資料6

評価結果（一覧）

2022/11/11 第5回がん診療ガイドライン評価委員会

十二指腸がん　癌診療ガイドライン 2021年版 第5版

＊ 7（強く同意）～1（強く不同意）

＊＊ 本委員会において2011/8/4以降に評価した69件のガイドラインの平均値

	項　目	評　価*	コメント	平均値**
DOMAIN 1. SCOPE AND PURPOSE				
1	The overall objective(s) of the guideline is (are) specifically described.	5	項目立てて記載されているのは大変結構ですが，より明確な記載をお願いします。	5.8
2	The health question(s) covered by the guideline is (are) specifically described.	5	希少がんなので限界もあると思いますが，「～は何か？」で終わるCQが多く，PICO形式が徹底されていないようです。PICO形式でのCQをご検討ください。	5.7
3	The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.	7	おそらく対象として「小児を意識されていない」と思われますので，P2にある「年齢を限定しない」という記載よりも，「小児を除く」と明示された方が，誤解を招かないのではないでしょうか。	5.5
DOMAIN 2. STAKEHOLDER INVOLVEMENT				
4	The guideline development group includes individuals from all relevant professional groups.	5	さまざまな職種の方が参加されています。それぞれの専門性をわかりやすく記載されるとよいでしょう。看護師や患者・家族の代表者の参画についても，ご検討ください。	4.9
5	The views and preferences of the target population (patients, public, etc.) have been sought.	5	患者のQOLについての記載が一部でみられます。希少疾患であり，遺伝相談，カウンセリングなどを含め，さらに患者の視点や意向などに配慮した記載を，増やしていただくようお願いします。	4.5
6	The target users of the guideline are clearly defined.	6	本ガイドラインは，その内容から専門医向けの印象を受けます。広く活用されるのは大変結構ですが，「すべての臨床医」を対象とするのであれば，それにあった配慮がさらに必要になると思います。	5.7
DOMAIN 3. RIGOUR OF DEVELOPMENT				
7	Systematic methods were used to search for evidence.	7	文献検索方法，検索期間，検索式等が丁寧に記載されています。	5.2
8	The criteria for selecting the evidence are clearly described.	5	文献検索式の詳細な記述があり，系統的な検索が行われたことが窺えます。一方で，エビデンスの採用基準に関する記載がないようです。	4.6
9	The strengths and limitations of the body of evidence are clearly described.	5	エビデンス総体を意識した記載がみられますが，より明確に記載されるとよいと思います。	4.8
10	The methods for formulating the recommendations are clearly described.	7	投票結果の記載はありますが，推奨の決定方法や過程について，より具体的な記載が望まれます。	5.4
11	The health benefits, side effects, and risks have been considered in formulating the recommendations.	5	エビデンスは少ないでしょうが，副作用やリスクに関してさらに検討され，記載を増やされるようお願いします。	5.5
12	There is an explicit link between the recommendations and the supporting evidence.	6	エビデンスの強さと推奨の強さは，概ね一致しているように思います。抽出された論文とエビデンスの強さの関連が，より詳細に記載されるとなおよいでしょう。	5.3
13	The guideline has been externally reviewed by experts prior to its publication.	2	パブリックコメントが行われた旨の記載がありますが，外部評価は行われていないようです。ぜひ外部評価を行っていただき，その結果や対応などについて，具体的な内容を追加記載されると良いでしょう。	5.1

	項 目	評 価*	コメント	平均値**
14	A procedure for updating the guideline is provided.	7	ガイドライン発刊後も委員会を残していただき，最新情報のアップデートを継続されるようお願いします。	5.1
DOMAIN 4. CLARITY OF PRESENTATION				
15	The recommendations are specific and unambiguous.	6	希少がんでありエビデンスは少なく，難しい面もあると思われますが，CQはPICO形式を徹底されると，より推奨が明確になります。	5.9
16	The different options for management of the condition or health issue are clearly presented.	6	アルゴリズムがあり，わかりやすく工夫されています。エビデンスは乏しく難しい面もあると思われますが，さらに充実を図ってください。	5.9
17	Key recommendations are easily identifiable.	7	CQや推奨を，わかりやすく一覧表にまとめてあります。さらに見やすくする工夫をお願いします。	5.9
DOMAIN 5. APPLICABILITY				
18	The guideline describes facilitators and barriers to its application.	5	CQ4-2では内視鏡治療について，術者や施設の条件についての言及があります。施設間格差や他科連携などについて，さらに記載の充実が望まれます。	4.9
19	The guideline provides advice and/or tools on how the recommendations can be put into practice.	5	CQ・推奨一覧があります。Web版公開など，さまざまなツールを作成いただき，積極的にご活用いただければ，さらによいでしょう。	5.3
20	The potential resource implications of applying the recommendations have been considered.	5	希少がんであり，保険適用がない治療法等もあるのではと思います。コストやリソースに関する記述を意識していただくとよいでしょう。	4.6
21	The guideline presents monitoring and/or auditing criteria.	4	Quality indicatorなど診療プロセスのモニタリングに必要な項目があれば，次回改訂に際し対応してください。	4.1
DOMAIN 6. EDITORIAL INDEPENDENCE				
22	The views of the funding body have not influenced the content of the guideline.	6	資金源の記載はありますが，独立性についても言及してください。	5.3
23	Competing interests of guideline development group members have been recorded and addressed.	7		5.5
OVERALL GUIDELINE ASSESSMENT				
1	Rate the overall quality of this guideline.	6		5.2
2	I would recommend this guideline for use.	Yes with modifications		
	Notes	希少がんであり，エビデンスの乏しい領域にもかかわらず，丁寧に作られていると思います。各アイテムへのコメントに加え，評価委員会で上がったいくつかの点について追記します。1）CQについて：困難とは思いますが，よりPICO 形式を意識されたCQを作成いただければと思われました。2）構成メンバーについて：方法論の専門家がいらっしゃるのは大変結構です。医師以外の医療職の参加も，検討されると良いでしょう。3）評価委員よりの意見：家族性大腸腺腫症，リンチ症候群を背景とした十二指腸がんについて，これらについての対応（フォローアップを含む）を記したCQがあると良いのでは，という意見が出ました。	

DOMAIN 1. SCOPE AND PURPOSE

1. The overall objective(s) of the guideline is (are) specifically described.

評　価	5	（5.8）	7（強く同意）～1（強く不同意） 括弧内の数字は本委員会において2011/8/4以降に評価した69件のガイドラインの平均値

コメント	項目立てて記載されているのは大変結構ですが，より明確な記載をお願いします。

User's Manual Description:

This deals with the potential health impact of a guideline on society and populations of patients or individuals. The overall objective(s) of the guideline should be described in detail and the expected health benefits from the guideline should be specific to the clinical problem or health topic. For example, specific statements would be:

- Preventing (long term) complications of patients with diabetes mellitus
- Lowering the risk of subsequent vascular events in patients with previous myocardial infarction
- Most effective population-based colorectal screening strategies
- Providing guidance on the most effective therapeutic treatment and management of patients with diabetes mellitus.

Where to Look:

Examine the opening paragraphs/chapters for a description of the scope and purpose of the guideline. In some cases, the rationale or need for the guideline is described in a document separate from the guideline, for instance, in the guideline proposal. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: introduction, scope, purpose, rationale, background, and objectives.

How to Rate:

Item content includes the following CRITERIA:

- health intent(s) (i.e., prevention, screening, diagnosis, treatment, etc.)
- expected benefit or outcome
- target(s) (e.g., patient population, society)

Additional CONSIDERATIONS:

- Is the item well written? Are the descriptions clear and concise?
- Is the item content easy to find in the guideline?

DOMAIN 1. SCOPE AND PURPOSE

2. The health question(s) covered by the guideline is (are) specifically described.

評　価	5	（ 5.7 ）	7（強く同意）～1（強く不同意） 括弧内の数字は本委員会において2011/8/4以降に評価した69件のガイドラインの平均値

コメント	希少がんなので限界もあると思いますが，「～は何か？」で終わるCQが多く，PICO形式が徹底されていないようです。PICO形式でのCQをご検討ください。

User's Manual Description:

A detailed description of the health questions covered by the guideline should be provided, particularly for the key recommendations (see Item 17), although they need not be phrased as questions. Following the examples provided in question 1:

- How many times a year should the HbA1c be measured in patients with diabetes mellitus?
- What should the daily aspirin dosage for patients with proven acute myocardial infarction be?
- Does population-based colorectal screening using the fecal occult blood test reduce mortality of colorectal cancer?
- Is self-monitoring effective for blood glucose control in patients with Type 2 diabetes?

Where to Look:

Examine the opening paragraphs/chapters for a description of the scope and purpose of the guideline. In some cases, the questions are described in a document separate from the guideline, for instance in a search specification. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: questions, scope, purpose, rationale, and background.

How to Rate:

Item content includes the following CRITERIA:

- target population
- intervention(s) or exposure(s)
- comparisons (if appropriate)
- outcome(s)
- health care setting or context

Additional CONSIDERATIONS:

- Is the item well written? Are the descriptions clear and concise?
- Is the item content easy to find in the guideline?
- Is there enough information provided in the question(s) for anyone to initiate the development of a guideline on this topic or to understand the patients/populations and contexts profiled in the guideline?

DOMAIN 1. SCOPE AND PURPOSE

3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.

評　価	7	（ 5.5 ）	7（強く同意）～1（強く不同意） 括弧内の数字は本委員会において2011/8/4以降に評価した69件のガイドラインの平均値

コメント	おそらく対象として「小児を意識されていない」と思われますので，P2にある「年齢を限定しない」という記載よりも，「小児を除く」と明示された方が，誤解を招かないのではないでしょうか。

User's Manual Description:

A clear description of the population (i.e., patients, public, etc.) covered by a guideline should be provided. The age range, sex, clinical description, and comorbidity may be provided. For example:

• A guideline on the management of diabetes mellitus only includes patients with non-insulin dependent diabetes mellitus and excludes patients with cardiovascular comorbidity.

• A guideline on the management of depression only includes patients with major depression according to the DSM-IV criteria, and excludes patients with psychotic symptoms and children.

• A guideline on screening of breast cancer only includes women, aged between 50 and 70 years, with no history of cancer and with no family history of breast cancer.

Where to Look:

Examine the opening paragraphs/chapters for a description of the target population of the guideline. The explicit exclusion of some populations (for instance children) is also covered by this item. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: patient population, target population, relevant patients, scope, and purpose.

How to Rate:

Item content includes the following CRITERIA:

• target population, gender and age
• clinical condition (if relevant)
• severity/stage of disease (if relevant)
• comorbidities (if relevant)
• excluded populations (if relevant)

Additional CONSIDERATIONS:

• Is the item well written? Are the descriptions clear and concise?
• Is the item content easy to find in the guideline?
• Is the population information specific enough so that the correct and eligible individuals would receive the action recommended in the guideline?

DOMAIN 2. STAKEHOLDER INVOLVEMENT

4. The guideline development group includes individuals from all relevant professional groups.

評　価	5

（ 4.9 ）　7（強く同意）～1（強く不同意）
括弧内の数字は本委員会において2011/8/4以降に評価した69件のガイドラインの平均値

コメント	さまざまな職種の方が参加されています。それぞれの専門性をわかりやすく記載されるとよいでしょう。看護師や患者・家族の代表者の参画についても，ご検討ください。

User's Manual Description:

This item refers to the professionals who were involved at some stage of the development process. This may include members of the steering group, the research team involved in selecting and reviewing/rating the evidence and individuals involved in formulating the final recommendations. This item excludes individuals who have externally reviewed the guideline (see Item 13). This item excludes target population representation (see Item 5). Information about the composition, discipline, and relevant expertise of the guideline development group should be provided.

Where to Look:

Examine the opening paragraphs/chapters, acknowledgement section or appendices for the composition of the guideline development group. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: methods, guideline panel member list, acknowledgements, and appendices.

How to Rate:

Item content includes the following CRITERIA:

*For each member of the guideline development group, the following information is included:

- name
- discipline/content expertise (e.g., neurosurgeon, methodologist)
- institution (e.g., St. Peter's hospital)
- geographical location (e.g., Seattle, WA)
- a description of the member's role in the guideline development group

Additional CONSIDERATIONS:

• Is the item well written? Are the descriptions clear and concise?
• Is the item content easy to find in the guideline?
• Are the members an appropriate match for the topic and scope? Potential candidates include relevant clinicians, content experts, researchers, policy makers, clinical administrators, and funders.
• Is there at least one methodology expert included in the development group (e.g., systematic review expert, epidemiologist, statistician, library scientist, etc.)?

DOMAIN 2. STAKEHOLDER INVOLVEMENT

5. The views and preferences of the target population (patients, public, etc.) have been sought.

評　価	5	（ 4.5 ）	7（強く同意）～1（強く不同意） 括弧内の数字は本委員会において2011/8/4以降に評価した69件のガイドラインの平均値

コメント	患者のQOLについての記載が一部でみられます。希少疾患であり，遺伝相談，カウンセリングなどを含め，さらに患者の視点や意向などに配慮した記載を，増やしていただくようお願いします。

User's Manual Description:

Information about target population experiences and expectations of health care should inform the development of guidelines. There are various methods for ensuring that these perspectives inform the different stages of guideline development by stakeholders. For example, formal consultations with patients/public to determine priority topics, participation of these stakeholders on the guideline development group, or external review by these stakeholders on draft documents. Alternatively, information could be obtained from interviews of these stakeholders or from literature reviews of patient/public values, preferences or experiences. There should be evidence that some process has taken place and that stakeholders' views have been considered.

Where to Look:

Examine the paragraphs on the guideline development process. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: scope, methods, guideline panel member list, external review, and target population perspectives.

How to Rate:

Item content includes the following CRITERIA:

• statement of type of strategy used to capture patients'/public's' views and preferences (e.g., participation in the guideline development group, literature review of values and preferences)
• methods by which preferences and views were sought (e.g., evidence from literature, surveys, focus groups)
• outcomes/information gathered on patient/public information
• description of how the information gathered was used to inform the guideline development process and/or formation of the recommendations

Additional CONSIDERATIONS:

• Is the item well written? Are the descriptions clear and concise?
• Is the item content easy to find in the guideline?

DOMAIN 2. STAKEHOLDER INVOLVEMENT

6. The target users of the guideline are clearly defined.

評　価	6	（ 5.7 ）	7（強く同意）～1（強く不同意） 括弧内の数字は本委員会において2011/8/4以降に評価した69件のガイドラインの平均値

コメント	本ガイドラインは，その内容から専門医向けの印象を受けます。広く活用されるのは大変結構ですが，「すべての臨床医」を対象とするのであれば，それにあった配慮がさらに必要になると思います。

User's Manual Description:

The target users should be clearly defined in the guideline, so the reader can immediately determine if the guideline is relevant to them. For example, the target users for a guideline on low back pain may include general practitioners, neurologists, orthopaedic surgeons, rheumatologists, and physiotherapists.

Where to Look:

Examine the opening paragraphs/chapters for a description of the target users of the guideline. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: target user and intended user.

How to Rate:

Item content includes the following CRITERIA:

• clear description of intended guideline audience (e.g. specialists, family physicians, patients, clinical or institutional leaders/administrators)
• description of how the guideline may be used by its target audience (e.g., to inform clinical decisions, to inform policy, to inform standards of care)

Additional CONSIDERATIONS:

• Is the item well written? Are the descriptions clear and concise?
• Is the item content easy to find in the guideline?
• Are the target users appropriate for the scope of the guideline?

DOMAIN 3. RIGOUR OF DEVELOPMENT

7. Systematic methods were used to search for evidence.

評　価	7	（ 5.2 ）	7（強く同意）～1（強く不同意） 括弧内の数字は本委員会において2011/8/4以降に評価した69件のガイドラインの平均値

コメント	文献検索方法，検索期間，検索式等が丁寧に記載されています。

User's Manual Description:

Details of the strategy used to search for evidence should be provided including search terms used, sources consulted, and dates of the literature covered. Sources may include electronic databases (e.g. MEDLINE, EMBASE, CINAHL), databases of systematic reviews (e.g. the Cochrane Library, DARE), handsearching journals, reviewing conference proceedings, and other guidelines (e.g. the US National Guideline Clearinghouse, the German Guidelines Clearinghouse). The search strategy should be as comprehensive as possible and executed in a manner free from potential biases and sufficiently detailed to be replicated.

Where to Look:

Examine the paragraphs/chapters describing the guideline development process. In some cases the search strategies are described in separate documents or in an appendix to the guideline. Examples of commonly labelled sections or chapters in a guideline where this information can be found include: methods, literature search strategy, and appendices.

How to Rate:

Item content includes the following CRITERIA:

• named electronic database(s) or evidence source(s) where the search was performed (e.g., MEDLINE, EMBASE, PsychINFO, CINAHL)
• time periods searched (e.g., January 1, 2004 to March 31, 2008)
• search terms used (e.g., text words, indexing terms, subheadings)
• full search strategy included (e.g., possibly located in appendix)

Additional CONSIDERATIONS:

• Is the item well written? Are the descriptions clear and concise?
• Is the item content easy to find in the guideline?
• Is the search relevant and appropriate to answer the health question? (e.g., all relevant databases and, appropriate search terms used)
• Is there enough information provided for anyone to replicate the search?

DOMAIN 3. RIGOUR OF DEVELOPMENT

8. The criteria for selecting the evidence are clearly described.

評　価	5

（ 4.6 ）

7（強く同意）～1（強く不同意）
括弧内の数字は本委員会において2011/8/4以降に評価した69件のガイドラインの平均値

コメント	文献検索式の詳細な記述があり，系統的な検索が行われたことが窺えます。一方で，エビデンスの採用基準に関する記載がないようです。

User's Manual Description:

Criteria for including/excluding evidence identified by the search should be provided. These criteria should be explicitly described and reasons for including and excluding evidence should be clearly stated. For example, guideline authors may decide to only include evidence from randomized clinical trials and to exclude articles not written in English.

Where to Look:

Examine the paragraphs/chapters describing the guideline development process. In some cases, the inclusion or exclusion criteria for selecting the evidence are described in separate documents or in an Appendix to the guideline. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: methods, literature search, inclusion/exclusion criteria, and appendices.

How to Rate:

Item content includes the following CRITERIA:

* description of the inclusion criteria, including
• target population (patient, public, etc.) characteristics
• study design
• comparisons (if relevant)
• outcomes
• language (if relevant)
• context (if relevant)
* description of the exclusion criteria (if relevant; e.g., French only listed in the inclusion criteria statement could logically preclude non-French listed in the exclusion criteria statement)

Additional CONSIDERATIONS:

• Is the item well written? Are the descriptions clear and concise?
• Is the item content easy to find in the guideline?
• Is there a rationale given for the chosen inclusion/exclusion criteria?
• Do inclusion/exclusion criteria align with the health question(s)?
• Are there reasons to believe that relevant literature may not have been considered?

DOMAIN 3. RIGOUR OF DEVELOPMENT

9. The strengths and limitations of the body of evidence are clearly described.

評　価	5

（ 4.8 ）

7（強く同意）～1（強く不同意）
括弧内の数字は本委員会において2011/8/4以降に評価した69件のガイドラインの平均値

コメント	エビデンス総体を意識した記載がみられますが，より明確に記載されるとよいと思います。

User's Manual Description:

Statements highlighting the strengths and limitations of the evidence should be provided. This ought to include explicit descriptions - using informal or formal tools/methods - to assess and describe the risk of bias for individual studies and/or for specific outcomes and/or explicit commentary of the body of evidence aggregated across all studies. This may be presented in different ways, for example: using tables commenting on different quality domains; the application of a formal instrument or strategy (e.g., Jadad scale, GRADE method); or descriptions in the text.

Where to Look:

Examine the paragraphs/chapters describing the guideline development process for information on how the methodological quality of the studies (e.g., risk of bias) were described. Evidence tables are often used to summarize quality features. Some guidelines make a clear distinction between description and interpretation of evidence, for instance, in a results section and a discussion section, respectively.

How to Rate:

Item content includes the following CRITERIA:

* descriptions of how the body of evidence was evaluated for bias and how it was interpreted by members of the guideline development group
* aspects upon which to frame descriptions include:
- study design(s) included in body of evidence
- study methodology limitations (sampling, blinding, allocation concealment, analytical methods)
- appropriateness/relevance of primary and secondary outcomes considered
- consistency of results across studies
- direction of results across studies
- magnitude of benefit versus magnitude of harm
- applicability to practice context

Additional CONSIDERATIONS:

- Is the item well written? Are the descriptions clear and concise?
- Is the item content easy to find in the guideline?
- Are the descriptions appropriate, neutral, and unbiased? Are the descriptions complete?

DOMAIN 3. RIGOUR OF DEVELOPMENT

10. The methods for formulating the recommendations are clearly described.

評　価	7	（5.4）	7（強く同意）～1（強く不同意） 括弧内の数字は本委員会において2011/8/4以降に評価した69件のガイドラインの平均値

コメント	投票結果の記載はありますが，推奨の決定方法や過程について，より具体的な記載が望まれます。

User's Manual Description:

A description of the methods used to formulate the recommendations and how final decisions were arrived at should be provided. For example, methods may include a voting system, informal consensus, and formal consensus techniques (e.g., Delphi, Glaser techniques). Areas of disagreement and methods of resolving them should be specified.

Where to Look:

Examine the paragraphs/chapters describing the guideline development process. In some cases, the methods used to formulate the recommendations are described in separate documents or in an appendix to the guideline. Examples of commonly labeled sections or chapters in a guideline where this information can be found include methods and guideline development process.

How to Rate:

Item content includes the following CRITERIA:

• description of the recommendation development process (e.g., steps used in modified Delphi technique, voting procedures that were considered)
• outcomes of the recommendation development process (e.g., extent to which consensus was reached using modified Delphi technique, outcome of voting procedures)
• description of how the process influenced the recommendations (e.g., results of Delphi technique influence final recommendation, alignment with recommendations and the final vote)

Additional CONSIDERATIONS:

• Is the item well written? Are the descriptions clear and concise?
• Is the item content easy to find in the guideline?
• Was a formal process used to arrive at the recommendations?
• Were the methods appropriate?

DOMAIN 3. RIGOUR OF DEVELOPMENT

11. The health benefits, side effects, and risks have been considered in formulating the recommendations.

評　価	5

（ 5.5 ）

7（強く同意）～1（強く不同意）
括弧内の数字は本委員会において2011/8/4以降に評価した69件のガイドラインの平均値

コメント	エビデンスは少ないでしょうが，副作用やリスクに関してさらに検討され，記載を増やされるようお願いします。

User's Manual Description:

The guideline should consider health benefits, side effects, and risks when formulating the recommendations. For example, a guideline on the management of breast cancer may include a discussion on the overall effects on various final outcomes. These may include: survival, quality of life, adverse effects, and symptom management or a discussion comparing one treatment option to another. There should be evidence that these issues have been addressed.

Where to Look:

Examine the paragraphs/chapters describing the guideline development process for a description of the body of evidence, its interpretation, and the translation to practice recommendations. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: methods, interpretation, discussion, and recommendations.

How to Rate:

Item content includes the following CRITERIA:

• supporting data and report of benefits
• supporting data and report of harms/side effects/risks
• reporting of the balance/trade-off between benefits and harms/side effects/risks
• recommendations reflect considerations of both benefits and harms/side effects/risks

Additional CONSIDERATIONS:

• Is the item well written? Are the descriptions clear and concise?
• Is the item content easy to find in the guideline?
• Is the discussion an integral part of the guideline development process? (i.e., taking place during recommendation formulation rather than post-formulation as an afterthought)
• Has the guideline development group considered the benefits and harms equally?

DOMAIN 3. RIGOUR OF DEVELOPMENT

12. There is an explicit link between the recommendations and the supporting evidence.

評　価	6	（ 5.3 ）	7（強く同意）～1（強く不同意） 括弧内の数字は本委員会において2011/8/4以降に評価した69件のガイドラインの平均値

コメント	エビデンスの強さと推奨の強さは，概ね一致しているように思います。抽出された論文とエビデンスの強さの関連が，より詳細に記載されるとなおよいでしょう。

User's Manual Description:

An explicit link between the recommendations and the evidence on which they are based should be included in the guideline. The guideline user should be able to identify the components of the body of evidence relevant to each recommendation.

Where to Look:

Define and examine the recommendations in the guideline and the text describing the body of evidence that underpins them. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: recommendations and key evidence.

How to Rate:

Item content includes the following CRITERIA:

• the guideline describes how the guideline development group linked and used the evidence to inform recommendations
• each recommendation is linked to a key evidence description/paragraph and/or reference list
• recommendations linked to evidence summaries, evidence tables in the results section of the guideline

Additional CONSIDERATIONS:

• Is there congruency between the evidence and recommendations?
• Is the link between the recommendations and supporting evidence easy to find in the guideline?
• When evidence is lacking or a recommendation is informed primarily by consensus of opinion by the guideline group, rather than the evidence, is this clearly stated and described?

DOMAIN 3. RIGOUR OF DEVELOPMENT

13. The guideline has been externally reviewed by experts prior to its publication.

評　価	2	（5.1）	7（強く同意）～1（強く不同意） 括弧内の数字は本委員会において2011/8/4以降に評価した69件のガイドラインの平均値

コメント	パブリックコメントが行われた旨の記載がありますが，外部評価は行われていないようです。ぜひ外部評価を行っていただき，その結果や対応などについて，具体的な内容を追加記載されると良いでしょう。

User's Manual Description:

A guideline should be reviewed externally before it is published. Reviewers should not have been involved in the guideline development group. Reviewers should include experts in the clinical area as well as some methodological experts. Target population (patients, public) representatives may also be included. A description of the methodology used to conduct the external review should be presented, which may include a list of the reviewers and their affiliation.

Where to Look:

Examine the paragraphs/chapters describing the guideline development process and the acknowledgement section. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: methods, results, interpretation, and acknowledgements.

How to Rate:

Item content includes the following CRITERIA:

• purpose and intent of the external review (e.g., to improve quality, gather feedback on draft recommendations, assess applicability and feasibility, disseminate evidence)
• methods taken to undertake the external review (e.g., rating scale, open-ended questions)
• description of the external reviewers (e.g., number, type of reviewers, affiliations)
• outcomes/information gathered from the external review (e.g., summary of key findings)
• description of how the information gathered was used to inform the guideline development process and/or formation of the recommendations (e.g., guideline panel considered results of review in forming final recommendations)

Additional CONSIDERATIONS:

• Is the item well written? Are the descriptions clear and concise?
• Is the item content easy to find in the guideline?
• Are the external reviewers relevant and appropriate to the scope of the guideline? Was there a rationale given for choosing the included reviewers?
•How was information from the external review used by the guideline development group?

DOMAIN 3. RIGOUR OF DEVELOPMENT

14. A procedure for updating the guideline is provided.

評　価	7

（ 5.1 ）

7（強く同意）～1（強く不同意）
括弧内の数字は本委員会において2011/8/4以降に評価した69件のガイドラインの平均値

コメント	ガイドライン発刊後も委員会を残していただき，最新情報のアップデートを継続されるようお願いします。

User's Manual Description:

Guidelines need to reflect current research. A clear statement about the procedure for updating the guideline should be provided. For example, a timescale has been given or a standing panel is established who receives regularly updated literature searches and makes changes as required.

Where to Look:

Examine the introduction paragraph, the paragraphs describing the guideline development process and the closing paragraphs. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: methods, guideline update, and date of guideline.

How to Rate:

Item content includes the following CRITERIA:

• a statement that the guideline will be updated
• explicit time interval or explicit criteria to guide decisions about when an update will occur
• methodology for the updating procedure is reported

Additional CONSIDERATIONS:

• Is the item well written? Are the descriptions clear and concise?
• Is the item content easy to find in the guideline?
• Is there enough information provided to know when an update will occur or what criteria would trigger an update?

DOMAIN 4. CLARITY OF PRESENTATION

15. The recommendations are specific and unambiguous.

評　価	6	（ 5.9 ）	7（強く同意）～1（強く不同意） 括弧内の数字は本委員会において2011/8/4以降に評価した69件のガイドラインの平均値

コメント	希少がんでありエビデンスは少なく，難しい面もあると思われますが，CQはPICO形式を徹底されると，より推奨が明確になります。

User's Manual Description:

A recommendation should provide a concrete and precise description of which option is appropriate in which situation and in what population group, as informed by the body of evidence.

• An example of a specific recommendation is: Antibiotics should be prescribed in children two years or older with a diagnosis of acute otitis media if the pain lasts longer than three days or if the pain increases after the consultation despite adequate treatment with painkillers; in these cases, amoxicillin should be given for 7 days (supplied with a dosage scheme).

• An example of a vague recommendation is: Antibiotics are indicated for cases with an abnormal or complicated course.

It is important to note that in some instances, evidence is not always clear cut and there may be uncertainty about the best care option(s). In this case, the uncertainty should be stated in the guideline.

Where to Look:

Define and examine the recommendations in the guideline. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: recommendations and executive summary.

How to Rate:

Item content includes the following CRITERIA:

• statement of the recommended action

• identification of the intent or purpose of the recommended action (e.g., to improve quality of life, to decrease side effects)

• identification of the relevant population (e.g., patients, public)

• caveats or qualifying statements, if relevant (e.g., patients or conditions for whom the recommendations would not apply)

Additional CONSIDERATIONS:

• In the event of multiple recommendations (e.g., management guidelines), is there clarity regarding to whom each recommendation applies?

• If there is uncertainty in the interpretation and discussion of the evidence, is the uncertainty reflected in the recommendations and explicitly stated?

DOMAIN 4. CLARITY OF PRESENTATION

16. The different options for management of the condition or health issue are clearly presented.

評　価	6	（ 5.9 ）	7（強く同意）～1（強く不同意） 括弧内の数字は本委員会において2011/8/4以降に評価した69件のガイドラインの平均値

コメント	アルゴリズムがあり，わかりやすく工夫されています。エビデンスは乏しく難しい面もあると思われますが，さらに充実を図ってください。

User's Manual Description:

A guideline that targets the management of a disease should consider the different possible options for screening, prevention, diagnosis or treatment of the condition it covers. These possible options should be clearly presented in the guideline.

For example, a recommendation on the management of depression may contain the following treatment alternatives:

a. Treatment with TCA

b. Treatment with SSRI

c. Psychotherapy

d. Combination of pharmacological and psychological therapy

Where to Look:

Examine the recommendations and their supporting evidence. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: executive summary, recommendations, discussion, treatment options, and treatment alternatives.

How to Rate:

Item content includes the following CRITERIA:

• description of options

• description of population or clinical situation most appropriate to each option

Additional CONSIDERATIONS:

• Is the item well written? Are the descriptions clear and concise?

• Is the item content easy to find in the guideline?

• Is this pertaining to a guideline broad or narrow in scope? This item may be more relevant to guidelines that are broad in scope (e.g., covering the management of a condition or issue rather than focusing on a particular set of interventions for a specific condition/issue).

DOMAIN 4. CLARITY OF PRESENTATION

17. Key recommendations are easily identifiable.

評　価	7	（ 5.9 ）	7（強く同意）～1（強く不同意） 括弧内の数字は本委員会において2011/8/4以降に評価した69件のガイドラインの平均値

コメント	CQや推奨を，わかりやすく一覧表にまとめてあります。さらに見やすくする工夫をお願いします。

User's Manual Description:

Users should be able to find the most relevant recommendations easily. These recommendations answer the main question(s) that have been covered by the guideline and can be identified in different ways. For example, they can be summarized in a box, typed in bold, underlined or presented as flow charts or algorithms.

Where to Look:

Examples of commonly labeled sections or chapters in a guideline where this information can be found include: executive summary, conclusions, and recommendations. Some guidelines provide separate summaries with key recommendations (e.g., quick reference guide).

How to Rate:

Item content includes the following CRITERIA:

• description of recommendations in a summarized box, typed in bold, underlined, or presented as flow charts or algorithms
• specific recommendations are grouped together in one section

Additional CONSIDERATIONS:

• Is the item well written? Are the descriptions clear and concise?
• Is the item content easy to find in the guideline?
• Are the key recommendations appropriately selected and do they reflect the key messages of the guideline?
• Are specific recommendations grouped in a section placed near the summary of the key evidence?

DOMAIN 5. APPLICABILITY

18. The guideline describes facilitators and barriers to its application.

評　価	5	（ 4.9 ）	7（強く同意）～1（強く不同意） 括弧内の数字は本委員会において2011/8/4以降に評価した69件のガイドラインの平均値

コメント	CQ4-2では内視鏡治療について，術者や施設の条件についての言及があります。施設間格差や他科連携などについて，さらに記載の充実が望まれます。

User's Manual Description:

There may be existing facilitators and barriers that will impact the application of guideline recommendations.
For example:
i. A guideline on stroke may recommend that care should be coordinated through stroke units and stroke services. There may be a special funding mechanism in the region to enable the formation of stroke units.
ii. A guideline on diabetes in primary care may require that patients are seen and followed up in diabetic clinics. There may be an insufficient number of clinicians available in a region to enable clinics to be established.

Where to Look:

Examine the paragraph/chapter on the dissemination/implementation of the guideline or, if available, additional documents with specific plans or strategies for implementation of the guideline. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: barriers, guideline utilization, and quality indicators.

How to Rate:

Item content includes the following CRITERIA:

• identification of the types of facilitators and barriers that were considered
• methods by which information regarding the facilitators and barriers to implementing recommendations were sought (e.g., feedback from key stakeholders, pilot testing of guidelines before widespread implementation)
• information/description of the types of facilitators and barriers that emerged from the inquiry (e.g., practitioners have the skills to deliver the recommended care, sufficient equipment is not available to ensure all eligible members of the population receive mammography)
• description of how the information influenced the guideline development process and/or formation of the recommendations

Additional CONSIDERATIONS:

• Is the item well written? Are the descriptions clear and concise?
• Is the item content easy to find in the guideline?
•Does the guideline suggest specific strategies to overcoming the barriers?

DOMAIN 5. APPLICABILITY

19. The guideline provides advice and/or tools on how the recommendations can be put into practice.

評　価	5

（ 5.3 ）

7（強く同意）～1（強く不同意）
括弧内の数字は本委員会において2011/8/4以降に評価した69件のガイドラインの平均値

コメント	CQ・推奨一覧があります。Web版公開など，さまざまなツールを作成いただき，積極的にご活用いただければ，さらによいでしょう。

User's Manual Description:

For a guideline to be effective it needs to be disseminated and implemented with additional materials.
For example, these may include: a summary document, a quick reference guide, educational tools, results from a pilot test, patient leaflets, or computer support. Any additional materials should be provided with the guideline.

Where to Look:

Examine the paragraph on the dissemination/implementation of the guideline and, if available, the specific accompanying materials that have been produced to support the dissemination and implementation of the guideline. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: tools, resources, implementation, and appendices.

How to Rate:

Item content includes the following CRITERIA:

* an implementation section in the guideline
* tools and resources to facilitate application:
• guideline summary documents
• links to check lists, algorithms
• links to how-to manuals
• solutions linked to barrier analysis (see Item 18)
• tools to capitalize on guideline facilitators (see Item 18)
• outcome of pilot test and lessons learned
* directions on how users can access tools and resources

Additional CONSIDERATIONS:

• Is the item well written? Are the descriptions clear and concise?
• Is the item content easy to find in the guideline?
• Is there information about the development of the implementation tools and validation procedures?

DOMAIN 5. APPLICABILITY

20. The potential resource implications of applying the recommendations have been considered.

評　価	5

（ 4.6 ）

7（強く同意）～1（強く不同意）
括弧内の数字は本委員会において2011/8/4以降に評価した69件のガイドラインの平均値

コメント	希少がんであり，保険適用がない治療法等もあるのではと思います。コストやリソースに関する記述を意識していただくとよいでしょう。

User's Manual Description:

The recommendations may require additional resources in order to be applied. For example, there may be a need for more specialized staff, new equipment, and expensive drug treatment. These may have cost implications for health care budgets. There should be a discussion in the guideline of the potential impact of the recommendations on resources.

Where to Look:

Examine the paragraph(s) on the dissemination/implementation of the guideline or, if available, additional documents with specific plans or strategies for implementation of the guideline. Some guidelines present cost implications in the paragraphs that discuss the evidence or decisions behind the recommendations. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: methods, cost utility, cost effectiveness, acquisition costs, and implications for budgets.

How to Rate:

Item content includes the following CRITERIA:

• identification of the types of cost information that were considered (e.g., economic evaluations, drug acquisition costs)
• methods by which the cost information was sought (e.g., a health economist was part of the guideline development panel, use of health technology assessments for specific drugs, etc.)
• information/description of the cost information that emerged from the inquiry (e.g., specific drug acquisition costs per treatment course)
• description of how the information gathered was used to inform the guideline development process and/or formation of the recommendations

Additional CONSIDERATIONS:

• Is the item well written? Are the descriptions clear and concise?
• Is the item content easy to find in the guideline?
• Were appropriate experts involved in finding and analyzing the cost information?

DOMAIN 5. APPLICABILITY

21. The guideline presents monitoring and/or auditing criteria.

評　価	4	（4.1）	7（強く同意）～1（強く不同意） 括弧内の数字は本委員会において2011/8/4以降に評価した69件のガイドラインの平均値

コメント	Quality indicatorなど診療プロセスのモニタリングに必要な項目があれば，次回改訂に際し対応してください。

User's Manual Description:

Measuring the application of guideline recommendations can facilitate their ongoing use. This requires clearly defined criteria that are derived from the key recommendations in the guideline. The criteria may include process measures, behavioral measures, clinical or health outcome measures. Examples of monitoring and audit criteria are:

- The HbA1c should be < 8.0%.
- The level of diastolic blood pressure should be < 95 mmHg.
- 80% of the population aged 50 years should receive colorectal cancer screening rates using fecal occult blood tests.
- If complaints of acute otitis media last longer than three days, amoxicillin should be prescribed.

Where to Look:

Examine the paragraph/chapter on auditing or monitoring the use of the guideline or, if available, additional documents with specific plans or strategies for evaluation of the guideline. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: recommendations, quality indicators, and audit criteria.

How to Rate:

Item content includes the following CRITERIA:

- identification of criteria to assess guideline implementation or adherence to recommendations
- criteria for assessing impact of implementing the recommendations
- advice on the frequency and interval of measurement
- descriptions or operational definitions of how the criteria should be measured

Additional CONSIDERATIONS:

- Is the item well written? Are the descriptions clear and concise?
- Is the item content easy to find in the guideline?
- Are a range of criteria provided including process measures, behavioural measures, and clinical or health outcomes?

DOMAIN 6. EDITORIAL INDEPENDENCE

22. The views of the funding body have not influenced the content of the guideline.

評　価	6	（ 5.3 ）	7（強く同意）～1（強く不同意） 括弧内の数字は本委員会において2011/8/4以降に評価した69件のガイドラインの平均値

コメント	資金源の記載はありますが，独立性についても言及してください。

User's Manual Description:

Many guidelines are developed with external funding (e.g., government, professional associations, charity organizations, pharmaceutical companies). Support may be in the form of financial contribution for the complete development, or for parts of it (e.g., printing of the guidelines). There should be an explicit statement that the views or interests of the funding body have not influenced the final recommendations.

Where to Look:

Examine the paragraphs/chapters on the guideline development process or acknowledgements section. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: disclaimer and funding source.

How to Rate:

Item content includes the following CRITERIA:

• the name of the funding body or source of funding (or explicit statement of no funding)
• a statement that the funding body did not influence the content of the guideline

Additional CONSIDERATIONS:

• Is the item well written? Are the descriptions clear and concise?
• Is the item content easy to find in the guideline?
• How did the guideline development group address potential influence from the funding body?

DOMAIN 6. EDITORIAL INDEPENDENCE

23. Competing interests of guideline development group members have been recorded and addressed.

評　価	7	（ 5.5 ）	7（強く同意）～1（強く不同意） 括弧内の数字は本委員会において2011/8/4以降に評価した69件のガイドラインの平均値

コメント	

User's Manual Description:

There are circumstances when members of the development group may have competing interests. For example, this would apply to a member of the development group whose research on the topic covered by the guideline is also funded by a pharmaceutical company. There should be an explicit statement that all group members have declared whether they have any competing interests.

Where to Look:

Examine the paragraphs/chapters describing the guideline development group or acknowledgements section. Examples of commonly labeled sections or chapters in a guideline where this information can be found include: methods, conflicts of interest, guideline panel, and appendix.

How to Rate:

Item content includes the following CRITERIA:

• description of the types of competing interests considered
• methods by which potential competing interests were sought
• description of the competing interests
• description of how the competing interests influenced the guideline process and development of recommendations

Additional CONSIDERATIONS:

• Is the item well written? Are the descriptions clear and concise?
• Is the item content easy to find in the guideline?
• What measures were taken to minimize the influence of competing interests on guideline development or formulation of the recommendations?

OVERALL GUIDELINE ASSESSMENT

2022/9/1 第4回がん診療ガイドライン評価委員会

1. Rate the overall quality of this guideline.

評　価	6

（ 5.2 ）

7（強く同意）～1（強く不同意）
括弧内の数字は本委員会において2011/8/4以降に評価した69件のガイドラインの平均値

2. I would recommend this guideline for use.

評　価	Yes with modifications

Yes, Yes with modifications, No

Notes

希少がんであり，エビデンスの乏しい領域にもかかわらず，丁寧に作られていると思います。各アイテムへのコメントに加え，評価委員会で上がったいくつかの点について追記します。1）CQについて：困難とは思いますが，よりPICO 形式を意識されたCQを作成いただければと思われました。2）構成メンバーについて：方法論の専門家がいらっしゃるのは大変結構です。医師以外の医療職の参加も，検討されると良いでしょう。3）評価委員よりの意見：家族性大腸腺腫症，リンチ症候群を背景とした十二指腸がんについて，これらについての対応（フォローアップを含む）を記したCQがあると良いのでは，という意見が出ました。

User's Manual Description:

The overall assessment requires the AGREE II user to make a judgment as to the quality of the guideline, taking into account the appraisal items considered in the assessment process.