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Protocol: a systematic review and meta-analysis of prevalence of, and risk factors for, pelvic floor disorders in community-dwelling women in low-and-middle income countries

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ABSTRACT

Introduction

Pelvic floor disorders (PFDs) including urinary incontinence, faecal incontinence and pelvic organ prolapse, are common debilitating conditions among women in high-income countries. However, PFDs in women in low-and middle-income countries (LMICs) have not been studied extensively. We aim to conduct a systematic review and meta-analysis of the available literature to determine the prevalence of, and/or risk factors for, PFDs in women in LMIC.

Methods and Analysis

We will search electronic databases including MEDLINE, EMBASE, PsycINFO, CINAHL, Maternity & Infant Care, and Google scholar for eligible studies. Inclusion criteria will be observational studies of healthy women, which have collected data using validated or non-validated tools, are published in English, and were conducted in community women in LMICs, defined by the World Bank. A standardised data extraction form will be developed and piloted, based on the template of the Cochrane good practice data extraction form. All included studies will be assessed based on a risk-of-bias tool specifically developed for prevalence studies. Pooled prevalence estimates of PFDs will be generated using RevMan V.5.2.1 software. Forest plots will be generated to display the overall random-effects pooled estimates with confidence intervals. A meta-regression will be conducted to identify sources of between-study heterogeneity in the pooled prevalence estimates. We will quantify heterogeneity using the I^2 measure and its confidence interval. We will use funnel plots to detect potential reporting biases and small-study effects. We will also conduct a sensitivity analysis to verify the robustness of the study conclusions, assessing the impact of methodological quality, study design, sample size, and the effect of missing data.

Ethics and Dissemination

Ethics committee approval or written informed consent will not be required for this study as primary data will not be collected. Review results will be published in a peer-reviewed journal and/or will be presented at relevant conferences.

Systematic review registration: PROSPERO CRD42016043881

Strengths and limitations of this study

- The strengths of our systematic review are that it will provide a comprehensive, objective and systematic assessment of the prevalence of, and risk factors for, pelvic floor disorders (PFDs) in low-and middle-income countries (LMICs).
- The results of this systematic review will help clinicians make decisions about treatment, and also provide evidence for researchers and policy makers for early intervention for prevention of PFDs in LMICs based on identified risk factors.
- The small sample sizes may affect the estimation of the prevalence of PFDs.
- These quantitative analyses undertaken will not be able to identify the structural, organisational and political factors that give rise to the high prevalence of PFDS and their risk factors in LMICs.

BACKGROUND

Pelvic floor disorders (PFDs) including urinary incontinence (UI), faecal incontinence (FI) and pelvic organ prolapse (POP), are common debilitating conditions among women across the world. In developed countries, one in every four women experience at least one or more PFDs [1, 2]. Evidence from these countries have established that advancing age, parity, obesity and vaginal birth are the risk factors of PFDs[1]. However, little is known about PFDs among women in low-and middle-income countries (LMICs)[3]. Furthermore, there are a paucity of studies that have comprehensively investigated all the conditions that comprise PFDs in LMICs. It is anticipated that, PFDs may be more prevalent among women living in LMICs than high-income countries due to increasing life expectancy, high parity with early marriage and childbearing, more vaginal deliveries, and frequent heavy weight lifting[3-8].The socio-economic, mental and physical consequences of PFDs for women in LMICs are also arguably more severe than that of women in developed countries[3, 9]. An earlier systematic review indicated that PFDs are among one of the significant causes of morbidity in LMICs[3], although there was substantial variation in the reported prevalences. However, the authors did not describe the reasons for the variation of prevalence reporting in detail. It was further limited by a narrow database search and data analysis. Thus, we will conduct a systematic review and meta-analysis which will aim to systematically analyse all available published articles that have documented the prevalence of, and/or risk factors for, PFDs among community-dwelling women in LMIC, and consider potential explanations for the variations in the findings.

METHODS

Data sources and search strategy

Two investigators (MRI and LR) will search the electronic databases of MEDLINE, EMBASE, PsycINFO, CINAHL, and Maternity & Infant Care. Additional searches will be conducted in Google Scholar and in grey literature sources such as conference and government websites. Hand-searching and retrospective searching of relevant published literature will also be undertaken. We will retrieve all English language studies that contain information on prevalence of, and risk factors for, PFDs in community-dwelling women in LMIC, defined by the World Bank[10]. The search strategy will be tested and revised as necessary across the different databases before being finalised. A database record will be maintained at each stage of the review process detailing how the search was undertaken including results of the search strategy. A senior medical librarian (LR) will assist in the final draft of the search strategy.

The search strategy will include a combination of subject terms and free text terms. These terms will be combined with 'OR' and 'AND' operators. The Medical Subject Headings (MeSH) terms will include pelvic floor disorders, pelvic organ prolapse, genital prolapse, uterine prolapse, urinary incontinence, stress/urge/mixed urinary incontinence, faecal incontinence, anal incontinence, prevalence, developing countries, resource-limit or resource-poor or low-income or lower-middle-income or middle-upper income countries. All MeSH terms will be exploded where necessary. The search strategy for MEDLINE is shown in Table 1.

Table 1 Search Strategy used in Ovid MEDLINE database from 1946 to March 2017

Number	Search Terms
1	Pelvic Floor Disorders/ or Pelvic Floor/ or exp Pelvic Organ Prolapse/
2	(pelvic floor or pelvic organ).mp.
3	((uterine or uterus or vagina* or cervix or pelvic) adj3 prolaps*).mp.
4	((urogenital or vault or bladder or rectal or anus) adj3 prolaps*).mp.
5	Urinary Incontinence, Urge/ or Fecal Incontinence/ or Urinary Incontinence, Stress/ or Urinary

6	incontinence.mp.
7	or/1-6
8	Developing Countries/ or exp africa/ or exp caribbean region/ or exp central america/ or latin america/ or
9	(Afghanistan* or Albania* or Algeria* or Angola* or Argentina* or Armenia* or Azerbaijan* or
10	(africa* or asia* or caribbean or central america* or latin america* or south america* or melanesia* or
11	(resource-limit* or resource-poor or low-resource* or limited-resource* or resource-constrain* or
12	((developing or underdeveloped or under-developed or emerging or less-developed or least-developed or
13	((developing or underdeveloped or under-developed or less-developed or least-developed) adj world).mp.
14	(third-world* or thirdworld* or 3rd-world*).mp.
15	or/8-14
16	(et or ep).fs.
17	exp Probability/
18	(epidemiolog* or etiolog* or prevalence or incidence or risk or factors or probabilit* or determinant* or
19	16 or 17 or 18
20	Cross-Sectional Studies/
21	(cross section* or disease frequency).mp.
22	20 or 21
23	7 and 15 and 19 and 22
24	exp case-control studies/ or exp cohort studies/
25	(case-control or cohort stud*).mp.
26	24 or 25
27	7 and 15 and 19 and 26
28	23 or 27
29	limit 28 to english language

Note: This search strategy will be suitable for other electronic databases.

Inclusion criteria

Observational studies, including cross-sectional, cohort or case-control studies, those including healthy women, using validated or non-validated tools, published in English language, and conducted in community settings will be included. If any study compared the prevalence of PFDs in a country from LMICs with a high-income country, information only for a LMIC country will be included. Where multiple papers were generated from the same data with same outcome, only the most relevant paper will be included. However, if multiple papers were generated from the same data with different outcomes including UI, FI and POP, all papers will be included.

Exclusion criteria

Studies that evaluated treatments for PFDs, studies of women with co-morbidities such as lower urinary tract symptoms, fistula, breast cancer, studies conducted to assess quality of life of women with any PFDs which did not assess the prevalence of PFDs and risk factors, will be excluded. Studies in employed women only, conducted in hospital/clinical settings, or including LMICs migrant women living in high-income countries will also be excluded. The reasons for exclusion of these studies are: the studies in hospital/clinical settings are likely to be highly selected (i.e. selection bias) resulting in inaccurate estimations of the true prevalence of PFDs, professional women are well educated and do not represent the community-dwelling women, and the prevalence of PFDs in women who migrate from LMICs to developed countries is likely to reflect the prevalence in the host country, not their country of origin. This is due to exposure to better health systems available in the host country[11-13]. Editorials, letters, opinion articles, narrative or systematic reviews, brief communications, and conference abstract and posters will also be excluded.

Screening strategy

Titles and/or abstracts of studies identified using the search strategy and those from additional sources will be distributed among two review authors (RMI, JO). These team members will independently assess the eligibility of the full text articles. Any disagreement between reviewers will be resolved through discussion with a third review author (SMH) on the study team.

Data extraction

A standardised data extraction form will be developed and piloted, based on the template of the Cochrane good practice data extraction form[14], to extract data from the selected studies.

Extracted information will include study design and methods, country, study setting, participant characteristics, study outcomes, risk factors, results, conclusions, and study funding sources. If essential data are missing, we will contact the authors for further information. The manuscript will be structured using the PRISMA-P checklist[15]. The data extraction form is shown in online supplementary Document 1.

Data Management

Literature search results will be stored in Endnote, and completed data extraction forms will be uploaded to Monash University faculty-allocated network storage, which will be password protected and only accessible to the reviewers. This shared network drive will facilitate the data extraction and data entry and keep a record of all review-related documents.

Risk-of-bias and quality assessment

To assess external and internal validity, a risk-of-bias tool will be used developed explicitly for the systematic review of prevalence studies[16]. Two review authors (MNK and DMEH) will extract data independently; inconsistencies will be identified and resolved through discussion including a third author (RMI) where necessary. The tool has 10 items: (i) national representativeness, (ii) target population representativeness, (iii) random selection or census undertaken, (iv) minimal nonresponse bias, (v) data collected from subjects, (vi) acceptable case definition used, (vii) valid and reliable study instrument used, (viii) same mode of data collection for all subjects, (xi) length of the shortest prevalence period, and (x) appropriateness of numerator(s) and denominator(s) for the parameter. Items 1 to 4 assess the external validity (selection and non-response bias) and items 5 to 10 assess the internal validity of the study (measurement and analysis bias). All of these items are rated high or low.

Item 11, the summary assessment, evaluates the overall risk of study bias and is based on the author's subjective judgement given responses to the preceding 10 items rated as low, moderate or high risk.

Ethics approval and dissemination

Our review is entirely based on published data. Thus, an ethics committee approval or written informed consent will not be required. The results will be disseminated by publication of the manuscript in a peer-reviewed journal and/or will be presented at relevant conferences.

Statistical analysis

Data synthesis

A detail process of conducting this systematic review and data synthesis of the included studies will be undertaken, for which we have developed a conceptual framework, shown in Figure 1. Pooled prevalence of PFDs will be estimated from the reported prevalence of eligible studies using RevMan V.5.2.1 software. Forest plots will be generated displaying prevalence with the corresponding 95% confidence intervals (asymptotic Wald) for each study. The overall random-effects pooled estimate with its confidence interval, will be reported. A meta-regression will be conducted to identify sources of between-study heterogeneity in the pooled prevalence (or incidence) estimates[17]. A multivariable meta-regression model will be built by adding each variable sequentially starting with the variable that shows the strongest association with PFDs prevalence in a univariate analysis. A variable will remain in the multivariable model if it will be independently associated with PFD prevalence at $p \leq 0.10$[18].

Assessment of heterogeneity

To examine the magnitude of the variation between studies, we will quantify the heterogeneity by using the I^2 measure and its confidence interval[19]. We will consider a two-sided probability value ≤0.05 as significant. Potential sources of heterogeneity will be specified a priori. The factors will be considered for those related to the characteristics of studies or subpopulations.

Assessment of reporting biases

We will use funnel plots to detect potential reporting biases and small-study effects. The Egger method[19] will be used to assess asymmetry if more than 10 studies are included in the meta-analysis.

Subgroup analysis

Stratified prevalence will be generated by the economic levels of the country (low income, lower-middle income, and upper-middle income), by sampling methods (random and convenience), and by type of questionnaires used (validated and non-validated).

Sensitivity analysis

We will conduct a sensitivity analysis to verify the robustness of the study conclusions, assessing the impact of methodological quality, study design, sample size and the effect of missing data as well as the analysis methods on the result of this review. We will also use sensitivity analyses to investigate suspected funnel plot asymmetry due to publication bias if any.

Dealing with missing data

We will attempt to collect additional information by contacting authors of included studies with missing data. If we fail to obtained sufficient data, the study with missing data will be omitted from the data synthesis.

DISCUSSION AND CONCLUSION

This systematic review and meta-analysis will provide pooled prevalence estimates of PFDs among women in LMICs. This study will also provide evidence of reasons for the substantial variation of prevalence reporting of PFDs in this context. This comprehensive rigorous systematic review and meta-analysis technique used in this study will ensure a robust knowledge synthesis of available data. By understanding the risk factors of PFDs, this study will provide empirical evidence necessary for clinicians, researchers, policy-makers and public health stakeholders to understand the perspective, future research need, as well as policy and programming priorities for the diagnosis, treatment, and prevention of PFDs in LMICs.

Contributors:

RMI, JO, SMH, DMEH, MNK and JF contributed to the generation of ideas for systematic review. RMI, JO and LR contributed to the development of the study protocol and search strategy for the review. All the authors will contribute to in review, revision and finalisation of the search strategy. RMI prepared the first draft of the protocol. JO, SMH, MNK, DMEH, LR and JF reviewed and provided subsequent feedback on the revision of the protocol and its finalisation. All the authors critically revised the first draft for content and contributed to the final draft.

Funding and Disclaimer:

This study is not supported by any funding body. Thus, no funding bodies had any role in the study design, data collection and analysis, decision to publish or preparation of the manuscript.

Competing interests:

None declared.

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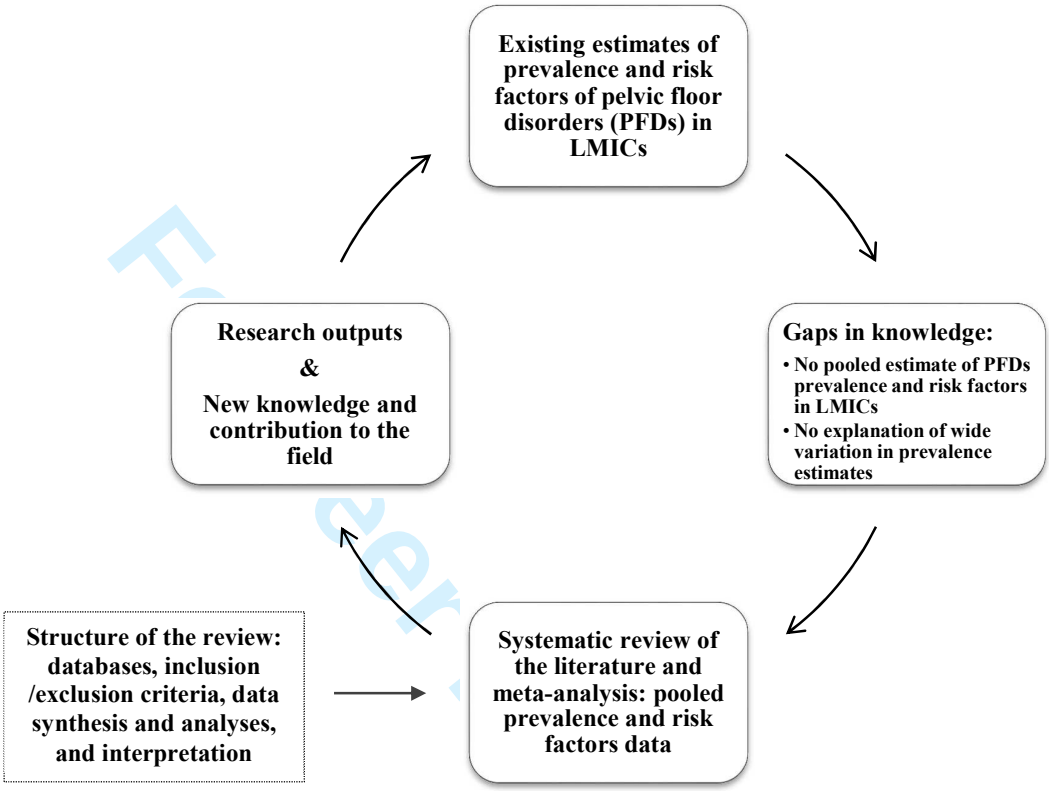
Figure 1 Conceptual framework



Data Extraction Form adapted from the Cochrane Collaboration

Title of the systematic review: *Prevalence of, and risk factors for, pelvic floor disorders in community-dwelling women in low-and-middle income countries: a systematic review and meta-analysis*

Trial Registration no: CRD42016043881

This form has been developed by adopting and customizing the "Data collection form for intervention review – RCTs and non-RCTs" of The Cochrane Collaboration. Some new sections have been added into this tool and the irrelevant sections have been removed from the original form. Information included on this form should be comprehensive, and may be used in the text of the review.

Notes on using this data extraction form:

- Be consistent in the order and style you use to describe the information for each included study
- Record any missing information as unclear or not described, to make it clear that the information was not found in the study report(s), not that you forgot to extract it.
- Include any instructions and decision rules on the Data Extraction Form, or in an accompanying document. It is important to practice using the form and give training to any other authors using the form.
- We will protect the document in order to use the form fields (Tools / Protect document)

1. General Information

1. **Date form completed** *(dd/mm/yyyy)*	
2. **Name/ID of person extracting data**	
3. **Report title** *(title of paper/ abstract/ report that data are extracted from)*	
4. **Report contact details of person extracting data**	
5. **Publication type** *(e.g. full report, abstract, letter)*	
6. **Study ID** *(e.g. 01 plus surname of first author and year first full report of study was published e.g. Smith 2001)*	
7. **Country in which the study conducted**	
8. **Economic level of the country in which the study conducted** *(e.g. low income, lower-middle income or upper-middle income)*	

9. **Study funding source** *(including role of funders)*	
10. **Possible conflicts of interest** *(for study authors e.g. not reported)*	
11. **Notes:**	

2. Eligibility

Study Characteristics	**Review Inclusion Criteria** *(Insert inclusion criteria for each characteristic as defined in the Protocol e.g. cross-sectional, cohort or case-control)*	**Location in text** *(page#/fig/ table)*
12. **Type of study**		P2
13. **Population description**		P2
14. **Focused diseases / conditions** *(Urinary incontinence, Faecal incontinence, pelvic organ prolapse, or at least one of them)*		P2
15. **Types of outcome measures** *(Prevalence/Risk factors)*		P1 P1
16. **Decision** *(with reasons for either inclusion or exclusion)*		
17. **Notes:**		

DO NOT PROCEED IF STUDY IS EXCLUDED FROM REVIEW

3. Population and setting

	Description	**Location in text** *(page#/fig/ table)*
18. **Population description** *(from which study participants are drawn)*		

	Description	Location in text *(page#/fig/ table)*
19. **Source/setting of the population** *(e.g. urban, rural, particular ethnic group)*		
20. **Method/s of recruitment of participants**		
21. **Notes:**		

4. Methods

	Descriptions as stated in report/paper	Location in text *(page#/fig/ table)*
22. **Aim of study**		
23. **Design** *(e.g. cross-sectional study, cohort study, case-control study)*		
24. **Sampling technique** *(e.g. random or convenience)*		
25. **Study start date**		
26. **Study End date/duration** *(if any cohort)*		
27. **Notes:**		

5. Participants

Provide overall data and, if available, comparative data for each intervention or comparison group.

	Description as stated in report/paper	Location in text *(page#/fig/ table)*
28. **Total number of participants/Sample size**		
29. **Age group**		

	Description as stated in report/paper	**Location in text** *(page#/fig/ table)*
30. **Menopause status** *(if any)*		
31. **Notes:**		

6. Outcomes

How outcomes measured	Description as stated in report/paper	Location in text *(page#/fig/ table)*
32. **Outcomes** *(detected by physical examination: who examined?)*		
33. **Self-reported reported outcomes** *(detected by questionnaire: validated or non-validated?)*		

Copy and paste table for each outcome.

Outcome 1: Prevalence **(Note:** Not detail here under outcome. Detail should be reported in results section**)**	**Description as stated in report/paper**	**Location in text** *(page#/fig/ table)*
34. **Outcome names** *(Urinary incontinence, Faecal incontinence, pelvic organ prolapse, or at least one of them)*		
35. **Time points measured** *(report the start year/specify whether from start and end of intervention)*		
36. **Time points reported**		

Outcome 1: Prevalence **(Note:** Not detail here under outcome. Detail should be reported in results section**)**	**Description as stated in report/paper**	**Location in text** *(page#/fig/ table)*
37. **Outcome definition** *(e.g. whether standard case definition used: some standard definitions are: Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6), Colorectal-Anal Distress Inventory 8 (CRADI-8), Question for Urinary Incontinence Diagnosis (QUID), Urinary Distress Inventory 8 (UD1-6), International Consultation on Incontinence Society (ICIS) etc.)*		
38. **Type of measurement** *(Percentage/Odds ratio/Risk ratio)*		
39. **Is outcome/tool validated?** *(Yes/No/Unclear/Not mentioned)*		
40. **Notes:**		

Outcome 2: Risk factors (not detail here)	**Description as stated in report/paper**	**Location in text** *((page#/fig /table)*
41. **Name of the risk factors** (e.g. risk factors of POP)		
42. **Time points measured** *(report the start year/specify whether from start and end of intervention)*		
43. **Time points reported**		
44. **Definition of risk factors** *(if any)*		
45. **Type of measurement** *(Percentage/Odds ratio/Risk ratio)*		
46. **Is outcome/tool validated?** *(Yes/No/Unclear/Not mentioned)*		
47. **Notes:**		

7. Results and findings

Copy and paste the appropriate table for each outcome, including additional tables for each time point and subgroup as required.

Outcome 1: Prevalence **(Note:** detail here)	**Description as stated in report/paper**	**Location in text** *(page#/fig/ table)*
48. **Outcome**		
49. **Subgroup** *(if any, e.g. age-specific prevalence reporting)*		
50. **Results**		
51. **Response/non-response rate**		
52. **Any other results reported**		
53. **Unit of analysis** *(e.g. by individuals)*		
54. **Statistical methods used and appropriateness of these methods** *(e.g. proportion/%s, RR/OR)*		
55. **Whether results weighted?** *(e.g. Yes/No)*		
56. **Notes:**		

Outcome 2: Risk factors **(Note:** detail here)	**Description as stated in report/paper**	**Location in text** *(page#/fig/ table)*
57. **Name of the risk factors** NB this is confusing; change to RF?		
58. **Results**		
59. **Response/non-response rate**		
60. **Any other results reported**		
61. **Unit of analysis** *(e.g. by individuals)*		
62. **Statistical methods used and appropriateness of these methods** *(e.g. proportion/%s, RR/OR)*		

Outcome 2: Risk factors **(Note:** detail here)	**Description as stated in report/paper**	**Location in text** *(page#/fig/ table)*
63. **All systematic and random error adjusted?** ***(e.g. confounding, effect medication etc.)***		
64. **Notes:**		

8. Limitation and mitigation strategy

	Description as stated in report/paper	Location in text*(page# /fig/table)*
65. **Strength**		
66. **Limitation**		
67. **Strategies to overcome the limitation**		
68. **Notes:**		

9. Conclusion and other information

	Description as stated in report/paper	**Location in text** *(page#/fig/ table)*
69. **Key conclusions of study authors**		
70. **Notes:**		

10. Risk of bias (Quality Assessment)

External/Internal Validity **(Note:** some criteria would be overlapping with what you have reported in earlier sections. So, please report again to get quick understanding of the quality of the paper)	**Often it would not be stated directly in the paper. So, data extractors is/are requested to find information and sate (Yes/No)**	**Location in text** *(page#/fig/ table)*

71. **Was the study's target population a close representation of the national population in relation to relevant variables?**		
72. **Was the sampling frame a true or close representation of the target population?**		
73. **Was some form of random selection used to select the sample, OR was a census undertaken?**		
74. **Was the likelihood of nonresponse bias minimal?**		
75. **Were data collected directly from the subjects (as opposed to a proxy)?**		
76. **Was an acceptable case definition used in the study?**		
77. **Was the study instrument that measured the parameter of interest shown to have validity and reliability?**		
78. **Was the same mode of data collection used for all subjects?**		
79. **Was the length of the shortest prevalence period for the parameter of interest appropriate** *(last two weeks or life time prevalence etc. please specify exact period over which symptoms were asked?*		
80. **Were the numerator(s) and denominator(s) for the parameter of interest appropriate?**		
81. **Notes**		

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Date Submitted by the Author:	23-Mar-2017
Complete List of Authors:	Islam, Rakibul; Dhaka University, Department of Population Sciences Oldroyd, John; Monash University, Dept of Epidemiology and Preventive Medi Karim, Md; Monash University, SPHPM; Hussain, Monira; Monash University, DEPM Hoque, Dewan; Monash University, School of Public Health and Preventive Medicine; International Centre for Diarrhoeal Diseases Research in Bangladesh, Centre for Child and Adolescent Health Romero, Lorena ; The Ian Potter Library, Ground Floor, AMREP Building, The Alfred Fisher, Jane; Monash University, Jean Hailes Research Unit, School of Public Health and Preventative Medicine
Primary Subject Heading:	Urology
Secondary Subject Heading:	Urology, Epidemiology, Public health
Keywords:	EPIDEMIOLOGY, GYNAECOLOGY, Urogynaecology < GYNAECOLOGY

Protocol: a systematic review and meta-analysis of prevalence of, and risk factors for, pelvic floor disorders in community-dwelling women in low-and-middle income countries

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ABSTRACT

Introduction

Pelvic floor disorders (PFDs) including urinary incontinence, faecal incontinence and pelvic organ prolapse, are common debilitating conditions among women in high-income countries. However, PFDs in women in low-and middle-income countries (LMICs) have not been studied extensively. We aim to conduct a systematic review and meta-analysis of the available literature to determine the prevalence of, and/or risk factors for, PFDs in women in LMIC.

Methods and Analysis

We will search electronic databases including MEDLINE, EMBASE, PsycINFO, CINAHL, Maternity & Infant Care, and Google scholar for eligible studies. Inclusion criteria will be observational studies of healthy women, which have collected data using validated or non-validated tools, are published in English, and were conducted in community women in LMICs, defined by the World Bank. A standardised data extraction form will be developed and piloted, based on the template of the Cochrane good practice data extraction form. All included studies will be assessed based on a risk-of-bias tool specifically developed for prevalence studies. Pooled prevalence estimates of PFDs will be generated using RevMan V.5.2.1 software. Forest plots will be generated to display the overall random-effects pooled estimates with confidence intervals. A meta-regression will be conducted to identify sources of between-study heterogeneity in the pooled prevalence estimates. We will quantify heterogeneity using the I^2 measure and its confidence interval. We will use funnel plots to detect potential reporting biases and small-study effects. We will also conduct a sensitivity analysis to verify the robustness of the study conclusions, assessing the impact of methodological quality, study design, sample size, and the effect of missing data.

Ethics and Dissemination

Ethics committee approval or written informed consent will not be required for this study as primary data will not be collected. Review results will be published in a peer-reviewed journal and/or will be presented at relevant conferences.

Systematic review registration: PROSPERO CRD42016043881

Strengths and limitations of this study

- The strengths of our systematic review are that it will provide a comprehensive, objective and systematic assessment of the prevalence of, and risk factors for, pelvic floor disorders (PFDs) in low-and middle-income countries (LMICs).
- The results of this systematic review will help clinicians make decisions about treatment, and also provide evidence for researchers and policy makers for early intervention for prevention of PFDs in LMICs based on identified risk factors.
- The small sample sizes may affect the estimation of the prevalence of PFDs.
- These quantitative analyses undertaken will not be able to identify the structural, organisational and political factors that give rise to the high prevalence of PFDS and their risk factors in LMICs.

BACKGROUND

Pelvic floor disorders (PFDs) including urinary incontinence (UI), faecal incontinence (FI) and pelvic organ prolapse (POP), are common debilitating conditions among women across the world. In developed countries, one in every four women experience at least one or more PFDs [1 2]. Evidence from these countries have established that advancing age, parity, obesity and vaginal birth are the risk factors of PFDs [2]. However, little is known about PFDs among women in low-and middle-income countries (LMICs) [3]. Furthermore, there are a paucity of studies that have comprehensively investigated all the conditions that comprise PFDs in LMICs. It is anticipated that, PFDs may be more prevalent among women living in LMICs than high-income countries due to increasing life expectancy (since increasing age is a risk factor for PFDs), high parity with early marriage and childbearing, more vaginal deliveries, and frequent heavy weight lifting [3-8]. These factors are interrelated and are underpinned by poor nutrition and mechanical stresses. These stresses include excessive stretching from first delivery at a young age and multiple births, the need to do manual work and heavy lifting (often during and immediately after pregnancy), larger baby sizes (related to gestational diabetes mellitus) and chronic cough [3]. The socio-economic, mental and physical consequences of PFDs for women in LMICs are arguably more severe than that of women in developed countries [3 9]. An earlier systematic review indicated that PFDs are among one of the significant causes of morbidity in LMICs [3]. Importantly, this systematic review found substantial variation in the reported prevalences of PFDs, although the authors did not describe the reasons for the variation of prevalence reporting in detail. It was further limited by a narrow database search and data analysis. Thus, we will conduct a systematic review and meta-analysis which will aim to systematically analyse all available published articles that have documented the prevalence of, and/or risk factors for, PFDs

among community-dwelling women in LMIC, and consider potential explanations for the variations in the findings.

METHODS

Data sources and search strategy

Two investigators (MRI and LR) will search the electronic databases of MEDLINE, EMBASE, PsycINFO, CINAHL, and Maternity & Infant Care. Additional searches will be conducted in Google Scholar and in grey literature sources such as conference and government websites. Hand-searching and retrospective searching of relevant published literature will also be undertaken. We will retrieve all English language studies that contain information on the prevalence of, and risk factors for, PFDs in community-dwelling women in LMIC, defined by the World Bank [10]. The search strategy will be tested and revised as necessary across the different databases before being finalised. A database record will be maintained at each stage of the review process detailing how the search was undertaken including results of the search strategy. A senior medical librarian (LR) will assist in the final draft of the search strategy.

The search strategy will include a combination of subject terms and free text terms. These terms will be combined with 'OR' and 'AND' operators. The Medical Subject Headings (MeSH) terms will include pelvic floor disorders, pelvic organ prolapse, genital prolapse, uterine prolapse, urinary incontinence, stress/urge/mixed urinary incontinence, faecal incontinence, anal incontinence, prevalence, developing countries, resource-limit or resource-poor or low-income or lower-middle-income or middle-upper income countries. All MeSH

terms will be exploded where necessary. The search strategy for MEDLINE is shown in Table 1.

Table 1 Search Strategy used in Ovid MEDLINE database from 1946 to March 2017

Number	Search Terms
1	Pelvic Floor Disorders/ or Pelvic Floor/ or exp Pelvic Organ Prolapse/
2	(pelvic floor or pelvic organ).mp.
3	((uterine or uterus or vagina* or cervix or pelvic) adj3 prolaps*).mp.
4	((urogenital or vault or bladder or rectal or anus) adj3 prolaps*).mp.
5	Urinary Incontinence, Urge/ or Fecal Incontinence/ or Urinary Incontinence, Stress/ or Urinary
6	incontinence.mp.
7	or/1-6
8	Developing Countries/ or exp africa/ or exp caribbean region/ or exp central america/ or latin america/ or
9	(Afghanistan* or Albania* or Algeria* or Angola* or Argentina* or Armenia* or Azerbaijan* or Bangladesh* or Belarus* or Beliz* or Benin* or Bhutan* or Bolivia* or Bosnia* or Herzegovin* or Botswan* or Brazil* or Bulgaria* or Burkina* or Burundi* or Cabo Verde* or Cape Verde* or Cambodia* or Cameroon* or Central African or Chad* or China or Chinese or Colombia* or Comor* or Congo* or Costa Rica* or Cote d'Ivoir* or Ivory Coast or Cuba* or Djibouti* or Dominica* or Ecuador* or Egypt* or El Salvador* or Eritrea* or Ethiopia* or Fiji* or Gabon* or Gambia* or Georgia* or Ghana* or Grenad* or Guatemala* or Guinea* or Guyan* or Haiti* or Hondura* or Hungar* or India* or Indonesia* or Iran* or Iraq* or Jamaica* or Jordan* or Kazakhstan* or Kenya* or Kiribati* or Korea* or Kosov* or Kyrgyz Republic or Lao* or Leban* or Lesotho* or Liberia* or Libya* or Macedonia* or Madagascar* or Malawi* or Malaysia* or Maldiv* or Mali* or Marshall Island* or Mauritania* or Mauriti* or Mexic* or Micronesia* or Moldova* or Mongolia* or Montenegr* or Morocc* or Mozambi* or Myanma* or Burmese or Namibia* or Nepal* or Nicaragua* or Niger* or Nigeria* or Pakistan* or Palau* or Panama* or Papua New Guinea* or Paraguay* or Peru* or Philippines or Filipino or Romania* or Rwanda* or Samoa* or Sao Tome* or Senegal* or Serbia* or Seychell* or Sierra Leon* or Solomon Island* or Somalia* or South Africa* or Sudan* or Sri Lanka* or St Lucia* or St Vincent or Grenadines or Surinam* or Swazi* or Syria* or Tajikistan* or Tanzania* or Thai* or Timor* or Togo* or Tonga* or Tunisia* or Turk* or Turkmenistan* or Tuvalu* or Uganda* or Ukrain* or Uzbekistan* or Vanuatu* or Venezuela* or Vietnam* or West Bank or Gaza or Yemen* or Zambia* or Zimbabwe*).mp Bangladesh* or Belarus* or Beliz* or Benin* or Bhutan* or Bolivia* or Bosnia* or Herzegovin* or Botswan* or Brazil* or Bulgaria* or Burkina* or Burundi* or Cabo Verde* or Cape Verde* or Cambodia* or Cameroon* or Central African or Chad* or China or Chinese or Colombia* or Comor* or Congo* or Costa Rica* or Cote d'Ivoir* or Ivory Coast or Cuba* or Djibouti* or Dominica* or Ecuador* or Egypt* or El Salvador* or Eritrea* or Ethiopia* or Fiji* or Gabon* or Gambia* or Georgia* or Ghana* or Grenad* or Guatemala* or Guinea* or Guyan* or Haiti* or Hondura* or Hungar* or India* or Indonesia* or Iran* or Iraq* or Jamaica* or Jordan* or Kazakhstan* or Kenya* or Kiribati* or Korea* or Kosov* or Kyrgyz Republic or Lao* or Leban* or Lesotho* or Liberia* or Libya* or Macedonia* or Madagascar* or Malawi* or Malaysia* or Maldiv* or Mali* or Marshall Island* or Mauritania* or Mauriti* or Mexic* or Micronesia* or Moldova* or Mongolia* or Montenegr* or Morocc* or Mozambi* or Myanma* or Burmese or Namibia* or Nepal* or Nicaragua* or Niger* or Nigeria* or Pakistan* or Palau* or Panama* or Papua New Guinea* or Paraguay* or Peru* or Philippines or Filipino or Romania* or Rwanda* or Samoa* or Sao Tome* or Senegal* or Serbia* or Seychell* or Sierra Leon* or Solomon Island* or Somalia* or South Africa* or Sudan* or Sri Lanka* or St Lucia* or St Vincent or Grenadines or Surinam* or Swazi* or Syria* or Tajikistan* or Tanzania* or Thai* or Timor* or Togo* or Tonga* or Tunisia* or Turk* or Turkmenistan* or Tuvalu* or Uganda* or Ukrain* or Uzbekistan* or Vanuatu* or Venezuela* or Vietnam* or West Bank or Gaza or Yemen* or Zambia* or Zimbabwe*).mp.
10	(africa* or asia* or caribbean or central america* or latin america* or south america* or melanesia* or
11	(resource-limit* or resource-poor or low-resource* or limited-resource* or resource-constrain* or
12	((developing or underdeveloped or under-developed or emerging or less-developed or least-developed or
13	((developing or underdeveloped or under-developed or less-developed or least-developed) adj world).mp.

14	(third-world* or thirdworld* or 3rd-world*).mp.
15	or/8-14
16	(et or ep).fs.
17	exp Probability/
18	(epidemiolog* or etiolog* or prevalence or incidence or risk or factors or probabilit* or determinant* or
19	16 or 17 or 18
20	Cross-Sectional Studies/
21	(cross section* or disease frequency).mp.
22	20 or 21
23	7 and 15 and 19 and 22
24	exp case-control studies/ or exp cohort studies/
25	(case-control or cohort stud*).mp.
26	24 or 25
27	7 and 15 and 19 and 26
28	23 or 27
29	limit 28 to english language

Note: This search strategy will be suitable for other electronic databases.

Inclusion criteria

Observational studies, including cross-sectional, cohort or case-control studies, studies of women with PFDs who were otherwise healthy, studies using validated or non-validated tools, published in English language, and conducted in community settings, will be included. If any study compared the prevalence of PFDs in a country from LMICs with a high-income country, information only for a LMIC country will be included. Where multiple papers were generated from the same data with same outcome, only the most relevant paper will be included. However, if multiple papers were generated from the same data with different outcomes including UI, FI and POP, all papers will be included.

Exclusion criteria

Studies that evaluated treatments for PFDs, studies of women with co-morbidities such as lower urinary tract symptoms, fistula, breast cancer, studies conducted to assess quality of life of women with any PFDs which did not assess the prevalence of PFDs and risk factors, will be excluded. Studies in employed women only, conducted in hospital/clinical settings, or

including LMICs migrant women living in high-income countries will also be excluded. The reasons for exclusion of these studies are: the studies in hospital/clinical settings are likely to be highly selected (i.e. selection bias) resulting in inaccurate estimations of the true prevalence of PFDs, professional women, especially working in the formal sector are well educated, use health care services and do not represent the community-dwelling women, and the prevalence of PFDs in women who migrate from LMICs to developed countries is likely to reflect the prevalence in the host country, not their country of origin. This is due to exposure to better health systems available in the host country [11-13]. Editorials, letters, opinion articles, narrative or systematic reviews, brief communications, and conference abstract and posters will also be excluded. However, a full-length article will be included if any are found in conference websites.

Screening strategy

Titles and/or abstracts of studies identified using the search strategy and those from additional sources will be distributed among two review authors (RMI, JO). These team members will independently assess the eligibility of the full text articles. Two other review authors (MNK, DMEH) will reassess all studies. Any disagreement between reviewers will be resolved through discussion with a third review author (SMH) on the study team.

Data extraction

A standardised data extraction form will be developed and piloted, based on the template of the Cochrane good practice data extraction form [14], to extract data from the selected studies. Extracted information will include study design and methods, country, study setting, participant characteristics, study outcomes, risk factors, results, conclusions, and study

funding sources. If essential data are missing, we will contact the authors for further information. The manuscript will be structured using the PRISMA-P checklist [15]. The data extraction form is shown in online supplementary Document 1.

Data Management

Literature search results will be stored in Endnote, and completed data extraction forms will be uploaded to Monash University faculty-allocated network storage, which will be password protected and only accessible to the reviewers. This shared network drive will facilitate the data extraction and data entry and keep a record of all review-related documents.

Risk-of-bias and quality assessment

To assess external and internal validity, a risk-of-bias tool will be used developed explicitly for the systematic review of prevalence studies [16]. Two review authors (MNK and DMEH) will extract data independently; inconsistencies will be identified and resolved through discussion including a third author (RMI) where necessary. The tool has 10 items: (i) national representativeness, (ii) target population representativeness, (iii) random selection or census undertaken, (iv) minimal nonresponse bias, (v) data collected from subjects, (vi) acceptable case definition used, (vii) valid and reliable study instrument used, (viii) same mode of data collection for all subjects, (xi) length of the shortest prevalence period, and (x) appropriateness of numerator(s) and denominator(s) for the parameter. Items 1 to 4 assess the external validity (selection and non-response bias) and items 5 to 10 assess the internal validity of the study (measurement and analysis bias). All of these items are rated high or low. Item 11, the summary assessment, evaluates the overall risk of study bias and is based on the

author's subjective judgement given responses to the preceding 10 items rated as low, moderate or high risk.

Ethics approval and dissemination

Our review is entirely based on published data. Thus, an ethics committee approval or written informed consent will not be required. The results will be disseminated by publication of the manuscript in a peer-reviewed journal and/or will be presented at relevant conferences.

Statistical analysis

Data synthesis

A detailed process of conducting this systematic review and data synthesis of the included studies will be undertaken, for which we have developed a conceptual framework, shown in Figure 1. Pooled prevalence of PFDs will be estimated from the reported prevalence of eligible studies using RevMan V.5.2.1 software. Forest plots will be generated displaying prevalence with the corresponding 95% confidence intervals (asymptotic Wald) for each study. The overall random-effects pooled estimate with its confidence interval, will be reported. A meta-regression will be conducted to identify sources of between-study heterogeneity in the pooled prevalence (or incidence) estimates [14 17]. A multivariable meta-regression model will be built by adding each variable sequentially starting with the variable that shows the strongest association with PFDs prevalence in a univariate analysis. A variable will remain in the multivariable model if it will be independently associated with PFD prevalence at $p \leq 0.10$ [18]. Risk factors of PFDs from all included studies will be synthesised descriptively to understand the key risk factors for PFDs in LMICs. Then, meta-

regression of the odds ratios of the key risk factors will be conducted to identify the individual effects of each risk factor for PFD [19].

Assessment of heterogeneity

To examine the magnitude of the variation between studies, we will quantify the heterogeneity by using the I^2 measure and its confidence interval [17]. We will consider a two-sided probability value ≤0.05 as significant. To assess the degree of heterogeneity the following I^2 cut-offs for low, moderate, and high heterogeneity will be used: a) between 0% to 40%: might not be important; b) 30% to 60%: may represent moderate heterogeneity; c) 50% to 90%: may represent substantial heterogeneity; d) 75% to 100%: considerable heterogeneity [20]. The significance will be determined by a chi-squared for Q, so a p-value < 0.05 will be considered as significant.

Assessment of reporting biases

We will use funnel plots to detect potential reporting biases and small-study effects. The Egger method [19] will be used to assess asymmetry if more than 10 studies are included in the meta-analysis.

Subgroup analysis

Stratified prevalence will be generated by the economic levels of the country (low income, lower-middle income, and upper-middle income), by sampling methods (random and convenience), and by type of questionnaires used (validated and non-validated).

Sensitivity analysis

We will conduct a sensitivity analysis to verify the robustness of the study conclusions, assessing the impact of methodological quality, study design, sample size and the effect of missing data as well as the analysis methods on the result of this review. We will also use sensitivity analyses to investigate suspected funnel plot asymmetry due to publication bias if any.

Dealing with missing data

We will attempt to collect additional information by contacting authors of included studies with missing data. If we fail to obtain sufficient data, the study with missing data will be omitted from the data synthesis.

DISCUSSION AND CONCLUSION

This systematic review and meta-analysis will provide pooled prevalence estimates of PFDs among women in LMICs. This study will also provide evidence of reasons for the substantial variation of prevalence reporting of PFDs in this context. This comprehensive rigorous systematic review and meta-analysis technique used in this study will ensure a robust knowledge synthesis of available data. By understanding the risk factors of PFDs, this study will provide empirical evidence necessary for clinicians, researchers, policy-makers and public health stakeholders to understand the perspective, future research need, as well as policy and programming priorities for the diagnosis, treatment, and prevention of PFDs in LMICs.

Contributors:

RMI, JO, MNK, SMH, DMEH and JF contributed to the generation of ideas for systematic review. RMI, JO and LR contributed to the development of the study protocol and search

strategy for the review. All the authors will contribute to in review, revision and finalisation of the search strategy. RMI prepared the first draft of the protocol. JO, MNK, SMH, DMEH, LR and JF reviewed and provided subsequent feedback on the revision of the protocol and its finalisation. All the authors critically revised the first draft for content and contributed to the final draft.

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This study is not supported by any funding body. Thus, no funding bodies had any role in the study design, data collection and analysis, decision to publish or preparation of the manuscript.

Competing interests:

None declared.

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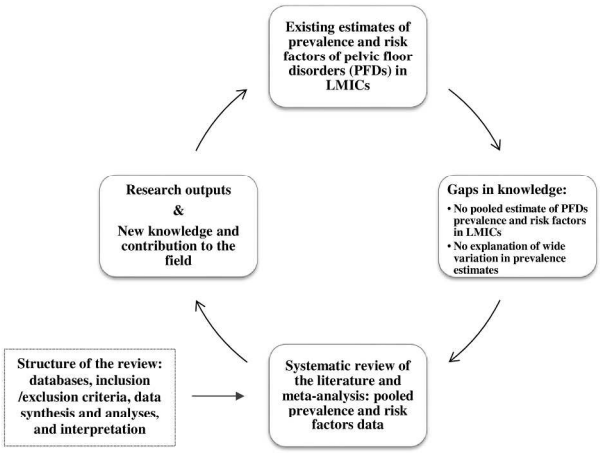
Figure 1 Conceptual framework



297x420mm (300 x 300 DPI)

Data Extraction Form adapted from the Cochrane Collaboration

Title of the systematic review: *Prevalence of, and risk factors for, pelvic floor disorders in community-dwelling women in low-and-middle income countries: a systematic review and meta-analysis*

Trial Registration no: CRD42016043881

This form has been developed by adopting and customizing the "Data collection form for intervention review – RCTs and non-RCTs" of The Cochrane Collaboration. Some new sections have been added into this tool and the irrelevant sections have been removed from the original form. Information included on this form should be comprehensive, and may be used in the text of the review.

Notes on using this data extraction form:

- Be consistent in the order and style you use to describe the information for each included study
- Record any missing information as unclear or not described, to make it clear that the information was not found in the study report(s), not that you forgot to extract it.
- Include any instructions and decision rules on the Data Extraction Form, or in an accompanying document. It is important to practice using the form and give training to any other authors using the form.
- We will protect the document in order to use the form fields (Tools / Protect document)

1. General Information

1. **Date form completed** *(dd/mm/yyyy)*	
2. **Name/ID of person extracting data**	
3. **Report title** *(title of paper/ abstract/ report that data are extracted from)*	
4. **Report contact details of person extracting data**	
5. **Publication type** *(e.g. full report, abstract, letter)*	
6. **Study ID** *(e.g. 01 plus surname of first author and year first full report of study was published e.g. Smith 2001)*	
7. **Country in which the study conducted**	
8. **Economic level of the country in which the study conducted** *(e.g. low income, lower-middle income or upper-middle income)*	

9. **Study funding source** *(including role of funders)*	
10. **Possible conflicts of interest** *(for study authors e.g. not reported)*	
11. **Notes:**	

2. Eligibility

Study Characteristics	**Review Inclusion Criteria** *(Insert inclusion criteria for each characteristic as defined in the Protocol e.g. cross-sectional, cohort or case-control)*	**Location in text** *(page#/fig /table)*
12. **Type of study**		P2
13. **Population description**		P2
14. **Focused diseases / conditions** *(Urinary incontinence, Faecal incontinence, pelvic organ prolapse, or at least one of them)*		P2
15. **Types of outcome measures** *(Prevalence/Risk factors)*		P1 P1
16. **Decision** *(with reasons for either inclusion or exclusion)*		
17. **Notes:**		

DO NOT PROCEED IF STUDY IS EXCLUDED FROM REVIEW

3. Population and setting

	Description	**Location in text** *(page#/fig /table)*
18. **Population description** *(from which study participants are drawn)*		

	Description	Location in text *(page#/fig /table)*
19. **Source/setting of the population** *(e.g. urban, rural, particular ethnic group)*		
20. **Method/s of recruitment of participants**		
21. **Notes:**		

4. Methods

	Descriptions as stated in report/paper	Location in text *(page#/fig /table)*
22. **Aim of study**		
23. **Design** *(e.g. cross-sectional study, cohort study, case-control study)*		
24. **Sampling technique** *(e.g. random or convenience)*		
25. **Study start date**		
26. **Study End date/duration** *(if any cohort)*		
27. **Notes:**		

5. Participants

Provide overall data and, if available, comparative data for each intervention or comparison group.

	Description as stated in report/paper	Location in text *(page#/fig /table)*
28. **Total number of participants/Sample size**		
29. **Age group**		

	Description as stated in report/paper	**Location in text** *(page#/fig /table)*
30. **Menopause status** *(if any)*		
31. **Notes:**		

6. Outcomes

How outcomes measured	Description as stated in report/paper	Location in text *(page#/fig/ table)*
32. **Outcomes** *(detected by physical examination: who examined?)*		
33. **Self-reported reported outcomes** *(detected by questionnaire: validated or non-validated?)*		

Copy and paste table for each outcome.

Outcome 1: Prevalence **(Note:** Not detail here under outcome. Detail should be reported in results section**)**	**Description as stated in report/paper**	**Location in text** *(page#/fig /table)*
34. **Outcome names** *(Urinary incontinence, Faecal incontinence, pelvic organ prolapse, or at least one of them)*		
35. **Time points measured** *(report the start year/specify whether from start and end of intervention)*		
36. **Time points reported**		

Outcome 1: Prevalence **(Note:** Not detail here under outcome. Detail should be reported in results section**)**	**Description as stated in report/paper**	**Location in text** *(page#/fig /table)*
37. **Outcome definition** *(e.g. whether standard case definition used: some standard definitions are: Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6), Colorectal-Anal Distress Inventory 8 (CRADI-8), Question for Urinary Incontinence Diagnosis (QUID), Urinary Distress Inventory 8 (UD1-6), International Consultation on Incontinence Society (ICIS) etc.)*		
38. **Type of measurement** *(Percentage/Odds ratio/Risk ratio)*		
39. **Is outcome/tool validated?** *(Yes/No/Unclear/Not mentioned)*		
40. **Notes:**		

Outcome 2: Risk factors (not detail here)	**Description as stated in report/paper**	**Location in text** *((page#/fig /table)*
41. **Name of the risk factors** (e.g. risk factors of POP)		
42. **Time points measured** *(report the start year/specify whether from start and end of intervention)*		
43. **Time points reported**		
44. **Definition of risk factors** *(if any)*		
45. **Type of measurement** *(Percentage/Odds ratio/Risk ratio)*		
46. **Is outcome/tool validated?** *(Yes/No/Unclear/Not mentioned)*		
47. **Notes:**		

7. Results and findings

Copy and paste the appropriate table for each outcome, including additional tables for each time point and subgroup as required.

Outcome 1: Prevalence **(Note:** detail here)	**Description as stated in report/paper**	**Location in text** *(page#/fig /table)*
48. **Outcome**		
49. **Subgroup** *(if any, e.g. age-specific prevalence reporting)*		
50. **Results**		
51. **Response/non-response rate**		
52. **Any other results reported**		
53. **Unit of analysis** *(e.g. by individuals)*		
54. **Statistical methods used and appropriateness of these methods** *(e.g. proportion/%s, RR/OR)*		
55. **Whether results weighted?** *(e.g. Yes/No)*		
56. **Notes:**		

Outcome 2: Risk factors **(Note:** detail here)	**Description as stated in report/paper**	**Location in text** *(page#/fig /table)*
57. **Name of the risk factors** NB this is confusing; change to RF?		
58. **Results**		
59. **Response/non-response rate**		
60. **Any other results reported**		
61. **Unit of analysis** *(e.g. by individuals)*		

Outcome 2: Risk factors **(Note:** detail here)	**Description as stated in report/paper**	**Location in text** *(page#/fig /table)*
62. **Statistical methods used and appropriateness of these methods** *(e.g. proportion/%s, RR/OR)*		
63. **All systematic and random error adjusted?** *(e.g. confounding, effect medication etc.)*		
64. **Notes:**		

8. Limitation and mitigation strategy

	Description as stated in report/paper	Location in text*(page# /fig/table)*
65. **Strength**		
66. **Limitation**		
67. **Strategies to overcome the limitation**		
68. **Notes:**		

9. Conclusion and other information

	Description as stated in report/paper	**Location in text** *(page#/fig /table)*
69. **Key conclusions of study authors**		
70. **Notes:**		

10. Risk of bias (Quality Assessment)

External/Internal Validity **(Note:** some criteria would be overlapping with what you have reported in earlier sections. So, please report again to get quick understanding of the quality of the paper)	**Often it would not be stated directly in the paper. So, data extractors is/are requested to find information and sate (Yes/No)**	**Location in text** *(page#/fig /table)*
71. **Was the study's target population a close representation of the national population in relation to relevant variables?**		
72. **Was the sampling frame a true or close representation of the target population?**		
73. **Was some form of random selection used to select the sample, OR was a census undertaken?**		
74. **Was the likelihood of nonresponse bias minimal?**		
75. **Were data collected directly from the subjects (as opposed to a proxy)?**		
76. **Was an acceptable case definition used in the study?**		
77. **Was the study instrument that measured the parameter of interest shown to have validity and reliability?**		
78. **Was the same mode of data collection used for all subjects?**		
79. **Was the length of the shortest prevalence period for the parameter of interest appropriate** *(last two weeks or life time prevalence etc. please specify exact period over which symptoms were asked?*		
80. **Were the numerator(s) and denominator(s) for the parameter of interest appropriate?**		
81. **Notes**		

BMJ Open

Protocol: a systematic review and meta-analysis of prevalence of, and risk factors for, pelvic floor disorders in community-dwelling women in low-and-middle income countries

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Keywords:	EPIDEMIOLOGY, GYNAECOLOGY, Urogynaecology < GYNAECOLOGY

Protocol: a systematic review and meta-analysis of prevalence of, and risk factors for, pelvic floor disorders in community-dwelling women in low-and-middle income countries

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ABSTRACT

Introduction

Pelvic floor disorders (PFDs) including urinary incontinence, faecal incontinence and pelvic organ prolapse, are common debilitating conditions among women in high-income countries. However, PFDs in women in low-and middle-income countries (LMICs) have not been studied extensively. We aim to conduct a systematic review and meta-analysis of the available literature to determine the prevalence of, and/or risk factors for, PFDs in women in LMIC.

Methods and Analysis

We will search electronic databases including MEDLINE, EMBASE, PsycINFO, CINAHL, Maternity & Infant Care, and Google scholar for eligible studies. Inclusion criteria will be observational studies of healthy women, which have collected data using validated or non-validated tools, are published in English, and were conducted in community women in LMICs, defined by the World Bank. A standardised data extraction form will be developed and piloted, based on the template of the Cochrane good practice data extraction form. All included studies will be assessed based on a risk-of-bias tool specifically developed for prevalence studies. Pooled prevalence estimates of PFDs will be generated using RevMan V.5.2.1 software. Forest plots will be generated to display the overall random-effects pooled estimates with confidence intervals. A meta-regression will be conducted to identify sources of between-study heterogeneity in the pooled prevalence estimates. We will quantify heterogeneity using the I^2 measure and its confidence interval. We will use funnel plots to detect potential reporting biases and small-study effects. We will also conduct a sensitivity analysis to verify the robustness of the study conclusions, assessing the impact of methodological quality, study design, sample size, and the effect of missing data.

Ethics and Dissemination

Ethics committee approval or written informed consent will not be required for this study as primary data will not be collected. Review results will be published in a peer-reviewed journal and/or will be presented at relevant conferences.

Systematic review registration: PROSPERO CRD42016043881

Strengths and limitations of this study

- The strengths of our systematic review are that it will provide a comprehensive, objective and systematic assessment of the prevalence of, and risk factors for, pelvic floor disorders (PFDs) in low-and middle-income countries (LMICs).
- The results of this systematic review will help clinicians make decisions about treatment, and also provide evidence for researchers and policy makers for early intervention for prevention of PFDs in LMICs based on identified risk factors.
- The small sample sizes may affect the estimation of the prevalence of PFDs.
- These quantitative analyses undertaken will not be able to identify the structural, organisational and political factors that give rise to the high prevalence of PFDS and their risk factors in LMICs.

BACKGROUND

Pelvic floor disorders (PFDs) including urinary incontinence (UI), faecal incontinence (FI) and pelvic organ prolapse (POP), are common debilitating conditions among women across the world. In developed countries, one in every four women experience at least one or more PFDs [1 2]. Evidence from these countries have established that advancing age, parity, obesity and vaginal birth are the risk factors of PFDs [2]. However, little is known about PFDs among women in low-and middle-income countries (LMICs) [3]. Furthermore, there are a paucity of studies that have comprehensively investigated all the conditions that comprise PFDs in LMICs. It is anticipated that, PFDs may be more prevalent among women living in LMICs than high-income countries due to increasing life expectancy (since increasing age is a risk factor for PFDs), high parity with early marriage and childbearing, more vaginal deliveries, and frequent heavy weight lifting [3-8]. These factors are interrelated and are underpinned by poor nutrition and mechanical stresses. These stresses include excessive stretching from first delivery at a young age and multiple births, the need to do manual work and heavy lifting (often during and immediately after pregnancy), larger baby sizes (related to gestational diabetes mellitus) and chronic cough [3]. The socio-economic, mental and physical consequences of PFDs for women in LMICs are arguably more severe than that of women in developed countries [3 9]. An earlier systematic review indicated that PFDs are among one of the significant causes of morbidity in LMICs [3]. Importantly, this systematic review found substantial variation in the reported prevalences of PFDs, although the authors did not describe the reasons for the variation of prevalence reporting in detail. It was further limited by a narrow database search and data analysis. Thus, we will conduct a systematic review and meta-analysis which will aim to systematically analyse all available published articles that have documented the prevalence of, and/or risk factors for, PFDs

among community-dwelling women in LMIC, and consider potential explanations for the variations in the findings.

METHODS

Data sources and search strategy

Two investigators (MRI and LR) will search the electronic databases of MEDLINE, EMBASE, PsycINFO, CINAHL, and Maternity & Infant Care. Additional searches will be conducted in Google Scholar and in grey literature sources such as conference and government websites. Hand-searching and retrospective searching of relevant published literature will also be undertaken. We will retrieve all English language studies that contain information on the prevalence of, and risk factors for, PFDs in community-dwelling women in LMIC, defined by the World Bank [10]. The search strategy will be tested and revised as necessary across the different databases before being finalised. A database record will be maintained at each stage of the review process detailing how the search was undertaken including results of the search strategy. A senior medical librarian (LR) will assist in the final draft of the search strategy.

The search strategy will include a combination of subject terms and free text terms. These terms will be combined with 'OR' and 'AND' operators. The Medical Subject Headings (MeSH) terms will include pelvic floor disorders, pelvic organ prolapse, genital prolapse, uterine prolapse, urinary incontinence, stress/urge/mixed urinary incontinence, faecal incontinence, anal incontinence, prevalence, developing countries, resource-limit or resource-poor or low-income or lower-middle-income or middle-upper income countries. All MeSH

terms will be exploded where necessary. The search strategy for MEDLINE is shown in Table 1.

Table 1 Search Strategy used in Ovid MEDLINE database from 1946 to March 2017

Number	Search Terms
1	Pelvic Floor Disorders/ or Pelvic Floor/ or exp Pelvic Organ Prolapse/
2	(pelvic floor or pelvic organ).mp.
3	((uterine or uterus or vagina* or cervix or pelvic) adj3 prolaps*).mp.
4	((urogenital or vault or bladder or rectal or anus) adj3 prolaps*).mp.
5	Urinary Incontinence, Urge/ or Fecal Incontinence/ or Urinary Incontinence, Stress/ or Urinary
6	incontinence.mp.
7	or/1-6
8	Developing Countries/ or exp africa/ or exp caribbean region/ or exp central america/ or latin america/ or
9	(Afghanistan* or Albania* or Algeria* or Angola* or Argentina* or Armenia* or Azerbaijan* or Bangladesh* or Belarus* or Beliz* or Benin* or Bhutan* or Bolivia* or Bosnia* or Herzegovin* or Botswan* or Brazil* or Bulgaria* or Burkina* or Burundi* or Cabo Verde* or Cape Verde* or Cambodia* or Cameroon* or Central African or Chad* or China or Chinese or Colombia* or Comor* or Congo* or Costa Rica* or Cote d'Ivoir* or Ivory Coast or Cuba* or Djibouti* or Dominica* or Ecuador* or Egypt* or El Salvador* or Eritrea* or Ethiopia* or Fiji* or Gabon* or Gambia* or Georgia* or Ghana* or Grenad* or Guatemala* or Guinea* or Guyan* or Haiti* or Hondura* or Hungar* or India* or Indonesia* or Iran* or Iraq* or Jamaica* or Jordan* or Kazakhstan* or Kenya* or Kiribati* or Korea* or Kosov* or Kyrgyz Republic or Lao* or Leban* or Lesotho* or Liberia* or Libya* or Macedonia* or Madagascar* or Malawi* or Malaysia* or Maldiv* or Mali* or Marshall Island* or Mauritania* or Mauriti* or Mexic* or Micronesia* or Moldova* or Mongolia* or Montenegr* or Morocc* or Mozambi* or Myanma* or Burmese or Namibia* or Nepal* or Nicaragua* or Niger* or Nigeria* or Pakistan* or Palau* or Panama* or Papua New Guinea* or Paraguay* or Peru* or Philippines or Filipino or Romania* or Rwanda* or Samoa* or Sao Tome* or Senegal* or Serbia* or Seychell* or Sierra Leon* or Solomon Island* or Somalia* or South Africa* or Sudan* or Sri Lanka* or St Lucia* or St Vincent or Grenadines or Surinam* or Swazi* or Syria* or Tajikistan* or Tanzania* or Thai* or Timor* or Togo* or Tonga* or Tunisia* or Turk* or Turkmenistan* or Tuvalu* or Uganda* or Ukrain* or Uzbekistan* or Vanuatu* or Venezuela* or Vietnam* or West Bank or Gaza or Yemen* or Zambia* or Zimbabwe*).mp Bangladesh* or Belarus* or Beliz* or Benin* or Bhutan* or Bolivia* or Bosnia* or Herzegovin* or Botswan* or Brazil* or Bulgaria* or Burkina* or Burundi* or Cabo Verde* or Cape Verde* or Cambodia* or Cameroon* or Central African or Chad* or China or Chinese or Colombia* or Comor* or Congo* or Costa Rica* or Cote d'Ivoir* or Ivory Coast or Cuba* or Djibouti* or Dominica* or Ecuador* or Egypt* or El Salvador* or Eritrea* or Ethiopia* or Fiji* or Gabon* or Gambia* or Georgia* or Ghana* or Grenad* or Guatemala* or Guinea* or Guyan* or Haiti* or Hondura* or Hungar* or India* or Indonesia* or Iran* or Iraq* or Jamaica* or Jordan* or Kazakhstan* or Kenya* or Kiribati* or Korea* or Kosov* or Kyrgyz Republic or Lao* or Leban* or Lesotho* or Liberia* or Libya* or Macedonia* or Madagascar* or Malawi* or Malaysia* or Maldiv* or Mali* or Marshall Island* or Mauritania* or Mauriti* or Mexic* or Micronesia* or Moldova* or Mongolia* or Montenegr* or Morocc* or Mozambi* or Myanma* or Burmese or Namibia* or Nepal* or Nicaragua* or Niger* or Nigeria* or Pakistan* or Palau* or Panama* or Papua New Guinea* or Paraguay* or Peru* or Philippines or Filipino or Romania* or Rwanda* or Samoa* or Sao Tome* or Senegal* or Serbia* or Seychell* or Sierra Leon* or Solomon Island* or Somalia* or South Africa* or Sudan* or Sri Lanka* or St Lucia* or St Vincent or Grenadines or Surinam* or Swazi* or Syria* or Tajikistan* or Tanzania* or Thai* or Timor* or Togo* or Tonga* or Tunisia* or Turk* or Turkmenistan* or Tuvalu* or Uganda* or Ukrain* or Uzbekistan* or Vanuatu* or Venezuela* or Vietnam* or West Bank or Gaza or Yemen* or Zambia* or Zimbabwe*).mp.
10	(africa* or asia* or caribbean or central america* or latin america* or south america* or melanesia* or
11	(resource-limit* or resource-poor or low-resource* or limited-resource* or resource-constrain* or
12	((developing or underdeveloped or under-developed or emerging or less-developed or least-developed or
13	((developing or underdeveloped or under-developed or less-developed or least-developed) adj world).mp.

14	(third-world* or thirdworld* or 3rd-world*).mp.
15	or/8-14
16	(et or ep).fs.
17	exp Probability/
18	(epidemiolog* or etiolog* or prevalence or incidence or risk or factors or probabilit* or determinant* or
19	16 or 17 or 18
20	Cross-Sectional Studies/
21	(cross section* or disease frequency).mp.
22	20 or 21
23	7 and 15 and 19 and 22
24	exp case-control studies/ or exp cohort studies/
25	(case-control or cohort stud*).mp.
26	24 or 25
27	7 and 15 and 19 and 26
28	23 or 27
29	limit 28 to english language

Note: This search strategy will be suitable for other electronic databases.

Inclusion criteria

Observational studies, including cross-sectional, cohort or case-control studies, studies of women with PFDs who were otherwise healthy, studies using validated or non-validated tools, published in English language, and conducted in community settings, will be included. If any study compared the prevalence of PFDs in a country from LMICs with a high-income country, information only for a LMIC country will be included. Where multiple papers were generated from the same data with same outcome, only the most relevant paper will be included. However, if multiple papers were generated from the same data with different outcomes including UI, FI and POP, all papers will be included.

Exclusion criteria

Studies that evaluated treatments for PFDs, studies of women with co-morbidities such as lower urinary tract symptoms, fistula, breast cancer, studies conducted to assess quality of life of women with any PFDs which did not assess the prevalence of PFDs and risk factors, will be excluded. Studies in employed women only, conducted in hospital/clinical settings, or

including LMICs migrant women living in high-income countries will also be excluded. The reasons for exclusion of these studies are: the studies in hospital/clinical settings are likely to be highly selected (i.e. selection bias) resulting in inaccurate estimations of the true prevalence of PFDs, professional women, especially working in the formal sector are well educated, use health care services and do not represent the community-dwelling women, and the prevalence of PFDs in women who migrate from LMICs to developed countries is likely to reflect the prevalence in the host country, not their country of origin. This is due to exposure to better health systems available in the host country [11-13]. Editorials, letters, opinion articles, narrative or systematic reviews, brief communications, and conference abstract and posters will also be excluded. However, a full-length article will be included if any are found in conference websites.

Screening strategy

Titles and/or abstracts of studies identified using the search strategy and those from additional sources will be distributed among two review authors (RMI, JO). These team members will independently assess the eligibility of the full text articles. Two other review authors (MNK, DMEH) will reassess all studies. Any disagreement between reviewers will be resolved through discussion with a third review author (SMH) on the study team.

Data extraction

A standardised data extraction form will be developed and piloted, based on the template of the Cochrane good practice data extraction form [14], to extract data from the selected studies. Extracted information will include study design and methods, country, study setting, participant characteristics, study outcomes, risk factors, results, conclusions, and study

funding sources. If essential data are missing, we will contact the authors for further information. The manuscript will be structured using the MOOSE guidelines [15]. The data extraction form is shown in online supplementary Document 1.

Data Management

Literature search results will be stored in Endnote, and completed data extraction forms will be uploaded to Monash University faculty-allocated network storage, which will be password protected and only accessible to the reviewers. This shared network drive will facilitate the data extraction and data entry and keep a record of all review-related documents.

Risk-of-bias and quality assessment

To assess external and internal validity, a risk-of-bias tool will be used developed explicitly for the systematic review of prevalence studies [16]. Two review authors (MNK and DMEH) will extract data independently; inconsistencies will be identified and resolved through discussion including a third author (RMI) where necessary. The tool has 10 items: (i) national representativeness, (ii) target population representativeness, (iii) random selection or census undertaken, (iv) minimal nonresponse bias, (v) data collected from subjects, (vi) acceptable case definition used, (vii) valid and reliable study instrument used, (viii) same mode of data collection for all subjects, (xi) length of the shortest prevalence period, and (x) appropriateness of numerator(s) and denominator(s) for the parameter. Items 1 to 4 assess the external validity (selection and non-response bias) and items 5 to 10 assess the internal validity of the study (measurement and analysis bias). All of these items are rated high or low. Item 11, the summary assessment, evaluates the overall risk of study bias and is based on the

author's subjective judgement given responses to the preceding 10 items rated as low, moderate or high risk.

Ethics approval and dissemination

Our review is entirely based on published data. Thus, an ethics committee approval or written informed consent will not be required. The results will be disseminated by publication of the manuscript in a peer-reviewed journal and/or will be presented at relevant conferences.

Statistical analysis

Data synthesis

A detailed process of conducting this systematic review and data synthesis of the included studies will be undertaken, for which we have developed a conceptual framework, shown in Figure 1. Pooled prevalence of PFDs will be estimated from the reported prevalence of eligible studies using RevMan V.5.2.1 software. Forest plots will be generated displaying prevalence with the corresponding 95% confidence intervals (asymptotic Wald) for each study. The overall random-effects pooled estimate with its confidence interval, will be reported. A meta-regression will be conducted to identify sources of between-study heterogeneity in the pooled prevalence (or incidence) estimates [14 17]. A multivariable meta-regression model will be built by adding each variable sequentially starting with the variable that shows the strongest association with PFDs prevalence in a univariate analysis. A variable will remain in the multivariable model if it will be independently associated with PFD prevalence at $p \leq 0.10$ [18]. Risk factors of PFDs from all included studies will be synthesised descriptively to understand the key risk factors for PFDs in LMICs. Then, meta-

regression of the odds ratios of the key risk factors will be conducted to identify the individual effects of each risk factor for PFD [19].

Assessment of heterogeneity

To examine the magnitude of the variation between studies, we will quantify the heterogeneity by using the I^2 measure and its confidence interval [17]. To assess the degree of heterogeneity the following I^2 cut-offs for low, moderate, and high heterogeneity will be used: a) between 0% to 40%: might not be important; b) 30% to 60%: may represent moderate heterogeneity; c) 50% to 90%: may represent substantial heterogeneity; d) 75% to 100%: considerable heterogeneity [20]. The significance will be determined by a chi-squared for Q, so a p-value < 0.05 will be considered as significant.

Assessment of reporting biases

We will use funnel plots to detect potential reporting biases and small-study effects. The Egger method [19] will be used to assess asymmetry if more than 10 studies are included in the meta-analysis.

Subgroup analysis

Stratified prevalence will be generated by the economic levels of the country (low income, lower-middle income, and upper-middle income), by sampling methods (random and convenience), and by type of questionnaires used (validated and non-validated).

Sensitivity analysis

We will conduct a sensitivity analysis to verify the robustness of the study conclusions, assessing the impact of methodological quality, study design, sample size and the effect of missing data as well as the analysis methods on the result of this review. We will also use sensitivity analyses to investigate suspected funnel plot asymmetry due to publication bias if any.

Dealing with missing data

We will attempt to collect additional information by contacting authors of included studies with missing data. If we fail to obtain sufficient data, the study with missing data will be omitted from the data synthesis.

DISCUSSION AND CONCLUSION

This systematic review and meta-analysis will provide pooled prevalence estimates of PFDs among women in LMICs. This study will also provide evidence of reasons for the substantial variation of prevalence reporting of PFDs in this context. This comprehensive rigorous systematic review and meta-analysis technique used in this study will ensure a robust knowledge synthesis of available data. By understanding the risk factors of PFDs, this study will provide empirical evidence necessary for clinicians, researchers, policy-makers and public health stakeholders to understand the perspective, future research need, as well as policy and programming priorities for the diagnosis, treatment, and prevention of PFDs in LMICs.

Contributors:

RMI, JO, MNK, SMH, DMEH and JF contributed to the generation of ideas for systematic review. RMI, JO and LR contributed to the development of the study protocol and search

strategy for the review. All the authors will contribute to in review, revision and finalisation of the search strategy. RMI prepared the first draft of the protocol. JO, MNK, SMH, DMEH, LR and JF reviewed and provided subsequent feedback on the revision of the protocol and its finalisation. All the authors critically revised the first draft for content and contributed to the final draft.

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This study is not supported by any funding body. Thus, no funding bodies had any role in the study design, data collection and analysis, decision to publish or preparation of the manuscript.

Competing interests:

None declared.

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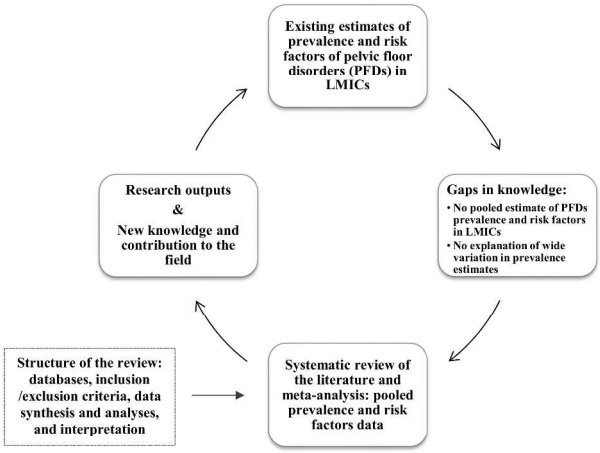
Figure legends:

Figure 1 Conceptual framework



209x297mm (300 x 300 DPI)

Data Extraction Form adapted from the Cochrane Collaboration

Title of the systematic review: *Prevalence of, and risk factors for, pelvic floor disorders in community-dwelling women in low-and-middle income countries: a systematic review and meta-analysis*

Trial Registration no: CRD42016043881

This form has been developed by adopting and customizing the "Data collection form for intervention review – RCTs and non-RCTs" of The Cochrane Collaboration. Some new sections have been added into this tool and the irrelevant sections have been removed from the original form. Information included on this form should be comprehensive, and may be used in the text of the review.

Notes on using this data extraction form:

- Be consistent in the order and style you use to describe the information for each included study
- Record any missing information as unclear or not described, to make it clear that the information was not found in the study report(s), not that you forgot to extract it.
- Include any instructions and decision rules on the Data Extraction Form, or in an accompanying document. It is important to practice using the form and give training to any other authors using the form.
- We will protect the document in order to use the form fields (Tools / Protect document)

1. General Information

1. **Date form completed** *(dd/mm/yyyy)*	
2. **Name/ID of person extracting data**	
3. **Report title** *(title of paper/ abstract/ report that data are extracted from)*	
4. **Report contact details of person extracting data**	
5. **Publication type** *(e.g. full report, abstract, letter)*	
6. **Study ID** *(e.g. 01 plus surname of first author and year first full report of study was published e.g. Smith 2001)*	
7. **Country in which the study conducted**	
8. **Economic level of the country in which the study conducted** *(e.g. low income, lower-middle income or upper-middle income)*	

9. **Study funding source** *(including role of funders)*	
10. **Possible conflicts of interest** *(for study authors e.g. not reported)*	
11. **Notes:**	

2. Eligibility

Study Characteristics	**Review Inclusion Criteria** *(Insert inclusion criteria for each characteristic as defined in the Protocol e.g. cross-sectional, cohort or case-control)*	**Location in text** *(page#/fig /table)*
12. **Type of study**		P2
13. **Population description**		P2
14. **Focused diseases / conditions** *(Urinary incontinence, Faecal incontinence, pelvic organ prolapse, or at least one of them)*		P2
15. **Types of outcome measures** *(Prevalence/Risk factors)*		P1 P1
16. **Decision** *(with reasons for either inclusion or exclusion)*		
17. **Notes:**		

DO NOT PROCEED IF STUDY IS EXCLUDED FROM REVIEW

3. Population and setting

	Description	**Location in text** *(page#/fig /table)*
18. **Population description** *(from which study participants are drawn)*		

	Description	Location in text *(page#/fig /table)*
19. **Source/setting of the population** *(e.g. urban, rural, particular ethnic group)*		
20. **Method/s of recruitment of participants**		
21. **Notes:**		

4. Methods

	Descriptions as stated in report/paper	Location in text *(page#/fig /table)*
22. **Aim of study**		
23. **Design** *(e.g. cross-sectional study, cohort study, case-control study)*		
24. **Sampling technique** *(e.g. random or convenience)*		
25. **Study start date**		
26. **Study End date/duration** *(if any cohort)*		
27. **Notes:**		

5. Participants

Provide overall data and, if available, comparative data for each intervention or comparison group.

	Description as stated in report/paper	Location in text *(page#/fig /table)*
28. **Total number of participants/Sample size**		
29. **Age group**		

	Description as stated in report/paper	Location in text *(page#/fig /table)*
30. **Menopause status** *(if any)*		
31. **Notes:**		

6. Outcomes

How outcomes measured	Description as stated in report/paper	Location in text *(page#/fig/ table)*
32. **Outcomes** *(detected by physical examination: who examined?)*		
33. **Self-reported reported outcomes** *(detected by questionnaire: validated or non-validated?)*		

Copy and paste table for each outcome.

Outcome 1: Prevalence **(Note:** Not detail here under outcome. Detail should be reported in results section**)**	**Description as stated in report/paper**	**Location in text** *(page#/fig /table)*
34. **Outcome names** *(Urinary incontinence, Faecal incontinence, pelvic organ prolapse, or at least one of them)*		
35. **Time points measured** *(report the start year/specify whether from start and end of intervention)*		
36. **Time points reported**		

Outcome 1: Prevalence **(Note:** Not detail here under outcome. Detail should be reported in results section**)**	**Description as stated in report/paper**	**Location in text** *(page#/fig /table)*
37. **Outcome definition** *(e.g. whether standard case definition used: some standard definitions are: Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6), Colorectal-Anal Distress Inventory 8 (CRADI-8), Question for Urinary Incontinence Diagnosis (QUID), Urinary Distress Inventory 8 (UD1-6), International Consultation on Incontinence Society (ICIS) etc.)*		
38. **Type of measurement** *(Percentage/Odds ratio/Risk ratio)*		
39. **Is outcome/tool validated?** *(Yes/No/Unclear/Not mentioned)*		
40. **Notes:**		

Outcome 2: Risk factors (not detail here)	**Description as stated in report/paper**	**Location in text** *((page#/fig /table)*
41. **Name of the risk factors** (e.g. risk factors of POP)		
42. **Time points measured** *(report the start year/specify whether from start and end of intervention)*		
43. **Time points reported**		
44. **Definition of risk factors** *(if any)*		
45. **Type of measurement** *(Percentage/Odds ratio/Risk ratio)*		
46. **Is outcome/tool validated?** *(Yes/No/Unclear/Not mentioned)*		
47. **Notes:**		

7. Results and findings

Copy and paste the appropriate table for each outcome, including additional tables for each time point and subgroup as required.

Outcome 1: Prevalence **(Note:** detail here)	**Description as stated in report/paper**	**Location in text** *(page#/fig /table)*
48. **Outcome**		
49. **Subgroup** *(if any, e.g. age-specific prevalence reporting)*		
50. **Results**		
51. **Response/non-response rate**		
52. **Any other results reported**		
53. **Unit of analysis** *(e.g. by individuals)*		
54. **Statistical methods used and appropriateness of these methods** *(e.g. proportion/%s, RR/OR)*		
55. **Whether results weighted?** *(e.g. Yes/No)*		
56. **Notes:**		

Outcome 2: Risk factors **(Note:** detail here)	**Description as stated in report/paper**	**Location in text** *(page#/fig /table)*
57. **Name of the risk factors** NB this is confusing; change to RF?		
58. **Results**		
59. **Response/non-response rate**		
60. **Any other results reported**		
61. **Unit of analysis** *(e.g. by individuals)*		

Outcome 2: Risk factors **(Note:** detail here)	**Description as stated in report/paper**	**Location in text** *(page#/fig /table)*
62. **Statistical methods used and appropriateness of these methods** *(e.g. proportion/%s, RR/OR)*		
63. **All systematic and random error adjusted?** *(e.g. confounding, effect medication etc.)*		
64. **Notes:**		

8. Limitation and mitigation strategy

	Description as stated in report/paper	Location in text*(page# /fig/table)*
65. **Strength**		
66. **Limitation**		
67. **Strategies to overcome the limitation**		
68. **Notes:**		

9. Conclusion and other information

	Description as stated in report/paper	**Location in text** *(page#/fig /table)*
69. **Key conclusions of study authors**		
70. **Notes:**		

10. Risk of bias (Quality Assessment)

External/Internal Validity **(Note:** some criteria would be overlapping with what you have reported in earlier sections. So, please report again to get quick understanding of the quality of the paper)	**Often it would not be stated directly in the paper. So, data extractors is/are requested to find information and sate (Yes/No)**	**Location in text** *(page#/fig /table)*
71. **Was the study's target population a close representation of the national population in relation to relevant variables?**		
72. **Was the sampling frame a true or close representation of the target population?**		
73. **Was some form of random selection used to select the sample, OR was a census undertaken?**		
74. **Was the likelihood of nonresponse bias minimal?**		
75. **Were data collected directly from the subjects (as opposed to a proxy)?**		
76. **Was an acceptable case definition used in the study?**		
77. **Was the study instrument that measured the parameter of interest shown to have validity and reliability?**		
78. **Was the same mode of data collection used for all subjects?**		
79. **Was the length of the shortest prevalence period for the parameter of interest appropriate** *(last two weeks or life time prevalence etc. please specify exact period over which symptoms were asked?*		
80. **Were the numerator(s) and denominator(s) for the parameter of interest appropriate?**		
81. **Notes**		