# Quality appraisal of guidelines on umbilical cord prolapse with AGREE II: a systematic review

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## Abstract

Background: Umbilical cord prolapse is an obstetric emergency that warrants urgent intervention. Although the incidence is low, it carries a high rate of fetal morbidity and mortality. Quality appraisal of well- developed practice guidelines provides clinicians with a framework for good clinical practice. Objective: To assess the quality of clinical practice guidelines on umbilical cord prolapse using AGREE II instrument-2010. Search strategy: A systematic review employing the principles of PRISMA 2020 was done to identify suitable practice guidelines available in digital databases from inception till 2021. Selection criteria: Practice guidelines on management of umbilical cord prolapse in English which have rigorous methodology of development and is between 2010-2021 were selected for the appraisal. Data collection and analysis: Selected guidelines were appraised utilizing the AGREE-II - 2010 instrument Results: Three practice guidelines were fulfilled the selection criteria. Two of the three guidelines were assigned sufficient scores based on the domains for quality appraisal, though they require further modifications. Conclusions: Practice guidelines on management of umbilical cord prolapse developed by the RCOG and RCPI achieved sufficient scores to be recommended for use in clinical practice. Professionals should provide patient care based on practice points tailored to patients' characteristics and resource availability. Keywords: umbilical cord prolapse, guidelines, clinical practice guidelines, quality appraisal Tweetable abstract: AGREE II was used to assess the quality of CPGs on umbilical CP, of which RCOG and RCPI guidelines were recommended.

## Title page

## Full title

Quality appraisal of guidelines on umbilical cord prolapse with AGREE II: a systematic review

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Shortened running title Quality appraisal of UCP guidelines with AGREE II

AbstractBackground: Umbilical cord prolapse is an obstetric emergency that warrants urgent intervention. Although the incidence is low, it carries a high rate of fetal morbidity and mortality. Quality appraisal of well- developed practice guidelines provides clinicians with a framework for good clinical practice. **Objective:** To assess the quality of clinical practice guidelines on umbilical cord prolapse using AGREE II instrument-2010. Search strategy: A systematic review employing the principles of PRISMA 2020 was done to identify suitable practice guidelines available in digital databases from inception till 2021. Selection criteria: Practice guidelines on management of umbilical cord prolapse in English which have rigorous methodology of development and is between 2010-2021 were selected for the appraisal. Data collection and analysis: Selected guidelines were appraised utilizing the AGREE-II - 2010 instrumentResults: Three practice guidelines were fulfilled the selection criteria. Two of the three guidelines were assigned sufficient scores based on the domains for quality appraisal, though they require further modifications. **Conclusions:** Practice guidelines on management of umbilical cord prolapse developed by the RCOG and RCPI achieved sufficient scores to be recommended for use in clinical practice. Professionals should provide patient care based on practice points tailored to patients' characteristics and resource availability. Keywords: umbilical cord prolapse, guidelines, clinical practice guidelines, quality appraisal, general obstetrics **Tweetable ab**stract: AGREE II was used to assess the quality of CPGs on umbilical CP, of which RCOG and RCPI guidelines were recommended.

#### Introduction

Umbilical cord prolapse (UCP) is an obstetric emergency that warrants urgent intervention by an efficient multidisciplinary team to avert adverse foetal outcomes. Conventionally, it is defined as presentation of the umbilical cord at the cervical os before the foetal presenting part<sup>1</sup>. There has been a marked reduction in incidence of UCP over the last three decades because of increased obstetric vigilance and increased employment of Caesarean deliveries for non-cephalic or unengaged presenting part. The overall incidence varies from 1-6 per 1000 hospital births<sup>2</sup>.

Compression and vasospasm of foetal vessels from exposure to extrauterine environment ultimately leads to foetal demise in the absence of timely intervention and delivery<sup>4</sup>. Perinatal mortality varies depending on gestational age, presentation characteristics and implementation of timely interventions. Higher rates of 23-27% are reported in low income countries and 6-10 % in high-income nations<sup>5,6</sup>.

Scrutiny of risk factors for UCP would alert the attending clinician to be prepared for the complication<sup>7</sup>.

To adequately manage this obstetric emergency, tested protocols should be set in place. Clinical practice guidelines developed by an expert committee, containing comprehensive information including risk factors and established management strategies, are relevant for good clinical practice<sup>8</sup>. Although adoption of clinical practice guidelines attempts to keep foetal morbidity and mortality to a minimum, such recommendations would be better appraised by auditing local foetal outcomes to reflect on the need for changes in care<sup>9</sup>.

In countries where there are no existing national guidelines, it is essential to adopt existing guidelines of high standards. Although several clinical protocols on UCP are available, an appraisal of these guidelines have not been done unlike the systematic appraisals of practice guidelines on gestational diabetes mellitus<sup>10</sup> and postpartum hemorrhage<sup>11</sup> utilizing AGREE II.

The Appraisal of Guidelines for Research & Evaluation Instrument (AGREE II), was designed by the AGREE Research Trust funded by the Canadian Institutes of Health Research. Its purpose is threefold, one of which is to assess a guideline before adopting its recommendations<sup>12</sup>. Another is to provide guideline developers a structure for rigorous development methodology. The Green-Top Guidelines by the RCOG (UK) follows such rigor<sup>13</sup>.

The aim of this review is to appraise the available guidelines on UCP using AGREE II -2010, based on their recommendations. Hopefully, this quality appraisal would provide an objective evaluation of selected CPGs on management of UCP.

# Methods

## Data sources and searches

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA 2020) guidelines utilized for systematic search and selection of clinical practice guidelines on UCP. All authors participated in the literature search and evaluation of suitable guidelines. Guidelines were searched on databases including PubMed, Google Scholar, EMBASE, Web of Science, Cochrane and guideline websites like the Royal College of Obstetricians & Gynaecologists, NICE, European, Australian, NZ, Canada, US, Malaysia, Singapore professional societies, from inception till November 2021. The study design is shown in the PRISMA 2020 flowchart (Fig.1.)

Our MeSH terms or keywords for the search were "cord prolapse" AND "guideline" AND "clinical practice guidelines". Guidelines were selected if they fulfilled all the predetermined inclusion criteria stated below. Three reviewers independently screened the retrieved records, before coming together to determine selection of the guidelines fulfilling our inclusion criteria. This decision was further reviewed by the fourth researcher. The guidelines were manually sought, and duplicates were removed manually without the use of a software due to the small number of guidelines available. Data collection was done by three reviewers independently using the AGREE II Instrument 2009 appraisal tool. This AGREE-II is an internationally recognized tool to assess the quality of guidelines. The guidelines were scored across 6 different domains namely, (i) scope and purpose; (ii) stakeholder involvement; (iii) rigor of development; (iv) clarity of presentation; (v) applicability; and (vi) editorial independence.

# Eligibility Criteria

Inclusion criteria:

- 1. A full clinical practice guideline on cord prolapse that has gone through a rigorous methodology of development. A prominent example is the method employed by Health Technology Assessment (HTA) in development of Clinical Practice Guidelines (CPG) Ministry of Health and Green-top Guidelines on CPG (RCOG)
- 2. CPGs developed for management of 'Cord Prolapse' in UK, Scotland, Ireland, Europe, Canada, ACOG, Australia and New Zealand, Singapore, and Malaysia, available in English
- 3. The selected guideline has been developed, reviewed, or revised between 2010-2021.

Exclusion criteria:

- 1. A translated version of a guideline
- 2. Guidelines for patients' reference
- 3. Brief version or a segment of a guideline
- 4. Practice guidelines developed for local use without having gone through rigorous development methods according to established protocol (GRADE etc.)

# Quality Appraisal

Prior review of domains in AGREE II were undertaken for familiarization with the scoring system to be adopted. Three researchers independently scrutinized the guidelines before giving scores for each domain with comments to support the assigned scores. The scores from the three reviewers were then compiled and compared with each other. If there was any discrepancy in scores of an item deviating more than 2, discussion with the senior researcher was carried out to come to a consensus of scores. Domain scores were then calculated using the following formula:

 $\frac{(obtained \ score - minimum \ possible \ score)}{(maximum \ possible \ score - minimum \ possible \ score)} x100$ 

Results were then denoted as percentages (%). The maximum possible score for a domain was:

The minimum possible score for a domain was:

Any guideline that achieved an overall score of more than 60% was deemed as having acceptable quality' and a score below 40% was deemed as low quality. However, each guideline was reviewed as whole, when it came to suggesting its adaptability into practice. Recommendations with their corresponding grading and level of evidence were summarized into a table, to aid the clinician in decision making.

#### **Data Extraction and Analysis**

After quality appraisal, data extraction and analysis were performed by one reviewer and checked by another one. Any discrepancies were resolved by discussion between them and the third reviewer. The main characteristics of these publications were extracted; this includes the development, organization, publication year, development method, and evidence grading system. Following that, the results of the AGREE II appraisals, which are the standardized domain scores based on the method mentioned above and results of the overall assessments, were compiled.

#### Statistics

Descriptive statistics analysis was done. The IBM SPSS Version 23.0 was used for all statistical analyses. Descriptive analysis values were of median and interquartile range of each CPG, as well as the mean in percentage (%) across domains. In order to measure agreement among reviewers, intra-class correlation coefficients (ICC) were calculated, with the following values:

Model: Two-way random, Type: Absolute agreement, Confidence interval: 95%.

ICC values above 0.75 were considered to represent good reliability and agreement among reviewers<sup>14-15</sup>.

## Results

# Guideline characteristics

Three practice guidelines were finally selected; these were from Royal College of Obstetricians and Gynaecologists, UK (RCOG), Royal College of Physicians (Ireland) RCPI, and South Australian Practice Guidelines (SAPPG). Guideline characteristics are shown in Table 1. RCPI and SAPPG did not indicate grades of evidence.

## Quality assessment

Table 2 shows the AGREE II domain scores for each guideline.

## **Overall** assessment

Table 2 displays the total score for each domain, and the overall quality of the guidelines. None of the guidelines were above 70%. The SAPPG scored lowest (27.78%), and thus not recommended by the reviewers. The RCOG (UK) guideline achieved the highest overall score (67.67%) and the RCPI guideline scored 50%. Both these guidelines were recommended for use, with modifications. The intraclass correlation was very good, as it was above 0.98 for each CPG reviewed, as values greater than 0.90 were obtained, indicating excellent reliability<sup>14</sup>.

## Assessment by domain

Scope and purpose

Only the RCOG scored well for this domain, it is its second highest domain among the 7 at 87.04%. The other two guidelines scored under 40%. The mean was 48.77%, skewed by RCOG's score. SAPPG and RCPI scored 24.07% and 35.19% respectively.

#### Stakeholder involvement

All three CPGs scored under 40%; none explicitly described stakeholder involvement. This is the only domain RCPI scored the highest at 38.89%.

#### Rigor of development

This domain has seven components and has the widest range of scores, with RCOG scoring 73.61% and the SAPPG guideline scoring 9.72%. The RCOG is rigorous in its development, mainly because it has a separate guideline drawn based on the AGREE II. The SAPPG, on the other hand, did not elaborate its process of development. Moreover, the guidelines had different methods of stating the level of evidence and grade of recommendations, with the SAPPG not citing their evidence within the text.

## Clarity of presentation

The domain "Clarity of Presentation" achieved the highest overall score with the tightest range. The SAPPG and RCPI guidelines scored almost similarly (87% and 87.04, respectively) whilst RCOG scored 92.59%. This was the highest scoring for all three guidelines individually, as well, with a mean score of 89%.

#### Applicability

All three guidelines had low scores, less than 25%; SA guideline was below 10%. This also showed in its mean as it was the poorest in among all domains, at 9.26% The major factor contributing the latter was not reporting implementation facilitators or resource implications.

#### Editorial independence

This was the lowest scoring domain, with the SAPPG and RCPI scoring 2.78%. RCOG score was 20% higher.

#### Discussion

#### Overall quality of clinical practice guidelines on umbilical cord prolapse

Most maternity units have local protocols for management of UCP. Conventionally, this emergency is included as part of clinical audits and drills are regularly conducted to deal with the complication. Algorithms are based on gestational age, foetal heart patterns and place of delivery. Expectant management is sensible when severe prematurity is encountered. Practice guidelines are needed for decision making in term pregnancies with UCP when the foetus is alive or there is abnormal foetal heart pattern due to foetal asphyxia. Our search showed three practice guidelines on the subject that were rigorous enough to be appraised. This low number could be due to accepted practice algorithms in most obstetric units, low prevalence of UCP due to easy access to CD in cases with risk factors, and less controversies in the management of UCP<sup>16</sup>. While the three CPGs provide clinical pathways in effective delivery in reducing perinatal morbidity and mortality, they could be further refined, based on the domain scores shown in this study. Table 2 displays the total score for each domain and the overall quality of the guidelines. All three had low overall scores; none were above 70%and five of the domains need further review. The RCOG and RCPI guidelines were recommended for use with modifications. The intraclass correlation was above  $0.98^{14}$ . All three guidelines scored the highest in the domain of 'clarity of presentation'. Overall, the recommendations were presented well, with a summary of recommendations and a flowchart on management. Delivery of the content was clear, precise, and easy to understand. The guideline by SAPPG also had images regarding the positions to relieve pressure on the cord. Three of the 6 domains received an average score below 30%, which is concerning. The domain of 'stakeholder involvement' achieved a mean score of 28.4%. All the guidelines did not mention the relevant stakeholders, particularly the target population, and if they were involved in developing the guideline. It can be assumed that they were not consulted. RCOG and SAPPG did not mention the qualifications of their developing committee, and none of the guidelines mentioned the respective roles of the guideline steering committee. The 'applicability' domain achieved a mean of 14.8%; this could be due to implicit meaning in developing practice guidelines by professional bodies i.e., for its members. All the guidelines do not mention the facilitators and barriers in the application of the suggested guidelines, and this may be partly due to the lack of feedback from key stakeholders, and the inability to pilot test the guidelines in view of the critical nature of the condition. Moreover, none of the guidelines explicitly state the resource implications that may incur due to the application of the recommendations, or the presence of any auditing strategies, to assess the adherence to guidelines and their implications. The domain of 'editorial independence' scored the lowest among all domains as none of the guidelines mentioned their funding body; only the RCOG committee declared 'no competing interests'. This could be an oversight as development of guidelines is often initiated as part of good clinical practice in professional bodies.

#### Grading of level of evidence

Apart from RCOG, none of the guidelines provide the level of evidence for their recommendations as shown in Table S1. This was inconvenient during the appraisal process, as we could only rely on the RCOG guideline for the grading of a recommendation. Moreover, the absence of grading makes the guidelines less reliable. Although RCPI does a decent job elaborating their cited reports, adding the grades to their recommendations would have added confidence.

#### Consensus

Glancing through the recommendations listed out in Table S1, a majority of them are based on weak evidence, including some relying only on "recommended best practice based on the clinical experience of the guideline development group". Strong evidence (2+) is seen in recommending vaginal examination after SROM in risk cases and with FH abnormalities. Resort to caesarean delivery and expertise in neonatal resuscitation also have high recommendations. Most recommendations are based on weak evidence; a consensus between different bodies that develop the CPGs can help in determining whether the recommendations can be considered as 'best clinical practice'. Table S2 summarizes and highlights the consensus on the recommendations listed. As an example, all 3 CPGs recommended 'knee chest' or 'left lateral' position for further reduction of cord compression, but the evidence for this method is considered weak<sup>17</sup>. This is due to the uncommon but emergency nature of the condition, resulting in randomized controlled trials not possible to be conducted. Both knee-chest and left lateral positions work by elevating the maternal pelvis which will create a pulling gravitational force on the foetal head. The gravitational force advantage over manual elevation and bladder filling was that it will not only help reduce the risk of further prolapse, but it is also indifferent to the foetal initial station (manual elevation and bladder filling is less effective when the initial station is high)<sup>18</sup>. However, due to the relatively low risk of the indicated manoeuvres, most clinicians adopt this technique. A recent study favours knee -chest position as it provides the best elevation effect<sup>19</sup>. Although it has a low evidence level, we can confidently consider it to be a good clinical practice as recommended by all three CPGs recommended it. Both RCPI and RCOG did not recommend routine ultrasound screening for predicting cord prolapse as it is not sensitive or specific to predict the cord  $\operatorname{prolapse}^{20}$ . However, ultrasound in mothers with high risk, such as breech presentation at term, has shown to give some benefit to the mother who wants to consider vaginal breech delivery<sup>21</sup>. RCOG was the only CPG to recommend avoiding low ARM if the foetal presenting part is high to avoid triggering cord prolapse. However, as it also a recommendation with weak evidence (Level 4), it is debatable whether it should be considered best clinical practice.

#### Limitations

This systematic review has several limitations. Guidelines in other languages besides English were not included. Moreover, only guidelines available in public digital databases have been included. Thus, we could have missed guidelines that may have been published in different forms, such as conference reports, PhD thesis and books. The AGREE-II tool used for the appraisal of the guidelines also has several shortcomings, including the lack of standardization for the scoring method, and also the absence of criteria to distinguish between high and low quality evidence provided in a guideline<sup>22</sup>. The lack of standardization in the scoring

system may amplify researcher bias. The team acknowledges domains on 'rigor of development' and 'clarity of presentation' played a more significant role in influencing the overall score of the guidelines, although the appraisal tool indicated that all domains play an equal role in appraising a guideline<sup>22</sup>.

## Conclusion

The authors reached a consensus that the guidelines on management of umbilical cord prolapse produced by the RCOG and RCPI can meet the criteria for recommendation for use in clinical practice with some modifications. All three guidelines present similar practice points. Clinical audits in the local context could be integral to quality of clinical practice. Updating the guidelines according to latest evidence is recommended.

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#### **Disclosure of interests**

The authors declare no conflicts of interests.

# Contribution to Authorship

AP, MZA and RR were involved in appraising the full text of the guidelines using AGREE II-2010, and wrote sections of the manuscript draft with guidance from SN.SN was the subject matter who advised on the selection of the topic for research and contributed to editing and refining the manuscript.

## Funding and ethical approval

This study was supported by the International Medical University (IMU) Malaysia, and received approval from the IMU - Joint Committee on Research & Ethics under the Project Number CSc/Sem6(16)2021. The funders had no involvement in the study design, data collection and analysis, decision to publish or preparation of the manuscript.

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## Table 1: Characteristics of Guidelines

Guideline	Guideline	Region	Development institute	Publication
1.	Umbilical Cord Prolapse. Green-top Guideline No.50	United Kingdom	RCOG	2014
2.	Clinical Practice Guideline Cord Prolapse	Ireland	RCPI	2017
3.	Cord Presentation and Prolapse	South Australia	SAPPG	2019

## Table 2: The AGREE II domain scores for each guideline

Domain	RCOG	RCPI	SAPPG	Mean
	(Percentage/Score)	(Percentage/Score)	(Percentage/Score)	
I Scope and	87.04% 56	$35.19\% \ 28$	24.07% $22$	48.77%
Purpose $(9-63)$				
II Stakeholder	29.63% 25	$38.89\% \ 30$	$16.67\% \ 18$	28.40%
Involvement (9-63)				
III Rigor of	$73.61\% \ 130$	46.53% 91	$9.72\% \ 38$	43.29%
Development				
(24-168)				
IV Clarity of	92.59% 59	87.04% 56	87% 56	89%
Presentation (9-63)				

V Applicability	22.22% 28	12.5% 21	$9.72\% \ 19$	14.81%
(12-84) VI Editorial	22.22% 14	2.78% 7	2.78% 7	9.26%
Independence (6-42) OVERALL (3-21)	$66.67\% \ 15$	$50\% \ 12$	27.78% 8	48.15%
Recommendation	YwM	YwM	Ν	40.1070
$Median \pm IQR$	$66.67\% \pm 64.82\%$	$38.89\% \pm 37.5\%$	$16.67\% \pm 18.06\%$	
ICC	0.994	0.991	0.986	

(Range of minimum possible score - maximum score) Percentage, obtained score. IQR = Interquartile range, ICC = Intraclass Correlation Coefficient N = No, YwM = Yes with modifications.

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