given over 10 minutes; additionally, the SPCs for tranexamic acid recommend a maximum rate of administration of 1mL(100mg) per minute which would mean a 2g bolus dose should be given over 20 minutes. Is a 20 minute bolus time practical in this situation? | Thank you for your comment. There was no information from Rowell trial regarding infusion time. The committee did not want to be prescriptive about infusion time as in clinical practice this is done in different ways: putting 2 grams of TXA in 100ml saline bag and then administering it as a slow infusion or pushed through syringe gently in boluses in 2mls/min (10 mins) or pushed in through syringe over 1-2 mins. Hence infusion time will be decided locally by individual service providers. |
| BNF Publications | Guideline | 012 | 013 - 014 | In children, 15-30mg/kg is a higher intravenous bolus dose than licensed dosing. We can see the logic in the rationale provided in the draft guidelines (page 51, lines 7-25), but we wondered if there is any experience of using this | Thank you for your comment. The committee agreed that they would like to keep the TXA dose range unchanged in the recommendation [15-30 mg/kg (up to maximum of 2g)] |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|---|---|
| | | | | dose in practice? Is there any evidence to support safety of this dosing in children? What will determine the choice of 15mg/kg vs 30mg/kg? | <p>TXA is currently used (at a dose of 15 mg/kg) in all age groups in children in clinical practice, where life-threatening bleeding is a clinical concern. TXA dose 30 mg/kg is currently not used very often in clinical practice.</p> <p>The committee discussed that TXA dose in children is open to clinicians' discretion as there are scenarios where higher dose may be required for example in skull fractures in neonates and infants. The amount of blood volume that can be lost due to isolated head trauma is greater in neonates and infants for two reasons. One, their skull sutures (the lines between the skull bones) have not yet fused, allowing for expansion of the intracranial space - this means that per kilo body weight, occult bleeds into the skull vault can be much more significant than in older children, as older children have a fixed volume into which blood can expand. Two, neonates and infants may experience profound blood loss into a subgaleal haematoma - this type of bleed is on the scalp, though strictly speaking extracranial, and can be life threatening in this age group.</p> <p>The committee are aware of an ongoing TXA trial in children younger than 18 years with haemorrhagic injuries</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------|-----------|---------|-----------|--|--|
| | | | | | to the torso and/or brain to evaluate the efficacy of TXA (TIC-TOC- Traumatic Injury Clinical Trial Evaluating Tranexamic Acid in Children). The trial compares 2 doses of TXA (15 mg/kg and 30 mg/kg) with placebo. The feasibility trial results did not show any evidence of harm with the higher dose. |
| BNF Publications | Guideline | 012 | 013 - 014 | We note that tranexamic acid by intravenous injection is not licensed in children under 1 year. What is the lower age range for this 15-30mg/kg dosing for head injury in children? Does it apply to neonates and infants? | Thank you for your comment. There is no lower age range proposed, and the guidance will be relevant to all. TXA is currently used (at a dose of 15 mg/kg) in all age groups in clinical practice, where life-threatening bleeding is a clinical concern. The amount of blood volume that can be lost due to isolated head trauma is greater in neonates and infants for two reasons. One, their skull sutures (the lines between the skull bones) have not yet fused, allowing for expansion of the intracranial space - this means that per kilo body weight, occult bleeds into the skull vault can be much more significant than in older children, as older children have a fixed volume into which blood can expand. Two, neonates and infants may experience profound blood loss into a subgaleal haematoma - this type of bleed is on the scalp, though strictly speaking extracranial, and can be life threatening in this age group |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------|-----------|---------|-----------|---|--|
| BNF Publications | Guideline | 012 | 009 - 010 | Is the Glasgow Coma Scale used in children and neonates, and is the GCS score of 12 or less contained in the indication for tranexamic acid appropriate for children and neonates? | Thank you for your comment. The Glasgow Coma Scale is used in children and infants (though a modified version is used in the younger age group to reflect the fact that they are pre-verbal). We have made it clear in the guideline (recommendation 1.3.4). As regards the cut point of 12, there is no direct evidence to inform this in children, and it is derived from adults, along with other recommendations for TXA usage (there have been no RCTs of sufficient size in children). This is therefore indirect evidence, but given that there are not numerous safety reports related to TXA use in children, this seems clinically reasonable. |
| British Geriatrics Society | Guideline | General | General | There is significant concern that for some groups who have a clear advanced plan admission to hospital for scanning may not be in keeping with their wishes or their best interests as it would not alter their management. It is important that there is a shared decision making process helpfully guided by advanced care plans. Care home residents may have recurrent unwitnessed falls and therefore can be transferred for scanning on multiple occasions especially if they are prescribed aspirin or | Thank you for your comment. The committee agreed these are important factors to consider. The committee has made two additional recommendations 1.1.1 and 1.1.2 which refer to the NICE guidelines on shared decision making and decision making and mental capacity (including advance care plans). These recommendations have been cross referred to in recommendations 1.2.2-1.2.5. The committee discussed making further reference to advance care plans but agreed that the cross references to the relevant NICE guidelines covered the key points. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------|-----------|---------|---------|--|---|
| | | | | clopidogrel. We acknowledge work is being undertaken in this area with the Ageing Well programme but would be keen for the updated guidance to indicate the importance of shared decision making and acting in best interests. We would advocate ensuring Respect forms are in place for this group of patients. | |
| British Geriatrics Society | Guideline | 006 | 018 | Amnesia is difficult to assess in patient with a dementia or delirium process. This needs further clarification | Thank you for your comment. This recommendation was not updated as part of this guideline update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. In addition, no clear evidence base to guide imaging was identified by the literature review hence the committee have made a research recommendation (5). |
| British Geriatrics Society | Guideline | 006 | 026 | Need to clarify if there is a difference between anticoagulation and anti-platelets and any impact this has on decision making | Thank you for your comment. We have added antiplatelet therapy (excluding aspirin monotherapy) to recommendation 1.2.3. |
| British Geriatrics Society | Guideline | 009 | 004 | There are several professionals that have been left out of this statement the rational for this is unclear and should be reviewed | Thank you for your comment. This recommendation was not updated as part of this guideline update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------|-----------|---------|---------|--|--|
| British Geriatrics Society | Guideline | 014 | 007 | Should Critical Care Practitioners also be included in this statement? | Thank you for your comment. The recommendation 1.4.6 has now been amended to include 'appropriately trained clinician to provide advanced airway management'. |
| British Geriatrics Society | Guideline | 018 | 009 | Older people will not have classic signs of head injury e.g. reduced consciousness or focal neurological deficit and their baseline GCS may be reduced due to a dementia process | Thank you for your comment. The evidence to support this recommendation included older people. Age 65 and over with GCS 15, but a history of loss of consciousness or amnesia is also an indication for scanning in recommendation 1.5.9. People can be referred to the ED where there is continued concern by the injured person, or their family or carer (1.2.5). The reduction of baseline GCS in dementia is recognised in recommendation 1.3.5. |
| British Geriatrics Society | Guideline | 018 | 023 | Older people with frailty can have significant head injuries due a fall from standing-the mechanism does not indicate the severity of injury in frailty | Thank you for your comment. This is addressed by our recommendation that people aged 65 and over with any history of head injury causing loss of consciousness or amnesia is an indication for CT brain scan regardless of injury mechanism (or presenting conscious level) in recommendation 1.5.9. The recommendations are to image people of all ages with high risk features within the hour of the indication being detected (1.5.8 and 1.5.10). |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------------------|-----------|-----------|---------|---|--|
| British Geriatrics Society | Guideline | 018 | 026 | People with cognitive impairment will not classically have retrograde amnesia for the event | Thank you the committee recognised the difficulty in assessing whether loss of consciousness or amnesia have occurred in people with pre injury cognitive impairment. No clear evidence base to guide imaging was identified by the literature review; hence, the committee have made a research recommendation. |
| British Geriatrics Society | Guideline | 031 | 006 | Consider if admitting an older person with frailty if assessment by a geriatrician is indicated | Thank you for your comment. This recommendation was not updated as part of this guideline update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| British Geriatrics Society | Guideline | 039 | 014 | Consider adding a referral for a multifactorial falls assessment for older people with frailty who have fallen from a standing height | Thank you for your comment. Recommendation 1.10.13 has been amended to include this. |
| British Orthopaedic Association (BOA) | Guideline | 022 - 024 | | The BOA considers that orthopaedic surgeons have a role to play in the assessment of potential cervical spine injuries in patients with concurrent head injury. The revised recommendations relating to criteria for imaging the cervical spine represent good practice (paras.1.56 – 1.59) | Thank you for your comment. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------------------|-----------|---------|---------|--|--|
| British Orthopaedic Association (BOA) | Guideline | 031 | | The BOA is concerned that a lack of clarity persists around which doctors are considered to be "trained in managing this condition" when patients with isolated head injury require admission but not surgery (para. 1.8.4). Local practice for admission of patients with traumatic brain injury varies widely across the country. Orthopaedic surgeons have no training in the assessment and management of traumatic brain injury beyond the initial assessment and early management of patients with multiple injuries, in line with ATLS guidelines. Orthopaedic surgeons are not an appropriate specialty to manage patients with isolated head injury. The BOA considers that the revised guidance should aim to resolve the national inconsistencies by outlining those specialties with relevant expertise. | Thank you for your comment. Training, configuration and delivery of services is outside the scope of this guideline and would need to be determined locally. |
| Christopher Lane Trust | Guideline | General | General | Suggested discharge advice for people 16 and over with a head injury, Section headed 'Long-term problems' Second paragraph 'A few people develop problems with their hormones.' 'A few' is misleading and needs to | Thank you for your comment. Relevant sections in the discharge advice document have been updated. Few has been changed to 'some'. We now mention growth hormone deficiency can occur but as this was not covered by any of our evidence reviews we have not |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|---|---|
| | | | | <p>be amended to 'some', since post-traumatic hypopituitarism is generally recorded as happening after around a quarter of head injuries http://jama.jamanetwork.com/article.aspx?articleid=208915</p> <p>Long term problems with hormones after head injury include two other important risks. The most frequent defect is growth hormone deficiency, Growth Hormone Deficiency Following Traumatic Brain Injury - PMC (nih.gov) which occurs after 12-20% of head injuries and can lead to suicidal depression, besides causing premature mortality. The second very serious risk is adrenal insufficiency, which occurs long-term after about 9% of head injuries (see table 4 in http://jama.jamanetwork.com/article.aspx?articleid=208915)</p> <p>If undiagnosed this can lead to adrenal crisis and death. Both these effects are more life-threatening than disturbance to the sex hormones, and would be more appropriate</p> | <p>added examples of symptoms. We had added that some problems can occur years after the injury. The management of these may have a resource impact which were unable to assess as this was outside of the scope of this guideline.</p> <p>The management of longer-term problems due to adrenal insufficiency is outside of the scope of this guideline. A separate NICE guideline on adrenal insufficiency is in development: Project information Adrenal insufficiency: acute and long-term management Guidance NICE</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--|----------------------|
| | | | | <p>examples to choose and describe.</p> <p>'These may occur several months after the injury'. Some effects only appear years after injury. Hypopituitarism following traumatic brain injury (1) Headway I would suggest 'These may occur several months or years after the injury.'</p> <p>Depression and weight gain or loss also need to be included in the list of symptoms that should prompt the patient to see his/her doctor, since these are symptoms either of growth hormone deficiency or adrenal insufficiency.</p> <p>May I add how important it is for the discharge advice to warn patients fully and accurately. Our charity, Christopher Lane Trust, has encountered people who have lost their careers and relationships and mental health, who can look back on decades of wasted life, all because their discharge advice did not give them the information that would have enabled them to fight for diagnosis and treatment.</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|---|----------------------|
| | | | | <p>Cost implications I am aware that diagnosing and treating more people with growth hormone deficiency will be expensive. However, against this has to be balanced the overall expense to the country of keeping undiagnosed people on benefits for years, and the cost of the extra suicides. The NHS could exploit more its power as large-scale customer of the pharmaceutical companies. Suggested discharge advice for people 16 and over with a head injuryIt has the clout to bring down the cost of growth hormone substantially. It could also increase its use of biosimilar growth hormone to its maximum possible extent.</p> <p>A forty-seven-year-old man would like to comment through Christopher Lane Trust. I have omitted his name, though he wished to give it, because of NICE's rule that medical information should not be given from which the person can be identified. I consider his story to be vitally relevant to the discharge advice and</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--|----------------------|
| | | | | <p>believe it would be wrong to redact it.</p> <p>His comments When I was nearly 13 years old I had a severe traumatic brain injury in a serious car accident. I was intubated and comatose for days with 2 weeks post traumatic amnesia.</p> <p>From then until last year I have suffered with typical symptoms of growth hormone deficiency – fatigue, weight gain, reduced sex drive, social isolation and depression which led to several suicide attempts. It was only last year that a stimulation test revealed that my growth hormone was severely deficient.</p> <p>After a year of ongoing treatment with Norditropin I have lost over 20kgs and I am regaining my sense of self-worth. But undoing 30 years of damage will not happen overnight.</p> <p>If my discharge advice had contained a warning about growth hormone deficiency it could have protected me from three decades of medical</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------|-----------|---------|---------|---|---|
| | | | | <p>neglect. I was treated for mental health issues from 1998 and even today I am still under the supervision of the mental health services – I believe full information in the discharge advice could have saved me from this, and maybe I would not now be on a mix of antipsychotic drugs and antidepressants, and the highly addictive zopiclone.</p> <p>What happened to me can equally well happen to adults. All discharge advice should mention the possibility of growth hormone deficiency.</p> | |
| Christopher Lane Trust | Guideline | General | General | <p>Suggested discharge advice for carers of people under 16 with a head injury, Section headed 'Long-term problems' Second paragraph</p> <p>'A few people develop problems with their hormones.' 'A few' is misleading and needs to be amended to 'some', since post-traumatic hypopituitarism is generally recorded as happening after around a quarter of head injuries http://jama.jamanetwork.com/article.aspx?article</p> | <p>Thank you for your comment. Relevant sections in the discharge advice document have been updated.</p> <p>Few has been changed to 'some'. We now mention growth hormone deficiency can occur but as this was not covered by any of our evidence reviews we have not added examples of symptoms. We had added that some problems can occur years after the injury.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--|----------------------|
| | | | | <p>id=208915</p> <p>Long term problems with hormones after head injury include two other important risks. The most frequent defect is growth hormone deficiency, Growth Hormone Deficiency Following Traumatic Brain Injury - PMC (nih.gov) which occurs after 12-20% of head injuries and can lead to suicidal depression, besides causing premature mortality. The second very serious risk is adrenal insufficiency, which occurs long-term after about 9% of head injuries (see table 4 in http://jama.jamanetwork.com/article.aspx?articleid=208915)</p> <p>If undiagnosed this can lead to adrenal crisis and death. Both these effects are more life-threatening than disturbance to the sex hormones, and would be more appropriate examples to choose and describe.</p> <p>'These may occur several months after the injury'. Some effects only appear years after injury. Hypopituitarism following traumatic brain</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|---|----------------------|
| | | | | <p>injury (1) Headway I would suggest 'These may occur several months or years after the injury.' This is particularly important in connection both with premature or delayed puberty.</p> <p>Depression and weight gain or loss also need to be included in the list of symptoms that should prompt the patient to see his/her doctor, since these are symptoms either of growth hormone deficiency or adrenal insufficiency.</p> <p>May I add how important it is for the discharge advice to warn patients fully and accurately. Our charity, Christopher Lane Trust, has encountered people who have lost their careers and relationships and mental health, who can look back on decades of wasted life, all because their discharge advice notes did not give them the information that would have enabled them to fight for diagnosis and treatment.</p> <p>Cost implications I am aware that diagnosing and treating more</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--|----------------------|
| | | | | <p>people with growth hormone deficiency will be expensive. However, against this has to be balanced the overall expense to the country of keeping undiagnosed people on benefits for years, and the cost of the extra suicides. The NHS could exploit more its power as large-scale customer of the pharmaceutical companies. It has the clout to bring down the cost of growth hormone substantially. It could also increase its use of biosimilar growth hormone to its maximum possible extent.</p> <p>A forty-seven-year-old man would like to comment through Christopher Lane Trust. I have omitted his name, though he wished to give it, because of NICE's rule that medical information should not be given from which the person can be identified. I consider his story to be vitally relevant to the discharge advice and believe it would be wrong to redact it.</p> <p>His comments When I was nearly 13 years old I had a severe traumatic brain injury in a serious car accident. I</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--|----------------------|
| | | | | <p>was intubated and comatose for days with 2 weeks post-traumatic amnesia.</p> <p>From then until last year I have suffered with typical symptoms of growth hormone deficiency – fatigue, weight gain, reduced sex drive, social isolation and depression which led to several suicide attempts. It was only last year that a stimulation test revealed that my growth hormone was severely deficient.</p> <p>After a year of ongoing treatment with Norditropin I have lost over 20kgs and I am regaining my sense of self-worth. But undoing 30 years of damage will not happen overnight.</p> <p>If my discharge advice had contained a warning about growth hormone deficiency it could have protected me from three decades of medical neglect. I was treated for mental health issues from 1998 and even today I am still under the supervision of the mental health services – I believe full information in the discharge advice could have saved me from this, and maybe I</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------|-----------|---------|---------|---|---|
| | | | | <p>would not now be on a mix of antipsychotic drugs and antidepressants, and the highly addictive zopiclone.</p> <p>I am pleased that the under-16s discharge advice mentions 'low mood, unexpected slow growth' but it does not go far enough. Central precocious puberty, which I experienced, occurs after up to 20% of childhood injuries https://www.jpeds.com/article/S0022-3476(87)80497-3/fulltext The wording should be amended to 'low mood, unexpected slow or accelerated growth.'</p> <p>What happened to me can equally well happen to adults. All discharge advice should mention the possibility of growth hormone deficiency.</p> | |
| Christopher Lane Trust | Guideline | General | General | <p>Suggested discharge advice for carers of people 16 and over with a head injury, Section headed 'Long-term problems' Second paragraph</p> <p>'A few people develop problems with their</p> | <p>Thank you for your comment. Relevant sections in the discharge advice document have been updated.</p> <p>Few has been changed to 'some'. We now mention growth hormone deficiency can occur but as this was not covered by any of our evidence reviews we have not</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|---|--|
| | | | | <p>hormones.' 'A few' is misleading and needs to be amended to 'some', since post-traumatic hypopituitarism is generally recorded as happening after around a quarter of head injuries http://jama.jamanetwork.com/article.aspx?articleid=208915</p> <p>Long term problems with hormones after head injury include two other important risks. The most frequent defect is growth hormone deficiency, Growth Hormone Deficiency Following Traumatic Brain Injury - PMC (nih.gov) which occurs after 12-20% of head injuries and can lead to suicidal depression, besides causing premature mortality. The second very serious risk is adrenal insufficiency, which occurs long-term after about 9% of head injuries (see table 4 in http://jama.jamanetwork.com/article.aspx?articleid=208915) If undiagnosed this can lead to adrenal crisis and death. Both these effects are more life-threatening than disturbance to the sex</p> | <p>added examples of symptoms. We had added that some problems can occur years after the injury.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|---|----------------------|
| | | | | <p>hormones, and would be more appropriate examples to choose and describe.</p> <p>'These may occur several months after the injury'. Some effects only appear years after injury. Hypopituitarism following traumatic brain injury (1) Headway I would suggest 'These may occur several months or years after the injury.'</p> <p>Depression and weight gain or loss also need to be included in the list of symptoms that should prompt the patient to see his/her doctor, since these are symptoms either of growth hormone deficiency or adrenal insufficiency.</p> <p>May I add how important it is for the discharge advice to warn patients fully and accurately. Our charity, Christopher Lane Trust, has encountered people who have lost their careers and relationships and mental health, who can look back on decades of wasted life, all because their discharge advice did not give them the information that would have enabled them to</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|---|----------------------|
| | | | | <p>fight for diagnosis and treatment.</p> <p>Cost implications I am aware that diagnosing and treating more people with growth hormone deficiency will be expensive. However, against this has to be balanced the overall expense to the country of keeping undiagnosed people on benefits for years, and the cost of the extra suicides. The NHS could exploit more its power as large-scale customer of the pharmaceutical companies. It has the clout to bring down the cost of growth hormone substantially. It could also increase its use of biosimilar growth hormone to its maximum possible extent.</p> <p>A forty-seven-year-old man would like to comment through Christopher Lane Trust. I have omitted his name, though he wished to give it, because of NICE's rule that medical information should not be given from which the person can be identified. I consider his story to be vitally relevant to the discharge advice and believe it would be wrong to redact it.</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--|----------------------|
| | | | | <p>His comments</p> <p>When I was nearly 13 years old I had a severe traumatic brain injury in a serious car accident. I was intubated and comatose for days with 2 weeks post-traumatic amnesia.</p> <p>From then until last year I have suffered with typical symptoms of growth hormone deficiency – fatigue, weight gain, reduced sex drive, social isolation and depression which led to several suicide attempts. It was only last year that a stimulation test revealed that my growth hormone was severely deficient.</p> <p>After a year of ongoing treatment with Norditropin I have lost over 20kgs and I am regaining my sense of self-worth. But undoing 30 years of damage will not happen overnight.</p> <p>If my discharge advice had contained a warning about growth hormone deficiency it could have protected me from three decades of medical neglect. I was treated for mental health issues</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------|-----------|---------|---------|---|---|
| | | | | <p>from 1998 and even today I am still under the supervision of the mental health services – I believe full information in the discharge advice could have saved me from this, and maybe I would not now be on a mix of antipsychotic drugs and antidepressants, and the highly addictive zopiclone.</p> <p>What happened to me can equally well happen to adults. All discharge advice should mention the possibility of growth hormone deficiency.</p> | |
| College of paramedics | Guideline | General | General | <p>General Question 1</p> <p>Our members, paramedics, would highlight that the current challenges, specifically related to flow would be a barrier in a number of stages of the patients journey.</p> <p>Ambulance response data is clear that patients are waiting unacceptable periods of time for a conveyance resource, a fall with head injury even when unconscious would not trigger the highest acuity call category and as such could be waiting not minutes but hours for a resource, this leading to the patient in this category falling outside of set times within guidance. Also of</p> | <p>Thank you for your comment. The committee recognised the challenges to implementing some of the recommendations given the current challenges in service delivery. Your comment will be considered by NICE where relevant support activity is being planned</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------|-----------|---------|---------|--|---|
| | | | | consideration at early triage all guidance points to call 999 to convey, it must be considered if the system will manage. | |
| College of paramedics | Guideline | General | General | General Question 2 Specifically relating to paramedic practice – no. | Thank you for your comment. |
| College of paramedics | Guideline | 005 | 014 | 1.1.2 This recommendation although understandable may lead to a cohort of patients awaiting conveyance who it may be more beneficial to be treated/monitored in situ, for example end of life care/ nursing home resident. | Thank you for your comment. This recommendation was not updated as part of this guideline update. However, the committee agreed that the recs 1.2.2 and 1.2.3 should apply to all remote modes of consultation and amended the wording to reflect this. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| College of paramedics | Guideline | 008 | 016 | 1.1.6 Consideration will need to be made in this matter if for example no relatives or care givers are able to be conveyed with the patient as during the pandemic. | Thank you for your comment. This recommendation was not updated as part of this guideline update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| College of paramedics | Guideline | 008 | 019 | 1.1.7 We would recommend and welcome clear guidance in how the professional should determine if an ambulance is needed and that they are clear that there are different response categories. | Thank you for your comment. This recommendation was not updated as part of this guideline update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------|-----------|---------|---------|--|--|
| College of paramedics | Guideline | 008 | 024 | 1.1.8 Unsure of the benefit of this suggestion, if no capacity is available at the receiving department a call will be of no value. | Thank you for your comment. This recommendation was not updated as part of this guideline update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| College of paramedics | Guideline | 009 | 004 | 1.1.9 consider please adding paramedic here, as paramedics work in many primary care settings outside of "ambulance crews" | Thank you for your comment. This recommendation was not updated as part of this guideline update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| College of paramedics | Guideline | 011 | 006 | 1.2.10 suggest rewording to align with common terminology of both ambulance service and emergency departments, suggest change standby call to "pre-alert" | Thank you for your comment. The wording in recommendation 1.2.10 has been amended as suggested. |
| College of paramedics | Guideline | 012 | 002 | 1.2.15 – Please consider the paramedic workforce in the wider context, paramedics are based in many settings outside of "ambulance crews" and its important we capture these. | Thank you for your comment. Paramedics has been added to recommendation 1.3.15 as suggested. |
| College of paramedics | Guideline | 018 | 003 | We agree with criteria however can it please be considered if we have a paramedic on scene and or critical care team who have stabilised the patient and have agreed the patient meets the criteria for scan, for that team to be able to directly contact and refer to CT as such bypassing A&E and reduce the time to definitive care. This aligns for age groups as listed. | Thank you for your comment. The committee were aware that some trusts do have referral pathways that allow for imaging to be requested directly from the community setting or primary care. But they noted the logistical challenges in the acute phase of a head injury in getting access to, and timely reporting of, imaging. They also noted the challenges faced in primary care and general practice in interpreting complex neuroradiology reports. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|-----------|---------|---------|--|---|
| | | | | | The committee therefore agreed that people should not be referred to imaging directly from the community. |
| Headway – the brain injury association | Guideline | 011 | 019 | Please consider including target timescales within which transport should be completed by. | Thank you for your comment. We refer to the NICE guideline on major trauma service delivery in recommendation 1.3.14. |
| Headway – the brain injury association | Guideline | 012 | 010 | “who are not thought to have extracranial bleeding” – please clarify what ‘who are not thought to have’ means. Is this suggested to be based upon clinical judgement, or scanning results? Please could we suggest changing this sentence to who are suspected by clinical judgement or confirmed by scanning to not have extracranial bleeding for clarification. | Thank you for your comment. The recommendation specifies that intervention is recommended prior to scanning on the basis of Rowell trial. |
| Headway – the brain injury association | Guideline | 014 | 024 | Please consider including target timescales within which reassessment should be completed by i.e. within xx hours of initial assessment. | Thank you for your comment. This recommendation was not updated as part of this guideline update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|-----------|---------|---------|--|---|
| Headway – the brain injury association | Guideline | 015 | 012 | Please could there be clarification as to how causes of injury are documented upon assessment, and if so whether there is a standardised method of documenting this, and at what level of detail? i.e. would it be possible to identify safeguarding concerns through the method of injury documented on assessment reports, especially in the event of repeat admissions? | Thank you for your comment. The detail specifying documentation of causes of injury is outside of the scope of this guideline. |
| Headway – the brain injury association | Guideline | 017 | 019 | Please consider including target timescales within which transfers should be made. | Thank you for your comment. This recommendation was not updated as part of this guideline update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| Headway – the brain injury association | Guideline | 017 | 023 | Please consider offering some detail as to how trauma networks should be ensuring this, for instance the logistics of transferring i.e. being aware of one another's waiting times etc. | Thank you for your comment. This recommendation was not updated as part of this guideline update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|-----------|---------|---------|---|---|
| Headway – the brain injury association | Guideline | 018 | 016 | We would suggest revising this to any episode of vomiting. | Thank you for your comment. The wording of these recommendations is based on evidence from Canadian CT head rules and the committee agreed that this was the correct risk factor. |
| Headway – the brain injury association | Guideline | 021 | 004 | We feel this section refers more to prognosis and providing advice rather than investigation so would suggest revising the title of this section. | Thank you for your comment. The title reflects the evidence review which was on investigating post-concussion syndrome. |
| Headway – the brain injury association | Guideline | 030 | 022 | Please can we clarify whether all involved clinicians will be familiar enough with the signs of PTA to be able to identify/ suspect these, or whether some information needs to be included in this section of signs to look out for such as confusion, unusual behaviour, etc. | Thank you for your comment. We have edited recommendation 1.9.1 to refer to ongoing post-traumatic amnesia which can be assessed by ED staff. |
| Headway – the | Guideline | 032 | 001 | We welcome this section regarding investigation and diagnosis of hypopituitarism. Please can we clarify how to ensure that clinicians are made | Thank you for your comment. The committee anticipate that these recommendations will raise awareness of hormonal issues. These are also mentioned in the |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|-----------|---------|---------|--|---|
| brain injury association | | | | aware of symptoms of hormonal issues, for instance will clinicians already be familiar with this or should there be training/information resources available such as posters to raise awareness of signs to look out for? | discharge letter to ensure that people affected by a head injury and their carers are also aware. |
| Headway – the brain injury association | Guideline | 037 | 020 | How are clinicians to ensure that people returning to a custodial setting are supervised and monitored? Please can we suggest stating that clinicians should liaise with appropriate contacts such as liaison officers to ensure people are supervised in custodial settings, as well as ensuring that contacts are aware of the possible consequences of head injury. At Headway we have produced guides for prison and probation officers to make them aware of the possible impact of acquired brain injuries, including head injury, and how to best support people accordingly. We would welcome readers of the guideline to be made aware of the existence of these resources, which are available free of charge on our website at www.headway.org.uk/about-brain-injury/individuals/information-library/ . | Thank you for your comment. Observation after discharge requires competent adult rather than any medical training. The instructions are detailed in the discharge advice. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|-----------|---------|---------|--|---|
| Headway – the brain injury association | Guideline | 039 | 014 | Please can some detail be added as to how this is going to be ensured, for instance will contact details of local neurorehabilitation services be made available to primary care contacts (including details of inclusion/exclusion criteria) or directly to the patient/their family? | Thank you for your comment. How this recommendation is implemented will depend on local service configurations. |
| Headway – the brain injury association | Guideline | 052 | 011 | <p>Guideline Rationale</p> <p>“mainly used to exclude intracranial bleeding” – We would suggest allowing direct access from the community for imaging where there is a suspicion of intracranial bleeding.</p> <p>Intracranial bleeding can be a medical emergency that may require direct access to imaging rather than waiting to be assessed in ED, which we know can take up to several hours and even longer in some instances. Also see https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5307932/: “Intracranial hemorrhage (ICH) is a significant medical event that accounts for up to 15% of strokes. The incidence of ICH is approximately 25 per 100,000 person-years,</p> | Thank you for your comment. The committee noted the logistical challenges in the acute phase of a head injury in getting access to, and timely reporting of, imaging. They also noted the challenges faced in primary care and general practice in interpreting complex neuroradiology reports. The committee therefore agreed that people should not be referred to imaging directly from the community. People may receive a CT scan within 1 hour if any of the criteria in recommendations 1.4.8 are met. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|-----------|---------|---------|---|---|
| | | | | and it has a mortality of 40% within one month of presentation. ICH may occur in multiple intracranial compartments and may be caused by diverse pathology. Neuroimaging is essential for the treating physician to understand the location and volume of hemorrhage, the risk of impending cerebral injury, and to guide often emergent patient treatment." | |
| Headway – the brain injury association | Guideline | 052 | 016 | Guideline Rationale "There has been important traumatic brain injury within 24 hour" – what does 'important' mean here? Please clarify i.e. severity, GCS score? | Thank you for your comment. This is explained in the recommendations in section 1.2 |
| Headway – the brain injury association | Guideline | 052 | 018 | Guideline Rationale The committee were aware that some trusts do have referral pathways that allow for imaging to be requested directly from the community setting or primary care. But they noted the logistical challenges in the acute phase of a head injury in getting access to, and timely reporting of, imaging - we understand the logistical challenges of accessing timely | Thank you for your comment. The committee agree that these logistical challenges need to be addressed but this is outside of the scope of this guideline. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|----------|---------|---------|--|---|
| | | | | assessment/ scans; however, we do not feel that this should be a reason to justify removing scanning from community as best practice guidance. Rather, we would call for the logistical challenges to be addressed however possible, although we appreciate addressing this is beyond the scope of this guideline. | |
| Kent Community Hospital Foundation NHS Trust | General | General | General | We are concerned that this guideline review has not included any update on the pre hospital section. We are a community trust and run 2 large Hospital at Home services as well as a cross Kent Urgent Community Response. We have repeatedly had to try advocate on behalf of our patients who are living with severe frailty who have falls with head injuries, or the falls are unwitnessed. Many of these patients are coming to the end of their life and do not wish "to be pulled around". They would not wish for surgery in the event of a cranial bleed. However, they are repeatedly taken to hospital against their wishes for a CT scan which will not affect their care. It is well known amongst Frailty Experts to be the worst piece of NICE guidance, overcoming patients wishes on a daily basis. | <p>Thank you for your comment. The committee agreed these are important factors to consider. The committee has made two additional recommendations 1.1.1 and 1.1.2 which refer to the NICE guidelines on shared decision making and decision making and mental capacity (including advance care plans) . These recommendations have been cross referred to in recommendations 1.2.2-1.2.5. The committee discussed making further reference to advance care plans but agreed that the cross references to the relevant NICE guidelines covered the key points.</p> <p>The committee noted that the ability to assess someone with head injury (and to be able to take into consideration an advance care plan), who are often on anticoagulant or antiplatelet therapy medication, at the scene will depend</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|-----------|---------|---------|--|--|
| | | | | <p>We are aware that all NICE guidance in guidance and not mandatory but it is being used contrary to this as there is no wording to allow shared decision making or patient focussed care.</p> <p>We urge you to not ignore this issue, despite the fact you did not review this section this time round. This is our only chance for many years to change a NICE guidance which is causing patient harm.</p> <p>Thank you</p> | <p>on their training, and that a person may need to be referred to hospital for a variety of reasons -other than the risk of intracranial bleeding. For example, the commonest cause of head injury in older adults is a fall from a standing height and a person on the aforementioned therapies may require assessment to explore possible acute medical events or unstable co-morbid conditions as causes of the fall (see recommendation 1.10.13). The management of any bleeding scalp/ head wound and the wholistic assessment for extracranial injury also requires expertise that may not be available at scene.</p> |
| Kent Community Hospital Foundation NHS Trust | Guideline | 006 | | <p>The guideline instructs that everyone with head injury should be sent to ED regardless of their proximity or otherwise to the end of their life, their informed wishes and any Advance Care Plan. Currently this results in ambulance services across the country bringing severely frail older people to the emergency department regardless of their wishes and of the potential to benefit for that individual. This is often against the wishes of the patient, their family or POA</p> | <p>Thank you for your comment. The committee agreed these are important factors to consider. The committee has made two additional recommendations 1.1.1 and 1.1.2 which refer to the NICE guidelines on shared decision making and decision making and mental capacity (including advance care plans). These recommendations have been cross referred to in recommendations 1.2.2-1.2.5. The committee discussed making further reference to advance care plans but</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|-----------|---------|---------|--|---|
| | | | | | agreed that the cross references to the relevant NICE guidelines covered the key points. |
| Kent Community Hospital Foundation NHS Trust | Guideline | 006 | 018 | Amnesia is difficult to assess in patient with a dementia or delirium process. This needs further clarification | Thank you for your comment. This recommendation was not updated as part of this guideline update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. In addition, no clear evidence base to guide imaging was identified by the literature review hence the committee have made a research recommendation (see evidence review E, appendix J). |
| Kent Community Hospital Foundation NHS Trust | Guideline | 017 | 017 | Guideline 17 1.4.5 Advice regarding transfer for head CT offered with no advice to ascertain patients' wishes/ potential to benefit. We are especially concerned that a severely frail person in a community hospital (for example) would have to be transferred for a head CT by staff who consulted the guideline. I personally have been asked by an ambulance staff member "Oh, does an ACP trump NICE guidelines then?" | Thank you for your comment. We have added two new recommendations about shared decision making and supporting people who lack capacity, including people with an advanced care plan (1.1.1 and 1.1.2). These recs apply to the whole guideline. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|-----------|---------|---------|--|--|
| London School of Hygiene and Tropical Medicine | Guideline | General | General | <p>Major comments: The recommendation that TXA should be administered to all patients with moderate and severe TBI within three hours of injury (regardless of the setting) is sound and a reasonable conclusion based on the available evidence. However, the conclusions are more uncertain than they need to be. There are two main reasons for this:</p> <p>First, the review only included randomised trials of the effectiveness of TXA in 'isolated head injury.' It ignored the evidence from the CRASH-2 trial that included over 20,000 polytrauma patients (i.e., patients with head injury and injury to other body regions). The pathophysiology of bleeding (coagulation and fibrinolysis) in the brain is similar to that for bleeding in other parts of the body. There is no good scientific reason to expect that the effects of TXA would be substantially different in patients with isolated TBI and those with polytrauma. The CRASH-3 trial should be seen as a trial that fills in a missing (isolated TBI) sub-group of the CRASH-2 trial. When considering the totality of the evidence, the scientific question is not whether</p> | <p>Thank you for your comments.</p> <p>Current NICE Major Trauma Guidance states that TXA should be administered to major trauma patients with significant bleeding (dose and site of bleeding are not specified); however, NHS evidence suggests that this is currently only happening in the patient group that were enrolled into CRASH 2 (Moran et al Lancet e clin med 2018) who have significant extracranial bleeding.</p> <p>This suggests that the community of practice are concerned that the impact of TXA may be different in isolated TBI. Hence the committee were interested to the review trials that enrolled these patients and excluded patients with significant extracranial bleeding.</p> <p>The review findings that informed the committee recommendations suggest dosage and timing (pre or post CT brain) of administration of TXA are important for determining the benefit for patients with isolated TBI. Healthcare system and severity of TBI were also shown to be important considerations. These important modifiers are not reflected in the adjacent forest plot. The committee's rationale is explained in the full evidence</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------------|-----------------------------|-----------------------------|-------------|---|----------------------|-----------------|---------|----|--------|------------------------------|--|--|--|--|---------|-------------------|-------------------|------|-------------|---------|-------------------|-------------------|------|-------------|--------|-----------------|-----------------|------|-------------|---------------|---------------------------|---------------------------|-------------|--------------------|-------------------------|--|--|--|--|---------|--------------------|--------------------|------|-------------|---------|--------------------|--------------------|------|-------------|-------------|------------------|------------------|------|-------------|--------|-----------------|------------------|------|-------------|---------------|-----------------------------|-----------------------------|-------------|--------------------|-------------------------------|--|--|--|--|---------|-------------------|-------------------|------|-------------|---------|------------------|------------------|------|-------------|-------------|-----------------|-----------------|------|-------------|--------|----------------|----------------|------|-------------|---------------|---------------------------|---------------------------|-------------|--------------------|--|
| | | | | <p>the results of the CRASH-3 trial are statistically significant compared to the null, but whether the results of the CRASH-2 and CRASH-3 trial are similar or different from each other (i.e., it's a question about heterogeneity). The results are not substantially different. They are remarkably similar and so our conclusions about the benefits and safety of TXA in trauma patients should be more certain. The Figure below shows the totality of the relevant evidence.</p> <p>Figure: Effects of TXA within 3 hours of trauma (trials with more than 500 patients).</p> <table border="1"> <thead> <tr> <th>Study</th> <th>Tranexamic acid</th> <th>Placebo</th> <th>RR</th> <th>95% CI</th> </tr> </thead> <tbody> <tr> <td colspan="5">Death within 24 hours</td> </tr> <tr> <td>CRASH-2</td> <td>410 / 6496 (6.3%)</td> <td>513 / 6435 (8.0%)</td> <td>0.79</td> <td>(0.70-0.90)</td> </tr> <tr> <td>CRASH-3</td> <td>112 / 3880 (2.9%)</td> <td>147 / 3757 (3.9%)</td> <td>0.74</td> <td>(0.59-0.94)</td> </tr> <tr> <td>STAAMP</td> <td>16 / 447 (3.6%)</td> <td>17 / 453 (3.8%)</td> <td>0.95</td> <td>(0.49-1.86)</td> </tr> <tr> <td>Pooled</td> <td>538 / 10813 (5.0%)</td> <td>677 / 10645 (6.4%)</td> <td>0.79</td> <td>(0.70-0.88)</td> </tr> <tr> <td colspan="5">Death at 28 days</td> </tr> <tr> <td>CRASH-2</td> <td>784 / 6486 (12.1%)</td> <td>923 / 6435 (14.3%)</td> <td>0.84</td> <td>(0.77-0.92)</td> </tr> <tr> <td>CRASH-3</td> <td>544 / 3880 (14.0%)</td> <td>568 / 3757 (15.1%)</td> <td>0.93</td> <td>(0.83-1.03)</td> </tr> <tr> <td>Rowell 2020</td> <td>93 / 603 (15.4%)</td> <td>50 / 285 (17.5%)</td> <td>0.88</td> <td>(0.64-1.20)</td> </tr> <tr> <td>STAAMP</td> <td>36 / 442 (8.1%)</td> <td>45 / 452 (10.0%)</td> <td>0.82</td> <td>(0.54-1.24)</td> </tr> <tr> <td>Pooled</td> <td>1457 / 11411 (12.8%)</td> <td>1586 / 10929 (14.5%)</td> <td>0.87</td> <td>(0.82-0.93)</td> </tr> <tr> <td colspan="5">Vasc. occlusive events</td> </tr> <tr> <td>CRASH-2</td> <td>161 / 9655 (1.7%)</td> <td>188 / 9682 (1.9%)</td> <td>0.86</td> <td>(0.70-1.06)</td> </tr> <tr> <td>CRASH-3</td> <td>77 / 5420 (1.4%)</td> <td>76 / 5302 (1.4%)</td> <td>0.99</td> <td>(0.72-1.36)</td> </tr> <tr> <td>Rowell 2020</td> <td>44 / 657 (6.7%)</td> <td>30 / 309 (9.7%)</td> <td>0.69</td> <td>(0.44-1.08)</td> </tr> <tr> <td>STAAMP</td> <td>2 / 447 (0.4%)</td> <td>2 / 456 (0.4%)</td> <td>1.02</td> <td>(0.14-7.21)</td> </tr> <tr> <td>Pooled</td> <td>284 / 16179 (1.8%)</td> <td>296 / 15749 (1.9%)</td> <td>0.87</td> <td>(0.74-1.02)</td> </tr> </tbody> </table> | Study | Tranexamic acid | Placebo | RR | 95% CI | Death within 24 hours | | | | | CRASH-2 | 410 / 6496 (6.3%) | 513 / 6435 (8.0%) | 0.79 | (0.70-0.90) | CRASH-3 | 112 / 3880 (2.9%) | 147 / 3757 (3.9%) | 0.74 | (0.59-0.94) | STAAMP | 16 / 447 (3.6%) | 17 / 453 (3.8%) | 0.95 | (0.49-1.86) | Pooled | 538 / 10813 (5.0%) | 677 / 10645 (6.4%) | 0.79 | (0.70-0.88) | Death at 28 days | | | | | CRASH-2 | 784 / 6486 (12.1%) | 923 / 6435 (14.3%) | 0.84 | (0.77-0.92) | CRASH-3 | 544 / 3880 (14.0%) | 568 / 3757 (15.1%) | 0.93 | (0.83-1.03) | Rowell 2020 | 93 / 603 (15.4%) | 50 / 285 (17.5%) | 0.88 | (0.64-1.20) | STAAMP | 36 / 442 (8.1%) | 45 / 452 (10.0%) | 0.82 | (0.54-1.24) | Pooled | 1457 / 11411 (12.8%) | 1586 / 10929 (14.5%) | 0.87 | (0.82-0.93) | Vasc. occlusive events | | | | | CRASH-2 | 161 / 9655 (1.7%) | 188 / 9682 (1.9%) | 0.86 | (0.70-1.06) | CRASH-3 | 77 / 5420 (1.4%) | 76 / 5302 (1.4%) | 0.99 | (0.72-1.36) | Rowell 2020 | 44 / 657 (6.7%) | 30 / 309 (9.7%) | 0.69 | (0.44-1.08) | STAAMP | 2 / 447 (0.4%) | 2 / 456 (0.4%) | 1.02 | (0.14-7.21) | Pooled | 284 / 16179 (1.8%) | 296 / 15749 (1.9%) | 0.87 | (0.74-1.02) | <p>review (Evidence review A) and the economic model. Further responses are:</p> <p>Dosage of TXA</p> <p>In Rowell et al a 2g prehospital bolus within 2 hours of injury resulted in an all cause mortality reduction at 28 days and 6 months but a 1g bolus followed by a 1gram infusion (the regime used in CRASH 2) increased mortality. This suggests that isolated TBI patients have a different response to TXA than that observed in CRASH 2 and therefore that bleeding and clotting in these different injury scenarios may respond differently to TXA. This is felt to result from breaching of the blood brain barrier and also high rates of pre injury anticoagulation in isolated TBI patients (Böhm, J.K., Güting, H., Thorn, S. et al. Global Characterisation of Coagulopathy in Isolated Traumatic Brain Injury (iTBI): A CENTER-TBI Analysis. Neurocrit Care 35, 184–196 (2021). https://doi.org/10.1007/s12028-020-01151-7)</p> <p>Pre or post imaging</p> |
| Study | Tranexamic acid | Placebo | RR | 95% CI | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Death within 24 hours | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CRASH-2 | 410 / 6496 (6.3%) | 513 / 6435 (8.0%) | 0.79 | (0.70-0.90) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CRASH-3 | 112 / 3880 (2.9%) | 147 / 3757 (3.9%) | 0.74 | (0.59-0.94) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| STAAMP | 16 / 447 (3.6%) | 17 / 453 (3.8%) | 0.95 | (0.49-1.86) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pooled | 538 / 10813 (5.0%) | 677 / 10645 (6.4%) | 0.79 | (0.70-0.88) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Death at 28 days | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CRASH-2 | 784 / 6486 (12.1%) | 923 / 6435 (14.3%) | 0.84 | (0.77-0.92) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CRASH-3 | 544 / 3880 (14.0%) | 568 / 3757 (15.1%) | 0.93 | (0.83-1.03) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Rowell 2020 | 93 / 603 (15.4%) | 50 / 285 (17.5%) | 0.88 | (0.64-1.20) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| STAAMP | 36 / 442 (8.1%) | 45 / 452 (10.0%) | 0.82 | (0.54-1.24) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pooled | 1457 / 11411 (12.8%) | 1586 / 10929 (14.5%) | 0.87 | (0.82-0.93) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Vasc. occlusive events | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CRASH-2 | 161 / 9655 (1.7%) | 188 / 9682 (1.9%) | 0.86 | (0.70-1.06) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CRASH-3 | 77 / 5420 (1.4%) | 76 / 5302 (1.4%) | 0.99 | (0.72-1.36) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Rowell 2020 | 44 / 657 (6.7%) | 30 / 309 (9.7%) | 0.69 | (0.44-1.08) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| STAAMP | 2 / 447 (0.4%) | 2 / 456 (0.4%) | 1.02 | (0.14-7.21) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pooled | 284 / 16179 (1.8%) | 296 / 15749 (1.9%) | 0.87 | (0.74-1.02) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

Second, instead of considering the totality

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--|---|
| | | | | <p>evidence on TXA in trauma, the guideline committee examined multiple subgroup analyses of the CRASH-3 trial data in isolation and considered pre-hospital and in-hospital trials separately. We believe this is the wrong scientific approach. Rather than cutting the data into smaller and smaller pieces with less information, they should consider the data in a wider scientific context, including all relevant information.</p> <p>In particular, there is no sensible biological rationale for considering pre-hospital and in-hospital trials separately. There is no biological reason why the effects of TXA should vary by the location of treatment and so it would have been more appropriate to consider all of the trials regardless of location. On the other hand, there is a good reason why the effects of TXA</p> | <p>The reason for considering the pre- and in-hospital trials separately was to address the real clinical concerns as to whether or not it is of benefit to wait for confirmation of intracranial injury on CT. In Rowell randomisation occurred prior to imaging, subsequently 40% of enrolled patients had no intracranial bleeding on CT brain scan and had other causes of a reduction in consciousness post head injury (intoxication mentioned by authors). However this potential dilution of the impact of TXA was accounted for in the study results, the committee were reassured by likely clinical and cost effectiveness in the 2g bolus arm.</p> <p>Our recommendation is therefore not specific to the prehospital environment and is applicable to the early ED pre-imaging phase. The potential benefit of delaying treatment to ED is to seek confirmation of bleeding on CT brain scan (targeting therapy at people with known bleeding but potentially losing benefit from earlier administration of tranexamic acid).</p> <p>The wording of recommendation 1.3.17 has now been amended for clarity: 'Give the tranexamic acid as soon as</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--|---|
| | | | | <p>should vary by time to treatment but location of treatment is not a valid proxy for this.</p> | <p>possible within 2 hours of the injury, <u>in the pre-hospital or hospital settings</u> and before imaging'.</p> <p>The directive to sites randomising moderate and severe TBI patients in CRASH 3 (GC included CRASH 3 PI) was randomisation prior to imaging in GCS 3-12; however, a significant proportion were randomised post CT making it difficult to recommend clearly whether TXA administration should occur pre or post imaging from this evidence. Also the published CRASH 3 analyses merge mild and moderate TBI which had different protocols (mild TBI patients were solely enrolled post CT).</p> <p>Dosage v extracranial bleeding</p> <p>There is no directive in the NICE Major Trauma Guidance for the TXA dosage that should be used in patients with suspected extracranial bleeding – and hence for head injury patients with suspected extracranial bleeding. Hence, whether or not the dosages differ by site of bleeding will be a decision for individual services. The BNF have published a recommended dose for people</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--|--|
| | | | | <p>As a result, while the conclusions are sound, the evidence on which they are based appears more uncertain than it really is, as demonstrated by you downgrading it for this reason. The evidence was also downgraded for indirectness or because total numbers randomised weren't reported. The latter can easily be calculated using the number and percentage of events, and the CRASH-3 data are available on a data sharing website.</p> <p>It is not clear from the current draft whether the committee recommends that all patients with moderate or severe TBI should receive a 2g</p> | <p>with significant haemorrhage following trauma. NICE will be collaborating with the BNF on the recommended dose for people with a head injury and a GCS of 12 or less who are not thought to have active extracranial bleeding.</p> <p>Severity of TBI.</p> <p>There is more questionable TXA benefit in mild TBI patients where a much lower proportion of those with indications for imaging have intracranial injury (2-8%); preliminary modelling suggests pre CT administration could be beneficial in a high risk group where rate of intracranial injury is 10% but the committee agreed a research recommendation for this group as further studies are needed. We understand from yourselves (CRASH 3 lead investigators) that there was no clear signal of benefit for mild TBI in CRASH 3 where randomisation was solely post CT.</p> <p>Income setting</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|---|---|
| | | | | <p>TXA bolus or whether there are two different regimens depending on the location of injury. I presume that it is the former since there would be no sensible biological basis for different dosing regimens based on location of treatment.</p> | <p>With regard to healthcare setting we also noted the differential benefit of TXA in severe TBI by healthcare setting (Williams et al high v low income).</p> <p>We noted the increased risk of seizures in Rowell et al in the 2 gram bolus group. The committee agreed that it was important to balance benefits and harms and agreed that the risk of seizure attributable to tranexamic acid was not clinically important as it was unlikely to have long term sequelae. The committee agreed that the increased seizure rate did not undermine the findings that suggest clinical and cost effectiveness for this treatment strategy – a 5% seizure rate in moderate and severe TBI patients was not considered unusual by the committee. Data provided on request by Rowell et al demonstrated that injury severity was higher than placebo in the 2g bolus TXA arm which is an alternative explanation for seizures. The paramedic and prehospital clinicians on the committee advised that the vast majority of moderate and severe TBI patients already receive a cannula in the prehospital phase making prehospital iv bolus administration not a concern re delay.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--|--|
| | | | | <p>The decision to recommend 2g IV TXA is surprising and appears to be based entirely on the Rowell trial. The dosing decision should be based on evidence from all relevant clinical trials but also information on the pharmacodynamics and pharmacokinetics of TXA, including the use of different routes. TXA is remarkably safe but data from randomised trials in surgery shown that it can cause seizures at high doses. See the reference below for further information.</p> | <p>IM route</p> <p>There was no evidence to recommend TXA IM injection. The committee discussed giving TXA as an intramuscular injection. However, to give 2 grams of TXA you would need to introduce 20mls intramuscularly (that would be too much for one anatomical site), so you would need to choose (probably) 4 sites for IM administration - which would be impractical.</p> <p>The committee did not find convincing evidence to make a recommendation that patients with isolated TBI presenting more than 2 hours after injury should receive TXA. Rowell et al only included patients who could be randomised within 2 hours. CRASH 3 has this unique data and undoubtedly the clinical community would welcome further analyses on patients GCS 3-12 randomised 2-3 hours after injury in high income settings.</p> <p>In designing the search strategy the committee took account of the CRASH 2 results and CRASH 3 protocol</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|---|--|
| | | | | <p>https://ccforum.biomedcentral.com/articles/10.1186/s13054-021-03799-9</p> <p>In the Rowell trial, participants in the 2g TXA bolus group were more likely to experience seizures (5%) than participants in the 1g TXA bolus followed by maintenance group (2%) or the placebo group (2%). These results are consistent with the results from trials in surgery. After a 2g bolus there is a high peak plasma TXA concentration and this may be responsible for the observed increase in seizures. On pharmacological grounds, a 2g TXA bolus is unnecessary since there is near complete inhibition of fibrinolysis after a 1g TXA dose.[1] Once fibrinolysis is inhibited there is nothing gained from a higher dose (even the duration of action is similar) but it may increase the risk of dose dependent side effects like seizures. Recommending 2g IV bolus for pre-hospital use also has practical implications. According to the summary of product characteristics, TXA should be given by slow (10 minutes) IV injection. Paramedics do not like doing this because 10 minutes seems like a long time in the pre-</p> | <p>revision and accepted the evidence that TXA was unlikely to be of benefit more than 3 hours post injury.</p> <p>Please see the above statements concerning directives to NHS sites recruiting to CRASH 3; however, the sentence on lack of clarity regarding protocol violations has been removed from the clinical evidence section in Evidence review A.</p> <p>Our understanding is the secondary data analysis available from CRASH 3 does not permit analysis of TXA benefit.</p> <p>We requested data from yourselves the CRASH 3 investigators so we could meta-analyse the moderate and severe TBI all cause mortality results with Rowell – unfortunately this data was not made available to the committee.</p> <p>The committee were disappointed not to have received the NIHR-funded data requested for which there were valid scientific hypotheses supported by some of the published CRASH 3 analyses (namely that clinical and</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|---|--|
| | | | | <p>hospital setting and it ties up a paramedic from doing other things.[2] As a result, they often omit giving TXA treatment which is bad decision considering that early treatment is live saving. If they had to give two slow 10-minute IV injections it is highly likely they would not give it at all. Furthermore, recent research has shown that TXA is well tolerated and rapidly absorbed after IM injection.[3,4] A 1g dose can be given rapidly as two 500mg IM TXA injections but four 500mg IM TXA injections would be problematic. If the motivation for the bolus is the desire to avoid a maintenance infusion, a more pragmatic approach would be to give a 1g bolus at the scene (IV or IM) followed by a second 1g bolus on arrival at hospital. This will ensure fibrinolytic inhibition over the time period when the risk of bleeding was greatest but avoid high peak levels that may be associated with dose dependent side effects like seizure.</p> <p>Minor comments The committee recommended TXA administration for moderate TBI and severe TBI within 2 hours of injury before imaging. Does</p> | <p>cost effectiveness vary by TBI severity group, timing of administration and healthcare setting). We have explained the rationale above. Rowell et al accepted our a-priori hypotheses and supplied additional data in line with our published search protocols, which informed our recommendations.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--|----------------------|
| | | | | <p>with TBI could be included if there was any intracranial bleeding on CT scan OR GCS ≤ 12 if no scan available. In other words, patients with a GCS ≤ 12 could be randomised before or after a scan. There is no lack of clarity and so this statement should be removed.</p> <p>The review states: Authors of the key paper CRASH-3 trial were contacted for additional data on outcomes by TBI (traumatic brain injury) severity grouping (GCS 3-8, GCS 9-12, GCS 13-15) to allow for stratification as per the protocol. Additional data was not shared by the authors.”</p> <p>This statement is not accurate. Additional data analyses were requested on nine separate outcome measures by four TBI severity groupings (GCS 3-8, GCS-4-8, GCS 9-12, GCS 13-15), three income level groups (high, middle and low income) and two time to treatment strata (<3 hours, >3 hours). In total, 216 separate measures of the effect of TXA were requested. No convincing scientific hypotheses were provided to justify these multiple analyses and the direction of the expected effects were</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--|----------------------|
| | | | | <p>not given. Since the request seemed to fly in the face of published guidelines for the conduct of valid sub-group analyses, the trial team declined to conduct the analyses.[5] As responsible data guardians, we considered the request to be scientifically inappropriate. However, we would emphasise that CRASH-3 trial data are readily available on our data sharing website and many research teams have downloaded the data for secondary analyses.</p> <p>References</p> <ol style="list-style-type: none"> 1. Picetti R, Shakur-Still H, Medcalf RL, Standing JF, Roberts I. What concentration of tranexamic acid is needed to inhibit fibrinolysis? A systematic review of pharmacodynamics studies. <i>Blood Coagul Fibrinolysis</i>. 2019; 30(1): 1- 10. 2. Goodwin L, Nicholson H, Robinson M, Bedson A, Black S, Kirby K, Taylor H, Voss S, Bengner J. Barriers and facilitators to the administration of prehospital tranexamic acid: a paramedic interview study using the theoretical domains framework. <i>Emerg Med J</i>. 2022 | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------|-----------|-----------|---------|---|---|
| | | | | <p>Jul;39(7):540-546.</p> <p>3. Grassin-Delyle S, Semeraro M, Lamy E, et al. Pharmacokinetics of tranexamic acid after intravenous, intramuscular and oral routes: a prospective, randomized, cross-over trial in healthy volunteers. Br J Anaesth. 2022 Jan 5 [Epub ahead of print]; 128: 465- 472.</p> <p>4. Grassin-Delyle S, Shakur-Still H, Picetti R, Roberts I. Pharmacokinetics of intramuscular tranexamic acid in bleeding trauma patients: a clinical trial. Br J Anaesth. 2021; 126(1): 201-209.</p> <p>5. Sun X, Briel M, Walter SD, Guyatt GH. Is a subgroup effect believable? Updating criteria to evaluate the credibility of subgroup analyses. BMJ. 2010 Mar 30;340:c117. doi: 10.1136/bmj.c117.</p> | |
| Neonatal and Paediatric Pharma | Guideline | 006 - 008 | General | <p>General for section 1.1.3 and 1.1.4</p> <p>For the list of risk factors mentioned in section 1.1.3 and 1.1.4 the committee feels there should be an additional bullet point including patients who have had other medicines which may have caused bone marrow suppression (and so have</p> | Thank you for your comment. This recommendation was not updated as part of this guideline update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|-----------|---------|---------|--|---|
| cist Group | | | | low platelets). For example, patients who have had recent chemotherapy may have low/very low platelet counts and so be more prone to bleeding. We have noted there is a bullet point for 'clotting disorder' but most of these patients are not diagnosed as having a clotting disorder and subsequently may be missed (especially in remote/community consultations?). | |
| Neonatal and Paediatric Pharmacist Group | Guideline | 012 | 013 | The committee feels dose range for tranexamic acid (15mg/kg to 30mg/kg) is too broad. The committee would like to see clarification on how clinicians can decide whether the patient requires the lower/higher end of the dosage range. Additionally, as tranexamic acid is given as a single dose there is more of an issue with under-dosing than overdosing therefore, would be more inclined to have a single dose recommend for under 16s of 30mg/kg. | <p>Thank you for your comment.</p> <p>There is no lower age range proposed, and the guidance will be relevant to all.</p> <p>The committee agreed that they would like to keep the TXA dose range unchanged in the recommendation [15-30 mg/kg (up to maximum of 2g)]. TXA is currently used (at a dose of 15 mg/kg) in all age groups in children in clinical practice, where life-threatening bleeding is a clinical concern. TXA dose 30 mg/kg is currently not used very often in clinical practice.</p> <p>The committee discussed that TXA dose in children is open to clinicians' discretion as there are scenarios where higher dose may be required for example in skull</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|----------|---|
| | | | | | <p>fractures in neonates and infants. The amount of blood volume that can be lost due to isolated head trauma is greater in neonates and infants for two reasons. One, their skull sutures (the lines between the skull bones) have not yet fused, allowing for expansion of the intracranial space - this means that per kilo body weight, occult bleeds into the skull vault can be much more significant than in older children, as older children have a fixed volume into which blood can expand. Two, neonates and infants may experience profound blood loss into a subgaleal haematoma - this type of bleed is on the scalp, though strictly speaking extracranial, and can be life threatening in this age group.</p> <p>The committee are aware of an ongoing TXA trial in children younger than 18 years with haemorrhagic injuries to the torso and/or brain to evaluate the efficacy of TXA (TIC-TOC- Traumatic Injury Clinical Trial Evaluating Tranexamic Acid in Children). The trial compares 2 doses of TXA (15 mg/kg and 30 mg/kg) with placebo. The feasibility trial results did not show any evidence of harm with the higher dose.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|---------|--|---|
| | | | | | |
| NHS England | Guideline | General | General | Guidelines could be improved further with inclusion of EDI considerations and to summarise possible considerations for management of patients with pre-existing condition or special circumstances such as osteoporosis or unwitnessed falls leading to signs of head injury or patients with pre-existing neurological pathologies. | Thank you for your comment. The committee have made an additional recommendation on referring people with a head injury for investigation into its causes and management of contributing factors (1.10.13). The management of pre-existing conditions was not within the scope of this guideline as they are covered by the relevant NICE guidelines on these. |
| NHS England | Guideline | General | General | It would be helpful to add separate sections in the guidelines for primary care and secondary care clinicians as some of the recommendations relevant to primary care practitioners are hidden or lost within the general descriptions and recommendations relevant to secondary care practitioners. | Thank you for your comment. The sections follow the patient pathway beginning with who needs to come to hospital from the community and transport to hospital and care at the scene. These apply to primary care. Care in the ED and observation ward/ transfer to neuroscience apply solely to secondary care. Discharge and follow up apply to both primary and secondary care. |
| NHS England | Guideline | General | General | There is no mention of the planned community diagnostic hubs and the role they might play in managing head injuries. | Thank you for your comment. Service delivery was outside of the scope of this guideline, but we anticipate the diagnostic hubs will be of relevance when implementing the guideline. Your comment will be |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|----------|---|--|
| | | | | | considered by NICE where relevant support activity is being planned |
| NHS England | Guideline | General | General | Stakeholders and Committee Member Lists We have noted that there are some AHP professional bodies who are in the stakeholders list. However, it is noticed by the office that one of the key AHP professional groups, Operating Department Practitioners could not be sighted in the stakeholders or the commitment members lists. Given their scope of practice and work within the operating theatres, it is important to include their views and comments in relation to the assessment and management of head injury. | Thank you for your comment. ODPs are mainly involved during intubation for patient with severe traumatic brain injury and during neurosurgery. Surgery was outside of the scope of this guideline. |
| NHS England | Guideline | 013 | 004, 005 | There is concern that removing direct access will make referral pathway of referring patients via ED will make the referral process more difficult for primary care staff. | Thank you for your comment. The committee were aware that some trusts do have referral pathways that allow for imaging to be requested directly from the community setting or primary care. But they noted the logistical challenges in the acute phase of a head injury in getting access to, and timely reporting of, imaging. They also noted the challenges faced in primary care and general practice in interpreting complex neuroradiology reports. The committee therefore agreed that people should not be referred to imaging directly from the community. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|---------|---|---|
| NHS England | Guideline | 020 | 001 | Recommendation is not clear about place of observations for people under 16 – is it hospital or home? | Thank you for your comment. This will be in the ED or acute hospital The wording has now been clarified. |
| NHS England | Guideline | 037 | 018 | The supervision and monitoring of patients with pre-injury cognitive impairment may lead to added burden on primary care services and needs further details about the nature of observations that need to be carried out. | Thank you for your comment. Recommendation 1.10.7 is not aimed at primary care services. Observation can be carried out by non-health professionals including carers or relatives. The instructions are detailed in the discharge advice. |
| NHS England | Guideline | 039 | 019 | We have launched the strategy for AHP colleagues in England recently. Together with the recommendations from a few published enquiry reports, we are committed to work collaboratively with other multidisciplinary team members to deliver safer and more personalised care to our patients and carers. We would therefore request consideration of adding allied health professions in the follow up section to further demonstrate our roles and responsibilities in rehabilitation and (post-concussion) symptoms management. | Thank you for your comment. It is not possible to cover all of the referrals that may need to be made for people with persisting problems so the committee highlighted the health professionals who may be involved including a multidisciplinary neurorehabilitation team which may include allied health professionals. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|-----------|---------|---------|--|--|
| NHS England | Guideline | 040 | 001 | Requires further or clearer information about expected recovery or criteria to be applied for the referral to endocrinology/investigations to be carried out. | Thank you for your comment. The committee agreed that the range of symptoms that may indicate hypopituitarism were too varied and general to include in the recommendation. The expected recovery was not included in the evidence review protocol (see appendix A, evidence review M). |
| NHS England - National Patient Safety Team | Guideline | General | General | <p>CARE SETTING</p> <p>The guidance understandably appears to focus on head injuries that have occurred outside of the hospital environment. However, it would be helpful for interpretation into clinical practice if there was a stated recognition that head injuries also occur whilst a patient is an inpatient therefore the recommendations should equally apply.</p> <p>It would also be helpful to clarify how the guidance should be applied to people in other care settings e.g., mental health, learning disability, community hospital and care homes many of which will not have onsite 24/7 medical staff or staff with appropriate skills to observe and manage suspected head injury</p> <p>We note the research recommendations but would also welcome additional clarity that</p> | Thank you for your comment. The scope and recommendations of this guideline covers head injuries included in all settings including those that occurred in the NHS. We now refer to inpatient units without an ED in section 1.2. The committee agreed that non-medical staff have the skills to observe and monitor people with a head injury outside of the hospital setting. Details of what to observe are included in the discharge letter. Clarity supporting decision making specifically with regard to threshold for CTH with frail persons and/ or those receiving anticoagulation and may not be a candidate for neurosurgical intervention, is outside of the scope of this guideline. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|-----------|---------|---------|---|--|
| | | | | supports decision making specifically with regard to threshold for CTH with frail persons and/ or those receiving anticoagulation and may not be a candidate for neurosurgical intervention | |
| NHS England - National Patient Safety Team | Guideline | General | General | <p>DROPPED BABIES</p> <p>Please consider specifically highlighting considerations regarding dropped babies</p> <p>The national patient safety team identified back in 2019 that in a previous 12-month period 182 babies had been dropped in obstetric/midwifery settings, 66 in paediatric wards, and 2 in mental health units – associated injuries included fractures skulls and/or intracranial bleeds. It was recognised at the time that whilst NICE guidelines provided ‘the core advice on assessment and early management of head injuries’, the immediate response to inpatient falls was inconsistent and automatic transfer of the baby to an ED department was not always appropriate.</p> <p>A Patient Safety Alert was issued in May 2019, with an associated guidance document to support the creation of local guidelines for the assessment and management of babies who</p> | Thank you for your comment. The committee are aware of the patients’ safety alert and advice from NHS England about local guidelines for dropped babies in hospitals. Dropped babies with suspected head injury are included in the population for this guideline and the relevant recommendations will apply. We now refer to inpatient units without an emergency department in section 1.2. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|-----------|---------|---------|--|--|
| | | | | are accidentally dropped in hospital. As above, please consider the content of the Alert and guidance document and consider how the points raised can be included and/or referenced in the updated NICE guidance. | |
| NHS England - National Patient Safety Team | Guideline | 033 | 009 | 1.8.11 onwards. It would be very helpful for interpretation into practice if the guideline could include recommendations as to when neurological observations may be stopped. In acute care settings this decision may be pragmatically reached by the MDT in partnership where possible with the patient or their representative but this is much more difficult to achieve in community care settings. | Thank you for your comment. The observations are for people in the ED and acute hospital wards not the community. We provide recommendations on who can be discharged to the community (section 1.10). |
| NHS England - National Patient Safety Team | Guideline | 044 | General | We are aware that the Royal College of Physicians are making an application to the Healthcare Quality Improvement Partnership (HQIP) to extend the scope of the National Audit of Inpatient Falls to include traumatic brain injury in the future audit programme. Under research recommendations, NICE make wish to liaise RCP to consider including as a research recommendation this proposed | Thank you for your comment. We can only make a research recommendation where we have specifically searched for evidence relating to the guideline scope and research recommendation. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------|-------------------|---------|---------|---|--|
| | | | | extension to the National Audit of Inpatient Falls. | |
| NHS Grampian | Evidence review D | General | General | The prioritisation of high sensitivity over acceptable sensitivity for clinical decision tools on head CT scanning is noted, with the comment that the risk of missing intracranial injury can have significant consequences including death. We do not believe this makes adequate consideration of the resource constraints of the NHS, which inherently prevent high sensitivity at the cost of specificity being applied to investigation by medical imaging in general. We believe there is not enough weight given to consideration of a 'realistic medicine' approach, in particular that a significant proportion of the patients who are captured by this guideline are unlikely to be suitable for neurosurgical or other intervention, as acknowledged in the guideline. Promotion of patient-centred decision making in such patients could be more compassionate to patients involved, and likely to be acceptable to patients and their relatives. We believe that a preventative approach in encouraging the | <p>Thank you for your comment. In assessing indications for CT brain scan the Guideline Committee (GC) took account of published evidence on Clinical Decision Rules from evidence reviews and coronial reports. Published evidence suggests that NOC and CHIP clinical decision rules are more sensitive and less specific for intracranial injury in adults than NICE recommendations, but the totality of evidence led the GC, which included lay representatives, to conclude that the current NICE imaging recommendations are indeed acceptably sensitive.</p> <p>We have recommended shared decision making to inform the decision to conduct a CT brain scan in asymptomatic people with head injury taking anticoagulants and antiplatelet agents.</p> <p>Falls prevention strategies and indications for anticoagulant and antiplatelet medication fall outside of the scope of the guideline. However, we have amended the discharge recommendation (1.10.13) to consider the need for falls assessment clinic referral. The NICE Falls assessment and prevention guideline is currently being updated:</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------|---------------------|---------|---------|--|---|
| | | | | review of anticoagulant and antiplatelet medication prescription to those at increased risk of falls and head injury, and provision of resource targeted at reducing both the risk of falls, and the risk of complication from falls, would be far more cost effective a strategy. | https://www.nice.org.uk/guidance/indevelopment/gid-ng10228 |
| NHS Grampian | Evidence review W E | General | General | In relation to the recommendations around CT head scanning for patients on anticoagulation/antiplatelet medication, it is unclear if the cost-effectiveness analysis performed either for previous iterations of the guidance, or the draft proposed, includes an the impact of the significantly increased out of hours CT capacity that is now needed to accommodate increased scanning, of which head injury guidance forms a major part. This includes the cost of altered radiographer rotas requiring additional locums (or a reduction in elective capacity) and cost of reporting, including the widespread use of teleradiology, who benefit significantly from the current practice of head injury guidance. | Thank you for your comment. The source of the cost of a CT scan in both the current model and previous models was the mean cost from the National Schedule of NHS costs: https://www.england.nhs.uk/costing-in-the-nhs/national-cost-collection/ This is calculated from data collected from NHS trusts, which should capture the full cost to the NHS including out of hours working. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------|-----------|-----------|---------|--|---|
| NHS Grampian | Guideline | General | General | Regarding the guidance relating to decision making in CT scanning, we believe that the head injury guidance in general is adopted too proscriptively by treating clinicians, and is widely seen as mandatory practice, with little scope for consideration of bespoke patient-centred decision making. In our experience, the guidance is also routinely over-applied to patients whom have sustained either minor facial injury, or no proven head injury (commonly due to being found on the floor in a confused state), in whom the detection rate of treatable head injury is vanishingly small. | Thank you for your comment. This guidance does not replace decision making based on how an individual presents and an assessment on the benefits and harms of investigations or interventions. The scope excluded adults, young people and children (including babies under 1 year) with superficial injuries to the eye or face without suspected or confirmed head or brain injury. The recommendations in section 1.2 (need for referral to hospital) are based on section 1.5 (indications for imaging) which have been shown to be cost effective. |
| NHS Grampian | Guideline | 058 - 059 | General | We recognise the lack of high-quality evidence in the areas highlighted, and endorse the research recommendations made. We believe that any future research should focus on neurosurgery as a primary endpoint, rather than the detection of any intracranial injury which includes a large population of patients who are not suitable for neurosurgical intervention. | Thank you for your comment. The committee considered the detection of intracranial injury to be important and this is reflected in the outcome used in the published evidence. |
| NHS Grampian | Guideline | 020 | General | The downgrading in wording of otherwise asymptomatic patients who are taking anticoagulation or antiplatelets, to 'consider' CT | Thank you for your comment. In the impact statement we have noted that 'it is uncertain whether this will lead to an overall increase or decrease in |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--|---|
| | | | | <p>head after risk assessment is a welcome development, however given significant sustained pressure on acute services, we would consider that such a risk assessment is unlikely to be a practical consideration in the vast majority of situations, and beds for observation are unlikely to be available. We would consider this change in wording is unlikely to significantly reduce the number of head CT scans being performed, and will not counteract the opposing effect of including all antiplatelets (other than aspirin monotherapy) in the guidance (although we acknowledge that in our setting this patient group is largely already being scanned due to pressure from treating clinicians).</p> | <p>scanning'. There was conflicting evidence from cohort studies on whether people who are on anticoagulants or antiplatelets are at higher risk of intracranial haemorrhage than people not on anticoagulants or antiplatelets. CT scans could be limited to people with symptoms of traumatic brain injury such as loss of consciousness or amnesia. However, the committee thought that the new evidence was not strong enough to warrant stopping imaging in people with a head injury who are on anticoagulants but have no other indication for imaging. So, they decided CT scanning should be considered rather than automatically done in this group. They also agreed that antiplatelets other than aspirin monotherapy should be included in this. The review findings suggested that people on anticoagulants (including warfarin and direct-acting oral anticoagulants) or antiplatelets (excluding people on aspirin monotherapy) with low-risk factors (no loss of consciousness, amnesia, a GCS of 15 and no other indications for CT brain scan) can be risk assessed (including for other injuries, supervision at home, cause of incident and risk of further falls). Then, if there are no risk factors and after shared decision making, they could be discharged safely without a CT scan, with the usual discharge advice (see the</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|---------|---|---|
| | | | | | recommendations in section 1.10). The committee highlighted that clinicians would either scan or admit someone for monitoring if any risks were identified. |
| NHSE | Guideline | Page 67 | Line 19 | <p>This line discusses "people with a pre-existing cognitive impairment" and includes autism in the list of examples. We would not view autism as a cognitive impairment. We think autism has been included in the list as it is trying to ensure monitoring advice for people who are less likely to recognise and raise the alarm about symptoms that indicate a late intracranial bleed. We are not sure what the evidence is for autistic people being less likely to raise the alarm about early signs of a bleed - the guidance suggests that it is "in the experience of the guideline group" which is a low level of evidence.</p> <p>If the guideline group feels the evidence is strong enough to include autistic people in this paragraph on monitoring, I suggest adding "people with a pre-existing cognitive impairment (such as LIST EXCLUDING AUTISM) and autistic people and others with sensory proprioception and interoception difficulties.</p> | Thank you for your comment. The rationale has been amended as suggested. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|---------|---|---|
| NHSE | Guideline | General | General | There is no reference of reasonable adjustments in the guidance. Reasonable adjustments are a legal requirement to make sure health services are accessible to all. | Thank you for your comment. We have considered this via the Equality Impact Assessment. No specific issues were identified for head injury. |
| NHSE | Guidance | 19 | 16 | We are concerned that referring to vomiting as a risk factor for clinically important traumatic brain injury may result in an excess number of children having CT scans and/or being admitted to hospital. There is evidence to suggested that vomiting is not a good indicator of clinically important traumatic brain (https://doi.org/10.1542/peds.2017-3123 and BMJ 2019;365:l1875 doi: 10.1136/bmj.l1875). The current guidance does not appear to acknowledge the evidence and the practical implication of this is that four discrete vomits becomes the benchmark for needing a CT scan. Because this is set within the NICE guidance with no comment on the ability for a senior | Thank you for your comment. These criteria are from the CHALICE tool. Updated evidence identified for this decision rule showed that it had good sensitivity when considering clinically important injuries or neurosurgical outcomes. It had much better specificity than the other tools (see evidence review D). The criteria to CT is 3 or more discrete episodes of vomiting to generate 4 hours post injury observation rather than CT - unless (recommendation 1,5,12(further concerns arise during this brief observation (by and large completed in the Emergency Department).It is therefore unlikely that admitting children with isolated vomiting is driving the majority of child head injury hospital admissions. Research suggests that less than 3 percent of child head injury ED attenders require CT with NICE Guidance: Ramjeeawon, Nataliea; Lecky, Fionab; Burke, Derek P.c; Ramlakhan, Shammic. Implementing the National Institute for Health and Clinical Excellence Head Injury |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|---|---|
| | | | | <p>decision maker to review and derogate, staff will be very unwilling not to scan, even with a very well appearing child in front of them.</p> <p>There is emerging evidence of the impact of radiation on developing brains (https://doi.org/10.1002/cncr.31947) and we would like to be assured the committee have considered this in when developing the guidance.</p> <p>Between March 2019 - October 2022, there have been 844,119 < 16 years old attendances with head injuries. 23,987 had a CT scan and 40697 were admitted to hospital. This number of CT scans and admissions has significant resource implications for NHS Hospitals. Significant traumatic brain injuries are rare in children who had a CT scan and/or were admitted to hospital (https://adc.bmj.com/content/101/6/527 and</p> | <p>2014 Guidelines in a major children's hospital emergency department. European Journal of Emergency Medicine: June 2019 - Volume 26 - Issue 3 - p 158-162 doi: 10.1097/MEJ.0000000000000512</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------|-----------|---------|---------|---|--|
| | | | | <p>Severe Injury In Children Report - 2019-20 (cld.bz).</p> <p>Altering the guidance on isolated vomiting could safely reduce this CT burden and/or number of children admitted to hospital. The balance of risks would favour this in our opinion</p> | |
| NHSE | Guidance | 12 | 9 | <p>We are concerned about NICE recommending to CYP< 16 to be treated with Tranexamic Acid in the absence of the trial data in this age group. We would prefer to wait until this trial has reported: Traumatic Injury Clinical Trial Evaluating Tranexamic Acid in Children: A Pilot and Feasibility Study - Full Text View - ClinicalTrials.gov</p> | <p>Thank you for your comment. TXA 15mg/kg is currently being given to injured people under 16 with no known safety issues (see NICE major trauma guideline). The feasibility study has also reported no safety issues with the higher doses. The committee therefore felt comfortable with making a recommendation. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.</p> |
| Nottinghamshire Healthcare NHS | Guideline | | | <p>1.8.18</p> <p>Perhaps think about adding something like:</p> <p>Where a patient is detained under the Mental Health Act (1983) and the decision is taken to</p> | <p>Thank you for your comment. The recommendations on referral to hospital (1.2) and 'admission and observation (1.9)' apply to people detained under the mental health act. The recommendations on observation refer to staff in the emergency department and acute observation wards -</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------|--|---|
| Foundation Trust | | | | <p>monitor within the psychiatric environment, ensure that medical, nursing and other staff taking observations are at minimum familiar with neurological observations described under 1.8.10 and are aware of local policies for escalating concerns to more qualified personnel.</p> <p>The reasoning behind this is that those detained under the MHA do not have freedom to decide to attend emergency services on their own. Psychiatric nurses are often not trained in the use of tools such as GCS. As well as the tragic personal consequences, deaths of patients held under the Act count as deaths in custody with all the complex legal follow-up this entails.</p> | the committee are not recommending that staff outside of this setting need to be trained in neurological observation. |
| Nottinghamshire Healthcare NHS Foundation | Guideline | | | <p>1.9.8</p> <p>Printed discharge information should be provided at the point the patient leaves the hospital at the latest.</p> | Thank you for your comment. We have produced an example discharge letter for when the person leaves hospital. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------|---|--|
| tion Trust | | | | | |
| Nottinghamshire Healthcare NHS Foundation Trust | Guideline | 1.1.3 | | <p>1.1.3</p> <p>There is little mention of change in vision. These are referenced under the postconcussion part of 'Terms used in this guideline' but not in the main body and not with recommendations.</p> <p>There is some evidence that retinal detachment may occur following even a minor head injury if there is pre-existing damage.</p> <p>Romanian Journal of Ophthalmology, Volume 59, Issue 4, October-December 2015. pp:273-27</p> <p>Ocular and vision damage has been reported previously as a consequence of traumatic brain injury, including minor TBI, as part of the postconcussion syndrome. Thus, symptoms of photo-sensitivity, blurred vision, double vision, decreased visual acuity, and visual field defects are often described. Animal studies show that</p> | <p>Thank you for your comment. This recommendation was not updated as part of this guideline update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------|---|---|
| | | | | <p>retinal and optic nerve damage occur in at least one animal model. This might be expected to especially affect those at risk of repetitive trauma such as military personnel, athletes, and psychiatric patients who engage in deliberate headbanging behaviours.</p> <p>Journal of Neuropathology & Experimental Neurology, Volume 73, Issue 4, April 2014, Pages 345–361,</p> <p>While I do not have evidence, it seems sensible that ophthalmic symptoms, especially those suggestive of a detached retina, be referred to an ophthalmologist once the patient is medically stable.</p> | |
| Royal College Emergency Medicine (RCEM) | Guideline | 008 | 012 | In the absence of the other risk factors we question the necessity for GPs, ambulance crews, NHS walk-in or minor injury units to refer patients to the ED merely because there is no one at home with them | Thank you for your comment. This recommendation was not updated as part of this guideline update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. This is standard clinical practice. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------------|--|---|
| Royal College Emergency Medicine (RCEM) | Guideline | 012 | 44 90 6 | The evidence for tranexamic acid (TXA) seems less clear in head injury than in 'Major Trauma' yet the recommendation suggests a higher dose. We wonder whether, in terms of pragmatic implementation of the use of TXA in isolated head injury, maintaining some uniformity of dosing and timing might be beneficial (1g within 3hr for both Major Trauma and Head Injury) | Thank you for your comment. There is no directive in the NICE Major Trauma Guidance for the TXA dosage that should be used in patients with suspected extracranial bleeding. The BNF have published a recommended dose for people with significant haemorrhage following trauma. NICE will be collaborating with the BNF on the recommended dose for people with a head injury and a GCS of 12 or less who are not thought to have active extracranial bleeding. |
| Royal College Emergency Medicine (RCEM) | Guideline | 020 | 13 – 17 | The use of the word 'consider' is likely to cause variation in implementation of this guidance nationally both in the pre-hospital setting and the ED setting. The inclusion of anti-platelet agents other than aspirin is likely to result in more CT head scans. | Thank you for your comment. In the impact statement we have noted that 'it is uncertain whether this will lead to an overall increase or decrease in scanning'. There was conflicting evidence from cohort studies on whether people who are on anticoagulants or antiplatelets are at higher risk of intracranial haemorrhage than people not on anticoagulants or antiplatelets. CT scans could be limited to people with symptoms of traumatic brain injury such as loss of consciousness or amnesia. However, the committee thought that the new evidence was not strong enough to warrant stopping imaging in people with a head injury who are on anticoagulants but have no other indication for imaging. So, they decided CT scanning should be considered |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------|---|--|
| | | | | | rather than automatically done in this group. They also agreed that antiplatelets other than aspirin monotherapy should be included in this. The review findings suggested that people on anticoagulants (including warfarin and direct-acting oral anticoagulants) or antiplatelets (excluding people on aspirin monotherapy) with low-risk factors (no loss of consciousness, amnesia, a GCS of 15 and no other indications for CT brain scan) can be risk assessed (including for other injuries, supervision at home, cause of incident and risk of further falls). Then, if there are no risk factors and after shared decision making, they could be discharged safely without a CT scan, with the usual discharge advice (see the recommendations in section 1.10). The committee highlighted that clinicians would either scan or admit someone for monitoring if any risks were identified. |
| Royal College Emergency Medicine (RCEM) | Guideline | 022 | 44875 | We wonder whether this statement needs qualifying to keep internal consistency within the document. In some patients this will be first line (and perhaps only) imaging whilst in others, especially in the emergency setting CT head and neck scans will be most appropriate perhaps followed by MRI scan. | Thank you for your comment. The committee has edited recommendation 1.6.9 to make it clearer than MRI will be done in addition to CT. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------|---|---|
| Royal College Emergency Medicine (RCEM) | Guideline | 025 | 44-869 | This is badly worded and is difficult to understand. Would recommend changing to “1.3.8 People who have been triaged on initial assessment to be at low risk for clinically important traumatic brain or cervical spine injury should be re-examined by an emergency department clinician to assess the need for CT imaging of the head or cervical spine”. | Thank you for your comment. We have edited this recommendation 1.4.9. |
| Royal College Emergency Medicine (RCEM) | Guideline | 026 | 14-23 | This is very difficult to do locally and will lead to multiple different pathways within a single trauma network. This should be decided on a national basis. | Thank you for your comment. This recommendation was not updated as part of this guideline update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| Royal College Emergency Medicine (RCEM) | Guideline | 030 | 19-22 | The inclusion of suspicion of post-traumatic amnesia as an indication for admission but not necessarily CT scan will lead to increased hospital admissions, | Thank you for your comment. We have amended recommendation 1.9.1 to state ‘suspicion of ongoing post-traumatic amnesia’. The committee understand that this this will not lead to increased hospitalisations as this is current practice. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------|--|--|
| Royal College Emergency Medicine (RCEM) | Guideline | 030 | 43800 | I would add to this section "if the CT findings would inform a decision to stop the anticoagulant or to undertake admission for potential neurosurgical intervention". In patients who have severe frailty in a nursing home then the anticoagulant could be stopped and the patient not conveyed to hospital for a CT scan. Discussions with local geriatricians would support this approach. Currently many patients are brought to the ED every day by ambulance for this indication which is not in the patients best interests. | Thank you for your comment. We have added two new recommendations about shared decision making and supporting people who lack capacity, including people with an advanced care plan (1.1.1 and 1.1.2). These recommendations apply to the whole guideline. |
| Royal College Emergency Medicine (RCEM) | Guideline | 036 | 017 | Consider amendment 'return to baseline GCS' | Thank you for your comment. Recommendation 1.10.2 has been amended as follows: 'the GCS has returned to 15 or the pre-injury baseline GCS'. |
| Royal College Emergency | Guideline | 037 | 18-22 | Without defining what 'supervised and monitored' is in a custodial setting, this is likely to lead to more admissions. It is unclear how healthcare professionals working in emergency | Thank you for your comment. The committee understand that this will not lead to more admissions as this is part of current ED practice. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|-----------|---------|---------|--|---|
| Medicine (RCEM) | | | | departments are likely to be able to 'ensure' the level of monitoring and supervision in a custodial setting. | |
| Royal College of Paediatrics and Child Health. | Guideline | General | General | Our overall observation is that the guideline makes insufficient reference to Trauma Networks. They have overall responsibility for setting standards relating to clinical care, but more specifically the referral routes of patients to tertiary trauma centres within any particular geographical area. | Thank you for your comment. The NICE guideline on major trauma service delivery is highlighted at the beginning of the recommendations in recognition of the importance of service delivery underpinning many of the recommendations |
| Royal College of Paediatrics and Child Health. | Guideline | General | General | We are satisfied with this draft guideline. The algorithms are particularly useful. | Thank you for your support. |
| Royal College of Paediatrics and | Guideline | 032 | 006 | Within the section on hypopituitarism, it mentions that in people admitted for head injury and showing persistently low sodium or blood pressure, investigations for hypopituitarism should be done. Within Paediatrics when children with a head injury are admitted, we | Thank you for your comment. The recommendation refers to "Persistent" implying that sodium levels or low blood pressure are measured more than once. The person would have had clinical indication for measuring these parameters and we are not recommending electrolytes be checked as screening for hypopituitarism. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------|--|--|
| Child Health. | | | | routinely monitor neuro-observations. Blood testing is not a routine part of observation. Does this guideline suggest that every child admitted for head injury observations should have their electrolytes checked? | |
| Royal College of Physicians | Guideline | General | General | The RCP is grateful for the opportunity to respond to the above consultation. We would like to endorse the response submitted by the British Geriatrics Society (BGS) | Thank you for your support. |
| Society of British Neurological Surgeons (SBNS) | Guideline | General | General | Overall, we find the draft guideline is a reasonable document and reflects safe practice. However we do have some specific concerns on some aspects as indicated below. | Thank you for your comment. |
| Society of British Neurological | Guideline | General | General | Question 1 Would it be challenging to implement of any of the draft recommendations? Please say why and for whom. Please include any suggestions that could help users overcome these | Thank you for your comment. A resource impact assessment will be published alongside the guideline. NICE research recommendations are reviewed regularly by the NIHR to help facilitate their funding and uptake. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------|--|---|
| Surgeons (SBNS) | | | | <p>challenges (for example, existing practical resources or national initiatives.</p> <p>Funding would need to be provided for research recommendations</p> | |
| Society of British Neurological Surgeons (SBNS) | Guideline | General | General | <p>Question 2 Would implementation of any of the draft recommendations have significant cost implications?</p> <p>Increase in number of CT scans of Head and spine as well as CTA and MRA</p> | <p>Thank you for answering this question. The committee agree that overall, there might be a net increase in head CT scanning attributable to the addition of antiplatelets as a risk factor, even though this has been changed to a 'consider' recommendation. Consider recommendations are used when there is a closer balance between benefits and harms than for a recommendation offering an intervention. We are aware that many clinicians are already imaging people taking clopidogrel with no other indications for a scan, so the impact is not expected to be large.</p> <p>The committee do not think there will be a significant increase in CT of the spine, as this has already become standard practice in adults and the recommendation has not changed for children.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|-----------|--|--|
| Society of British Neurological Surgeons (SBNS) | Guideline | 012 | 009 - 019 | <p>Rec 1.2.17</p> <p>Tranexamic acid - The SBNS cannot support a recommendation for TXA for isolated TBI without seeing the evidence from CRASH 3 for the mild and moderate patients reported separately. The recommendation for patients GCS less than 12 is not supported by the CRASH-3 results that did not show benefit for patients with severe injury i.e. GCS <8.</p> | <p>Thank you for your comment.</p> <p>The totality of evidence including evidence from Rowell and CRASH-3 trials were used to make TXA recommendations.</p> <p>CRASH-3 trial subsequently re-analysed data in Williams et al, there was reduction in 28-day head injury mortality in severe TBI in high income countries. The committee would have liked the data split by mild and moderate and also for all cause mortality, but this was not made available. Communication with the CRASH 3 study authors suggested significant uncertainty about tranexamic acid's effect in mild traumatic brain injury. Hence it would appear that in high income settings the CRASH 3 results do not undermine those of Rowell et al.</p> <p>We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date should this subgroup analysis become available.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|----------|----------------------|
| | | | | | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|-----------|--|--|
| Society of British Neurological Surgeons (SBNS) | Guideline | 019 | 014 - 015 | <p>Rec 1.4.10</p> <p>Comment from a SBNS member:</p> <p>This seems reasonable. However, has there been any proof that 5cm is the right cut-off as opposed to 4cm or 6cm?</p> | <p>Thank you for your comment. The recommendation was based on the CHALICE clinical decision rule, which was derived from 22,772 children attending Emergency Departments in the UK. Therefore, various lengths of bruising, swelling or laceration are likely to have been considered.</p> |
| Society of British Neurological Surgeons (SBNS) | Guideline | 022 | 012 - 015 | <p>Rec 1.5.4</p> <p>We agree with this recommendation. However, the guideline does not cover vascular injuries of the major vessels in the skull base e.g. internal carotid associated with skull base as well as complex facial fractures. We recommend that this aspect should be specifically mentioned with CTA/MRA advised to be performed in this group of patients based on the Denver criteria (https://radiopaedia.org/articles/denver-criteria-for-blunt-cerebrovascular-injury-1?lang=gb)</p> | <p>Thank you for your comment. We have edited this recommendation (1.6.10) but we did not review the evidence for the Denver criteria as CT angiography was not included in the review protocol. However, we have added this to the committee's discussion of the evidence in evidence review H.</p> |
| Society of British Neurological Surgeons (SBNS) | Guideline | 025 | 013 - 014 | <p>Comment from a member</p> <p>Expert Witnesses in Emergency Medicine consider that ED consultants and senior</p> | <p>Thank you for your comment.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|-----------|--|---|
| General Surgeons (SBNS) | | | | trainees should be capable of reading CT scans for lesions such as subdural and extradural haematomas. | |
| Society of British Neurological Surgeons (SBNS) | Guideline | 032 | 002 - 012 | Recs 1.8.6, 1.8.7, 1.8.8 We agree with the recommendation to be aware of Hypopituitarism following TBI. However, we feel that the TBI-pituitary recommendations can go further in terms of management by linking to the British Neurotrauma Group guidance: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5740545/ | Thank you for your comment. We are unable to link to guidance other than that produced or accredited by NICE. |
| Society of British Neurological Surgeons (SBNS) | Guideline | 073 | | Table 1 Rec 1.2.9 CERVICAL SPINE IMMOBILISATION We note the referral to the new NICE guidelines regarding spinal injury. There is an ongoing study of cervical immobilisation versus movement minimisation following blunt injury (https://fundingawards.nihr.ac.uk/award/NIHR131430) that will give definitive evidence. We believe it important to support this study and not change guidelines ahead of evidence. | Thank you for your comment. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|--------------------|---------|--|---|
| Society of British Neurological Surgeons (SBNS) | Guideline | 044, 047, 059, 060 | | BIOMARKERS – We recommend further research in the use of Biomarkers specifically in acute diagnosis and triage for CT following TBI.. | Thank you for your comment. The committee have made a research recommendation on 'What is the diagnostic accuracy of brain injury biomarkers for predicting acute complications after a traumatic brain injury?' See appendix J in evidence report G. |
| The Royal College of Speech and Language Therapists | Guideline | General | General | The current (closed) consultation from the Department of Health and Social Care investigated the issues of supporting children and adults with brain injuries and is due to make recommendations shortly. However, there is no timeframe on the next steps. In the absence of this, the gaps in implementing this NICE Guideline remain. | Thank you for your comment. Your comment will be considered by NICE where relevant support activity is being planned. A NICE guideline on Rehabilitation for chronic neurological disorders including acquired brain injury is currently being developed: Project information Rehabilitation for chronic neurological disorders including acquired brain injury Guidance NICE |
| The Royal College of Speech and | Guideline | General | General | The RCSLT welcomes that the updated 2022 sections link into custodial settings. | Thank you for your support. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------|---|--|
| Language Therapists | | | | | |
| The Royal College of Speech and Language Therapists | Guideline | General | General | People experiencing homelessness are a considerable vulnerable cohort - not only are they at high risk for acquired brain injury / head injury but also do not necessarily have ready or consistent access to services or support for care needs. They are not considered in the equality impact assessment. RCSLT recommends that consideration be given to this group in the guidelines, particularly in relation to discharge. | Thank you for your comment. Recommendations 1.9.1 and 1.10.5 and 1.10.9 apply equally to people who are homeless in recognition of the importance of supervised observation for at least 24hours post head injury and monitoring post discharge. If the person cannot be supervised then they would be admitted for a period of observation. |
| The Royal College of Speech and Language Therapists | Guideline | General | General | Whilst post head injury monitoring is emphasised, the RCSLT recommends that it needs to be further highlighted that it can take a long time (months / years) for the impact of acquired brain injury / head injury to be noticed, particularly in children and young people (where smiling / walking competency can mask cognitive dysfunction / impairment). The RCSLT recommends that a flag or an alert needs to remain on documentation long term (school | Thank you for your comment. This is beyond the scope of this guideline which is focused on initial assessment and management. However, the committee highlight the possibility of longer-term problems in the recommendations under the sections on 'discharge advice' and 'follow up' and in the discharge advice letter. A NICE guideline on Rehabilitation for chronic neurological disorders including acquired brain injury is currently being developed: Project information |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------|---|--|
| | | | | records, custodial, GP, etc) that the person has had an acquired brain injury / head injury. | Rehabilitation for chronic neurological disorders including acquired brain injury Guidance NICE. |
| The Royal College of Speech and Language Therapists | Guideline | 014 | 024 | Section 1.3.8 – The RCSLT is concerned that there are no references to the indicators or timeframes for individuals to be re-examined. | Thank you for your comment. This recommendation was not updated as part of this guideline update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| The Royal College of Speech and Language Therapists | Guideline | 037 | 018 | Section 1.9.6 - The RCSLT is concerned that the reference to ongoing supervision or monitoring will be challenging to provide within constraints of current NHS and justice budgets. There is also no named lead to take this forward and ensure that this crucial support is provided. | Thank you for your comment. The committee do not think this will require additional resources as this is current practice. Observation after discharge requires competent adult rather than any medical training. Observation can be carried out by non-health professionals including carers or relatives. The instructions are detailed in the discharge advice. |
| The Royal | Guideline | 038 | 002 | Section 1.9.7 - The RCSLT is concerned that the reference to ongoing supervision or | Thank you for your comment. The committee do not think this will require additional resources as this is current |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------|--|---|
| College of Speech and Language Therapists | | | | monitoring will be challenging to provide within constraints of current NHS and justice budgets. There is also no named lead to take this forward and ensure that this crucial support is provided. | practice. Observation after discharge requires competent adult rather than any medical training. Observation can be carried out by non-health professionals including carers or relatives. The instructions are detailed in the discharge advice. |
| The Royal College of Speech and Language Therapists | Guideline | 038 | 007 | Section 1.9.8 – As this guideline is for children and young people as well as adults, the RCSLT recommend that the guideline also refers to the “Babies, children and young people's experience of healthcare NICE guideline [NG204]”. | Thank you for your comment. We have added a link to the guidance as suggested. |
| The Royal College of Speech and | Guideline | 038 | 012 | Section 1.9.8 -The RCSLT welcomes the highlight of the NICE Guideline on 'patient experience in NHS Services' for verbal and written discharge advice being accessible | Thank you for your comment. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------|--|---|
| Language Therapists | | | | | |
| The Royal College of Speech and Language Therapists | Guideline | 039 | 014 | Section 1.9.13 – The RCSLT recommends the addition that an individual may benefit from seeing allied health professionals including speech and language therapists and occupational therapists. Individuals may have difficulties with insight and not able to seek help themselves. | Thank you for your comment. It is not possible to cover all of the referrals that may need to be made for people with persisting problems so the committee highlighted the health professionals who may be involved including a multidisciplinary neurorehabilitation team which may include speech and language therapists and occupational therapists. The discharge advice is aimed at patients and their carers and highlights the possibility of longer term symptoms and who to contact. This will be covered in the guideline on rehabilitation after chronic neurological disorders (including acquired brain injury) (in development): Project information Rehabilitation for chronic neurological disorders including acquired brain injury Guidance NICE |
| The Royal College of Speech and | Guideline | 039 | 021 | Section 1.9.14 -The RCSLT welcomes the recommendation about further investigation where patients are experiencing symptoms of hypopituitarism or not recovering as expected. | Thank you for your comment. The possibility of hormonal problems is included in the discharge advice. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------|-----------|---------|---------|---|--|
| Language Therapists | | | | RCSLT would also recommend that the hospital discharge advice which the patient is given after head injury should include an explicit warning about possible pituitary problems, under the existing heading 'Will I have any long-term problems?'. The wording we would suggest, taken from the previous version of Derriford Hospital's discharge advice, is: If you start to feel that things are not quite right (eg mild headache, feeling sick, problems concentrating, poor memory, irritability, tiredness, problems sleeping, lack of appetite, sexual and fertility difficulties, weight problems) then please see your GP so that he/she can make sure you are recovering properly; occasionally further investigations (eg pituitary blood tests) may be required. | |
| UK Hospital | Guideline | | | UK H@H Response to the NICE GUID NG 10164, Head injury: assessment and early management | Thank you for your comment. The committee agreed these are important factors to consider. The committee has made two additional recommendations 1.1.1 and 1.1.2 which refer to the NICE guidelines on shared |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------|----------|---------|---------|--|---|
| Home Society | | | | <p>We wish to express our concern over the lack of guidance relating to head injuries in older people, particularly those living with frailty and cognitive impairment at home and in institutional settings and recommend that the new guidance is changed to specifically consider this patient population.</p> <p>Older people constitute a significant proportion of those falling and consequently sustaining head injuries.1,2</p> <p>Although falls in older people are not inevitable, they are a recognised consequence of ageing and the development of multi-morbidity which is a feature of our older population in the UK.3</p> <p>Many of our patients, particularly living in care homes are prone to falls, many of which are accompanied by minor head injuries.</p> <p>Given the co-existence of multi-morbidity, particularly atrial fibrillation and thromboembolic disease, significant numbers of our patients</p> | <p>decision making and decision making and mental capacity (including advance care plans). These recommendations have been cross referred to in recommendations 1.2.2-1.2.5. The committee discussed making further reference to advance care plans but agreed that the cross references to the relevant NICE guidelines covered the key points.</p> <p>The committee noted that the ability to assess someone with head injury (and to be able to take into consideration an advance care plan), who are often on anticoagulant or antiplatelet therapy medication, at the scene will depend on their training, and that a person may need to be referred to hospital for a variety of reasons -other than the risk of intracranial bleeding. For example, the commonest cause of head injury in older adults is a fall from a standing height and a person on the afore mentioned therapies may require assessment to explore possible acute medical events or unstable co-morbid conditions as causes of the fall (see recommendation 1.10.13). The management of any bleeding scalp/ head wound and the wholistic assessment for extracranial</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--|---|
| | | | | <p>receive oral anticoagulation.4</p> <p>The current and future guidance advises urgent transfer to hospital for CT scanning in situations where patients have sustained even minor head injuries; this is in many instances translated in the instance of so-called unwitnessed falls (when a care home resident is found to have fallen without witnesses) to be interpreted, however wrongly or inappropriately as a potential head injury.</p> <p>The net result of the current guidance is significant numbers of older people transferred to Emergency Departments for CT scans, the vast majority of which are normal.</p> <p>In the minority who fall and sustain significant injury, such as subdural or extradural haematomas, given their advanced frailty and in particular cognitive impairment, they are never appropriate candidates for surgical intervention, the management is therefore conservative. 5</p> | <p>injury also requires expertise that may not be available at scene.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|---|----------------------|
| | | | | <p>The result of these actions is significant upheaval for patients (the trauma of transfer to ED, time in departments and subsequent wait to return to their care home, added pressure on Emergency Departments and hospitals (many of those patients are unnecessarily or inappropriately admitted to hospital systems) without any benefit to those who have fallen.</p> <p>UK Hospital at Home Society members who are part of the new Urgent Care Response (UCR) teams see many older patients taking anticoagulants in care homes who fall and sustain head injuries without clinical sequelae. Patients and families often support a pragmatic strategy to mitigate risk without immediate transfer to emergency departments with long waits for CT scanning, risk of unnecessary investigation, treatment and admission as well as worsening of delirium.</p> <p>Currently, this draft guidance does not allow for delivery of a personalised approach to risk mitigation after head injury in severely frail</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--|----------------------|
| | | | | <p>patients on anticoagulants that takes patient and family preferences and values into consideration, in the context of an absence of any surgical approach to acute pathology that could be seen on CT scanning.</p> <p>We as a society caring for older people living in the community wish to recommend the guidelines address this issue, acknowledging that falls and head-injuries in younger, community dwelling and otherwise healthy people are very different clinical entities to those in older people living with frailty to include a caveat recommending for example,</p> <p>'Those living in care homes who sustain head injuries or experience unwitnessed falls when taking oral anticoagulants should have an individualised assessment to mitigate risk which could include a period of observation in the care home following clinical review with temporary cessation of anticoagulants, re-starting if there is no clinical evidence of deterioration. Decisions to transfer patients to emergency</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|---|----------------------|
| | | | | <p>departments for further investigation should only be taken after discussion with patient and family or carer and in the absence of Advance Directives or Advance Care Planning documentation.'</p> <p>The Society would happily provide expert support for the future development of this guideline.</p> <p>Many thanks for your consideration.</p> <p>The UK Hospital at Home Society</p> <p>1 Peters, Matthew E., and Raquel C. Gardner. "Traumatic brain injury in older adults: do we need a different approach?." Concussion3.3 (2018): CNC56.</p> <p>2 Gardner, Raquel C., et al. "Geriatric traumatic brain injury: epidemiology, outcomes, knowledge gaps, and future directions." Journal</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------|-----------|---------|------------|--|---|
| | | | | <p>of neurotrauma^{35.7} (2018): 889-906.</p> <p>3 Clegg, Andrew, et al. "Frailty in elderly people." <i>The lancet</i>^{381.9868} (2013): 752-762.</p> <p>4 Bauersachs, Rupert M., and Joerg Herold. "Oral anticoagulation in the elderly and frail." <i>Hämostaseologie</i>^{40.01} (2020): 074-083.</p> <p>5 Edlmann, Ellie, and Peter C. Whitfield. "The changing face of neurosurgery for the older person." <i>Journal of Neurology</i>^{267.8} (2020): 2469-2474.</p> | |
| UK Hospital at Home Society | Guideline | 020 | 12, 18, 22 | <p>Various sections of the guideline related to head injuries in patients prescribed anticoagulants.</p> <p>We request that special consideration is given to those living with frailty or dementia particularly in institutional settings (nursing and residential homes) who have admission avoidance care plans or advance directives; please see below:</p> | <p>Thank you for your comment. We have added two new recommendations about shared decision making and supporting people who lack capacity, including people with an advanced care plan (1.1.1 and 1.1.2). These recommendations apply to the whole guideline.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|-----------|---------|---------|---|---|
| University of Essex (NIHR202980 Heads Together: Understanding Acquired Brain Injury: Addressing the knowledge and skills gap in Social Work education in | Guideline | 001 | 007 | Initial Title Page - Table 'Healthcare and Social Care professionals' – beneficial to add social care professionals from the outset as often missed and critical to early assessment and management with particular involvement in 1.6 Information and support for families and carers, and 1.9 Discharge and Follow-up . | Thank you for your comment. We have added social workers to the text of recommendations 1.10.8 and 1.10.12. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|-----------|---------|---------|--|---|
| order to improve practice and outcomes (April 2022 – Mar 2024). | | | | | |
| University of Essex (NIHR202980 Heads Together: Understanding Acquired Brain Injury: | Guideline | 007 | Table | <p>Any history of domestic violence (https://www.thedtgroup.org/foundation/news/the-impact-of-brain-injury-and-domestic-abuse-a-further-analysis)</p> <p>Oxygen deprivation at birth (https://mft.nhs.uk/app/uploads/sites/4/2018/04/Bliss-HIE-Hypoxic-ischaemic-encephalopathy.pdf)</p> | Thank you for your comment. This recommendation was not updated as part of this guideline update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------|--|--|
| Addressing the knowledge and skills gap in Social Work education in order to improve practice and outcomes (April 2022 – Mar 2024). | | | | | |
| University of | Guideline | 007 | 007 | Include social work and care practitioners in list of community health and care services | Thank you for your comment. This recommendation was not updated as part of this guideline update. We will pass |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|----------|---------|---------|----------|--|
| Essex (NIHR202980 Heads Together: Understanding Acquired Brain Injury: Addressing the knowledge and skills gap in Social Work education in order to improv | | | | | your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------|-------------------------|---|
| e practice and outcomes (April 2022 – Mar 2024). | | | | | |
| University of Essex (NIHR202980 Heads Together: Understanding Acquired Brain Injury: Addressing the | Guideline | 010 | 022 | Social Work Core Course | Thank you for your comment. This recommendation was not updated as part of this guideline update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|-----------|---------|---------|---|--|
| knowledge and skills gap in Social Work education in order to improve practice and outcomes (April 2022 – Mar 2024). | | | | | |
| University of Essex (NIHR2) | Guideline | 015 | 012 | Question: should there be reference to patients admitted to mental health hospitals? Why 'clinical features' as infers purely medical model? It would be useful to reference here | Thank you for your comment. The committee were aware of special consideration for people of black and minority ethnic origin but the aim of this recommendation was to |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|----------|---------|---------|---|---|
| 02980 Heads Together: Understanding Acquired Brain Injury: Addressing the knowledge and skills gap in Social Work education in order to improve practice | | | | what is being learned about presentations from the black and ethnic minority communities (including bruising/discolouration & potential for bias https://www.nhs.uk/wp-content/uploads/2021/03/Pulse-oximetry-racial-bias-report.pdf and https://www.essex.ac.uk/blog/posts/2022/03/31/an-inclusive-and-decolonised-health-and-social-care-curriculum?fbclid=IwAR3jThW3Xr9VKmd3xtas9K86YX97qrO55DMOvITmeLK_DqOFecP6MMr2vOw). | highlight the abuse, neglect and other safeguarding issues. People in mental health hospitals should be assessed in the ED if they have a suspected head injury and any of the indications in rec 1.2.4. During the initial assessment of head injury in the ED the person is being assessed clinically but the committee are aware that other features may also need to be assessed. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|-----------|---------|---------|--|--|
| and outcomes (April 2022 – Mar 2024). | | | | | |
| University of Essex (NIHR2 02980 Heads Together: Understanding Acquired Brain Injury: Addressing the knowledge | Guideline | 015 | 022 | Question: this implies no social work involvement in hospitals. Would there be scope to consider inclusion of following local safeguarding procedures including referral to hospital social work team. | Thank you for your comment. A referral to the hospital social work team may be appropriate and is covered by the recommendation 1.4.13 referring to following local safeguarding procedures. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|-----------|---------|---------|---|--|
| and skills gap in Social Work education in order to improve practice and outcomes (April 2022 – Mar 2024). | | | | | |
| University of Essex (NIHR2 02980 Heads | Guideline | 026 | 021 | Question: acknowledging 'clinical and social care management is essential'. Not to complicate the guidance however by not referencing social care throughout there is a missed opportunity such as the role of hospital | Thank you for your comment. Social care workers are not routinely involved in decisions to transfer people to a neuroscience unit. This role of social workers will be covered in the guideline on rehabilitation after chronic neurological disorders: Project information Rehabilitation |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|----------|---------|---------|--|--|
| <p>Together: Understanding Acquired Brain Injury: Addressing the knowledge and skills gap in Social Work education in order to improve practice and outcomes</p> | | | | <p>social workers in that ongoing liaison between medical, care and family supports.</p> | <p>for chronic neurological disorders including acquired brain injury Guidance NICE.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------|--|--|
| es (April 2022 – Mar 2024). | | | | | |
| University of Essex (NIHR2 02980 Heads Together: Understanding Acquired Brain Injury: Addressing the knowledge and skills | Guideline | 026 | 024 | Consideration should be given to recognising the role of social work and social care throughout the guidance however inclusion specifically here regarding family and carer support is essential as this is a core remit including referral on to local and national patient support – including specialist brain injury case managers, specialist social worker and charity support teams (eg Headway, Brain Injury Social Work Group). | Thank you for your comment. Social care workers are not routinely involved in decisions to transfer people to neuroscience unit. This role of social workers in rehabilitation will be covered in the guideline on rehabilitation after chronic neurological disorders: Project information Rehabilitation for chronic neurological disorders including acquired brain injury Guidance NICE. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------|--------------------------------------|--|
| gap in Social Work education in order to improve practice and outcomes (April 2022 – Mar 2024). | | | | | |
| University of Essex (NIHR202980 Heads Together: | Guideline | 029 | 006 | Amend: "health and social care team" | Thank you for your comment. Social care workers are not routinely involved in decisions to transfer people to a neuroscience unit. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|----------|---------|---------|----------|----------------------|
| Understanding Acquired Brain Injury: Addressing the knowledge and skills gap in Social Work education in order to improve practice and outcomes (April | | | | | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------|--|--|
| 2022 – Mar 2024). | | | | | |
| University of Essex (NIHR2 02980 Heads Together: Understanding Acquired Brain Injury: Addressing the knowledge and skills gap in Social | Guideline | 031 | 020 | Observation: the guidance moves from admission to discharge without referencing at which point hospital and community social work should become involved. In line with severity of need, early referral would enable improved care management planning. It would be useful to acknowledge there is space for improved outcomes the earlier social work is aware (it may be discharge is the key point of intervention – including signposting - however planning should run in parallel with care planning such as awareness of medical journey and impact). Often discharge is a point of crisis for patients and families in that hospitals are considered a safe space following trauma so preparation for discharge will support to ease the anxiety and better prepare all concerned. | Thank you for your comment. The scope of this guideline was the early assessment and management. The NICE guideline on rehabilitation for chronic neurological disorders including acquired brain injury (in development) is covering identification and referral: Project information Rehabilitation for chronic neurological disorders including acquired brain injury Guidance NICE . Social workers are now specifically referred to in the section 1.10 on discharge and follow up. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------|---|---|
| Work education in order to improve practice and outcomes (April 2022 – Mar 2024). | | | | | |
| University of Essex (NIHR202980 Heads Together: Understanding | Guideline | 036 | 011 | Consideration to include domestic violence as an indicator and to include social work as guiding safe discharge from a social care perspective. | Thank you for your comment. Domestic violence is covered in recommendation 1.4.12. Social workers and safeguarding referrals are now referred to in section 1.10. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|----------|---------|---------|----------|----------------------|
| Acquired Brain Injury: Addressing the knowledge and skills gap in Social Work education in order to improve practice and outcomes (April 2022 – | | | | | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------|---|---|
| Mar 2024). | | | | | |
| University of Essex (NIHR202980 Heads Together: Understanding Acquired Brain Injury: Addressing the knowledge and skills gap in Social Work | Guideline | 036 | 026 | Consideration to be given to referral to social services as appropriate support structures for safe transfer to the community and for subsequent care | Thank you for your comment. The term 'appropriate support structures' could include a referral to social services. Social workers are now specifically referred to in section 1.10. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|-----------|---------|---------|---|---|
| education in order to improve practice and outcomes (April 2022 – Mar 2024). | | | | | |
| University of Essex (NIHR202980 Heads Together: Understanding Acquire | Guideline | 037 | 015 | Referral to be made to social services if there is no carer at home upon discharge. | Thank you for your comment. This recommendation was not updated as part of this guideline update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|----------|---------|---------|----------|----------------------|
| d Brain Injury: Addressing the knowledge and skills gap in Social Work education in order to improve practice and outcomes (April 2022 – Mar 2024). | | | | | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|-----------|---------|---------|---|--|
| University of Essex (NIHR202980 Heads Together: Understanding Acquired Brain Injury: Addressing the knowledge and skills gap in Social Work education in | Guideline | 038 | 011 | This should include 'social worker' where appropriate | Thank you for your comment. Social workers are now specifically referred to in section 1.10. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|-----------|---------|---------|---|--|
| order to improve practice and outcomes (April 2022 – Mar 2024). | | | | | |
| University of Essex (NIHR202980 Heads Together: Understanding Acquired Brain Injury: | Guideline | 038 | 025 | This should 'social services' and specialist brain injury support groups (eg Headway) | Thank you for your comment. It is not possible to list of all the potentially relevant health professionals/services. Support organisations are included in the recommendations (recommendation 1.10.9 last bullet point). |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------|--|--|
| Addressing the knowledge and skills gap in Social Work education in order to improve practice and outcomes (April 2022 – Mar 2024). | | | | | |
| University of | Guideline | 039 | 012 | This should also include social worker | Thank you for your comment. Recommendation 1.10.14 has been amended to include a multidisciplinary |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|----------|---------|---------|----------|---|
| Essex (NIHR202980 Heads Together: Understanding Acquired Brain Injury: Addressing the knowledge and skills gap in Social Work education in order to improv | | | | | neurorehabilitation team which could include a social worker. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---|-----------|---------|---------|---|---|
| e practice and outcomes (April 2022 – Mar 2024). | | | | | |
| University of Essex (NIHR202980 Heads Together: Understanding Acquired Brain Injury: Addressing the | Guideline | 046 | | Training for social workers to be trained to provide specialist support for people affected by head injuries This is especially important for people with brain injury which is diagnosed in 70% of head injury. Evidence shows that there is a need for social workers to be trained in brain injury. The Heads Together project led by the University of Essex is currently working to bridge the knowledge gap in social worker knowledge of head injury and brain injury. The project is currently carrying out a systematic review of existing literature on brain injury related social work research to understand social work understanding of brain injury. A survey is being carried out with social work | Thank you for your comment and for highlighting this important project. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--|----------|---------|---------|---|----------------------|
| knowledge and skills gap in Social Work education in order to improve practice and outcomes (April 2022 – Mar 2024). | | | | <p>educators to gain an insight into current social work education of brain injury and also social workers are being interviewed to ascertain the level of understanding practitioners have of brain injury. The participants include newly qualified social workers, managers and specialist social workers. A key aspect of this project is the perspectives of people affected by brain injury including people with brain injury, their family members and carers, and the professionals who support them.</p> <p>All of these would inform the research which aims to improve social worker knowledge of brain injury and outcomes for people affected by this condition.</p> <p>https://www.essex.ac.uk/news/2022/03/11/improving-the-support-network-for-people-with-brain-injuries</p> <p>https://www.essex.ac.uk/blog/posts/2022/11/03/the-heads-together-project</p> <p>https://www.nihr.ac.uk/news/new-research-to-</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--|----------------------|
| | | | | <p>improve-social-support-for-people-with-brain-injuries/30163#:~:text=The%20Heads%20Together%20programme%20aims,%2C%20crime%2C%20homelessness%20or%20suicide.</p> <p>Holloway, M. (2014). How is ABI assessed and responded to in non-specialist settings? Is specialist education required for all social care professionals? <i>Social Care and Neurodisability</i> 5:201–213.</p> <p>Holloway, M (2015) <i>Acquired Brain Injury, Social Work and the Challenges of Personalisation</i> <i>The British Journal of Social Work</i>. Volume 46, Issue 5, July 2016 (Accesses 20 May 2020)</p> <p>Mantell, A., Simpson, G., Vungkhanching, M., Jones, K., Strandberg, T and Simonson, P (2017). Social work-generated evidence in traumatic brain injury from 1975 to 2014: A systematic scoping review. <i>Health & Social Care in the Community</i> 26. 433-448</p> | |

**None of the stakeholders who comments on this clinical guideline have declared any links to the tobacco industry.*

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Head injury

Consultation on draft guideline - Stakeholder comments table

23/10/2022 - 04/11/2022

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees