WHO recommendation on **duration of bladder catheterization after surgical repair of simple obstetric urinary fistula**

World Health Organization

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Contents

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Acronyms and abbreviations

CI	confidence interval
DOI	declaration of interest
FWC	Family, Women's and Children's Health (WHO cluster)
GDG	Guideline Development Group
GRC	Guideline Review Committee
GRADE	Grading of Recommendations Assessment, Development and Evaluation
GREAT	Guideline development, Research priorities, Evidence synthesis, Applicability of evidence, Transfer of knowledge – the GREAT Network (WHO project)
FIGO	International Federation of Gynecology and Obstetrics
LMIC	Low- and middle-income country
MCA	Maternal, Newborn, Child and Adolescent Health (WHO Department)
MPA	Maternal and Perinatal Health & Preventing Unsafe Abortion (a team in WHO's RHR Department)
PICO	population (P), intervention (I), comparator (C), outcome (O)
RHR	Reproductive Health and Research (WHO Department)
RR	relative risk
UNFPA	United Nations Population Fund
USAID	United States Agency for International Development
WHO	World Health Organization

Executive summary

Introduction

An obstetric fistula is an abnormal opening between a woman's genital tract and her urinary tract and/or rectum caused by prolonged obstructed labour. Obstetric fistula has devastating consequences for the lives of women and their families.

The prevalence of obstetric fistula is approximately 1.6 per 1000 women of reproductive age in sub-Saharan Africa and 1.2 per 1000 in South Asia.

Most obstetric urinary (vesicovaginal) fistulae can be repaired surgically, and the routine postoperative care of these patients involves the use of an indwelling urinary catheter to promote continuous urine drainage and to allow tension-free healing of the surgical scar. The duration of routine postoperative bladder catheterization is not standardized and varies widely in clinical practice, ranging from 5 to 42 days, with direct health and budgetary implications.

Long duration of bladder catheterization to allow complete healing can be inconvenient for the woman, her family and care providers as it is associated with more discomfort and inconvenience to patients, increased risk of infection and erosion related to catheterization, more intensive nursing care and more cost per patient. Shorter periods of postoperative bladder catheterization have been tested and shown to be effective in allowing complete healing with improved patient comfort and potentially lower risks of catheter-related urinary tract infections.

Evidence-based guidance on the duration of bladder catheterization after surgery can improve the health and well-being of women with obstetric fistula. The goal of the present guideline is to consolidate guidance for the effective management of the indwelling catheter in women after the surgical repair of simple obstetric urinary fistula.

Target audience

The primary audience for this guideline is health-care professionals, particularly fistula surgeons and nurses providing postoperative care to women after surgery for obstetric urinary fistula. The guideline will also be useful to national and local policy-makers, and staff of nongovernmental and other organizations involved in fistula care services.

Guideline development methods

This guideline was developed following standardized operating procedures in accordance with the process described in the *WHO handbook for guideline development*. Briefly, this process included: (i) identification of the priority question and critical outcomes; (ii) retrieval of the evidence; (iii) assessment and synthesis of the evidence; (iv) formulation of the recommendation; and (v) planning for the dissemination, implementation, impact evaluation and updating of the guideline. The scientific evidence supporting the recommendation was evaluated using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. A systematic review was conducted, and this was used to prepare evidence profiles for the priority question. The World Health Organization (WHO) subsequently convened a Technical Consultation in May 2017 where an international group of experts – the Guideline Development Group (GDG) – formulated and approved the recommendation based on the synthesized evidence.

Recommendation

At the WHO Technical Consultation, the GDG adopted the following recommendation covering the priority question related to the duration of catheterization after surgical repair of simple obstetric urinary fistula:

For women in the postoperative period after the surgical repair of a simple obstetric urinary fistula, short duration bladder catheterization (7 to 10 days) is recommended as an alternative to longer duration of catheterization.

Remarks

- The GDG acknowledges that there are several ways of defining the severity of fistula. For the purposes of this recommendation, the GDG considered "simple" fistula as a mid-anterior vaginal wall fistula with minimal scarring and with a diameter of 3 cm or less.
- For fistula cases that are not considered simple, an option different to the one recommended in this guideline may be required.
- The GDG acknowledges the variation in the use of bladder catheter after fistula surgery and notes that some surgeons may consider "short" duration of catheterization to be less than 7 days. However, for the purposes of this recommendation, the GDG defines short duration as 7 to 10 days.
- This recommendation is applicable to any context where women experience simple obstetric urinary fistula due to obstructed labour.
- The GDG accepts the uncertainty in the outcomes for shorter and longer duration of bladder catheterization in light of other benefits, such as improvement in patients' comfort, potential reduction in the risk of infections associated with the catheterization, and decrease in patients' needs for health services.
- While shorter hospitalization associated with shorter postoperative bladder catheterization would increase the availability of fistula care services (so that more patients could potentially be treated), this should be carefully balanced with the quality of services (i.e. the provision of a holistic care package to women who are recovering from obstetric fistula repair).

For this recommendation, the overall quality of evidence was graded as low to moderate. In the formulation of the recommendation, the GDG also considered the balance between benefits and harms, the values and preferences of stakeholders, and the resource implications of the intervention. To ensure that the recommendation is correctly understood and applied in practice, the contributing experts formulated a set of remarks, as listed above, to accompany the recommendation, based on key points of discussion. Guideline users should refer to these remarks, as well as the evidence summary (presented in the full text of the guideline) if there is any doubt as to the basis for the recommendation or any question about how to best implement it.

In accordance with WHO guideline development procedures, this recommendation will be regularly reviewed and updated following identification of new evidence, with major reviews and updates at least every five years. WHO welcomes suggestions regarding additional questions for inclusion in future updates of the guideline.

1. Introduction

1.1 Background

An obstetric fistula is an abnormal opening between a woman's genital tract and her urinary tract and/or rectum caused by prolonged obstructed labour. Obstructed labour is associated with soft tissue ischaemia resulting from compression by the fetal head against the pelvic bones. When the mother's pelvis is too narrow or the baby is too large or presenting in an abnormal position, labour can last several days and often results in the death of the baby and/or the mother. If the mother survives, she could develop a fistula and become unable to control her rectal and/or urinary functions and be constantly soiled and/or wet.

While obstetric fistula is a rare condition in high-income countries *(1)*, in sub-Saharan Africa and South Asia prevalence is estimated at 1.6 and 1.2 per 1000 women, respectively *(2)*. Most obstetric urinary (vesicovaginal) fistulae can be repaired surgically and the routine postoperative care of these patients involves the use of an indwelling urinary catheter to promote continuous urine drainage and to allow tension-free healing of the surgical scar *(3)*. The duration of routine postoperative bladder catheterization is not standardized and varies widely in clinical practice, ranging from 5 to 42 days, with direct health and budgetary implications *(4,5)*.

Long duration of bladder catheterization to allow complete healing can be inconvenient for the woman, her family and care providers. A long duration of bladder catheterization translates into the need for longer hospitalization in low-income countries, since these women cannot be managed as outpatients because of their catheter needs. Long bladder catheterization is also associated with more discomfort and inconvenience to patients, increased risk of infection and erosion related to catheterization, more intensive nursing care and more cost per patient *(6)*. Shorter periods of postoperative bladder catheterization have been tested in simple cases of obstetric fistula and shown to be effective in allowing complete healing with improved patient comfort and potentially lower risks of catheter-related urinary tract infections *(7)*.

The surgical repair of obstetric fistulae depends on the availability of operating rooms and adequate bed space for the recovery period, trained surgeons with specialized skills and, in many cases, funding from donors to support the operations and the postoperative care of these patients. In most contexts in low- and middle-income countries (LMICs), the need for fistula repair services far exceeds the available human and infrastructural capacity of the health system. A shorter duration of bladder catheterization would mean shorter hospital stays and consequently increased numbers of fistula patients who could be treated in existing facilities.

Evidence-based guidance on the duration of bladder catheterization after surgery can improve the health and well-being of women with fistula.

1.2 Rationale and objectives

Decisions related to fistula care are often based on the preferences of individual surgeons rather than on evidence from research, and despite the scarcity of evidence-based data on the management of fistula, there is a need to make formal recommendations about fistula care to improve women's health and well-being.

As part of the World Health Organization's (WHO's) normative work on supporting evidence-informed policies and practices, the Department of Reproductive Health and Research has produced, as a first step, this guideline focused on the duration of bladder catheterization after the surgical repair of simple obstetric urinary fistula, as this is an intervention that can be implemented by any appropriately trained surgeon, including one with less experience, and it has direct health and cost implications in LMICs.

This guideline provides a foundation for the sustainable implementation of this intervention, which will help to alleviate the suffering of many women with simple obstetric urinary fistula.

1.3 Target audience

The primary target audience for this guideline is health-care professionals, particularly fistula surgeons and nurses providing postoperative care to women after surgery for obstetric urinary fistula. The guideline will also be useful to national and local policy-makers, and staff of nongovernmental and other organizations involved in fistula care services.

1.4 Scope of the guideline

The population affected by this guideline includes women diagnosed with simple obstetric urinary fistula, a condition which is defined as a vesicovaginal fistula caused by obstructed labour. The guideline does not cover complex obstetric fistulae or those that do not have an obstetric cause.

2. Methods

This document represents WHO's normative support for using evidence-informed policies and practices in all countries. The guideline was developed following standardized operating procedures in accordance with the process described in the *WHO handbook for guideline development (8)*. In summary, the process included: (i) identification of the priority question and critical outcomes; (ii) retrieval of the evidence; (iii) assessment and synthesis of the evidence; (iv) formulation of the recommendation; and (v) planning for the dissemination, implementation, impact evaluation and updating of the guideline.

The guideline development process involved the formation of four main groups to guide and implement the process. Their specific roles are described in the next subsection. The members of all these groups and other contributors are listed in Annex 1.

2.1 Contributors to the guideline

WHO Steering Group

The WHO Steering Group, comprising WHO staff members from the Departments of Reproductive Health and Research (RHR) and Maternal, Newborn, Child and Adolescent Health (MCA), guided and managed the entire guideline development process. The Steering Group drafted the initial scope of the guideline and drafted the priority question in PICO format, and also identified members for the Guideline Development Group (GDG), the External Review Group and the Systematic Review Team, including

the guideline methodologists. In addition, the Steering Group supervised the retrieval and synthesis of evidence, organized the GDG meeting (the WHO Technical Consultation on Duration of Catheterization after Surgical Repair of Simple Obstetric Fistula, held in May 2017 in Geneva, Switzerland), drafted and finalized the guideline document and managed the guideline dissemination, implementation, and impact assessment.

Guideline Development Group

The Steering Group identified 11 external experts and relevant stakeholders from the WHO African Region, the Region of the Americas, the East Mediterranean Region and the European Region to constitute the GDG. This diverse group of individuals had expertise in research, guideline development methods, and clinical policy and programmes relating to obstetric fistula. The group also included representatives of women who will be affected by the recommendation. The GDG members were selected in a way that ensured geographic representation and gender balance, and there were no important conflicts of interest. Selected members of this group provided input into the drafting of the guideline scope and the PICO question, and participated in prioritization of outcomes that guided the evidence reviews. Additionally, the group appraised the evidence that was used to inform the guideline, advised on the interpretation of this evidence, formulated the final recommendation based on the draft prepared by the WHO Steering Group, and reviewed and approved the final guideline document.

External Review Group

The External Review Group (ERG) included four technical experts with sufficient experience in the provision of evidence-based fistula care from the WHO African, European and South-East Asia Regions. None of the ERG members declared a conflicting interest. The ERG reviewed the final guideline document to identify any errors of fact and commented on clarity of the language, contextual issues and implications for implementation. The group ensured that the guideline decision-making processes had considered and incorporated contextual values and preferences of potential users of the recommendations (i.e. patients), as well as health-care professionals and policy-makers. The ERG did not change the recommendation that was formulated by the GDG.

Systematic Review Team, led by guideline methodologists

A systematic review was conducted by the Systematic Review Team, led by two guideline methodologists, and with input from members of the WHO Steering Group *(9)*. The Steering Group worked closely with the guideline methodologists to appraise the evidence using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology *(10)*.

External partners and observers

Representatives of the International Federation of Gynecology and Obstetrics (FIGO), the United Nations Population Fund (UNFPA) and the United States Agency for International Development (USAID) attended the GDG meeting as observers. All these organizations are potential implementers of the proposed guideline with a long history of collaboration with WHO's RHR Department in the area of guideline dissemination and implementation. The names of observers who participated at the GDG meeting are also provided in Annex 1.

2.2 Identification of the priority question and critical outcomes

In consultation with members of the GDG, the Systematic Review Team and the guideline methodologists, the WHO Steering Group first drafted the priority question and the potential "critical" and "important" outcomes related to the management of the catheter after surgery for simple obstetric urinary fistula. The priority question was written in the PICO format, mentioning the population, intervention, comparator and outcome in turn. The potential critical and important outcomes were identified through a search of key sources – relevant published articles. This exercise generated a total of nine outcomes, which were then ranked by the Steering Group. Five outcomes were rated as critical and four were rated as important. All nine outcomes were included within the scope of this document for the purposes of evidence searching, retrieval and grading and for formulation of the recommendation. The priority/PICO question and the list of critical and important outcomes are provided in Annex 2.

2.3 Evidence identification and retrieval

To gather evidence on the priority question, the Steering Group and the guideline methodologists collaboratively screened Cochrane and non-Cochrane reviews of randomized controlled trials (RCTs). No systematic review of RCTs relevant to the question was found, so they decided to conduct a new systematic review. For this purpose, the Steering Group provided the methodologists with the standard operating procedures, the terms of reference enumerating the desired output of the systematic review, as well as the format for reporting and timelines.

The guideline methodologists, together with members of the Steering Group, developed a protocol with clear criteria for the identification and selection of studies for the systematic review, including methods for assessing risk of bias, and also developed a data analysis plan before embarking on the review. The protocol of the systematic review has been registered in PROSPERO, an international database of prospectively registered systematic reviews (CRD42017056320). The systematic review process followed standard methods recommended by the *Cochrane handbook for systematic reviews of interventions* and the PRISMA reporting guidelines *(11,12)*. The WHO librarian prepared the search strategy (presented in Annex 3). The search was run in five electronic databases (MEDLINE, Embase, CINAHL, GIM and POPLINE) and two trial register platforms. The entire systematic review development process was interactive, with the systematic reviewers and guideline methodologists constantly communicating with the members of the WHO Steering Group to discuss challenges and agree on solutions.

Evidence for the recommendation presented in this guideline was sourced from the systematic review *(9)*.

2.4 Quality assessment and grading of the evidence

Quality assessment of the body of evidence for each outcome was performed using the GRADE approach *(10)*. Using this approach, the quality of evidence for each outcome was rated as "high", "moderate", "low" or "very low", based on a set of established criteria. The final rating of quality of evidence was dependent on the factors described briefly below.

Study design limitations: The risk of bias was first examined at the level of individual study and then across studies contributing to the outcome. For the review of RCTs, quality was first rated as "high" and then downgraded by one level (to "moderate") or by two or three levels (to "low" or "very low"), depending on the minimum quality criteria met by the majority of the studies contributing to the outcome.

Inconsistency of the results: The similarity in the results for a given outcome was assessed by exploring the magnitude of differences in the direction and size of effects observed from different studies. The quality of evidence was not downgraded when the directions of the findings were similar and confidence limits overlapped, whereas quality was downgraded when the results were in different directions and confidence limits showed minimal or no overlap.

Indirectness: The quality of evidence was downgraded where there were serious or very serious concerns regarding the directness of the evidence, i.e. if there were important differences between the research reported and the context for which the recommendation was being prepared. Such differences were related, for instance, to populations, interventions, comparators or outcomes of interest.

Imprecision: This assessed the degree of uncertainty around the estimate of effect. As this is often a function of sample size and number of events, studies with relatively few participants or events – and thus wide confidence intervals around effect estimates – were downgraded for imprecision.

Publication bias: The quality rating could also be affected by perceived or statistical evidence of bias leading to underestimation or overestimation of the effect of an intervention as a result of selective publication based on study results. We considered downgrading evidence by one level for strong suspicion of publication bias.

GRADE profiler software was used to construct "summary-of-findings" tables for the priority question. These tables included the assessment and judgements on the above-described elements for each outcome, and the estimated risks. Relevant information and data were extracted in a consistent manner from the systematic review relating to the priority question by applying the following procedures. First, up-to-date review documents and/or data (e.g. RevMan file) were obtained from the review authors. Secondly, analyses relevant to the critical and important outcomes were identified and selected. The data were then imported and manually entered into the GRADE profiler software. For each outcome, GRADE assessment criteria (as described above) were applied to evaluate the quality of evidence. In the final step of the assessment process, GRADE evidence profiles were generated for the guideline question.

2.5 Formulation of the recommendation

The GRADE framework was applied to formulate the recommendation based on the synthesized evidence. The WHO Steering Group used the summary of evidence for the critical outcomes, the overall quality of the evidence, and information on the balance between benefits and harms, values and preferences, and cost/resource implications, to draft the recommendation. The draft recommendation, the evidence summary, the corresponding GRADE table, and other related documents

were provided to members of the GDG. The GDG members and other participants were then invited to attend a Technical Consultation at WHO headquarters in Geneva, Switzerland, in May 2017. At the Technical Consultation (or GDG meeting), the GDG members thoroughly reviewed and discussed the documents to finalize the recommendation.

2.6 Declaration of interests by external contributors

According to WHO regulations, all external experts must declare their relevant interests prior to participation in the WHO guideline development process and meetings. All GDG members and external contributors were therefore required to complete a standard WHO Declaration of Interest (DOI) form before engaging in the guideline development process and before participating in guideline-related meetings. The WHO Steering Group reviewed all DOI forms before finalizing the invitations for experts to participate in the development of the guideline. Where any conflict of interest was declared, the Steering Group determined whether it was serious enough to affect the expert's objective judgement relating to the guideline development process and formulation of the recommendation. To ensure consistency, for each expert, the Steering Group applied the criteria for assessing the severity of conflicts of interest in the *WHO handbook for guideline development (8)*. All findings from the received DOI statements were managed in accordance with the WHO DOI guidelines on a case-by-case basis and communicated to the experts. Where a conflict of interest was not considered significant enough to pose any risk to the guideline development process or reduce its credibility, the experts were only required to openly declare such conflict at the beginning of the GDG meeting and no further actions were taken.

Annex 4 provides a summary of the experts' declared interests and information on how any conflicts of interest were managed by the WHO Steering Group.

2.7 Decision-making during the WHO Technical Consultation

The GDG, during the Technical Consultation, discussed the draft recommendation prepared by the WHO Steering Group. In addition to evaluating the scientific evidence and its quality, the GDG considered values and preferences, the balance between benefits and harms, cost/resource implications, as well as issues of equity, acceptability and feasibility, when formulating the final recommendation. The consideration of values and preferences and the evaluation of cost/resource implications were based on the experience and opinions of the GDG members and supported by evidence from the literature, where available. "Evidence-to-decision" tables were used to note and synthesize these considerations.

The decision on the wording and strength of the recommendation was based on consensus, defined as the agreement of at least three quarters of the participants. None of the GDG members expressed strong opposition to the final wording of the recommendation or the remarks.

2.8 Document preparation

Prior to the Technical Consultation, the WHO Steering Group prepared a draft of the evidence summary and the recommendation. The draft document was made

available to the participants of the Technical Consultation two weeks before the meeting. During the meeting, the draft recommendation was modified in line with participants' deliberations and remarks. Following the meeting, members of the WHO Steering Group prepared a draft of the full guideline document including revisions that accurately reflected the deliberations and decisions of the GDG members. The draft guideline document was sent electronically to GDG members for further comments before it was sent to the External Review Group for peer review.

2.9 Peer review

The draft guideline and recommendation document, as prepared by the GDG members and WHO Steering Group, was sent to the four External Review Group (ERG) members for peer review. The WHO Steering Group subsequently carefully evaluated the inputs of the peer reviewers for inclusion in the guideline document. After the Technical Consultation and peer review were completed, any further modifications made by the Steering Group to the guideline were limited to correction of factual errors and improvement in language to address any lack of clarity.

3. Results: recommendation and evidence

Evidence on the effectiveness of the intervention was derived from one systematic review, which therefore provided the evidence base for the recommendation included in this guideline *(9)*. The sub-sections below present the recommendation and associated remarks, followed by the corresponding narrative summary of evidence for the priority/PICO question: For women in the postoperative period after the surgical repair of a simple obstetric urinary fistula (P), is shorter duration of bladder catheterization (10 days or less) (I) as effective as longer duration (more than 10 days) (C), in preventing repair breakdown (O)?

The evidence base is summarized in one GRADE table, which is presented separately in the Web annex to this document.[1] Annex 5 presents the evidence-to-decision table, summarizing the quality of the evidence, values and preferences, the balance between benefits and harms, the cost/resource implications, as well as issues of equity, acceptability and feasibility, which were all considered in formulating the recommendation and in determining its strength and direction.

3.1 Recommendation

This guideline includes one recommendation adopted by the Guideline Development Group (GDG). To ensure that the recommendation is correctly understood and appropriately implemented in practice, remarks summarizing the key points of the GDG discussions are presented with the recommendation.

1 Available at: www.who.int/reproductivehealth/publications/surgical-repair-obstetric-urinary-fistula/en/

RECOMMENDATION: For women in the postoperative period after the surgical repair of a simple obstetric urinary fistula, short duration of bladder catheterization (7 to 10 days) is recommended as an alternative to longer duration of catheterization.

Remarks

- The Guideline Development Group (GDG) acknowledges that there are several ways of defining the severity of fistula. For the purposes of this recommendation, the GDG considered "simple" fistula as a mid-anterior vaginal wall fistula with minimal scarring and with a diameter of 3 cm or less.
- For fistula cases that are not considered simple, an option different to the one recommended in this guideline may be required.
- The GDG acknowledges the variation in the use of bladder catheter after fistula surgery and notes that some surgeons may consider "short" duration of catheterization to be less than 7 days. However, for the purposes of this recommendation, the GDG defines short duration as 7 to 10 days.
- This recommendation is applicable to any context where women experience simple obstetric urinary fistula due to obstructed labour.
- The GDG accepts the uncertainty in the outcomes for shorter and longer duration of bladder catheterization in light of other benefits, such as improvement in patients' comfort, potential reduction in the risk of infections associated with catheterization, and decrease in patients' needs for health services.
- While shorter hospitalization associated with shorter postoperative bladder catheterization would increase the availability of fistula care services (so that more patients could potentially be treated), this should be carefully balanced with the quality of services (i.e. the provision of a holistic care package to women who are recovering from obstetric fistula repair).

3.2 Summary of evidence

Description of the studies contributing evidence

- Evidence on the duration of bladder catheterization after surgical repair of simple obstetric urinary fistula was derived from the systematic review that was conducted for the purposes of the development of this guideline *(9)*. The systematic review included two RCTs with a combined sample of 684 women *(6,7)*.
- The two included trials were conducted in eight African countries (the Democratic Republic of the Congo, Ethiopia, Guinea, Kenya, Niger, Nigeria, Sierra Leone and Uganda) and recruited women with a simple urinary fistula that was closed after surgery (with outcome determined by dye test). Both studies were designed to show non-inferiority of two durations of bladder catheterization.
- Barone et al., 2015, included women with simple obstetric urinary fistula as determined by the surgeon after repair surgery. Nardos et al., 2012, included women with simple obstetric urinary fistula assessed at physical exam before surgery.
- Barone et al. excluded women who were pregnant, any fistula was not simple or was multiple, and any fistula that was radiation induced, associated with cancer,

or due to lymphogranuloma venereum. Nardos et al. excluded women with a history of fistula repair, and any current vesicovaginal fistula with circumferential involvement of the urethra.

- Both trials compared shorter with longer duration of bladder catheterization postoperatively. The longer duration was the same in both trials (14 days), whereas the shorter time was 10 days in Nardos et al. and 7 days in Barone et al.
- Barone et al. reported the primary outcome (fistula repair breakdown after catheter removal) based on dye test results in all participants. Nardos et al. defined cure (the primary outcome) as the absence of leakage after catheter removal and confirmed it with a dye test only in symptomatic women.

Outcomes

- Five outcomes are considered "critical" in the context of length of postoperative bladder catheterization. There were no statistically significant differences between shorter versus longer duration of bladder catheterization for four critical outcomes: (i) the risk of fistula repair breakdown before hospital discharge (risk ratio [RR]: 1.14, 95% confidence interval (CI): 0.49–2.64; 1 study, 495 women; low-quality evidence); (ii) the risk of fistula repair breakdown after hospital discharge (RR: 1.64, 95% CI: 0.81–3.31; 1 study, 495 women; moderate-quality evidence); (iii) urinary incontinence after hospital discharge (RR: 1.16, 95% CI: 0.62–2.18; 1 study, 495 women; low-quality evidence); and (iv) extended hospital stay (RR: 9.33, 95% CI: 0.51–172.41; 1 study, 495 women; moderate-quality evidence). The fifth critical outcome – maternal satisfaction with care – was not reported in any of the studies.
- The remaining four outcomes are classified as "important" in the context of postoperative bladder catheterization. There were no statistically significant differences between shorter versus longer duration of bladder catheterization for three outcomes: (i) post-repair urinary infection (RR: 5.18, 95% CI: 0.25–107.44; 1 study, 495 women; low-quality evidence); (ii) urinary incontinence during hospital stay (RR: 1.15, 95% CI: 0.54–2.43; 1 study, 189 women; very low-quality evidence); and (iii) urinary retention after catheter removal (RR: 1.34, 95% CI: 0.79–2.27; 2 studies, 684 women; moderate-quality evidence). The fourth important outcome – the cost of care – was not reported in any of the studies.

Additional considerations

Balance of benefits and harms

The evidence base does not indicate any significant differences in adverse clinical outcomes for women after surgery for simple obstetric urinary fistula depending on whether they undergo shorter or longer periods of postoperative bladder catheterization. However, shorter duration of postoperative bladder catheterization is considered to be more convenient for the women as it represents reduced discomfort and lower probability of having complications associated with catheterization.

Quality of evidence

Available evidence is limited to two RCTs, with one contributing the majority of data on outcomes. The overall quality of the evidence was low to moderate for critical outcomes.

The main reason for downgrading the quality of the evidence from "high" was imprecision in the effect estimates (rarity of events and wide confidence intervals).

Values and preferences

Women with fistula, irrespective of which country they are from, are likely to place a high value on shorter duration of catheterization. Shorter bladder catheterization represents less discomfort and inconvenience to the women, allowing them to regain personal health and well-being more quickly and resume their lives. Prolonged bladder catheterization equates to extended need for health services (e.g. hospitalization, since outpatient management is not possible for those with catheter needs) and increased risk of pain, infection and erosion related to the catheter. No systematic review was identified and/or conducted for this criterion. The panel is confident that health-care providers and women from different countries and settings value shorter treatment duration similarly highly.

Resources and costs

Neither of the trials included in the systematic review captured the cost of care or other resource implications. However, the implementation of the shorter duration of catheterization is likely to reduce costs and lead to more cost-effective use of health-care resources. Patients treated for a shorter period would have less risk of complications such as nosocomial infections, and may need fewer health-care services (e.g. shorter hospital stays).

Equity

The recommendation is likely to reduce health inequities. Women with shorter duration of catheterization would be able to regain health and well-being and to socially reintegrate more quickly than those who are catheterized for longer periods. Resuming their roles in the family and in the community is of paramount importance for these women, who are often marginalized from their families and communities while living with fistula, such that their quality of life is severely affected.

Acceptability

The short duration of catheterization after the surgical repair of simple obstetric urinary fistula is not associated with adverse clinical outcomes. By implementing the shorter duration of catheterization, health-care managers and providers would be able to offer fistula repair services to more women as the postoperative nursing care would be shorter and patients would be discharged from hospital sooner. For the patients, having the catheter in place for a shorter period would potentially reduce the risk of complications associated with catheterization, and would mean shorter hospital stays and faster social reintegration.

Feasibility

The shorter duration of catheterization post-surgery does not warrant additional care when it is compared to the longer duration. Both methods are considered equally feasible as the catheterization procedures are the same. No additional resources, infrastructure or training are needed.

4. Research implications

Despite the burden of fistula, the evidence backing the recommendation made in this guideline was limited to two RCTs and the quality of the evidence was generally rated as low. Therefore, the GRADE methodology suggests that further research is very likely to have an impact on the direction and/or strength of the recommendation.

Based on this approach, the GDG identified critical gaps in current evidence. The two available trials are only applicable to cases of simple fistula, and they did not evaluate the effectiveness of treatment with catheter for less than 7 days. The following are the research gaps (remaining questions) related to catheterization after fistula repair surgery identified during the guideline development process.

- For women in the postoperative period after the surgical repair of a simple obstetric urinary fistula, is 3–5 days of bladder catheterization as effective as 7 days, in terms of preventing repair breakdown?
- For women in the postoperative period after surgical repair of any type of obstetric urinary fistula (including complex), is shorter duration of bladder catheterization as effective as longer duration, in terms of preventing repair breakdown?
- For women in the postoperative period after the surgical repair of any type of obstetric urinary fistula (including complex), is shorter duration of bladder catheterization more cost-effective than longer duration?

In addition, the following research issues were identified during the GDG meeting for overall area of obstetric fistula.

- Evaluate existing strategies for reducing the incidence of obstetric fistula at the country level.
- Develop and evaluate community-based interventions for the prevention of obstetric fistula.
- Introduce symphysiotomy in emergency obstetric care for prevention of fistula.
- Develop and evaluate perioperative fistula training programmes for fistula surgeons and midwives to improve fistula surgery outcomes.
- Assess the effectiveness of physical exercise before and after surgery/ rehabilitation for improving surgical outcomes.
- Determine if simple surgical procedures (i.e. 2–3 simple sutures to adapt fistula edges) could enhance spontaneous closure of the fistula or increase the success rate of the repair surgery.
- Determine the optimal time between the occurrence of the fistula and the repair.
- Describe the bladder dysfunctions after fistula surgery and determine the best interventions to prevent or treat them.
- Assess the effectiveness of one layer closure of bladder versus a two-layer closure.

- Assess the effectiveness of conservative management with a Foley bladder catheter for fresh urinary fistula.
- Assess the effectiveness of physiotherapy to enhance bladder functioning postoperatively, following fistula repair.
- Assess the incidence of fistula repair breakdown or recurrence months and/or years after repair.
- Develop and evaluate fistula rehabilitation programmes for women following fistula repair to ensure successful social reintegration.
- Identify rehabilitation determinants with a focus on legal rights support, mental health needs, paediatric rehabilitation for live-born infants and patient-identified gaps in services related to the full spectrum of mother and infant morbidities caused by prolonged obstructed labour.

5. Dissemination and implementation of the guideline

The overall goal of this guideline is to improve the surgical outcomes and the quality of care of women with obstetric urinary fistula. Dissemination and implementation of the recommendation in this guideline is to be considered by all actors implicated in the provision of care for women with obstetric fistula at the international, national and local levels. There is a vital need to increase access and strengthen the capacity of health-care facilities to provide high-quality services for the care of women living with fistula, including fistula repair and postoperative care. It is therefore crucial that this recommendation is put into practice at fistula treatment programmes in all countries.

5.1 Guideline dissemination and evaluation

The recommendation made in this guideline will be disseminated through WHO regional and country offices, ministries of health, professional organizations, WHO collaborating centres, other United Nations (UN) agencies, and nongovernmental organizations, among others. This guideline will also be available on the WHO website[2] and the WHO Reproductive Health Library (RHL).[3] To increase awareness of the guideline, a short commentary will be published in a peer-reviewed journal. The guideline will also be disseminated during meetings and scientific conferences attended by staff of WHO's Department of Reproductive Health and Research (RHR). The executive summary will be translated into the six UN languages and disseminated through the WHO regional offices. Technical assistance will be provided to any WHO regional office willing to translate the full guideline into any of the six UN languages.

The guideline was evaluated using the AGREE-II appraisal instrument to assure that the document meets international quality standards and reporting criteria.[4]

2 Department of Reproductive Health and Research, departmental website: http://www.who.int/reproductivehealth/about_us/en/
3 Available at: https://extranet.who.int/rhl/about
4 Further information available at: www.agreetrust.org/agree-ii/

5.2 Guideline implementation

The Maternal and Perinatal Health & Preventing Unsafe Abortion team of the WHO's RHR Department will support national and local groups to adapt and implement the guideline based on the strategy used by the GREAT (Guideline-driven, Research priorities, Evidence synthesis, Application of evidence, and Transfer of knowledge) Network, which was established by WHO and partners in 2012.[5] The GREAT Network uses a unique evidence-based knowledge translation (KT) approach to support low- and middle-income countries (LMICs) in the adaptation and implementation of guidelines relating to reproductive, maternal, perinatal and newborn health, which has been successfully employed for other guidelines in many countries. Specifically, the GREAT Network brings together relevant stakeholders to identify and assess the priorities, barriers and facilitators to guideline implementation, and supports the efforts of these stakeholders to develop strategies for guideline adaptation and implementation, tailored to the local context. This support includes technical support provided to local guideline implementers in the development of training manuals, flow charts and quality indicators, as well as support for participation in stakeholders meeting.

6. Applicability issues

6.1 Anticipated impact on the organization of care and resources

The implementation of this recommendation will not require additional resources since the recommendation only affects the duration of an intervention that is already practised in fistula care settings. The GDG noted that including this recommendation in the fistula training curricula would facilitate its broader implementation and thus increase the impact. Standardizing the methods of postoperative management by including this recommendation would strengthen the capacity of fistula centres to provide high-quality services for more women living with obstetric urinary fistula.

6.2 Monitoring and evaluating the impact of the guideline

The implementation and impact of the recommendation in this guideline should be monitored at the health-service, regional and country levels based on the following indicators: fistula repair breakdown before hospital discharge, fistula repair breakdown after hospital discharge, urinary incontinence after hospital discharge, length of hospital stay and maternal satisfaction with care. The recommended set of indicators can be adapted at the regional and country levels to assess the impact of implementation of and adherence to the recommendation.

In collaboration with the monitoring and evaluations teams of the WHO Departments of RHR and MCA, data on country- and regional-level implementation of the recommendation will be collected and evaluated in the short-to-medium term to evaluate its impact on the national policies of individual WHO Member States.

5 Further information available at: www.greatnetworkglobal.org

7. Updating the guideline

In accordance with the concept of the GREAT Network, which employs a systematic and continuous process of identifying and bridging evidence gaps following guideline implementation,[6] this guideline will be updated five years after publication unless significant new evidence emerges which necessitates earlier revision. The WHO Steering Group will continue to follow research developments in the area of obstetric fistula. Following publication and dissemination of the guideline, any concerns about the validity of the recommendation will be promptly communicated to guideline implementers globally and plans will be made to update the recommendation accordingly.

As the guideline nears the end of the proposed five year validity period, the responsible technical officer (or another designated WHO staff person), in conjunction with the Steering Group, will assess the validity of the recommendation in light of current evidence, and the need for new guidance on the topic. If there are concerns about the validity of the recommendation based on new evidence, the systematic review addressing the primary question will be updated. To update the review, the existing search strategy used for the initial review will be reapplied in order to capture more recently published studies, possibly by the same systematic review team or another team if the initial review team is no longer available. Any new questions identified following the scoping exercise at the end of five years will undergo a similar process of evidence retrieval, synthesis and grading in accordance with the WHO process for guideline development.

WHO welcomes suggestions regarding additional questions for inclusion in the updated guideline. Please email your suggestions to: mpa-info@who.int

6 Further information available at: www.greatnetworkglobal.org

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Annex 2. Critical and important outcomes for decision-making

PICO question	Priority outcomes
For women in the postoperative period after the surgical repair of a simple obstetric urinary fistula (P), is shorter duration of bladder catheterization (10 days or less) (I) as effective as longer duration (more than 10 days) (C), in preventing repair breakdown (O)?	Critical outcomes: • Fistula repair breakdown before hospital discharge • Fistula repair breakdown after hospital discharge • Urinary incontinence after hospital discharge • Extended hospital stay • Maternal satisfaction with care
	Important outcomes: • Post-repair urinary tract infection • Urinary incontinence during hospital stay • Cost of care • Urinary retention after catheter removal

PICO:
P: population
I: intervention
C: comparator
O: outcome

Annex 3. Search strategy

Search conducted: 29 December 2016

#	Database: PubMed - http://www.pubmed.gov	Results
1	"Vaginal Fistula" [Mesh] OR ((Vesicovaginal [TW] OR urinary [TW] OR obstetric [TW] OR "female genital" [TW] OR Vaginal [TW]) AND Fistula [TW])	12 001
2	("Catheterization" [Mesh] OR Catheteri* [TW] OR Cannulat* [TW])	221 369
3	Step 1 AND Step 2	736
#	**Database Embase - http://www.embase.com**	**Results**
1	((Vesicovaginal OR urinary OR obstetric OR "female genital" OR vaginal):ti,ab AND Fistula:ti,ab) OR "rectovaginal fistula"/exp OR "cystovaginal fistula"/exp	11 341
2	"Catheterization"/exp OR catheteri*:ti,ab OR "cannulation"/exp OR cannulat*:ti,ab	2 237 720
3	Step 1 AND Step 2	643
#	**Database: POPLINE - http://www.popline.org**	**Results**
1	(((Keyword:Vesicovaginal fistula)) OR ((Title:Vesicovaginal OR Title:urinary OR Title:obstetric OR Title:"female genital" OR Title:vaginal) AND (Title:fistula*))) AND (((catheter*)))	16
#	**Database: Global Index Medicus - http://pesquisa.bvsalud.org/**	**Results**
1	(((tw:(vescovagin* OR urinary OR obstetric OR (female genital) OR vaginal)) AND ((tw:(fistula*)))) AND ((tw:(catheteri*) OR (cannulat*))))	44
#	**Database: CINAHL Full Text - http://www.ebsco.com**	**Results**
1	(MH "Vaginal Fistula+") OR ((TI Vesicovaginal OR TI urinary OR TI obstetric OR TI "female genital" OR TI Vaginal) AND TI Fistula*) OR ((AB Vesicovaginal OR AB urinary OR AB obstetric OR AB "female genital" OR AB Vaginal) AND AB Fistula*)	616
2	(MH "Catheterization+") OR (MH "Catheter Care+") OR TI Catheter* OR TI cannulat* OR AB catheter* OR AB cannulat*	61 594
3	Step 1 AND Step 2	54

Annex 4. Summary and management of declared interests from Guideline Development Group (GDG) members

Name and expertise contributed to the guideline development	Declared interest	Management of conflict of interest
Dr Dolores Nembunzu Content expert and end-user	Served as investigator to the Barone 2015 trial. Received research support in the area of fistula care.	Dr Nembunzu was accepted as a member of the GDG but did not have voting rights.
Dr Mulu Muleta Content expert and end-user	Served as investigator to the Barone 2015 trial.	Dr Muleta was accepted as a member of the GDG but did not have voting rights.
Dr Sohier Elneil Content expert and end-user	None declared	Not applicable
Dr Oladosu Ojengbede Content expert and end-user	None declared	Not applicable
Dr Serigne Gueye Content expert and end-user	None declared	Not applicable
Dr Farzana Wali Jebran Content expert and end-user	None declared	Not applicable
Dr Steven Arrowsmith Content expert and end-user	Received research support in the area of fistula care. Served as co-investigator to the Barone 2015 trial.	Dr Arrowsmith was accepted as a member of the GDG but did not have voting rights.
Dr Torvid Kiserud Content expert and end-user	None declared	Not applicable
Dr Lauri Romanzi Content expert and implementer	Authored a copyright book on pelvic organ prolapse.	The conflict was not considered serious enough to affect the GDG membership or participation in the meeting.
Dr Mark Barone Content expert and implementer	Served as principal investigator to the Barone 2015 trial.	Dr Barone did not have voting rights and did not participate in discussions on the formulation of the final recommendation.
Dr Asseefa Mekonnen Consumer representative	None declared	Not applicable
Dr Maria Regina Torloni Methodologist	None declared	As one of the methodologists for this guideline, Dr Torloni did not have voting rights.
Ms Ewelina Rogozińska Methodologist	None declared	As one of the methodologists for this guideline, Ms Rogozinska did not have voting rights.

Annex 5. Evidence-to-decision table

The table below summarizes the quality of the evidence, values and preferences, the balance between benefits and harms (desirable and undesirable effects), the cost/resource implications, as well as issues of equity, acceptability and feasibility, which were all considered in determining the strength and direction of the recommendation.

Desirable effects	- Don't know	✓ Varies		- Trivial	- Small	- Moderate	- Large
Undesirable effects	- Don't know	✓ Varies		- Large	- Moderate	- Small	- Trivial
Certainty of the evidence	- No included studies			- Very low	✓ Low	- Moderate	- High
Values and preferences				- Important uncertainty or variability	- Possibly important uncertainty or variability	- Probably no important uncertainty or variability	✓ No important uncertainty or variability
Balance of effects	- Don't know	- Varies	- Favours the comparison	- Probably favours the comparison	✓ Does not favour either the intervention or the comparison	- Probably favours the intervention	- Favours the intervention
Resources required	- Don't know	- Varies	- Large costs	- Moderate costs	- Negligible costs or savings	✓ Moderate savings	- Large savings
Certainty of evidence on required resources	✓ No included studies			- Very low	- Low	- Moderate	- High
Cost-effectiveness	- Don't know	- Varies	- Favours the comparison	- Probably favours the comparison	- Does not favour either the intervention or the comparison	✓ Probably favours the intervention	- Favours the intervention
Equity	- Don't know	- Varies	- Reduced	- Probably reduced	- Probably no impact	✓ Probably increased	- Increased
Acceptability	- Don't know	- Varies		- No	- Probably No	✓ Probably Yes	- Yes
Feasibility	- Don't know	- Varies		- No	- Probably No	- Probably Yes	✓ Yes

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