# A Protocol for Developing a Clinical Practice Guideline for Prevention and Management of Perineal Tears at Vaginal Delivery

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**Protocol**

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# Abstract

**Introduction:** Perineal tear is a distressing obstetric complication affecting females globally. More than 85% of women sustain some degree of perineal tears during childbirth, resulting in potential effects on women's well-being and quality of life. Although different institutions around the world have developed some related clinical practice guidelines (CPGs), a few recommendations are inconsistent, unspecific, and some CPGs are silent on certain matters, which might confuse guideline users. Nowadays, there is still no domestic CPG for prevention and management of perineal tears in China to guide clinical practice.

**Methods:** This CPG will be developed in line with the latest guideline definition from Institute of Medicine (IOM) and comply with the World Health Organization handbook for guideline. We will adhere closely to the six domains of the Appraisal of Guidelines for Research & Evaluation II (AGREE II) and apply the Grade of Recommendations Assessment, Development and Evaluation (GRADE) system to appraise the quality of evidence and develop recommendations. We have established a guideline working group (including a guideline steering group, a guideline development group, a guideline secretary group, and a system evaluation group), formulated 21 questions in the form of Population, Intervention, Comparison, Outcome (PICO) and completed a literature search. The recommendations will be formed via evidence search, syntheses, and 2 to 3 rounds of Delphi process to reach consensus. We will also consider patients' values or preferences, peer review results in this CPG.

**Ethics and dissemination:** The CPG has been registered on the International Practice Guidelines Registry Platform. The need for ethics approval has been exempted by the Institutional Review Boards of the Southern Medical University. The CPG is to be published in peer-reviewed journals and will form the care standard for perineal care for Chinese women with vaginal delivery.


# 1 Background

Perineal tear is one of the most common complications during vaginal delivery affecting females globally. More than 85% of women sustain some degree of perineal tear during vaginal birth [1, 2], mostly first- and second-degree tears [2, 3]. Obstetric anal sphincter injuries (OASIS) is the most severe form, also called third- and fourth –degree tears, which is reported to be approximately 11% [4], with higher rates in instrumental vaginal delivery [5]. Perineal tear is associated with short- and long-term complications such as persistent pain [6], dyspareunia [7], urinary and anal incontinence [8, 9]. OASIS may also result in sexual dysfunction or rectovaginal fistulae, with potentially devastating effects on women's psychological well-being and family relationships [10]. Sometimes, these complications may persist for year after childbirth [11]. It has been reported that 60–70% perineal tears need to be repaired [12]. The number of complications is likely to be higher when poorly managed. Hence, prevention and appropriate management of perineal tears especially OASIS is of paramount importance in current clinical practice. Evidence based knowledge and practice on prevention and management of perineal tears may improve prognosis [13].

Several institutions had developed related CPGs to guide the practice. We have assessed the quality of the existing CPGs on prevention and management of perineal tears and analyzed the recommendations of the CPGs (data to be published). We systematically searched related CPGs in PubMed, Cochrane Library, Embase, CNKI, CMB, WanFang database as well as the guideline website such as NGC, GIN, NICE, SIGN and the websites related to professional association. The literature retrieval time was May 10th, 2021. Eighteen CPGs (Appendix 1) were included and we used the AGREE II instrument to evaluate the CPGs quality. We found that the quality of the 18 CPGs were variable and the quality scores of most CPGs were moderate to low. Besides, only two CPGs [14, 15] adopted the GRADE systems to evaluate the quality of evidence. However, the scope of the two CPGs was intrapartum care for women and babies, not focusing on perineal tears. Thus, this finding is an impetus to guideline developers towards improving quality. In addition, there are some variations among the existing CPGs in global clinical practice in relation to prevention and management of perineal tears. For example, CPGs by WHO[14] and ACOG [16] recommended use of perineal massage in the second stage of labor, whereas it was contraindicated in the second stage of labor by CPGs developed by NICE [15] and SNS [17]. Besides, for the delivery posture in the second stage of labor, CPG by WHO [14] suggested a semi-recumbent or all-fours position just before expulsion of the fetus to reduce perineal tears, while CPG by RCOG [18] strongly recommended lying down lateral positions for women with epidural analgesia and upright or lateral positions for women without epidural analgesia. In addition, CPGs by CNGOF [19] and SNS [17] strongly recommended that women should adopt the most comfortable position for them during labor. Regarding the management of perineal tears, some CPGs are silent on certain matters. For instance, for repair of first-degree tear, one CPG [16] has described the choice of suture such as standard suture, and three CPGs [15, 17, 19] have suggested the condition when suture is needed, but no recommendation on suture technique. As for the management of OASIS, several countries have their own national guidelines. Roper et al [20] conducted a review of available guidelines on OASIS and found that there are discrepancies and variations within each guideline, which leads to variation in obstetric practice in relation to the management of OASIS.

Thus, we aim to develop an evidence-based CPG for perineal tears prevention and management, suitable for the medical environment in China, in accordance with the WHO Handbook for Guideline Development (2nd edition, 2014) [21] to provide empirical support for the clinical practice of perineal tears prevention and management at vaginal delivery. This paper aims to outline a detailed methodology and technical route for CPG development to improve transparency with regard to the methods and reduce unnecessary duplication and potential bias.

# 2 Methods

## 2.1 Principle

Regarding guideline development, we will follow the new guideline definition from the IOM [22], comply with the World Health Organization handbook for guideline [21]and follow the Grading of Recommendations Assessment, Development and Evaluation (GRADE) tool to form recommendations [23]. In addition, we will closely adhere to the six domains of the AGREE II [24] and the Reporting Items for

Practice Guidelines in Healthcare (RIGHT) working group [25]. We have registered the CPG on the International Practice Guidelines Registry Platform (http://www.guidelines-registry.cn/user/guid/tail/1276), and the registration number is IPGRP-2021CN305. The need for ethics approval was waived by the Institutional Review Boards of the XX University.

### 2.2 Participating institutions

The CPG started in May 2021 and was launched by Evidence-based Nursing and Midwifery Practice Center, Southern Medical University, and Evidence-based Medicine Center, Lanzhou University, which will be titled, 'Prevention and Management of Perineal Tears at Vaginal Delivery: An Evidence-based Clinical Practice Guideline'.

### 2.3 Guideline working group

The Guideline working Group, consisting of a Guideline Steering Group, a Guideline Development Group, a Systematic Evaluation Group, a Guideline Secretary Group and an External Review Group, has been established in May 2021.

The Guideline Steering Group has been composed of 2 clinical medical experts, 2 midwifery experts and 1 nursing expert. This group will be in charge of the following mission: (1) identifying and approving members of the other four groups and collecting all member's statements of interest conflicts, (2) supervising the whole process such as authorizing the CPG's scope, supervising literature search and systematic reviews, examining the quality of evidence, developing the final recommendations based on the revised Delphi approach and ratifying the release of the CPG, (3) responding to the end-user's feedback, (4) tracking new evidence and deciding whether the CPG needs to be updated.

To ensure fair representation by gender and region, the Guideline Development Group has consisted of 22 members from multiple fields of specialization. There are 2 obstetric experts, 7 midwifery experts, 9 nursing managers (with rich obstetric working experience), 1 nursing educator and 3 evidence-based medical experts. The 22 members come from14 provinces, 2 municipalities, and 1 autonomous region in China, covering China's northeast, northwest, north, southwest, south, and other regions. The Guideline Development Group will be in charge of the following mission: (1) developing the scope of the guideline, drafting the Population, Intervention, Comparison, Outcomes (PICOs), (2) prioritizing the critical outcomes, (3) formulating the recommendations after considering the overall balance of benefits and harms under Chinese Context, (4) dealing with the opinions from the External Review Group, (5) approving the final CPG, (6) publishing and promoting the CPG.

The Systematic Evaluation Group has been composed of 11 members with the experience of producing systematic reviews, whose primary responsibilities are: (1) conducting evidence retrieval and synthesis for each recommendation, (2) critically assessing the quality of the evidence, (3) making the summary of findings tables (SoFs tables), (4) drafting the initial recommendations.

The External Review Group has been composed of 1 obstetrician, 4 midwifery experts and 1 methodological expert, mainly responsible for reviewing the recommendations and the final guideline document.

The Guideline Secretary Group has been composed of 3 members, whose primary responsibilities are: (1) assisting the guideline steering group in the development of the guidelines, (2) collecting initial clinical questions, (3) surveying patients' views and favors, (4) recording the details of the whole process, and (5) drafting and finalizing the CPG.

### 2.4 Guidelinetarget users and population

The target users of the CPG include obstetricians, gynecologists, midwives, nursing staff, journal editors as well as relevant researchers. The target population include pregnant women who intend to have vaginal delivery or being undergoing vaginal delivery and women with perineal tears during vaginal delivery.

### 2.5 Declaration of Interests and Funding Support

All individuals engaged in the Guideline Working Group were required to complete declaration of interest forms to enhance the transparency and credibility of the CPG. The CPG has been supported by XX University.

### 2.6 Formulating clinical questions and choosing outcomes

A theoretical analysis of existing evidence on perineal tears prevention and management plus surveys with target users and population, have been used to determine the initial list of clinical questions. These questions have been sent to the Guideline Development Group for review, revision, and supplementation via Delphi surveys. The identified clinical questions have then be structured in PICO format. Furthermore, the outcomes have been rated in order of importance by the Guideline Development Group through online surveys. Panelists have been asked to score each outcome from 1 to 9 (7–9 indicate critical for a decision, 4–6 indicate important, and 1–3 indicate not important) based on the effectiveness and safety of the interventions. Then the PICOs of the CPG and the outcomes have been finalized by the Guideline Steering Group. This CPG has covered 21 clinical questions and these clinical questions can be grouped into two categories: (1) What are the effective and safety interventions to prevent perineal tears at vaginal delivery, (2) What are the effective and safety interventions to manage perineal tears.

### 2.7 Evidence Retrieval and Synthesis

The following electronic databases have been systematically searched for eligible studies in PubMed, Embase, the Cochrane Library, CINAHL and three Chinese literature databases (CBM, CNKI and WanFang). The search deadline was August in 2021. Our search terms were a combination of text free terms and Medical Subject Headings (MeSH) terms. The search strategy has been appropriately adjusted

according to the specific PICO questions and the characteristics of each database. The reference lists of the included literature have been scrutinized to identify additional relevant studies.

Endnote X9 software has used to screen and manage the literature. Randomized controlled trials (RCTs) related to the study have been retrieved for each PICO question and based on review of the titles, abstracts, and full texts. To ensure the consistency of the literature selection standards, all members of the Systematic Evaluation Group conducted a pre-test. We randomly selected 20 references for the pre-test. By summarizing the results of our literature selection and discussing the inconsistencies, all members had a definite understanding of the inclusion and exclusion criteria.

In order to incorporate China's domestic literature, a systematic review will be undertaken by the Systematic Evaluation Group for each of the PICO questions following the Cochrane Handbook version 5.1.0. The risk of bias of the included studies will be assessed by two independent reviewers using the Cochrane Collaboration tool (risk of bias, ROB) for assessing randomized controlled trials. The data of the included studies have then been extracted by the two researchers independently using a standardized data extraction form, which has been cross-checked by two reviewers. A senior reviewer will be asked to resolve any disagreements through a group discussion. If the extracted data show effect homogeneity across studies, then these data can be combined using meta-analyses. Conversely, if heterogeneity exists, the evidence will be presented in a narrative synthesis. The systematic review will be presented in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement.

### 2.8 Evaluating evidence and developing recommendation strength

The guideline methodologists will be in charge of training all members of Systematic Evaluation Group to evaluate the evidence quality. The GRADE system will be adopted by the Systematic Evaluation Group to rate the quality of the body of evidence as high, moderate, low or very low. The GRADE evidence profiles [26] and the SoFs tables [27]for each PICO question will be prepared and presented to the guideline development group. The group will discuss the quality of the evidence, the patients' values and preferences, the balance between the pros and cons, the economic analysis and the impact of resources according to the GRADE tool. The strength of recommendations will be preliminarily determined through 2–4 rounds of the Delphi process by using GRADE grid [28]. The strength of recommendation is divided into strong recommendation, weak recommendation, unclear recommendation, weak no recommendation, strong no recommendation. The recommendation will be adopted on each item if the approval ratio of the experts is more than 50% for any option or more than 70% for one of the two options on same side. Otherwise, the item will be deemed controversial and will need one more round of the Delphi process. The draft recommendations will be sent to the External Review Group for peer review, then be submitted to Guideline Steering Group for final approval.

### 2.9 Drafting the guideline

The CPG will be drafted according to the RIGHT statement [25]. The Guideline Secretary Group and the Guideline Steering Group will draft the CPG collaboratively.

### 2.10 Peer Review of Guideline

The draft CPG will be peer reviewed by external experts. The Guideline Secretary Group will record the review process and the Guideline Development Group will respond to the comments after a full discussion of these comments. The draft CPG can be appropriately revised if necessary.

### 2.11 Release and update of the guideline

It is estimated that the full text will be published in 2022. This CPG will be translated into English and published in relevant journals. The Guideline Development Group will update the guidelines 3–5 years, with the consideration of specific conditions such as emergence of new relevant evidence after the publication of the CPG and evidence changes affecting the CPG recommendations or changes in the strength of the CPG recommendations.

### 2.12 Promotion, implementation, and evaluation of the guideline

After releasing the CPG, the dissemination and promotion of the CPG will be implemented by School of Nursing, Southern Medical University. It will be in charge of the following tasks: (1) proposing the CPG in relevant seminars and forums, (2) organizing a learning session or conference to release the CPG to obstetricians, midwives, nursing staff and other related personnel, (3) writing articles related to the CPG and publishing them in journals, popular medical or official health websites, (4) conducting a research to evaluate the impact of the CPG in China and assessing the implementation of the CPG in 2 years after its publication.

### 2.13 Patient and Public Involvement statement

Women of childbearing age only shall be involved in our study as patient representatives. They will participate in our survey to formulate the clinical questions and choose outcomes.

## 3 Conclusion

This will be the first CPG developed in China to provide standards for perineal tears prevention and management. In this CPG, we will strickly follow the new guideline definition from IOM, abide by the methodology from the World Health Organization handbook for guideline and adopt the GRADE approach to rate the quality of evidence and develop recommendations, in hopes that result in an enhanced quality guideline which is expected to be implemented more widely and standardly than previously, thus improving the effectiveness and safety of perineal tears prevention and management. We believe that this CPG for perineal tears prevention and management based on the available high-quality evidence and tailored to the Chinese health care system will help medical staff in delivery rooms or Obstetric Department effectively prevent and manage perineal tears.

# Strengths And Limitations Of This Study

- This protocol outlines the development of the first evidence-based CPG on prevention and management of perineal tears in China.
- This protocol will ensure that the process of guideline development is normative, scientific, and transparent.
- A limitation of our study is the non-international panel of experts and stakeholders so the CPG is only tailored to the Chinese health care system.

# Declarations

### Ethics approval and consent to participate

The need for ethics approval was waived by the Institutional Review Boards of the Southern Medical University. The consent to participate is not applicable.

### Consent for publication

Not applicable.

### Availability of data and materials

Not applicable.

### Competing interests

The authors declare that they have no competing interests.


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### Authors' contributions

SL and XL wrote the manuscript and they contributed to the study equally. TJH and ZLL conceived the study. GL provided methodological guidance. LST and LYY participated in arranging members of Guideline Development Group. All authors read and approved the final manuscript.


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# References

1. Kettle C, Tohill S. Perineal care. Clin Evid (Online) 2008. [http://www.ncbi.nlm.nih.gov/pubmed/19445799] (accessed 20th June 2012).
2. Smith LA, Price N, Simonite V, Burns EE. Incidence of and risk factors for perineal trauma: a prospective observational study. BMC Pregnancy Childbirth. 2013,13:59. https://doi.org/10.1186/1471-2393-13-59.
3. Monteiro M, Pereira G, Aguiar R, Azevedo RL, Correia-Junior MD, Reis Z. Risk factors for severe obstetric perineal lacerations. Int Urogynecol J. 2016,27:61–67. doi: 10.1007/s00192-015-2795-5.
4. Dudding TC, Vaizey CJ, Kamm MA. Obstetric anal sphincter injury: incidence, risk factors, and management. Ann Surg. 2008, 247:224–237. doi: 10.1097/SLA.0b013e318142cdf4.
5. Ekeus C, Nilsson E, Gottvall K. Increasing incidence of anal sphincter tears among primiparas in Sweden: a population-based register study. Acta Obstet Gynecol Scand. 2008,87:564–573. doi:10.1080/00016340802030629.
6. Sundquist JC. Long-term outcome after obstetric injury: A retrospective study. Acta Obstet Gynecol Scand 2012,91(6):715–18. doi:10.1111/j.1600-0412.2012.01398.x.
7. Gommesen D,Nøhr E, Qvist N, Rasch V. Obstetric perineal tears, sexual function and dyspareunia among primiparous women 12 months postpartum: a prospective cohort study. BMJ.2019,16,9(12):e032368. doi: 10.1136/bmjopen-2019-032368.
8. Royal College of Obstetricians and Gynaecologists. The Management of Third- and Fourth-Degree Perineal Tears (Green top 29). London: Royal College of Obstetricians and Gynaecologists, 2015.
9. Australian Institute of Health and Welfare. Mothers and Babies Report. In: Australian Institute of Health and Welfare, ed. Canberra: Australian Government, 2018.
10. Priddis H, Dahlen H, Schmied V. Women's experiences following severe perineal trauma: a meta-ethnographic synthesis. J Adv Nurs 2013, 69(4): 748–759. doi: 10.1111/jan.12005.

11. Sultan AH, Thakar R, Fenner DE, editors. Perineal and anal sphincter trauma: diagnosis and clinical management. London: Springer, 2007.
12. Fernando RJ, Williams AA, Adams EJ. Royal College of Obstetricians and Gynaecologists .The management of third and fourth degree perineal tears. RCOG Green top Guidelines No 29. 2007.
13. Koelbl HIT, Salvatore S, Laterza RM, Lowry A, Sievert KD. Pathophysiology of urinary incontinence, faecal incontinence and pelvic organ prolapse. In: Abrams P, Cardozo L, Khoury S, Wein A, editors. Incontinence. 5th ed. ICUD-EAU, 2013, 261–359.
14. WHO recommendations: intrapartum care for a positive childbirth experience Geneva: Health Organization, 2018. Licence: CC BY-NC-SA 3.0 IGO. [EB/OL]. (2018-01-01).https://www.who.int/reproductivehealth/publications/intrapartum-care-guidelines/en/
15. NICE.Intrapartum care for healthy women and babies [EB/OL]. (2017-02-21)[2021-05-23]. https://www.nice.org.uk/guidance/cg190/chapter/Update-information
16. Waldman R. ACOG Practice Bulletin No. 198: prevention and management of obstetric lacerations at vaginal delivery [J]. Obstet Gynecol, 2019, 133(01): 185.
17. Clinical Practice Guideline on Care in Normal Childbirth. Quality Plan for the Spanish National Healthcare System of the Spanish Ministry for Health and Social Policy. Health Technology Assessment Agency of the Basque Country (OSTEBA). Health Technology Assessment Agency of Galicia (avalia-t). 2010. Clinical Practice Guidelines in the Spanish National Healthcare System: OSTEBA No. 2009/01.
18. Murphy D, Strachan B, Bahl R, on behalf of the Royal College of Obstetricians and Gynaecologists. Assisted Vaginal Birth: Green-top Guideline No. 26 . BJOG: An International Journal of Obstetrics & Gynaecology, 2020, 127(9): e70-e112. doi: 10.1111/1471-0528.16092.
19. Ducarme G, Pizzoferrato A-C, De Tayrac R, Schantzd C, Thuberte T, Rayf CL, Riethmullerg D,Verspyckh E, Gachoni B, Pierrei F, Artzner F, Jacquetin B, Fritel X. Perineal prevention and protection in obstetrics: CNGOF clinical practice guidelines. Journal of gynecology obstetrics and human reproduction, 2019, 48(7): 455-60. doi: 10.1016/j.jogoh.2018.12.002.
20. Roper J C , Amber N , Wan O, Sultan AH, Thakar R. Review of available national guidelines for obstetric anal sphincter injury. International Urogynecology Journal, 2020, 31:2247-2259. doi: 10.1007/s00192-020-04464-5.
21. World Health Organization. (2014). WHO handbook for guideline development, 2nd ed. World Health Organization. https://apps.who.int/iris/handle/10665/145714
22. Institute of MedicineClinical practice guidelines we can trust. Washington DC: The National Academies Press, 2011.
23. Guyatt GH, Oxman AD, Vist GE, Kunz R, Falck-Ytter Y, Alonso-Coello P, Schünemann HJ. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ, 2008,336(7650): 924–926. doi: 10.1136/bmj.39489.470347.AD.
24. Brouwers MC, Kerkvliet K, Spithoff K. The AGREE Reporting Checklist: a tool to improve reporting of clinical practice guidelines. BMJ 2016,352:i1152. doi: 10.1136/bmj.i1152.

25. The RIGHT Group: Essential Reporting Items for Practice Guidelines in Healthcare (RIGHT). 2014. cited 2014 http://www.right-statement.org/ (accessed 5 May 2014) .
26. Schünemann HJ, Mustafa RA, Brozek J,Steingartd KR, Leeflange M, Muradf MH, Bossuyte P, Glaszioug P, Jaeschke R, Lange S, Meerpohl J, Langendam M, Hultcrantz M, Vist GE, Akl EA, Helfand M, Santesso N, Hooft L, Guyatt GH. GRADE guidelines: 21 part 2. Test accuracy: inconsistency, imprecision, publication bias, and other domains for rating the certainty of evidence and presenting it in evidence profiles and summary of findings tables. J Clin Epidemiol 2020,122:142-52. doi: 10.1016/j.jclinepi.2019.12.021.
27. Carrasco-Labra A, Brignardello-Petersen R, Santesso N, Neumann I, Mustafa RA, Mbuagbaw L, Ikobaltzeta IE, Stio CD, McCullagh LJ, Alonso-Coello P, Meerpohl JJ, Vandvik PO, Brozek JL, Akl EA, Bossuyt P, Churchill R, Glenton C, Rosenbaum S, Tugwell P, Welch V, Garner P, Guyatt G, Schünemann HJ. Improving GRADE evidence tables part 1: a randomized trial shows improved understanding of content in summary of findings tables with a new format. J Clin Epidemiol 2016,74:7-18. doi: 10.1016/j.jclinepi.2015.12.007.
28. Jaeschke R, Guyatt GH, Dellinger P, Schünemann HJ, Levy MM, Kunz R, Norris S, Bion J. Use of GRADE grid to reach decisions on clinical practice guidelines when consensus is elusive. BMJ 2008,337:a744. doi: 10.1136/bmj.a744.

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Appendix1characteristicsof18CPGs.pdf