

GUIDELINES

Evaluation of traumatic brain injury guidelines using AGREE instrument

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Abstract: Background: This study aims to assess the quality of four selected traumatic brain injuries management guidelines used mainly in the US and in Europe.

Methods: The instrument Appraisal of Guidelines Research & Evaluation was selected to provide a framework for guidelines appraisal. Four guidelines addressing a specific topic related to the treatment of traumatic brain injury were selected for evaluation: three developed in the United States of America and one from the United Kingdom. A trauma surgeon, one anaesthesiologist, one emergency physician and a public health specialist evaluated the guidelines.

Results: In the overall assessment of all guidelines, the United Kingdom guidelines attracted the best score, achieving the highest score of all four guidelines in five of six domains. The scientific quality of collected evidence was excellent and well documented in all four guidelines. Overall, the domains of Stakeholder involvement and Applicability were the lowest scoring for all the guidelines.

Conclusion: A Broad spectrum of stakeholders should be represented in the brain trauma management guidelines development. The potential organizational and financial barriers for the application of guidelines need to be considered during their development. The paper provides suggestions for those who develop new guidelines for the management of patients with head injuries (Tab. 8, Ref. 29). Full Text (Free, PDF) www.bmj.sk. Key words: guidelines, traumatic brain injury, AGREE.

Available data on the annual incidence rate of hospital referred head injury show that moderate and severe TBI is a relatively rare disease, but still the main cause of death and life-long disability (1). Head injury is often referred to as “the silent epidemic”, causing great personal suffering to victims and relatives and economic burden to the society (2, 3).

Until the 1990s there had been considerable variations in clinical management of head injury, not only between individual countries (4, 5), but within one country as well (6, 7), leading to a conclusion that a patient with severe head injury is likely to be managed differently, depending on where and by whom (7). The situation was a result of non existing management standards. Standards of care are important as a clinical guide for the treating personnel. Research shows also positive association of the

use of standardized treatment guidelines and protocols with improved patient health outcomes (8), better use of available health resources and consistency in the treatment process (9).

The first prognostic measure that had been adopted in brain trauma management was Glasgow Coma Score scale (GCS), assessing severity of brain injury, developed by Teasdale and Jennett (10). GCS score is a predictor of both immediate and long-term outcome after traumatic brain injury (11, 12). Severity of injury and patient’s age, are accepted as the two most important factors in outcome prediction. The Marshall computed tomography (CT) classification is being used as a further predictor of patient’s health outcome (13). It identifies six groups of patients with TBI, based on morphological abnormalities on the CT scan. The Large IMPACT project looking into the prognostic factors pronounced the age, GCS motor score, pupil response, Marshall CT classification and traumatic subarachnoid haemorrhage to be the most powerful independent prognostic variables (14).

To standardize the treatment of severe traumatic brain injury, clinical guidelines have been developed in the course of the last decade. The first guidelines developed were the Guidelines for the Management of Severe Head Injury in 1995 by the US Brain Trauma Foundation (BTF) (15). These were updated by BTF and the revised guidelines were published in 2000 (16). BTF has also developed and published the Guidelines for Prehospital Management of Traumatic Brain Injury (17). In 2001 the Guidelines for Management and Prognosis of Penetrating

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Tab. 1. List and description of domains of AGREE instrument.

No.	Domain title	Description
1.	Scope and purpose (items 1–3)	is concerned with the overall aim of the guideline, the specific clinical questions and the target patient population.
2.	Stakeholder involvement (items 4–7)	focuses on the extent to which the guideline represents the views of its intended users.
3.	Rigour of development (items 8–14)	relates to the process used to gather and synthesise the evidence, the methods to formulate the recommendations and to update them.
4.	Clarity and presentation (items 15–18)	deals with the language and format of the guideline.
5.	Applicability (items 19–21)	pertains to the likely organisational, behavioural and cost implications of applying the guideline
6.	Editorial independence (items 22–23)	is concerned with the independence of the recommendations and acknowledgement of possible conflict of interest from the guideline development group.

Brain Injury (18) were developed in the US by group of experts and with contribution and support of the Brain Injury Association (BIA), the International Brain Injury Association (IBIA), the American Association of Neurological Surgeons (AANS), and the Congress of Neurological Surgeons (CNS).

The European Brain Injury Consortium (EBIC), network of European neurotrauma centers, developed recommendations for brain trauma management in 1997 (19).

National Institute for Clinical Excellence (NICE) of the United Kingdom has commissioned development of TBI management guidelines and the work was carried out by the Collaborative Centre for Acute Care in London and published in 2003 (20).

Despite the intensive international guideline development of the last decade, there is no unique consensus on brain trauma treatment. There are several treatment guidelines being used worldwide for brain trauma management and the treatment standards still vary cross-country as well as locally. The reasons for the variations are the differences in management policies and arrangements for neurosurgical services in individual countries and regions (21).

The International Neurotrauma Research Organization (INRO) based in Vienna, Austria, worked with the US guidelines for management of patients with severe TBI since 2000. Since practical evidence shows some of the recommendations of different guidelines vary, the INRO team decided to assess the process of development of the US guidelines, since the organization works with them, as well as the UK guidelines, that are the most used in Europe. For the assessment of the clinical guidelines for brain trauma management the instrument AGREE was used (22). The AGREE instrument is being used widely for quality of guidelines evaluation in various fields of medicine, such as for stroke rehabilitation (23), gynaecologic oncology (24), psychiatric care (25), etc. However, the evaluation of quality of guidelines for traumatic brain injury management by the AGREE instrument was not reported yet.

Hence the aim of this paper is to assess the process of development and quality of four selected TBI management guidelines used mainly in the US and in Europe, thus assisting health care professionals using the guidelines in practice and providing information for future development of brain trauma guidelines.

Methods

Four guidelines were selected for the appraisal: Guidelines for the Management of Severe Head Injury, c 1995, Brain Trauma Foundation (16); Guidelines for Prehospital Management of Traumatic Brain Injury, Brain Trauma Foundation, US, 2000 (17); Management and Prognosis of Penetrating Brain Injury, US, 2000 (18); and Head Injury: Triage, Assessment, Investigation and Early Management of Head Injury in Infants, Children and Adults. NICE, UK, 2003 (20).

The guidelines were appraised by the AGREE instrument (22). AGREE stands for “Appraisal of Guidelines Research and Evaluation” and the instrument was developed by an international collaboration of researchers and policy makers from Europe, the USA, Canada and New Zealand. The AGREE instrument assesses the quality of guideline development, quality of the reporting and of some aspects of recommendations. By quality of clinical practice guidelines authors of the AGREE instrument understand the confidence that the potential biases of guideline development have been addressed adequately and that the recommendations are both internally and externally valid, and are feasible for practice. This process involves taking into account the benefits, harms and costs of the recommendations, as well as the practical issues attached to them. Therefore, the assessment includes judgments about the methods used for developing the guidelines, the content of final recommendations, and the factors linked to their uptake.

The instrument does not assess the impact of a guideline on patients’ outcomes.

AGREE consists of 23 items organized in 6 domains. The items are questions characterizing the domains. Each domain is intended to capture a separate dimension of guideline quality (Tab. 1).

Each item is rated on a 4-point scale: 4 ‘Strongly agree’, 3 ‘Agree’, 2 ‘Disagree’, 1 ‘Strongly disagree’.

A trauma surgeon, one anaesthesiologist, one emergency physician and a public health specialist evaluated the four selected guidelines. Every appraiser reviewed all guidelines and scored each item. Domain scores were calculated by summing up all the scores of the individual items in a domain and by standardizing the total as a percentage of the maximum possible score

Tab. 2. Percentages of the maximum possible score for appraised guidelines in the individual domains.

Domain	TBI-US	Penetrating	GUIDELINE Prehosp-US	Prehosp-UK	Average Score
	Standardized Domain Score				
Scope and Purpose	100.0	97.2	94.4	94.4	96.5
Stakeholder Involvement	37.5	45.8	50.0	81.3	53.7
Rigour of Development	79.8	73.8	75.0	85.7	78.6
Clarity and Presentation	81.3	70.8	77.1	87.5	79.2
Applicability	36.1	33.3	30.6	66.7	41.7
Editorial Independence	66.7	66.7	75.0	95.8	76.1
Average Score	66.9	64.6	67.0	85.2	

Tab. 3. Percentages of the maximum scores of the appraised guidelines for the Domain 1: Scope and Purpose.

Items	TBI-US	Penetrating	GUIDELINE Prehosp-US	Prehosp-UK
	1. The overall objective(s) of the guideline is (are) specifically described.	4	4	4
2. The clinical question(s) covered by the guideline is(are) specifically described.	4	4	4	4
3. The patients to whom the guideline is meant to apply are specifically described.	4	4	3.5	4

Tab. 4. Percentages of the maximum scores of the appraised guidelines for the Domain 2: Stakeholder Involvement.

Items	TBI-US	Penetrating	GUIDELINE Prehosp-US	Prehosp-UK
	1. The guideline development group includes individuals from all the relevant professional groups	2	2.5	3
2. The patients' views and preferences have been sought	1.5	1.5	1	4
3. The target users of the guideline are clearly defined	2.5	3	4	3.5
4. The guideline has been piloted among target users	1.5	2	1.5	2

for that domain. The six domain scores are independent and not aggregated into a single quality score. However, there is a table for the Overall Assessment of a guideline at the end of the instrument, where the appraisers take into account all the criteria and express their recommendation of the guideline for further use.

Results

The average scores for all the guidelines, broken down by the domains, as well as summary scores, are displayed in Table 2. The domain scores are stated as a percentage of the maximum possible score (100 %) for that domain. Tables 3–8 provide average points for every item within individual domains after the evaluation by four independent appraisers. The maximum point an item can receive is 4 and the minimum is 1 (4 ,Strongly agree', 3 ,Agree', 2 ,Disagree' 1 ,Strongly disagree').

In the overall assessment of all guidelines, looking at the mean score of all the domains, the UK guidelines scored highest

(85.2 %) (Tab. 2). They achieved the highest mean score of all four guidelines in five of the six domains: Stakeholder involvement, Rigour of development, Clarity and presentation, Applicability, Editorial Independence.

The UK guidelines had the highest mean score in the domain Editorial Independence (95.8 %), where all the other domains scored lower. The domain assesses whether or not the views or interests of the organization funding the guideline development have influenced the final recommendations. The UK guidelines received the maximum of 4 points for both domain items, uniformly from all the appraisers (Tab. 8).

The second highest scoring domain for the UK guidelines was Scope and Purpose (94.4 %) (Tab. 2), although the other appraised guidelines scored the same or better here. Table 3 shows almost uniform maximum or near-maximum points in the Scope and Purpose domain for all the guidelines.

The UK guidelines scored high above the other guidelines in the domain of Stakeholder involvement (81.3 %, compared to

Tab. 5. Percentages of the maximum scores of the appraised guidelines for the Domain 3: Rigour of Development.

Items	GUIDELINE			
	TBI-US	Penetrating	Prehosp-US	Prehosp-UK
1. Systematic methods were used to search for evidence	3.5	4	3	4
2. The criteria for selecting the evidence are clearly described	4	4	4	4
3. The methods used for formulating the recommendations are clearly described	4	3	4	3.5
4. The health benefits, side effects and risks have been considered in formulating the recommendations	3.5	2.5	3	3.5
5. There is an explicit link between the recommendations and the supporting evidence	4	4	4	4
6. The guideline has been externally reviewed by experts prior to its publication	4	3.5	4	4
7. A procedure for updating the guideline is provided	2	1.5	1	2

Tab. 6. Percentages of the maximum scores of the appraised guidelines for the Domain 4: Clarity and Presentation.

Items	GUIDELINE			
	TBI-US	Penetrating	Prehosp-US	Prehosp-UK
1. The recommendations are specific and unambiguous	4	4	4	3.5
2. The different options for management of the condition are clearly presented	3	3	3	4
3. Key recommendations are easily identifiable	4	4	4	3.5
4. The guideline is supported with tools for application	3	1.5	3	4

the scores of 50 %, 45.8 % and 37.5 % of the other guidelines) (Tab. 2). The UK guideline scored high namely in the item No. 1: “The guideline development group includes individuals from all the relevant professional groups” and the item No. 2: “The patients’ views and preferences have been sought”. The UK guidelines received highest possible evaluation points for both items (Tab. 4). The US Guidelines for Prehospital Management of Traumatic Brain Injury received highest points in this domain for the item No. 3: “The target users of the guideline are clearly defined” (Tab. 4). All the guidelines scored low (1.5 to 2 points) in the item No. 4: “The guideline has been piloted among target users” (Tab. 4).

The second highest overall score was obtained by the US Guidelines for Prehospital Management of Traumatic Brain Injury, Brain Trauma Foundation, 2000 (Prehospital US guidelines) (67 %) (Tab. 2). These guidelines achieved highest score in the domain Scope and Purpose (94.4 %) (Tab. 2), however this was the lowest score for that domain of all guidelines (scoring the same as the UK guidelines for that domain).

The guidelines scored higher than the others (but lower than the UK guidelines) in the domains of Editorial Independence and Stakeholder Involvement (Tab. 2).

The Prehospital US guidelines scored the lowest of all guidelines in the Applicability domain.

The third scored the US Guidelines for the Management of Severe Head Injury (TBI US guidelines), with the overall result almost identical as the Prehospital US guidelines (66.9 % compared to 67 %) (Tab. 2). These guidelines scored the best of all guidelines in the domain Scope and Purpose (100 %).

The lowest scoring guidelines of all were the US guidelines Management and Prognosis of Penetrating Brain Injury (Penetrating US guidelines) (64.6 %) (Tab. 2). These guidelines scored high in the Scope and Purpose domain (97.2 %) and very low in the Applicability (33.3 %) and the Stakeholder Involvement domains (45.8 %) (Tab. 2).

All appraised guidelines scored high in the Scope and Purpose domain (the average score 96.5 %, with the range of TBI-US guidelines scoring 100% up to 94.4 % of both Prehospital US and UK guidelines).

All appraised guidelines received the lowest scores of all domains in the Applicability domain (the highest score was achieved by the UK guidelines, 66.7 %, the other guidelines scored from 30.6 to 36.1 %, the average score was 41.7 % (Tab. 2). The Applicability domain followed these items: 1) The potential organizational barriers in applying the recommendations have been discussed, 2) The potential cost implications of applying the recommendations have been considered and 3) The guideline presents key review criteria for monitoring and/or audit purposes.

Tab. 7. Percentages of the maximum scores of the appraised guidelines for the Domain 5: Applicability.

Items	GUIDELINE			
	TBI-US	Penetrating	Prehosp-US	Prehosp-UK
1. The potential organisational barriers in applying the recommendations have been discussed.	1.5	2	1.5	2
2. The potential cost implications of applying the recommendations have been considered	1.5	1.5	1.5	4
3. The guideline presents key review criteria for monitoring and/or audit purposes	2.5	2	2	4

Tab. 8. Percentages of the maximum scores of the appraised guidelines for the Domain 6: Editorial Independence.

Items	GUIDELINE			
	TBI-US	Penetrating	Prehosp-US	Prehosp-UK
1. The guideline is editorially independent from the funding body	3.5	3.5	3.5	4
2. Conflicts of interest of guideline development members have been recorded	2	2	3	4

Table 7 shows scoring for the individual items of the Applicability domain. All three US guidelines received low points for all the items (1.5 to 2.5 points) and only UK guidelines received the maximum points for the items 2 and 3.

Table 5 summarizes evaluation of 7 items of the Rigour of Development domain. All guidelines scored uniformly high for all the items, with the exception of item No. 7: “A procedure for updating the guideline is provided”, where all achieved mean points were low (1 to 2).

Individual items of the Clarity and Presentation domain are evaluated in the Table 6. The domain inquires about the specificity and applicability of recommendations and all guidelines scored high in all the items (points 3 to 4) (Tab. 6), with the exception of Penetrating US Guidelines in the item No. 4: “The guideline is supported with tools for application” (1.5 points).

Independence from the funding body and consideration of conflicts of interest in the process of guideline development are evaluated in the domain of Editorial Independence (Tab. 8). The UK guidelines achieved the maximum points in both domain items, the other guidelines received 2 to 3.5 points.

Discussion

It is important to stress out the AGREE instrument evaluates the process of development of the guidelines and how is this process presented, not their content.

The appraised guidelines achieved the highest mean average score in the Scope and Purpose domain and the lowest in the Applicability domain. This is in line with other studies using AGREE instrument for guideline evaluation (23–28), they all report the lowest scores in the Applicability domain and many of them also the highest scores in the Scope and Purpose domain.

As mentioned above, the highest mean score of all the appraised guidelines was achieved by the UK guidelines. They achieved the highest mean score in the Editorial Independence domain, which is due to the fact that the development of the UK guidelines was commissioned by the National Institute for Clinical Excellence and the development itself was carried out by the National Collaborating Centre for Acute Care. The two other guidelines were supported and implemented by a nongovernmental organization Brain Trauma Foundation in the US and the fourth one was developed by group of experts collaborating with several professional organizations.

The UK guidelines scored significantly better than the others in the domain Stakeholder Involvement since, unlike the other guidelines, there was a patient representative present in the Guideline Development Group, as well as in the Guideline Advisory Committee and a broad scope of stakeholders was involved in the guideline development. The UK guidelines present also recommendations for methods of support to family and carers, encouraging proper communication between health professionals and patient’s family, family’s contact with and access to the patient, proper information about patients’ care and possible long-term outcomes.

The Prehospital US guidelines scored the best in one of the items in this domain for defining the target users, which is the injured person since the first contact with the health care personnel till the admittance into the hospital delivering the care.

All guidelines scored low for piloting among target users. None of the guidelines reports specific piloting of the guidelines.

All guidelines scored high in the Scope and Purpose domain, since they all described well the guideline objective, clinical questions covered and patients group concerned.

All guidelines scored the lowest in the Applicability domain. Only the UK guidelines achieved high scores for considering potential cost implications of applying the guidelines recommendations and for presenting key review criteria for monitoring and audit purposes. The UK guidelines include an appendix defining objectives and measures of audit on brain trauma management, with detailed criteria to follow. Several studies assessing quality of guidelines in other fields of medicine also suggest guideline developers should focus more on the applicability (25). A common suggestion of the appraisers is also to report the methodology for the assembly of evidence used to develop the guideline (29) and better and more detailed reporting on the process of guideline development in general (26).

The second highest scoring were the Prehospital US Guidelines. Their high score in the domains of Editorial Independence and Stakeholder Involvement is due to the fact of involving also other than health care professionals (such as representatives of city fire department and US Department of Transportation) in the guideline development.

Process of development of all appraised guidelines was evaluated by high points, with the exception of the tool for updating the guidelines.

Within the Clarity and Presentation domain, the Penetrating US Guidelines scored low in the item evaluating if the guideline is being supported by tools for application. The UK guidelines have information about brain trauma for the public as well as suggested written discharge advice cards for people after traumatic brain injury. The Prehospital US guidelines have an Algorithm for Prehospital Assessment. All the widely used TBI guidelines had rigorously appraised the evidence. The UK guidelines scored highest due to greater stakeholder involvement which should be a part of all future guideline development. Consideration of applicability is also important for the future.

Conclusions

In comparison with other studies of the quality of guidelines appraised by the AGREE instrument, the evaluated brain trauma management guidelines scored well and are recommended for use in practice. For new guidelines for traumatic brain injury treatment it is recommended to include broad spectrum of the stakeholders in the process of development and consider the potential organizational and financial barriers for the application of the guidelines.

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