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# CRITICAL EVALUATION OF THE EXISTING GUIDELINES ON MILD TRAUMATIC BRAIN INJURY

Paul M. Peloso,[1] Linda J. Carroll,[2] J. David Cassidy,[2,3,4] Jörgen Borg,[5] Hans von Holst,[6] Lena Holm[4] and David Yates[7]

*From the [1]Department of Internal Medicine, University of Iowa Health Center, Iowa City, Iowa, USA, [2]Alberta Centre for Injury Control and Research, Department of Public Health Sciences, University of Alberta, Edmonton, Alberta, Canada, [3]Department of Medicine, University of Alberta, Edmonton, Alberta, Canada, [4]Section for Personal Injury Prevention, Department of Clinical Neurosciences, Karolinska Institutet, Stockholm, Sweden, [5]Department Neuroscience, Rehabilitation Medicine, Uppsala University, Uppsala, Sweden, [6]Department of Neurosurgery, Karolinska Institutet, Stockholm, Swede, [7]Emergency Department, Hope Hospital, University of Manchester, Manchester, UK*

**The purpose of guidelines is to reduce practice variability, but they need to be evidence-based. We examine current mild traumatic brain injury guidelines, critique their basis in evidence and examine their variability in recommendations. A systematic search of the literature found 38,806 abstracts, with 41 guidelines. There were 18 sports-related guidelines, 13 related to admission policies, 12 related to imaging and 5 related to neuropsychological assessment. Some guidelines addressed several areas. Only 5 guidelines reported a methodology for the assembly of evidence used to develop the guideline. After appraising the guidelines against a validated index, we found that 3 of the 41 guidelines could be categorized as evidence-based. Two of these focused on paediatric patients and 1 on adult patients. Limited methodological quality in the current guidelines results in conflicting recommendations amongst them.**

*Key words:* guidelines, mild traumatic brain injury, critical appraisal, evidence-based medicine.

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*Correspondence address: Paul M. Peloso, University of Iowa Health Care, Room E 330 GH, 200 Hawkins Drive, Iowa City, IA, 52242, USA.*
*E-mail: paul-peloso@uiowa.edu*

## INTRODUCTION

Mild traumatic brain injury (MD) is a common condition, with significant variability in its medical management. Evidence-based guidelines are important tools in reducing practice variability and improving care. Guidelines have been described as systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific circumstances (1). To be useful, clinical practice recommendations should be practical and should address the consequences, both positive and negative, of following the recommendations. In addition, the strength of the recommendations should be clearly linked to the strength of the evidence used in developing the recommendations (2, 3). Thus guidelines ought to contain carefully developed statements that result from a systematic search of the literature, a critical evaluation of that literature, and recommendations based on the evidence found.

The aim of this paper is to provide a description and critical appraisal of existing MTBI guidelines. We also contrast recommendations across the guidelines.

## METHODS

### *Search for MTBI guidelines*

The WHO Collaborating Centre Task Force on MTBI performed a comprehensive systematic search of the world literature on MTBI, the details of which are documented elsewhere (4). Briefly, Medline and PsycInfo were searched from 1980 to 2000, Cinahal from 1982 to 2000 and Embase from 1988 to 2000. Indexed thesaurus terms (e.g. Medical Subject Headings for Medline) and text words, such as concussion, mild brain/head injury and others were used to search these databases to ensure that all relevant articles were captured. Inclusion/exclusion criteria were then applied to screen the retrieved abstracts for relevance to the mandate of the task force (5). These criteria include studies that refer to concussion and/or MTBI, or criteria that would indicate concussion or MTBI, and studies that include data on more than 10 subjects with concussion or MTBI (with the exception of rare complications such as second impact syndrome). We excluded studies on penetrating brain injuries, brain damage due to birth trauma, shaken-baby syndrome, or other cerebrovascular events. Also excluded were narrative reviews, editorials and letters without data, animal studies, cadaver studies and biomechanical simulation studies. Where guidelines were reported in several different periodicals or other forums with varying degree of detail, we selected the version with the most detailed description of its development. All distinct guidelines were appraised for quality.

### *Criteria for assessing methodological quality*

We followed 2 procedures for evaluating the quality of the guidelines. Those guidelines that described a methodology for assembling the evidence that was used for their development were subjected to a detailed critical review, using *a priori* criteria for scientific rigour. These criteria have been applied in similar work undertaken in the past (6–8). As detailed in Carroll et al. (4), the scientific merit and biases of each paper were considered, and the final decision on scientific admissibility was made by group consensus, based on the quality of the work.

At the time the task force began its work, there were no uniformly accepted criteria to judge methodological rigour of guidelines. Therefore, we developed a set of methodological criteria that allowed us to probe scientific quality, based on standard textbooks on evidence-based medicine and expert opinion on important aspects of guideline development (3, 9–13). The guidelines reporting a methodology for assembling evidence were subjected to this full review, and those guidelines judged as scientifically acceptable are included in our best-evidence synthesis.

Secondly, all guidelines found in our search were assessed against a

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validated index, even if they did not report their methodology in sufficient detail to permit a critical review of that methodology. The goal in using this checklist index was to identify areas of methodological deficiency in current MTBI guidelines. We used an index developed by Shaneyfelt et al. (14) in 1999, which is a checklist with 3 domains including, methodological standards on guideline development and format (10 items), methodological standards on evidence identification and summary (10 items) and methodological standards on formulation of recommendations (5 items). To this list of 25 items, we added 1 item that assesses whether the limitations of the primary data were discussed by the guideline developers. These 26 items are listed in Table I. Items that are present are scored as a "Yes", while absent or ambiguous items are scored as a "No".

## RESULTS

The search strategy identified 38,806 citations (4), of which 41 were distinct guidelines. Eighteen guidelines focused on sports (15–32), 13 on hospital admission policies (33–45), 12 on radiological imaging (35–39, 41–43, 45–48), 5 on neuropsychological assessment (35, 41, 47, 49, 50), and 2 on management of children with MTBI (51, 52). Several guidelines addressed more than 1 area.

### *Results of our critical review*

Of the 41 guidelines, only 5 used a search strategy to find primary studies and could be subjected to detailed critical review. Of these 5, only 3 were judged to be methodologically sound (43, 51, 52). These are guidelines for diagnostic imaging and subsequent management of adults and children with MTBI, and are included in a best-evidence synthesis on diagnostic studies (53). Of these, only the guideline relating to management of adults is based on sufficient evidence to consider it to be evidence-based. The paucity of evidence available to formulate guidelines for diagnostic imaging and management of children with MTBI means that, although these 2 guidelines were developed in a methodologically rigorous fashion, the recommendations are based primarily on expert opinion, rather than strong empirical evidence.

### *Checklist criteria met by existing guidelines*

We evaluated how many of the 26 criteria were met by each of the guidelines, and, in addition, how many criteria in each of the 3 domains (development and format, evidence identification, and formulation of recommendations) were met (Tables II–V and Fig. 1). The median number of criteria met across all 26 questions was 8, with a minimum of 3 and maximum of 22 (interquartile range of 6–12). Only 3 guidelines met at least 18 of the criteria, with the 2 paediatric guidelines each meeting 22 and the 1 guideline related to management of adults with MTBI meeting 18 of the 26 criteria.

As shown in Fig. 1 and Table III, the criteria related to development and format were most adequately met. The median number of criteria met in this category was 6 out of 10, although some guidelines met only 2 out of the 10 criteria. As Fig. 1 shows, the least often met criteria related to identifying the principal diagnostic and therapeutic choices (item 7), the

Table I. *Criteria for evaluating guidelines on mild traumatic brain injury*

| Criterion | Type |
|---|---|
| 1. Purpose of the guideline is specified | D |
| 2. Rationale and importance of the guidelines explained | D |
| 3. The participants in the guideline development and their expertise are specified | D |
| 4. Targeted health problem is clearly defined | D |
| 5. Targeted patient population is identified | D |
| 6. Intended audience or users of the guideline are specified | D |
| 7. The principal preventive, diagnostic, and therapeutic choices available to clinicians and patients are specified. | D |
| 8. Health outcomes are specified | D |
| 9. The method by which the guideline underwent peer review is identified | D |
| 10. An expiry date is specified | D |
| 11. The method of identifying scientific data is specified | I |
| 12. The time period from which the evidence is gathered is specified | I |
| 13. The evidence used is referenced by citation | I |
| 14. Method of data extraction is specified | I |
| 15. Method of grading or classifying studies specified | I |
| 16. Formal methods of combining scientific studies and expert opinion are specified | I |
| 17. Benefits or harms of health practices are specified | I |
| 18. Benefits and harms are quantified | I |
| 19. The effect on healthcare costs from adopting a specific practice is specified | I |
| 20. Costs are quantified | I |
| 21. The role of value judgements used by the guideline developers in making the recommendations is discussed | F |
| 22. The role of patient preferences is discussed | F |
| 23. Recommendations are specific and apply to the stated goal of the guideline | F |
| 24. Limitations and completeness of available data is discussed | F[1] |
| 25. Recommendations are graded according to the strength of the evidence | F |
| 26. Flexibility in the recommendations is specified. | F |

D = criteria on Guideline Development and Format; I = criteria on Evidence Identification and Summary; F = criteria on Formulation of Recommendations (F)
[1]Criterion 24 was added by our task force.

Table II. *Methodological rigour of mild traumatic brain injury guidelines*

| Guideline type | Median (IQR) 26 criteria | Minimum – maximum | Mean (SD) 26 criteria | Number evidence-based |
|---|---|---|---|---|
| Sports ($n = 18$) | 8 (6–11) | 4–14 | 8.3 (3.0) | 0 |
| Admission ($n = 13$) | 8 (7–11) | 4–18 | 8.5 (3.0) | 1 |
| Imaging ($n = 12$) | 7.5 (7–9) | 4–18 | 8.1 (2.5) | 1 |
| Neuropsychology ($n = 5$) | 8 (7–9) | 6–11 | 8.2 (1.9) | 0 |
| Paediatrics ($n = 2$) | 22 | 22–22 | 22 (0.0) | 2 |
| Overall ($n = 41$) | 8 (6–12) | 4–22 | 8.8 (3.8) | 3 |

IQR = interquartile range; SD = standard deviation.

Table III. *Development and format criteria*

| Guideline type | Median IQR 10 criteria | Minimum – maximum | Mean (SD) 10 criteria |
|---|---|---|---|
| Sports ($n = 18$) | 7 (3–8) | 2–8 | 6.2 (1.9) |
| Admission ($n = 13$) | 6 (4–7) | 3–8 | 5.5 (1.4) |
| Imaging ($n = 12$) | 6 (5–7) | 4–8 | 5.8 (1.2) |
| Neuropsychology ($n = 5$) | 6 (5–7) | 4–7 | 6.0 (1.0) |
| Pediatrics ($n = 2$) | 9 | 9–9 | 9.0 (0.0) |
| Overall ($n = 41$) | 6 (3–5) | 3–9 | 6.1 (1.6) |

IQR = interquartile range; SD = standard deviation.

Table IV. *Evidence identification and summary criteria*

| Guideline type | Median (IQR) 10 criteria | Minimum – Maximum | Mean (SD) 10 criteria |
|---|---|---|---|
| Sports ($n = 18$) | 0 (0–1) | 0–4 | 0.7 (1.1) |
| Admission ($n = 13$) | 1 (1–4) | 1–7 | 2.2 (2.5) |
| Imaging ($n = 12$) | 0 (1–4) | 0–7 | 1.7 (2.4) |
| Neuropsychology ($n = 5$) | 0 (0–0) | 0–4 | 0.8 (1.8) |
| Paediatrics ($n = 2$) | 8 | 8–8 | 8.0 (0.0) |
| Overall ($n = 41$) | 1 (0–2) | 0–8 | 1.6 (2.4) |

IQR = interquartile range; SD = standard deviation.

Table V. *Formulation of recommendations criteria*

| Guideline type | Median (IQR) 6 criteria | Minimum – Maximum | Mean (SD) 6 criteria |
|---|---|---|---|
| Sports ($n = 18$) | 1 (1–2) | 0–3 | 1.5 (0.9) |
| Admission ($n = 13$) | 1 (1–2) | 0–5 | 1.5 (0.8) |
| Imaging ($n = 12$) | 1 (1–3) | 0–3 | 1.5 (1.1) |
| Neuropsychology ($n = 5$) | 1 (1–2) | 1–3 | 1.4 (0.5) |
| Paediatrics ($n = 2$) | 5 (5–5) | 5–5 | 5.0 (0.0) |
| Overall ($n = 41$) | 1 (1–3) | 0–6 | 1.6 (1.1) |

IQR = interquartile range; SD = standard deviation.

method by which the guideline underwent peer review (item 9) and the expiration date (item 10). In fact, no guideline reported an expiration date.

In contrast to questions on development and format, the 10 criteria that relate to evidence identification were rarely met, and no criteria was met by more than 30% of the guidelines (Fig. 1). The median number of criteria met in this domain was 1; and of the sports, radiological imaging, and neuropsychology guidelines, the median number of criteria met in this domain was zero (Table IV). Twenty-eight of the 41 guidelines (68%) did not meet any of the criteria for identification of the evidence. In particular, the methods used for identifying scientific data, for grading or classifying evidence, for combining scientific studies and expert opinion, and the effects on healthcare costs from adopting a specific practice were almost never reported.

The 6 criteria that relate to formulation of recommendations were also poorly met, with a median score of 1 out of 6 (Table V). These guidelines rarely reported on the role of value judgements by the developers, considered patient preferences, considered the limitations and completeness of the available evidence, graded recommendations according to the strength of the evidence, or addressed the role of flexibility in the

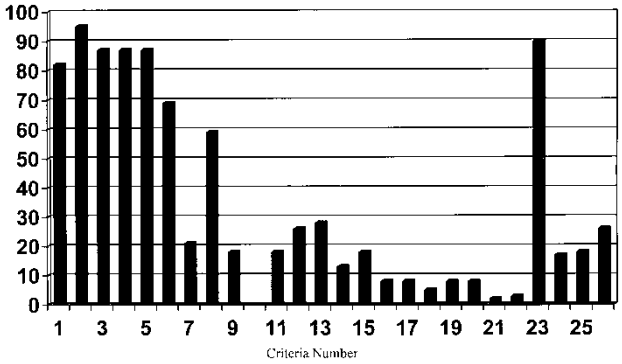


*Fig. 1.* Percentage of guidelines meeting individual methodological criteria.

recommendations being specified (items 21–22, 24–26) The items that were most commonly missing included items 21, 22, 24, 25 and 26. However, most guidelines made specific recommendations that apply to the stated goals of the guideline (Fig. 1).

While no relationship between year of publication and final quality scores for the full 26 criteria was found, recent guidelines were more likely to have met the criteria related to identification of evidence. To be considered an evidence-based guideline, it should be expected that the guideline developers would address at least the following 3 issues: perform a systematic search for the evidence, grade the quality of the evidence, and link their recommendations to the evidence. This was the case in only 3 of the 41 guidelines found.

*Consistency of recommendations across guidelines*

*Sports guidelines.* Recent sports guidelines have highlighted the lack of an evidence base in the prior guidelines, and point out the need for high-quality primary studies to provide the evidence base for sports-related MTBI (16). Given this lack of evidence, it is not surprising that sports recommendations vary widely, since expert opinions are likely to vary widely.

The current sports guidelines do not suggest a standard method of grading MTBI severity during sports competition. While some approaches highlight the importance of loss of consciousness (LOC) (22, 24), others recommend including post-traumatic amnesia (PTA) as a marker of severity (18), while others suggest that symptoms are also important (16).

There is also variability in recommendations on return to play after MTBI. Several guidelines suggest that the athlete's symptoms are important (16, 25, 54). Most guidelines recommend complete cessation of symptoms before return-to-play. However this recommendation is not based on evidence of harm in those who continue to play with persistent symptoms (55), nor is it based on evidence of lack of harm in athletes who play after their symptoms have completely resolved.

Given this lack of an evidence base, there is also variability in recommendations about an athlete's career and the number of concussions that an athlete can sustain. Two writers have been instrumental in creating awareness of the need for guidelines in sports (20–22, 26, 56–58) and in developing the framework for such guidelines. A Citation Index evaluation on these 2 authors disclosed more than 100 articles citing their influence. Their contribution has been essential in highlighting the importance of sports-related brain injuries. The challenge now is to create both the evidence base for high quality guidelines, as well as high quality, evidence-based guidelines.

*Hospital admission policies.* Thirteen guideline articles addressed admission policies for adults (33–45). Only 1 of these was evidence based and deemed of high quality by the task force (43). This guideline used a systematic search strategy, graded the evidence and made evidence-based recommendations for adults presenting to the emergency department with a Glasgow Coma Scale (GCS) of 15. The authors of this guideline highlight the variability in recommendations about assessment and hospital admission after MTBI seen in non-evidence based guidelines. For example, some guidelines suggest that any LOC is reason to admit patients to hospital (33, 34, 36, 38, 39, 41, 44). Others recommend that individuals with LOC less than 15 minutes could be observed for several hours and then sent home if there is no deterioration (40, 45). Others recommend a (computerized tomography) CT scan and a decision to admit based on CT scan result (35, 42).

However, there is consensus among these guidelines that patients with MTBI with LOC, or are intoxicated, or have coexisting injuries or other important comorbidities, or are on warfarin, or do not have a reliable assessor to observe them at home, should be admitted (36–39, 41, 42, 44). All guidelines suggest that patients with skull fractures should be admitted. For individuals with a GCS 15 and no LOC, most guidelines suggest that decisions about admission to hospital should depend on non-head injury factors. The evidence-based guideline from the American College of Emergency Physicians (43), which grades their recommendations on a scale of A to C (with C being the weakest level of recommendations), outlines a grade C level recommendation that suggests that those individuals meeting the American College of Rehabilitation definition of MTBI and who have GCS 15 on presentation to the emergency department, a normal clinical examination, and a normal CT can be safely discharged from the emergency department. Our task force evaluated this guideline and found it had scientific merit, and therefore we have included it in our best-evidence synthesis and guidelines relating to hospital admission after MTBI (53).

*Guidelines on radiological imaging.* Twelve guidelines addressed the issue of radiological studies in MTBI (35–39, 41–43, 45–48). Only 1 of these was evidence based (43) and, as described in the previous section, addresses those individuals meeting the American College of Rehabilitation Medicine's definition of MTBI (59), and presenting to the emergency department with GCS of 15. This guideline concludes that skull films are not recommended for the evaluation of MTBI, because their sensitivity is not sufficient to be a useful screening test (Recommendation level B). In addition, the authors report that a head CT scan is not indicated in patients with MTBI without the

presence of clinical risk factors (Recommendation level A). Our guideline agrees with this approach, and we specifically propose the clinical risk factors that indicate the need for CT scan examination after acute MTBI (53).

The poor quality guidelines that deal with radiological imaging give variable recommendations concerning skull X-rays and CT scans. Some recommend skull radiographs for patients that are discharged home, to be certain a fracture has not been missed (33). Several recommend skull X-rays if there is any LOC or PTA (37, 41, 45, 48). More recent guidelines have favoured CT scans over skull radiographs for those with LOC (35, 36, 42, 46). However, there is variability in recommendations about whether CT scanning should be routine with hospital admission for those with abnormal clinical findings, or whether hospital admission should be routine with CT scanning for those who deteriorate. This controversy was highlighted by the recent report from the Swedish Council on Health Technology (60), which noted

> "Regardless of the treatment strategy, the risks for patients with minor head injury appear to be low, but potentially serious. No comparative studies on the two strategies are available. Such a study is essential. Furthermore, there are no larger studies on the ongoing course following minor head injury. Reliable information about the frequency and scope of late symptoms is needed, as is information about the social and economic consequences of potential residual conditions. It is also essential to investigate the extent to which the patient's recovery depends on the acute care strategy used."

Most guidelines agreed that individuals who are difficult to assess should undergo imaging studies. This includes individuals using alcohol, those with other injuries, those with comorbid medical problems, those on anti-coagulants and those lacking a reliable observer on discharge. Only the guideline from the American College of Radiology suggested that magnetic resonance imaging (MRI) is appropriate (46), and it suggests that MRI might be useful in those with focal neurological deficits on examination. However our task force did not find sufficient evidence to recommend MRI imaging in MTBI (53). Interestingly, no guidelines addressed the role of biochemical markers of brain injury, and we also did not find sufficient evidence to recommend their use (53).

*Neuropsychological evaluation.* There are no consistent recommendations across the 5 guidelines addressing neuropsychological testing. None of the 5 guidelines dealing with this were judged to be methodologically rigorous (35, 41, 47, 49, 50). The recommendations on timing of neuropsychological assessment are not uniform. One guideline recommends assessment whenever there is more than 5 minutes of LOC, more than 24 hours of PTA or more than 2 weeks of symptoms (49), whereas another recommends assessments in those who do not return to work after 1 week (41). One suggests that those with symptoms lasting more than 6 weeks be assessed (35), whereas 2 suggest that post-discharge testing may identify those at risk of a poor outcome (35, 50). Specific tests are not recommended, but there are consistent recommendations that attention/concentration, speed of information processing, and learning and memory should be assessed. All guidelines suggest that neuropsychological assessment can be of value in subjects with persistent complaints to outline deficits and provide advice on treatment plans, although the evidence supporting these views is not extensively outlined. Our task force found very little evidence suggesting the optimal role for neuropsychological testing (53). This is another area that requires more rigorous research.

*Paediatric guidelines.* There are 2 guidelines dedicated to management of children sustaining MTBI. Both guidelines meet 22 of the 26 quality assessment criteria (Table I) (51, 52). However, these guidelines are limited by the lack of empirical evidence in this area, and the recommendations in both guidelines are largely based on a consensus of expert opinions.

For children older than 2 years the published recommendations are separated into those with and without LOC (51). However, our task force found very limited evidence on the value of LOC and other clinical predictors of intracranial lesions in children (53). For those children under 2 years of age, 1 guideline divides patients into 4 categories of risk, and recommendations are based on these risk states (52). Once again, our task force did not find evidence to support this risk classification, or the subsequent recommendations based on these risk strata. Thus, although these 2 guidelines were developed in a systematic and methodologically sound manner, they are not really evidence-based because of the paucity of sound evidence available to formulate the recommendations.

## DISCUSSION

We found many common deficiencies across all the guidelines, with some elements of guideline development (14) to be more problematic than others (Fig. 1). Notably, 68% of the guidelines met none of the criteria relating to identification, grading and summarizing of the evidence used in the guideline development. Published guidelines also met the criteria relating to formulation of the guidelines infrequently. Guideline developers seldom provided descriptions of how developer judgement factored into recommendations, and patient preferences are rarely considered. However, we found that the more recent guidelines have somewhat greater methodological rigour with respect to identification of the sources of evidence and providing details about the processes used in their formulation.

Of the 41 guidelines uncovered in our search, only 5 described a search strategy. Of these 5, we judged only 3 as having been rigorously developed. However, despite the methodological rigour in their development, the formulation of recommendations in 2 of these guidelines relied heavily on expert opinion because of the paucity of empirical evidence. Therefore, these guidelines cannot be considered truly evidence-based. This underscores the need for high-quality studies in MTBI, a prerequisite for high-quality, evidence-based guidelines.

Given the lack of evidence used in formulating the majority of

the guidelines overall, predictably there was significant divergence in their recommendations. We found that, in the absence of clear evidence, experts frequently disagree. Clear, comprehensive, evidence-based guidelines dealing with MTBI are urgently needed.

None of the sports-related guidelines were evidence-based. Therefore, research in this area needs to be a priority. Likewise, there is considerable variation and uncertainty about the value of neuropsychological testing. Further research is necessary here as well. The area with the highest quality research, which is imaging and hospital admission policies in adults with GCS of 15, allows recommendations that are evidence-based, and our review of the evidence identified similar clinical risk factors for intracranial injury (43, 53). While our task force identified the paediatric guidelines (52, 51) as meeting our criteria for having been developed and reported in a methodologically sound manner, the evidence underpinning these guidelines is sparse and weak (53). Testing of clinical prediction rules proposed for children must also be a research priority.

It is important to iterate that our task force did not use a cut-off score to decide if guidelines were acceptable or not. This is consistent with the "best evidence synthesis" approach (61) and with past task forces (7, 8, 62). The use of the criteria by Shaneyfelt et al. (14) to judge guidelines was performed only to highlight methodological issues. Both approaches highlight the lack of an evidence basis for the majority of the currently available MTBI guidelines.

## CONCLUSION

Of 41 guidelines found in a systematic search of the MTBI literature, only 5 described a search strategy for assembling the evidence used to develop recommendations. Of these, only 3 were subsequently determined to be methodologically sound, and the recommendations in 2 of these were based primarily on expert opinion because the evidence was sparse and weak. In comparing all guidelines against a validated index (14), we found that most guidelines performed poorly. In general, criteria relating to guideline development and format, such as specifying the targeted patient population and purpose of the guideline, were most frequently met. However, criteria regarding identification and grading of evidence used to formulate the recommendations were seldom met. In addition, some otherwise methodologically sound guidelines were limited by the lack of available evidence.

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