



BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open

The impact of violence against women on severe acute maternal morbidity in the intensive care unit: a case-control study protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-020147
Article Type:	Protocol
Date Submitted by the Author:	16-Oct-2017
Complete List of Authors:	Ayala Quintanilla, Beatriz; La Trobe University College of Science Health and Engineering, Judith Lumley Centre; Peruvian National Institute of Health, Lima Taft, Angela; La Trobe University, Mother and Child Health Research McDonald, SJ; Midwifery Professorial Unit, La Trobe University/Mercy Hospital for Women Pollock, Wendy; La Trobe University, The Judith Lumley Centre; Mercy Hospital for Women
Keywords:	Severe acute maternal morbidity, violence against women, intimate partner violence, intensive care unit, social determinants, near miss

SCHOLARONE™
Manuscripts

Title Page

Study Protocol

The impact of violence against women on severe acute maternal morbidity in the intensive care unit: a case-control study protocol

Corresponding autor:

Dr. Beatriz Paulina Ayala Quintanilla.
Address: 215 Franklin Street, Melbourne, Vic 3000, Victoria, Australia.
Telephone: +61 3 9479 8800. Fax: +61 3 9479 8811.
Email: ayalaquintanilla.b@students.latrobe.edu.au

Authors: Beatriz Paulina Ayala Quintanilla^{1, 2, 4}, Angela Taft¹, Susan McDonald^{1, 2}, Wendy Pollock^{1, 2, 3}

Author affiliations

- ¹ The Judith Lumley Centre, La Trobe University, Melbourne, Australia
- ² Mercy Hospital for Women, Melbourne, Australia
- ³ University of Melbourne, Melbourne, Australia
- ⁴ Peruvian National Institute of Health, Lima, Peru

Keywords: Severe acute maternal morbidity, violence against women, intimate partner violence, intensive care unit, social determinants, near miss.

Words in the abstract: 299 words.

Words in article: 3,276 words, excluding title page, abstract and references.

ABSTRACT

Introduction: Preventing and reducing violence against women (VAW) and maternal mortality are Sustainable Development Goals. Worldwide, the maternal mortality ratio has fallen about 44% in the last 25 years; however, the majority of maternal deaths (99%) continue to occur in developing countries. In addition, for one maternal death there are many women affected by severe acute maternal morbidity (SAMM) requiring management in the intensive care unit (ICU). These women represent the most critically ill obstetric patients of the maternal morbidity spectrum and should be studied to complement the review of maternal mortality. Furthermore, many women (30%) endure violence usually exerted by their intimate partners and VAW is thought to be a contributory factor to maternal mortality; but, the impact on SAMM is unknown. Thus, this study aims to investigate the impact of VAW on SAMM in the ICU.

Methods and analysis: This will be a prospective case-control study undertaken in a tertiary healthcare facility in Lima-Peru. We calculated the sample size of 218 participants, 109 cases (maternal ICU admissions) and 109 controls (non-maternal ICU admissions), considering a confidence interval (CI) of 95% and a power of 80%. After obtaining individual written informed consent, data on social determinants, medical and obstetric characteristics, VAW, pregnancy and neonatal outcome will be collected through interviews and medical records. VAW will be assessed by using the World Health Organization (WHO) instrument. Binary logistic regression models will be developed to assess any association between VAW and SAMM.

Ethics and dissemination: Ethical approval has been granted by the La Trobe University Human Ethics committee, Melbourne, Australia and the tertiary healthcare facility in Lima-Peru. This research follows the WHO ethical and safety recommendations for research on VAW to ensure the safety of the participants and interviewer. Findings will be presented at conferences, and published in peer-reviewed journals.

Strengths and limitations of this study

- This prospective study will examine for the first time worldwide the influence of violence against women (VAW) on severe acute maternal morbidity (SAMM).
- Studying the stage before maternal death (SAMM) can be considered as a complement to maternal death review, and may provide evidence that gives useful insight into factors that may prevent maternal deaths and improve the mother-baby dyad health.
- Assessing VAW can be challenging, because it is a sensitive issue and can be underestimated due to recall and cultural bias. The sensitivity may have an impact on willingness to participate in the study. This study will follow the ethical and safety recommendations for research on VAW, and use standardised and pre-tested questions for the assessment of VAW and other variables of interest to maximize participation.
- This study is within one very large tertiary hospital and further multi-centre studies are needed, based on these replicable methods.

INTRODUCTION

Preventing and reducing violence against women (VAW) and maternal mortality are Sustainable Development Goals (SDG).¹ Worldwide, the maternal mortality ratio (MMR) has declined by 44% with a reduction from 385 to 216 maternal deaths per 100,000 live births between 1990 (532,000 maternal deaths) and 2015 (303,000 maternal deaths). This equates to approximately 830 women dying daily, of which 99% of maternal deaths occurred in developing countries.² However, maternal mortality is only a small proportion of the global burden of the maternal morbidity spectrum.³⁻⁵ This is because for one maternal death there are many women affected by severe acute maternal morbidity (SAMM) during pregnancy, childbirth and the postpartum period⁵⁻¹¹ including those obstetric patients who require multidisciplinary management in the intensive care unit (ICU).¹¹⁻¹⁹

ICU admission can be an alternative marker for defining SAMM,^{13 15 20-25} and SAMM can be named as near miss; either term has been widely used to study this population of obstetric patients.^{15 17 21 25-28} Although the World Health Organization (WHO) has developed a set of (clinical, laboratory and management) criteria to facilitate the identification of near miss, taking into account organ system dysfunction parameters,^{26 29} many researchers have argued the applicability of using these criteria in both low-income and high-income countries.^{13 30-34} As a result, in some studies, researchers have used an adapted version of the WHO criteria according to the local context and characteristics of healthcare system resources, including the availability of advanced laboratory measures and well-trained healthcare professionals.^{31 32 35-38}

Accordingly, there are no internationally accepted criteria for defining SAMM and its definition could differ across studies.^{13 15 20 25 27 39-44} The use of ICU admission to identify severe maternal morbidity has high sensitivity (86.4%), specificity (87.8%) and positive predicted value (0.85).^{22 27 45-48} This may not identify the wide range of severe obstetric complications because ICU admission criteria may vary across setting and countries according to guidelines established by the healthcare facility, hospital resources availability, among other factors.^{26 49-51} However, women with SAMM in the ICU represent the most critically ill obstetric patients,^{11 15 52} whose treatment requires timely managed care and involves unique challenges due to the physiologic changes of pregnancy and the care of the mother-baby dyad.^{11 13 14 18 19 53-59}

The incidence of maternal ICU admission varies from 0.04 to 4.54%, and the common causes are mainly direct obstetric clinical conditions.^{13 15 16 28} According to Pollock, et al.,¹⁶ hypertensive disorders were the leading cause of ICU admission (0.09% of deliveries), followed by obstetric haemorrhage (0.07%), and sepsis (0.02%); and, although the ICU admission profile was similar worldwide there were higher rates of maternal deaths in the ICUs of developing countries.

VAW is a global public health problem and many women of reproductive age endure violence usually exerted by their intimate partners (IPV). Globally, 30% of women have experienced partner abuse.⁶⁰⁻⁶² However, the IPV rate varies across studies ranging from 15 to 71% and from 1 to 28% during pregnancy.⁶³ Diverse studies have also reported a wide range of IPV rate during pregnancy from 0.9 to 20.1% in developed countries,⁶⁴ 3 to 44% in Latin America and Caribbean countries⁶⁵ and 2 to 57% in African countries.⁶⁶

Several studies have reported negative and mortal consequences of IPV on reproductive age women.⁶⁷⁻⁷⁰ During pregnancy, these adverse health outcomes affect the mother-baby dyad; and, can be augmented by consequent risky health behaviors (smoking, alcohol consumption, substance abuse, poor nutrition, lack of seeking health care, among others)⁷⁰⁻⁷² and physiological mechanisms through neural, neuroendocrine, and immune responses to acute and/or chronic stress originating from exposure to violence.^{68 73} All of this may exacerbate preexisting medical conditions and/or lead to diverse pregnancy complications.^{65 68 74-76} Even though women could be more vulnerable to IPV during the pregnancy and puerperium periods, no data on VAW of obstetric patients in the ICU have been reported in Peru or elsewhere. Thus, further investigations are urgently needed to fill this significant gap in understanding factor affecting the burden of maternal morbidity. We are conducting this study in Peru, an upper-middle income country⁷⁷ with a lifetime IPV rate of 68.2% (emotional 64.2%, physical 31.7% and sexual 6.6%).⁷⁸ In Peru, there are about 9 cases of femicide monthly⁶⁹ and a MMR of 68, which fell 72.9% from 251 between 1990 and 2015.²

VAW is also thought to contribute to maternal deaths, and there has been increased concern about the negative influence of VAW on maternal mortality.^{74 79-82} This association was first analysed in the 1997-1999 UK Confidential Enquiry into Maternal Death⁸³ and then in the 2000–2002 UK Confidential Enquiry into Maternal Death.⁸⁴ However, there is a paucity of studies evaluating this association and further studies are needed to investigate the role of VAW on SAMM, which may be used as a complement to review maternal deaths.^{22 85-87} Therefore, this research of the stage before maternal death (SAMM) will provide for the first time globally, a better understanding about what potential factors, such as VAW, are affecting deterioration from a healthy pregnancy to SAMM. This will make an important contribution to global knowledge of causes of maternal morbidity to prevent and/or reduce maternal morbidity-mortality and improve maternal health.

HYPOTHESIS

We hypothesised that violence against women is significantly associated with severe acute maternal morbidity in obstetric patients managed in the intensive care unit.

OBJECTIVES

- To investigate the impact of VAW on women with SAMM in the ICU of a tertiary healthcare facility in Lima-Peru.
- To evaluate pregnancy and neonatal outcome of women with SAMM in the ICU of a tertiary healthcare facility in Lima-Peru.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

29

30

31

32

33

34

35

36

37

38

39

40

41

42

43

44

45

46

47

48

49

50

51

52

53

54

55

56

57

58

59

60

METHODS

This is a prospective case-control study protocol and follows the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) criteria.^{88 89}

Study design

In this case-control study, cases will be obstetric patients experiencing SAMM in the ICU (s) including miscarriage, therapeutic abortion, unsafe abortion, and ectopic pregnancy prospectively identified from the ICU register. The inclusion criteria of cases include: i) a woman with a maternal ICU admission due to a complication (s) during pregnancy, delivery or within 42 days of the ending of pregnancy, with favorable evolution and who fulfils eligibility prior to hospital discharge; ii) 18-year-old or older; iii) Spanish speaker; and iv) gives written informed consent. The exclusion criteria are: i) a woman with mental illness or disabilities or other similar disabling pathologies; ii) not able to provide informed consent; iii) an obstetric patient referred from other healthcare facilities for maternity care; iv) ICU stay less than 24 hours. Controls are non-maternal ICU admission with favorable evolution from the same source population that gives rise to the cases, selected randomly by using allocated computer-generated random numbers, and whose other criteria are consistent with all other inclusion and exclusion criteria of the cases.

Setting

This study will be undertaken in a tertiary hospital located in the capital city of Peru (where about one third of the Peruvian population live). This institution is the main national referral hospital for high risk maternal and neonatal patients throughout Peru, where there are over 22,000 deliveries yearly, which equates to approximately 1 delivery every 25 minutes.⁹⁰

Ethics

Ethical approval has been granted by the La Trobe University Human Ethics committee (HEC15-023), Melbourne, Australia and the Institutional Review Board of the tertiary healthcare hospital in Lima, Peru. Individual written informed consent will be obtained from participants prior to data collection. The present research follows the WHO and other ethical and safety recommendations for research on gender-based violence to ensure the safety of the participants and the interviewer.^{63 91-95}

Sample size

The sample size will comprise 218 participants (109 controls and 109 cases) which has been calculated by using the Sample Size Calculation for Unmatched Case-Control Studies of the software open EPI⁹⁶ with a confidence level of 95% and a power of 80%. There are not preceding studies assessing the prevalence of VAW among obstetric patients with SAMM in the ICU. We estimated an IPV rate of 24.3% for controls and 43.1% for cases in accordance with previous research investigating the relationship between IPV and preeclampsia in Peruvian pregnant women at this maternity hospital.⁹⁷

Recruitment Method

Participants will be invited to participate and recruited during their hospital stay once their acute medical condition (s) have been resolved (this will be after they were discharged from the ICU for the case women), and before they are discharged from hospital to going home. Women in the control group will be invited to participate within one week of a case woman being interviewed. The interviewer, a Spanish speaking midwife, has been trained and has research experience working on VAW studies and research ethics. She will ensure that the potential participants understand the participant information statement and answer all their questions, and explain to the participants that they can refuse or withdraw their participation at any time without affecting their health care and rights.

Data Collection

Data collection commenced on 23rd October 2015 and is still ongoing. Currently, we are collecting data from the medical records. Women who give consent will be interviewed once in private using a structured questionnaire (Appendix 1). We will also extract information from their medical records using a pretested form developed by the team members (Appendix 2).

Interview

The following information will be obtained during the face to face interview: socio-demographic characteristics (age, place of residence, educational level, marital status, occupation and type of health insurance) of the participant and her partner; behavioural factors (smoking, use of alcohol or drugs); medical (previous and current diseases) and obstetric characteristics (number of pregnancies, previous abortions, prenatal care visits, previous cesarean sections, and vaginal births; use of family planning methods; anemia during pregnancy and use of iron supplements during pregnancy); and VAW evaluation.

VAW will be assessed by using the set of standardized questions of the WHO instrument.⁶³ These questions were validated, translated and adapted rigorously, since Peru was one of the countries selected in the WHO Multi-country study instrument.⁶³ They have been also used by other researchers for investigating VAW in Peru,⁷⁸ and an adapted version was applied in the Peruvian Demographic and Family Health Survey.

VAW evaluation will comprise emotional (including controlling behaviours), physical and sexual abuse exerted by intimate-partners and by non-intimate partners (relatives, friends or others) assessed 12 months before and during pregnancy. The participants will answer the frequency (once or twice or many) for each act of emotional, physical or sexual violence. VAW will be examined in an empathetic, supportive and non-judgmental manner, giving the participants the opportunity not to answer any questions that make them feel uncomfortable or to reschedule or terminate the interview at any time. The interview will only be conducted with the woman alone and in private. If the interview is interrupted, the interviewer will change the topic or may terminate the interview correspondingly. It is expected that the interview will take approximately 25 to 30 minutes. After the interview, information about free social support services for domestic violence (available at this maternity hospital) will be offered to every participant including a referral if they wish. There will be also debriefing sessions for the well-

being of the interviewer. Individual support/counselling can be arranged at the hospital for the interviewer or participant if it is needed.

Extracting data from medical records

We will extract data from the medical reports of the mothers and newborns (if applicable) related to SAMM, pregnancy outcome, fetal and neonatal characteristics and outcome.

SAMM data will include hospital admission date, clinical causes for hospitalization and/or ICU admission, diagnoses after being discharged from the ICU and/or the hospital, number of hospital stay days and ICU stay days, type of delivery, additional procedures, weeks of pregnancy when SAMM occurs, organ failure (s), use of technologies, main delays, and pregnancy outcome (Appendix 2).

Fetal and neonatal data will include: birth weight; birth age; sex; Apgar score (at 1 and 5 minutes); outcome at birth; clinical cause (s) for Neonatal ICU (NICU); number of days at the NICU (if applicable) or at the hospital; use of technologies and/or antibiotics at the NICU; feeding type (breastfeeding, formula or both); discharge status; and diagnoses from the hospital and/or the NICU (Appendix 2).

Data entry and analysis

Data will be entered using SPSS V.24.0. Univariate analysis will be carried out to describe the characteristics of SAMM, social determinants, VAW and pregnancy and neonatal outcomes. Quantitative variables will be displayed as the mean ± SD and/or median (interquartile rate) after verifying their normal or asymmetrical distribution. Difference of means analyses between variables will be performed using appropriate statistical tests (Student's t-test or Mann–Whitney U test or other similar). Qualitative variables will be displayed as frequencies.

We will apply the following bivariate analysis: i) model 1 will include VAW (partner and non-partner) as independent variable and evaluate its association with SAMM; ii) model 2 will evaluate the association with partner violence only; iii) model 3 will evaluate the association with non-partner violence only.

We will fully assess VAW as a risk factor using multivariate logistic regression modeling adjusted for important confounding variables (to the model 1, 2 and 3) and Odds Ratio with 95% CI. Statistical significance will be set at $p < 0.05$. The final model will include all variables with a probability of <0.25 , those which were statically significant in the univariate analysis, and socio-demographic characteristics (such as household income, partner’s educational level, partner’s occupation, etc.) for SAMM according to literature review. The Hosmer-Lemeshow’s goodness-of-fit test will be used to assess model adequacy and stepwise multiple regression analysis performed to select and identify the predictive factors in the final models.⁹⁸

PRESENTING AND REPORTING RESULTS

This prospective case-control study will examine for the first time worldwide the influence of VAW on women affected by severe acute maternal morbidity who require management in the ICU, and evaluate their pregnancy and neonatal outcomes. We will present major findings in

tables and also describe results in narrative format outlining effect sizes and their parameters. The findings and further publications will be reported following the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) criteria,^{88 89} which is part of the Enhancing the quality and transparency of health research (EQUATOR) Network website.

DISCUSSION

Although, the negative contribution of VAW to maternal deaths has been described in the 1997-1999 Confidential Enquiry into Maternal Death,⁸³ and many studies have reported negative and fatal repercussions of IPV on women's health including during all stages of pregnancy,^{65 67-76} there is a paucity of studies assessing the relationship between VAW and SAMM. Investigating women affected by SAMM could complement the review of maternal deaths^{22 85-87} to understand which underlying factors are influencing the sequence of events from a healthy pregnancy through minor complications to life threatening obstetric conditions and even death in childbearing women.^{26 99 100}

This case-control study will contribute to evidence about the potential negative consequences of VAW of obstetric patients with SAMM in the ICU, who represent the most critically ill patients^{11 15 52} and have been shown to be an important component of the maternal morbidity spectrum requiring timely managed care.^{11-19 53-59} This may help to highlight that non-biological factors (VAW), which are potentially modifiable, may be associated with SAMM and are important to address to reduce maternal morbidity-mortality in Peru and in other low and middle-income countries. Acute or chronic exposure to violence adversely affects both the mothers and their babies and can be augmented by any risky health behaviors⁷⁰⁻⁷² and through physiological (neural, neuroendocrine, and immune) mechanisms in response to this abuse.^{68 73} All of this may exacerbate preexisting medical conditions and/or lead to diverse pregnancy complications.^{65 68 74-76} Thus, it would be important to know if VAW is a risk factor for SAMM in the ICU, and to understand the complete picture of the global burden of maternal morbidity-mortality to improve mother-baby dyad health and women's well-being.

This study may also help participants affected by violence to disclose abuse in a safe and supportive environment; and, give an opportunity for those abused women to understand that it is possible to prevent violence and improve their and other women's lives, since they will be informed and/or referred to the free social support services available for domestic violence provided by the Peruvian government.

We understand that the findings of this study should be interpreted cautiously and some limitations should be noted. Firstly, this research will be undertaken in a single center. It will be important to carry out further multi-centre and multi-country studies. Other limitations may include recall, cultural and measurement bias.⁶³ This is because the assessment of VAW is complex and challenging. Accordingly, this research follows the ethical and safety recommendations for research on VAW;^{63 91-95} and uses standardized questions for the assessment of VAW (WHO instrument) and a pretested questionnaire for the evaluation of other factors. Amendments to this protocol are not expected. However, if any are required, these amendments will be reported transparently.

Notwithstanding these limitations, we hope that this study will contribute to the global effort towards achieving SDGs by providing valuable information for a better understanding of SAMM and VAW in Peru. This will make an important contribution to global knowledge of causes of maternal mortality and morbidity by providing evidence of the relationship between VAW and SAMM, which is important for preventing and/or reducing maternal morbidity-mortality and improve maternal health. Therefore, we expect that this research will extend knowledge in an identified research gap, and may provide direction for further studies in obstetric women affected by SAMM in the ICU.

ETHICS AND DISSEMINATION

Ethical issues

Ethical approval has been granted by the La Trobe University Human Ethics Committee, Melbourne, Australia (HEC15-023) and the Institutional Review Board of tertiary healthcare facility in Lima, Peru.

Publication plan

It is planned that the findings of this case-control study will be presented at La Trobe University and national and/or international conferences, and it will be also published in a peer review journal. It is expected that these finding will inform policymakers, patients, and the public through these presentations.

Authors' contributions

BPAQ, AT, SMc and WP conceived and designed the study protocol. This study is part of the first's author PhD thesis. BPAQ drafted the manuscript and all authors edited following versions of the draft. BA, AT, SMc, and WP revised critically the methodological and clinical content of the protocol to make contributions. All authors reviewed and approved the final manuscript.

Funding

This study is part of a doctoral study at La Trobe University funded by the Peruvian Government through PRONABEC (National Program of Scholarship and Educational Loan) and with the support of La Trobe University.

Disclaimer

No funding bodies will have any role in study design, collecting data, analysing data, interpreting findings, and writing, reviewing or deciding to publish the manuscript.

Competing interest

The authors declare that they have no competing interest.

REFERENCES

1. United Nations. Transforming our world: the 2030 Agenda for Sustainable Development. Resolution adopted by the General Assembly on 25 September 2015. 2015. <https://sustainabledevelopment.un.org/post2015/transformingourworld> (accessed 6 May 2017).
2. World Health Organization. Trends in maternal mortality: 1990 to 2015. Estimates by WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division. Secondary Trends in maternal mortality: 1990 to 2015. Estimates by WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division. 2015. <http://www.who.int/classifications/icd/factsheet/en/> (accessed 15 Feb 2016).
3. Mantel GD, Buchmann E, Rees H, et al. Severe acute maternal morbidity: a pilot study of a definition for a near-miss. *Br J Obstet Gynaecol* 1998;105:985-90.
4. Geller SE, Cox SM, Callaghan WM, et al. Morbidity and mortality in pregnancy: laying the groundwork for safe motherhood. *Womens Health Issues* 2006;16:176-88.
5. Firoz T, Chou D, von Dadelszen P, et al. Measuring maternal health: focus on maternal morbidity. *Bull World Health Organ* 2013;91:794-6.
6. Ashford L. Hidden suffering: disabilities from pregnancy and childbirth in less developed countries. Secondary Hidden suffering: disabilities from pregnancy and childbirth in less developed countries. 2002. <http://www.prb.org/pdf/hiddensufferingeng.pdf> (accessed 23 Jul 2014).
7. Fottrell E, Kanhonou L, Goufodji S, et al. Risk of psychological distress following severe obstetric complications in Benin: the role of economics, physical health and spousal abuse. *Br J Psychiatry* 2010;196:18-25.
8. Pacagnella RC, Cecatti JG, Camargo RP, et al. Rationale for a long-term evaluation of the consequences of potentially life-threatening maternal conditions and maternal "near-miss" incidents using a multidimensional approach. *J Obstet Gynaecol Can* 2010;32:730-8.
9. Wilson RE, Salihu HM. The paradox of obstetric "near misses": converting maternal mortality into morbidity. *Int J Fertil Womens Med* 2007;52:121-7.
10. Storeng KT, Drabo S, Ganaba R, et al. Mortality after near-miss obstetric complications in Burkina Faso: medical, social and health-care factors. *Bull World Health Organ* 2012;90:418-25B.
11. Plaat F, Naik M. Critical care in pregnancy. *Crit Care* 2011;15:1014 doi: <http://dx.doi.org/10.1186/cc10479> [published Online First: 22 December 2013].
12. Oud L. Epidemiology of Pregnancy-Associated ICU Utilization in Texas: 2001 - 2010. *J Clin Med Res* 2017;9:143-53 doi: 10.14740/jocmr2854w [published Online First: 17 January 2017].
13. Zieleskiewicz L, Chantry A, Duclos G, et al. Intensive care and pregnancy: Epidemiology and general principles of management of obstetrics ICU patients during pregnancy. *Anaesth Crit Care Pain Med* 2016;35 (Suppl 1):S51-7 doi: 10.1016/j.accpm.2016.06.005 [published Online First: 5 July 2016].
14. Guntupalli KK, Hall N, Karnad DR, et al. Critical illness in pregnancy Part I: an approach to a pregnant patient in the ICU and common obstetric disorders. *Chest* 2015;148:1093-104.
15. Senanayake H, Dias T, Jayawardena A. Maternal mortality and morbidity: Epidemiology of intensive care admissions in pregnancy. *Best Pract Res Clin Obstet Gynaecol* 2013;27:811-20.
16. Pollock W, Rose L, Dennis C. Pregnant and postpartum admissions to the intensive care unit: a systematic review. *Intensive Care Med* 2010;36:1465-74.
17. Baskett TF. Epidemiology of obstetric critical care. *Best Pract Res Clin Obstet Gynaecol* 2008;22:763-74.
18. Martin SR, Foley MR. Intensive care in obstetrics: an evidence-based review. *Am J Obstet Gynecol* 2006;195:673-89.
19. Germain S, Wyncoll D, Nelson-Piercy C. Management of the critically ill obstetric patient. *Curr Obstet Gynaecol* 2006;16:125-33.

20. Bouvier-Colle MH, Mohangoo AD, Gissler M, et al. What about the mothers? An analysis of maternal mortality and morbidity in perinatal health surveillance systems in Europe. *BJOG* 2012;119:880-9; discussion 90.

21. Reichenheim ME, Zylbersztajn F, Moraes CL, et al. Severe acute obstetric morbidity (near-miss): a review of the relative use of its diagnostic indicators. *Arch Gynecol Obstet* 2009;280:337-43.

22. Hirshberg A, Srinivas SK. Epidemiology of maternal morbidity and mortality. *Semin Perinatol* Published Online First: 17 August 2017. doi: 10.1053/j.semperi.2017.07.007.

23. Brace V, Penney G, Hall M. Quantifying severe maternal morbidity: a Scottish population study. *BJOG* 2004;111:481-4.

24. Lawton BA, Wilson LF, Dinsdale RA, et al. Audit of severe acute maternal morbidity describing reasons for transfer and potential preventability of admissions to ICU. *Aust N Z J Obstet Gynaecol* 2010;50:346-51.

25. Chantry AA, Deneux-Tharaux C, Bonnet MP, et al. Pregnancy-related ICU admissions in France: Trends in rate and severity, 2006-2009. *Crit Care Med* 2015;43:78-86.

26. Say L, Souza JP, Pattinson RC. Maternal near miss--towards a standard tool for monitoring quality of maternal health care. *Best Pract Res Clin Obstet Gynaecol* 2009;23:287-96.

27. Callaghan WM, Grobman WA, Kilpatrick SJ, et al. Facility-based identification of women with severe maternal morbidity: it is time to start. *Obstet Gynecol* 2014;123:978-81.

28. Tuncalp O, Hindin MJ, Souza JP, et al. The prevalence of maternal near miss: a systematic review. *BJOG* 2012;119:653-61.

29. World Health Organization. Evaluating the quality of care for severe obstetric complication. The WHO near-miss approach for maternal health 2011. 2011. http://apps.who.int/iris/bitstream/10665/44692/1/9789241502221_eng.pdf (accessed 15 Jan 2015).

30. Witteveen T, de Koning I, Bezstarosti H, et al. Validating the WHO Maternal Near Miss Tool in a high-income country. *Acta Obstet Gynecol Scand* 2016;95:106-11.

31. Witteveen T, Bezstarosti H, de Koning I, et al. Validating the WHO maternal near miss tool: comparing high- and low-resource settings. *BMC Pregnancy Childbirth* 2017;17:194 doi: 10.1186/s12884-017-1370-0 [published Online First: 19 June 2017].

32. Nelissen E, Mduma E, Broerse J, et al. Applicability of the WHO maternal near miss criteria in a low-resource setting. *PloS One* 2013;8:e61248 doi: 10.1371/journal.pone.0061248 [published Online First: 16 April 2013].

33. Menezes FEF, Galvão LPL, de Mendonça CMM, et al. Similarities and differences between WHO criteria and two other approaches for maternal near miss diagnosis. *Trop Med Int Health* 2015;20:1501-6 doi: 10.1111/tmi.12568 [published Online First: 5 August 2015].

34. Knight M. Severe maternal morbidity-actions are more important than definitions. *BJOG* 2016;123:954 doi:10.1111/1471-0528.13699 [published Online First: 3 November 2015].

35. Goldenberg RL, Saleem S, Ali S, et al. Maternal near miss in low-resource areas. *Int J Gynaecol Obstet* 2017;138:347-55 doi: 10.1002/ijgo.12219 [published Online First: 13 June 2017].

36. Jayaratnam S, Burton A, Connan KF, et al. Maternal 'near miss' at Royal Darwin Hospital: An analysis of severe maternal morbidity at an Australian regional tertiary maternity unit. *Aust N Z J Obstet Gynaecol* 2016;56:381-6.

37. Nelissen EJ, Mduma E, Ersdal HL, et al. Maternal near miss and mortality in a rural referral hospital in northern Tanzania: a cross-sectional study. *BMC Pregnancy Childbirth* 2013;13:141 doi: 10.1186/1471-2393-13-141 [published Online First: 4 July 2013].

38. Rulisa S, Umuziranenge I, Small M, et al. Maternal near miss and mortality in a tertiary care hospital in Rwanda. *BMC pregnancy childbirth* 2015;15:203 doi: 10.1186/s12884-015-0619-8 [published Online First: 3 September 2015].

39. van Roosmalen J, Zwart J. Severe acute maternal morbidity in high-income countries. *Best Pract Res Clin Obstet Gynaecol* 2009;23:297-304.

40. Lewis G. Reviewing maternal deaths to make pregnancy safer. *Best Pract Res Clin Obstet Gynaecol* 2008;22:447-63.

41. Souza JP, Cecatti JG, Parpinelli MA, et al. Appropriate criteria for identification of near-miss maternal morbidity in tertiary care facilities: a cross sectional study. *BMC Pregnancy Childbirth* 2007;7:20 doi: 10.1186/1471-2393-7-20 [published Online First: 11 September 2007]

42. Donati S, Senatore S, Ronconi A, et al. Obstetric near-miss cases among women admitted to intensive care units in Italy. *Acta Obstet Gynecol Scand* 2012;91:452-57.

43. David E, Machungo F, Zanconato G, et al. Maternal near miss and maternal deaths in Mozambique: a cross-sectional, region-wide study of 635 consecutive cases assisted in health facilities of Maputo province. *BMC Pregnancy Childbirth* 2014;14:401 doi: 10.1186/s12884-014-0401-3 [published Online First: 10 December 2014].
44. You WB, Chandrasekaran S, Sullivan J, et al. Validation of a scoring system to identify women with near-miss maternal morbidity. *Am J Perinatol* 2013;30:21-4.
45. Kilpatrick SJ, Berg C, Bernstein P, et al. Standardized severe maternal morbidity review: rationale and process. *Obstet Gynecol* 2014;124:361-6.
46. Kilpatrick SK, Ecker JL. Severe maternal morbidity: screening and review. *Am J Obstet Gynecol* 2016;215:B17-22.
47. Geller SE, Rosenberg D, Cox S, et al. A scoring system identified near-miss maternal morbidity during pregnancy. *J Clin Epidemiol* 2004;57:716-20.
48. Main EK, Abreo A, McNulty J, et al. Measuring severe maternal morbidity: validation of potential measures. *Am J Obstet Gynecol* 2016;214:643.e1-10 doi: 10.1016/j.ajog.2015.11.004 [published Online First: 12 November 2015].
49. Gaffney A. Critical care in pregnancy-Is it different? *Semin Perinatol* 2014;38:329-40.
50. Bouvier-Colle MH, Varnoux N, Salanave B, et al. Case-control study of risk factors for obstetric patients' admission to intensive care units. *Eur J Obstet Gynecol Reprod Biol* 1997;74:173-77.
51. Van Parys AS, Verstraelen H, Roelens K, et al. Maternal Intensive Care': a systematic literature review. *Facts Views Vis Obgyn* 2010;2:161-7.
52. Zwart JJ, Dupuis JR, Richters A, et al. Obstetric intensive care unit admission: a 2-year nationwide population-based cohort study. *Intensive Care Med* 2010;36:256-63.
53. Shapiro JM. Critical care of the obstetric patient. *J Intensive Care Med* 2006;21:278-86.
54. Honiden S, Abdel-Razeq SS, Siegel MD. The management of the critically ill obstetric patient. *J Intensive Care Med* 2013;28:93-106.
55. Neligan PJ, Laffey JG. Clinical review: Special populations--critical illness and pregnancy. *Crit Care* 2011;15:227.
56. Soubra SH, Guntupalli KK. Critical illness in pregnancy: An overview. *Crit Care Med* 2005;33(Suppl 10):S248-55.
57. Trikha A, Singh P. The critically ill obstetric patient - Recent concepts. *Indian J Anaesth* 2010;54(5):421-7.
58. Aoyama K, Seaward PG, Lapinsky SE. Fetal outcome in the critically ill pregnant woman. *Crit Care* 2014;18(3):307 doi: 10.1186/cc13895 [published Online First: 27 May 2014].
59. Munnur U, Bandi V, Guntupalli KK. Management Principles of the Critically Ill Obstetric Patient. *Clin Chest Med* 2011;32:53-60.
60. World Health Organization. Global and regional estimates of violence against women: prevalence and health effects of intimate partner violence and non-partner sexual violence. 2013. http://apps.who.int/iris/bitstream/10665/85239/1/9789241564625_eng.pdf?ua=1 (accessed 13 Nov 2014).
61. Devries KM, Mak JY, Garcia-Moreno C, et al. Global health. The global prevalence of intimate partner violence against women. *Science* 2013;340:1527-8 doi:10.1126/science.12409373042 [published Online First: 28 June 2013].
62. World Health Organization. The Global status report on violence prevention 2014. 2014. http://www.who.int/violence_injury_prevention/violence/status_report/2014/en/ (accessed 28 May 2015).
63. Garcia-Moreno C, Jansen HAFM, Ellsberg M, et al. Prevalence of intimate partner violence: findings from the WHO multi-country study on women's health and domestic violence. *Lancet* 2006;368:1260-9.
64. Gazmararian JA, Lazorick S, Spitz AM, et al. Prevalence of violence against pregnant women. *JAMA* 1996;275:1915-20.
65. Han A, Stewart DE. Maternal and fetal outcomes of intimate partner violence associated with pregnancy in the Latin American and Caribbean region. *Int J Gynaecol Obstet* 2014;124:6-11.
66. Shamu S, Abrahams N, Temmerman M, et al. A systematic review of African studies on intimate partner violence against pregnant women: prevalence and risk factors. *PloS One* 2011;6(3):e17591 doi: 10.1371/journal.pone.0017591 [published Online First: 8 March 2011].
67. Stockl H, Devries K, Rotstein A, et al. The global prevalence of intimate partner homicide: a systematic review. *Lancet* 2013;382:859-65.
68. Black MC. Intimate Partner Violence and Adverse Health Consequences: Implications for Clinicians. *J Womens Health (Larchmt)* 2011;5:428-39.

69. Ayala Quintanilla BP, Taft A, McDonald S, et al. An examination of femicides in Peru between 2009 and 2014. *Int J Gynaecol Obstet* 2016;134:342-3 doi: 10.1016/j.ijgo.2016.03.020 [published Online First: 4 June 2016].

70. Sugg N. Intimate partner violence: prevalence, health consequences, and intervention. *Med Clin North Am* 2015;99(3):629-49.

71. Sarkar NN. The impact of intimate partner violence on women's reproductive health and pregnancy outcome. *J Obstet Gynaecol* 2008;28:266-71.

72. Chambliss LR. Intimate partner violence and its implication for pregnancy. *Clin Obstet Gynecol* 2008;51(2):385-97.

73. Chisholm CA, Bullock L, Ferguson JEJ, 2nd. Intimate partner violence and pregnancy: epidemiology and impact. *Am J Obstet Gynecol* 2017;217(2):141-4.

74. Knight M, Tuffnell DJ, Kenyon S, et al. Saving Lives, Improving Mothers' Care - Surveillance of maternal deaths in the UK 2011-13 and lessons learned to inform maternity care from the UK and Ireland Confidential Enquiries into Maternal Deaths and Morbidity 2009-13. Oxford: National Perinatal Epidemiology Unit, University of Oxford. 2015. <https://www.npeu.ox.ac.uk/> (accessed 15 Apr 2016).

75. Alhusen JL, Ray E, Sharps P, et al. Intimate partner violence during pregnancy: maternal and neonatal outcomes. *J Womens Health (Larchmt)* 2015;24:100-6.

76. Hill A, Pallitto C, McCleary-Sills J, et al. A systematic review and meta-analysis of intimate partner violence during pregnancy and selected birth outcomes. *Int J Gynaecol Obstet* 2016; 133:269-76 doi:10.1016/j.ijgo.2015.10.023 [published Online First: 11 March 2013].

77. World Bank. Data 2017. <http://data.worldbank.org/about/country-and-lending-groups> (accessed 4 Jun 2017).

78. INSTITUTO NACIONAL DE ESTADISTICA E INFORMATICA. Encuesta Demografica y de Salud Familiar 2016 - Nacional y Regional 2016. 2017. https://www.inei.gob.pe/media/MenuRecursivo/publicaciones_digitales/Est/Lib1356/. (accessed 12 Jun 2017).

79. United Nation, Every Woman Every Child. EVERY NEWBORN. An Action Plan To End Preventable Deaths. Secondary EVERY NEWBORN. An Action Plan To End Preventable Deaths 2014. http://apps.who.int/iris/bitstream/10665/127938/1/9789241507448_eng.pdf?ua=1 (accessed 14 Mar 2016).

80. Farquhar C, Sadler L, Masson V, et al. Beyond the numbers: classifying contributory factors and potentially avoidable maternal deaths in New Zealand, 2006–2009. *Am J Obstet Gynecol* 2011;205:331.e1-31e-8 doi:10.1016/j.ajog.2011.07.044 [published Online First: 30 July 2011].

81. Knight M., Kenyon S., Brocklehurst P., et al. Saving Lives, Improving Mothers' Care - Lessons learned to inform future maternity care from the UK and Ireland Confidential Enquiries into Maternal Deaths and Morbidity 2009 –12. Oxford: National Perinatal Epidemiology Unit, University of Oxford. 2014. <https://www.npeu.ox.ac.uk/downloads/files/mbrace-uk/reports/Saving%20Lives%20Improving%20Mothers%20Care%20report%202014%20Full.pdf> (accessed 27 Apr 2016).

82. Murphy NJ, Quinlan JD. Trauma in pregnancy: assessment, management, and prevention. *Am Fam Physician* 2014;90(10):717-22.

83. The Confidential Enquiries into Maternal Deaths in the United Kingdom. 2001. Why mothers die 1997–1999. The fifth report of the Confidential Enquiries into Maternal Deaths. <http://www.hqip.org.uk/national-programmes/a-z-of-clinical-outcome-review-programmes/cmace-reports/> (accessed 2 Aug 2014).

84. The Confidential Enquiries into Maternal and Child Health in the United Kingdom. 2004. Why Mothers Die 2000–2002. The Sixth Report of the Confidential Enquiries into Maternal Deaths. <http://www.hqip.org.uk/assets/NCAPOP-Library/CMACE-Reports/33.-2004-Why-Mothers-Die-2000-2002-The-Sixth-Report-of-the-Confidential-Enquiries-into-Maternal-Deaths-in-the-UK.pdf> (accessed 9 Aug 2014).

85. Knight M, Lewis G, Acosta CD, et al. Maternal near-miss case reviews: the UK approach. *BJOG* 2014;121 Suppl 4:112-6.

86. Ananth CV, Smulian JC. Chapter 1 Epidemiology of Critical Illness in Pregnancy. In Belfort MA, Saade G, Foley MR, et al., eds. *Critical Care Obstetrics* Fifth Edition 2011:1-10.

87. Knight M, Acosta C, Brocklehurst P, et al. Beyond maternal death: improving the quality of maternal care through national studies of 'near-miss' maternal morbidity. *Programme Grants Appl Res* 2016;4(9).

88. von Elm E, Altman DG, Egger M, et al. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *The Lancet* 2007;370(9596):1453-57.
89. von Elm E, Altman DG, Egger M, et al. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies. *Int J Surg* 2014;12:1495-9.
90. Instituto Nacional Materno Perinatal. Boletín Estadístico 2015 - 2016. 2016. <http://www.inmp.gob.pe/institucional/boletines-estadisticos/1422371837> (accessed 28 May 2017).
91. Jewkes R, Dartnall E, Sikweyiya Y. Ethical and Safety Recommendations for Research on the Perpetration of Sexual Violence. Sexual Violence Research Initiative Pretoria, South Africa: Medical Research Council. 2012. <http://www.svri.org/EthicalRecommendations.pdf> (accessed 28 May 2015).
92. Ellsberg M, Heise L. Researching Violence Against Women: A Practical Guide for Researchers and Activists Washington DC, United States: World Health Organizationb PATH. 2005. http://whqlibdoc.who.int/publications/2005/9241546476_eng.pdf?ua=1 (accessed 26 May 2015).
93. World Health Organization. Putting Women First: Ethical and Safety Recommendations for Research on Domestic Violence Against Women. 2001. <http://www.who.int/gender/violence/womenfirtseng.pdf> (accessed 27 May 2015).
94. Jansen HAFM, Watts C, Ellsberg M, et al. Interviewer Training in the WHO Multi-Country Study on Women's Health and Domestic Violence. 2004. http://www.who.int/gender/documents/Interviewer_training.pdf (accessed 27 May 2015).
95. Garcia-Moreno C, Jansen HAFM, Ellsberg M, et al. WHO Multi-country Study on Women's Health and Domestic Violence Against Women. Initial results on prevalence, health outcomes and women's responses. 2005. <http://www.who.int/reproductivehealth/publications/violence/24159358X/en/> (accessed 2 Jul 2014).
96. Open Epi. Sample Size Calculation for Unmatched Case-Control Studies. Version 3.03.17. 2014. <http://web1.sph.emory.edu/cdckms/sample%20size%20%20grps%20case%20control.html> (accessed 2 Jul 2015).
97. Sanchez SE, Qiu C, Perales MT, et al. Intimate partner violence (IPV) and preeclampsia among Peruvian women. *Eur J Obstet Gynecol Reprod Biol* 2008;137:50-5 doi: 10.1016/j.ejogrb.2007.05.013 [published Online First: 27 Jun 2007].
98. Hosmer DV, Lemeshow S. Applied Logistic Regression. Second Edition ed. USA: A Wiley-Interscience Publication. 2000:375.
99. Karolinski A, Mercer R, Micone P, et al. The epidemiology of life-threatening complications associated with reproductive process in public hospitals in Argentina. *BJOG* 2013;120:1685-95.
100. Filippi V, Chou D, Ronsmans C, et al. Levels and Causes of Maternal Mortality and Morbidity. In: Black RE, Laxminarayan R, Temmerman M, et al., eds. 2016. Reproductive, Maternal, Newborn, and Child Health. Disease Control Priorities, third edition, volume 2. Washington, DC: World Bank. doi:10.1596/978-1-4648-0348-2. License: Creative Commons Attribution CC BY 3.0 IGO.



Appendix 1


Judith Lumley Centre for mother, infant and family health research

College of Science, Health and Engineering

La Trobe University

Maternal health research in a tertiary health care facility in Lima, Peru

Structured questionnaire for face to face interview

Code number: 

Interview Date: / /
D D M M Y Y Y Y

Thank you for agreeing to participate in this study.

You are free to not answer any questions. If any of the questions are unclear, or you need more information the interviewer will be happy to provide you with the information you need.

Before I start, do you have any questions?

SECTION A. GENERAL INFORMATION

WOMAN INFORMATION

First I would like to ask you some questions about your background.

A1.How old are you? _____ (Years)

A2. Place of residence

1. **Lima Norte**
(Ancón, Carabayillo, Comas, Independencia, Los Olivos, Puente Piedra, San Juan de Lurigancho, San Martín de Porres, Santa Rosa)
2. **Lima Este**
(Ate, Cieneguilla, Chaclacayo, El Agustino, Lurigancho, San Luis, Santa Anita)
3. **Lima Sur**
(Chorrillos, Lurín, Pachacamac, Pucusana, Punta Hermosa, Punta Negra, San Bartolo, San Juan de Miraflores, Santa María del Mar, Villa el Salvador, Villa María del Triunfo)
4. **Residencial Lima**
(Barranco, Jesús María, La Molina, Lince, Magdalena, Miraflores, Pueblo Libre, San Borja, San Isidro, San Miguel, Santiago de Surco, Surquillo)
5. **Callao**
(Bellavista, Callao District, Carmen de la Legua Reynoso, La Perla, La Punta, Ventanilla District)
6. **Central Lima**
(Breña, La Victoria, Downtown Lima, Rimac)

A3. What is your level of education? Would you say?

1. Primary level
2. Secondary level
3. Technical studies
4. University level
5. Other (Specify) _____
- 9 Do not know / Not Sure

A4. What is your current marital status?

1. Single
2. Married
3. Cohabitant
4. Separated/Divorced
5. Widowed
9. Do not know / Not Sure

A5. What is your occupation?

1. Unemployed
2. Student
3. Employed
4. Self-employed
5. Housewife
6. Other (specify) _____
7. Do not know / Not Sure

A6. How hard is it for you (and your family) to pay for the very basics like food?

- 1 Very hard
- 2 Hard
- 3 Somewhat hard
- 4 Not very hard
- 9 Do not know / Not Sure

A7. How hard is it for you (and your family) to pay for medical care?

- 1 Very Hard
- 2 Hard
- 3 Somewhat hard
- 4 Not very hard
- 9 Do not know / Not Sure

A8. How much is the estimated monthly income of your nuclear family?

A9. How many household members are dependent on this monthly income (specify)?

A10. Are you a SIS beneficiary?

- 1 No
- 2 Yes
- 9 Do not know / Declined to answer

A11. Can you tell me your SIS category?

- 1 Low risk
- 2 Medium risk
- 3 High risk
- 9 Do not know / Declined to answer

A12. If you do not have SIS, which health insurance do you have?

- 1 Private company
- 2 Other (specify) _____
- 3 Do not have any health insurance
- 9 Do not know / Declined to answer

A13. What about smoking, do you smoke during this pregnancy?

- 1 No → **Skip to A15**
- 2 Yes → **Continue to A14**
- 9 Do not know / Declined to answer

A14. If yes, would you say?

1. Daily
2. Occasionally
3. Not at all
- 9 Do not know / Declined to answer

A15. What about alcohol use, do you drink alcohol during this pregnancy?

- 1 No → **Skip to A17**
- 2 Yes → **Continue to A16**
- 9 Do not know / Declined to answer

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- A16. If yes, would you say?
1. Every day or nearly every day
2. Once or twice a week
3. 1 – 3 times a month
4. Occasionally, less than once a month
5. Never
9. Do not know / Declined to answer

- 8
- 9
- 10
- 11
- 12
- A17. What about drug use, do you use any illegal drugs during this pregnancy?
1. No
2. Yes
9. Do not know / Declined to answer

13

14

PARTNER INFORMATION

- 15
- 16
- A18. What is the age of your partner _____ (Years)

- 17
- 18
- 19
- 20
- 21
- 22
- A19. What is the level of education of your husband/partner?
1. Primary level
2. Secondary level
3. Technical studies
4. University level
5. Other (Specify) _____
9. Do not know / Declined to answer

- 23
- 24
- 25
- 26
- 27
- 28
- 29
- A20. What is the occupation of your husband/partner?
1. Unemployed
2. Student
3. Employed
4. Self-employed
5. Other (specify) _____
9. Do not know / Declined to answer

- 30
- 31
- 32
- 33
- A21. What about alcohol use, does/did your husband/partner drink alcohol during your pregnancy?
1. No → Skip to A25
2. Yes → Continue to A22

- 34
- 35
- 36
- 37
- 38
- 39
- A22. If yes, would you say?
1. Every day or nearly every day
2. Once or twice a week
3. 1 – 3 times a month
4. Occasionally, less than once a month
5. Never
9. Do not know / Declined to answer

- 40
- 41
- 42
- 43
- 44
- A23. Does/did your husband/partner get drunk during your pregnancy?
1. No → Skip to A25
2. Yes → Continue to A24
9. Do not know/Declined to answer

- 45
- 46
- 47
- 48
- 49
- 50
- A24. If yes, would you say?
1. Most days
2. Weekly
3. Once a month
4. Less than once a month
5. Never
9. Do not know / Declined to answer

- 51
- 52
- 53
- 54
- 55
- A25. What about drug use, does/did your partner use any illegal drugs during your pregnancy?
1. No
2. Yes
9. Do not know / Declined to answer

B. PREGNANCY AND PRENATAL CHARACTERISTICS

Now I would like to ask you some questions about your pregnancy history

- B1. How many weeks of pregnancy were you at your first prenatal visit? ____ (Weeks)
- B2. Did you receive prenatal care during this pregnancy?
1. No → **Skip to B4**
 2. Yes → **Continue to B3**
 - 9 Do not know / Not sure
- B3. How many antenatal care visits did you receive during pregnancy? _____ times [999 = Do not know]
- B4. How much was your weight before you became pregnant this time? _____ Kilograms [999 = Do not know]
- B5. How much weight did you gain since becoming pregnant? _____ Kilograms [999 = Do not know]
- B6. What is your height? _____ Centimeters [999 = Do not know]
- B7. GRAVIDITY = Number of pregnancies (including this pregnancy) ____
- B8. PARITY = Number of live births >22 weeks (including this pregnancy) ____
- B9. Number of vaginal deliveries (including this pregnancy) ____
- B10. Number of cesarean sections (including this pregnancy) ____
- B11. Number of total previous abortions ____
- B12. Miscarriages ____
- B13. Unsafe abortions ____
- B14. Therapeutic abortions ____
- B15. Number of Molas ____
- B16. Number of ectopic pregnancies ____
- B17. Number of alive children ____
- B18. Number of stillborns ____
- B19. Number of dead children ____
- B20. Did you plan to become pregnant this time?
- 1 No
 - 2 Yes
 - 9 Do not know / Declined to answer
- B21. Are you aware of family planning methods to avoid getting pregnant?
1. No → **Skip to B24**
 2. Yes → **Continue to B22**
 - 9 Do not know / Declined to answer
- B22. Which family planning methods do you use to avoid getting pregnant (if it is more than one, only consider the main method)?
- 1 Pills/Tablets
 - 2 Injectable
 - 3 Diaphragm/foam/jelly
 - 4 IUD
 - 5 Condoms
 - 6 Natural Method (calendar/mucus method)
 - 7 Withdrawal
 - 8 Other (specify) _____
- B23. How often do you use family planning methods?
1. Often
 2. Rarely
 3. Never (because of)
 - 3.1. Because of ignorance about them
 - 3.2. Because of logistic/administrative issues
 - 3.3. Because of unwillingness to use them
 - 3.4. Because of partner unwillingness to use them
 - 3.5. Because of the cost
 - 3.6. Other (specify) _____
 9. Do not know / Declined to answer

- B24.** Did you receive vaccination against tetanus in the last 10 years?
- 1. No
 - 2. Yes
 - 9 Do not know / Not sure
- B25.** Did a doctor ever tell you that you have anemia during this pregnancy?
- 1. No → **Skip to B30**
 - 2. Yes → **Continue to B26**
 - 9 Do not know / Not sure
- B26.** Which trimester, did a doctor tell you that you have anemia during this pregnancy?
- 1 I Trimester
 - 2 II Trimester
 - 3 III Trimester
 - 9 Do not know / Not sure
- B27.** Did you take any ferrous iron supplement during this pregnancy?
- 1. No → **Skip to B30**
 - 2. Yes → **Continue to B28**
 - 9 Do not know / Not sure
- B28.** If yes, how many pills/tablets per day? _____ pills per day [99: Do not know / not sure]
- B29.** And, how many months did you drink these pills/tablets? _____ months [99: Do not know / not sure]
- B30.** How many times did you visit the emergency room during this pregnancy? _____ time/times [99: Do not know / not sure]
- B31.** Has a doctor ever told you that you have or do you have?

Diseases	You have had			You have		
	No	Yes	Do not know / not sure	No	Yes	Do not know / not sure
a Chronic hypertension	1	2	99	1	2	99
b Anemia	1	2	99	1	2	99
c Tuberculosis	1	2	99	1	2	99
d Diabetes Mellitus	1	2	99	1	2	99
e Heart disease	1	2	99	1	2	99
f Thyroid disease	1	2	99	1	2	99
g HIV infection	1	2	99	1	2	99
h Other (specify) _____	1	2	99	1	2	99

- B32.** Did you ever have one or more of the following condition (s) during previous pregnancy (es)?

Clinical conditions	NO	YES	Do not know / not sure
1 Hypertensive related disease	1	2	99
a Severe Preeclampsia	1	2	99
b Eclampsia	1	2	99
c HELLP Syndrome	1	2	99
2 Antepartum hemorrhage in the second trimester of pregnancy because of (specify):	1	2	99
a Placenta previa	1	2	99
b Uterine rupture	1	2	99
c Abruptio placentae			
d Other (specify)	1	2	99
3 Antepartum hemorrhage in the third trimester of pregnancy because of (specify):	1	2	99
a Placenta previa	1	2	99
b Uterine rupture	1	2	99
c Abruptio placentae	1	2	99

d Other (specify)	1	2	99
4 Postpartum hemorrhage complication	1	2	99
a Uterine atony	1	2	99
b Cervical laceration/tear	1	2	99
c Retained products/fetal membranes	1	2	99
d Ruptured uterus	1	2	99
e Accreta placenta	1	2	99
f Other (specify)	1	2	99
5 Sepsis (obstetric origin)	1	2	99
a Chorioamnionitis	1	2	99
b Surgical wound infection	1	2	99
c Endometritis	1	2	99
d Other (specify)	1	2	99
6 Sepsis (non-obstetric origin)	1	2	99
a Urine infection	1	2	99
b Other (specify)	1	2	99
7 Sepsis (pulmonary origin)	1	2	99
a Pneumonia	1	2	99
b Viral cause	1	2	99
b.1 H1N1	1	2	99
b.2 Varicella	1	2	99
b.3 Other (specify)	1	2	99
c Other (specify)	1	2	99
8 Clinical condition	1	2	99
a Oligohydramnios	1	2	99
b Intrauterine growth restriction	1	2	99
c Fetal macrosomy	1	2	99
d Other (specify)	1	2	99
9 Other associated pathologies			
a Premature rupture of fetal membranes	1	2	99
b Disseminated intravascular coagulation (DIC)	1	2	99
c Maternal pulmonary edema	1	2	99
d Amniotic fluid embolism	1	2	99
e Retroplacental clot	1	2	99
f Septic shock.	1	2	99
g Hypovolemic Shock	1	2	99
h Cervical cancer	1	2	99
i Other (specify)	1	2	99

C. ASSESSMENT OF VAW (IPV AND NON-IPV)

When two people marry or live together, they usually share both good and bad moments. I would now like to ask you some questions about your current and past relationships and how your husband / partner treats (treated) you. If anyone interrupts us I will change the topic of conversation. I would again like to assure you that your answers will be kept secret, and that you do not have to answer any questions that you do not want to. May I continue?

Assessing IPV			BEFORE PREGNANCY						DURING PREGNANCY				
			(In the past 12 months before pregnancy)										
I am going to ask you about some situations that are true for many women. Would you say it is generally true that he:	(A) (If YES continue with B. If NO, ask during pregnancy and if NO skip to next item)		(B) Has this happened <u>in the past 12 months before this pregnancy?</u> (If YES ask C, if NO ask D)		(C) <u>In the past 12 months before this pregnancy</u> , would you say that this has happened once, a few times or many times? (after answering C, go to D)			(D) Has this happened <u>during this pregnancy?</u> (If YES ask E)		(E) <u>During Pregnancy</u> , would you say that this has happened once, a few times, or many times?			
	YES	NO	YES	NO	One	Few	Many (>5 times)	YES	NO	One	Few	Many (>5 times)	
	C1. Tries to keep you from seeing your friends?	1	2	1	2	1	2	3	1	2	1	2	3
	C2. Tries to restrict contact with your family of birth?	1	2	1	2	1	2	3	1	2	1	2	3
	C3. Insists on knowing where you are at all times?	1	2	1	2	1	2	3	1	2	1	2	3
	C4. Ignores you and treats you indifferently?	1	2	1	2	1	2	3	1	2	1	2	3
	C5. Gets angry if you speak with another man?	1	2	1	2	1	2	3	1	2	1	2	3
	C6. Is often suspicious that you are unfaithful?	1	2	1	2	1	2	3	1	2	1	2	3
	C7. Expects you to ask his permission before seeking health care for yourself?	1	2	1	2	1	2	3	1	2	1	2	3

The next questions are about things that happen to many women, and that your current partner, or any other partner may have done to you.

Assessing IPV			BEFORE PREGNANCY						DURING PREGNANCY				
			(In the past 12 months before pregnancy)										
Has your <u>current</u> husband/partner or <u>any</u> other partner ever	(A) (If YES continue with B. If NO, ask during pregnancy and if NO skip to next item)		(B) Has this happened in the <u>past 12 months before this pregnancy?</u> (If YES ask C, if NO ask D)		(C) <u>In the past 12 months before this pregnancy</u> , would you say that this has happened once, a few times or many times? (after answering C, go to D)			(D) Has this happened <u>during this pregnancy?</u> (If YES ask E)		(E) <u>During Pregnancy</u> would you say that this has happened once, a few times, or many times?			
	YES	NO	YES	NO	One	Few	Many (>5 times)	YES	NO	One	Few	Many (>5 times)	
C8. Insulted you or made you feel bad about yourself?	1	2	1	2	1	2	3	1	2	1	2	3	
C9. Belittled or humiliated you in front of other people?	1	2	1	2	1	2	3	1	2	1	2	3	
C10. Done things to scare or intimidate you on purpose (e.g., by the way he looked at you, by yelling and smashing things)?	1	2	1	2	1	2	3	1	2	1	2	3	
C11. Threatened to hurt you or someone you care about	1	2	1	2	1	2	3	1	2	1	2	3	

Assessing IPV			BEFORE PREGNANCY						DURING PREGNANCY				
			(In the past 12 months before pregnancy)										
Has your <u>current</u> husband/partner or <u>any</u> other partner ever	(A)		(B)		(C)			(D)		(E)			
	(If YES continue with B. If NO, ask during pregnancy and if NO skip to next item)		Has this happened in the past 12 months before this pregnancy? (If YES ask C, if NO ask D)		In the past 12 months before this pregnancy, would you say that this has happened once, a few times or many times? (after answering C, go to D)			Has this happened during this pregnancy? (If YES ask E)		During Pregnancy, would you say that this has happened once, a few times, or many times?			
	YES	NO	YES	NO	One	Few	Many (>5 times)	YES	NO	One	Few	Many (>5 times)	
	C12. Slapped you or thrown something at you that could hurt you?	1	2	1	2	1	2	3	1	2	1	2	3
	C13. Pushed you or shoved you or pulled your hair?	1	2	1	2	1	2	3	1	2	1	2	3
	C14. Hit you with his fist or with something else that could hurt you?	1	2	1	2	1	2	3	1	2	1	2	3
	C15. Kicked you, dragged you or beat you up?	1	2	1	2	1	2	3	1	2	1	2	3
	C16. Choked or burnt you on purpose?	1	2	1	2	1	2	3	1	2	1	2	3
C17. Threatened to use or actually used a gun, knife or other weapon against you?	1	2	1	2	1	2	3	1	2	1	2	3	

Assessing IPV			BEFORE PREGNANCY					DURING PREGNANCY				
			(In the past 12 months before pregnancy)									
	(A)		(B)		(C)			(D)		(E)		
Has your <u>current</u> husband/partner or <u>any</u> other <u>partner</u> ever	(If YES continue with B. If NO ask during pregnancy, and if NO skip to next item)		Has this happened <u>in the past 12 months before this pregnancy</u> ? (If YES ask C, if NO ask D)		<u>In the past 12 months before this pregnancy</u> , would you say that this has happened once, a few times or many times? (after answering C, go to D)			Has this happened <u>during this pregnancy</u> ? (If YES ask E)		<u>During Pregnancy</u> , would you say that this has happened once, a few times, or many times?		
	YES	NO	YES	NO	One	Few	Many (>5 times)	YES	NO	One	Few	Many (>5 times)
C18. Did your <u>current</u> husband/partner or <u>any</u> other <u>partner</u> ever physically force you to have sexual intercourse when you did not want to?	1	2	1	2	1	2	3	1	2	1	2	3
C19. Did you ever have sexual intercourse you did not want to because you were afraid of what your partner or any other partner might do?	1	2	1	2	1	2	3	1	2	1	2	3
C20. Did your partner or any other partner ever force you to do something sexual that you found degrading or humiliating?	1	2	1	2	1	2	3	1	2	1	2	3

NON-IPV

In their lives, may women experience different forms of violence from relatives, other people that they know, and/or from strangers. If you don't mind. I would like to briefly ask you about some of these situations. If anyone interrupts us I will change the topic of conversation. Everything that you say will be kept private. May I continue?

Assessing Non-IPV		BEFORE PREGNANCY							DURING PREGNANCY						
		(In the past 12 months before pregnancy)													
	(A) (If YES continue with B. If NO, ask during pregnancy and if NO skip to next item)	(B) Has this happened in the past 12 months before this pregnancy? (If YES ask C, if NO ask D)		(C) In the past 12 months before this pregnancy, would you say that this has happened once, a few times or many times? (after answering C, go to D) (in total from all the persons she mentioned)				(D) Has this happened during this pregnancy? (If YES ask Who was/were) And would you say that this has happened once, a few times, or many times? (in total from all the persons she mentioned) (choose "one", "few" or many" considering in total from all the persons she mentioned)							
	YES	NO	YES	Who did this to you? (multiple responses)	No	One	Few	Many (>5 times)	YES	Who did this to you? (multiple responses)	No	One	Few	Many (>5 times)	
C21. Insulted you or made you feel bad about yourself?	1	2	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3	
C22. Belittled or humiliated you in front of other people?	1	2	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3	
C23. Done things to scare or intimidate you on purpose (e.g., by the way he looked at you, by yelling and smashing things)?	1	2	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3	
C24. Threatened to hurt you or someone you care about?	1	2	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3	

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Continue with the following questions.....

Assessing Non-IPV			BEFORE PREGNANCY						DURING PREGNANCY					
			(In the past 12 months before pregnancy)											
Since the age of 15 years, has anyone (other than your partner/husband):	(A)		(B)			(C)			(D)					
	(If YES continue with B. If NO, ask during pregnancy and if NO skip to next item)		Has this happened in the past 12 months before this pregnancy? (If YES ask C, if NO ask D)			In the past 12 months before this pregnancy, would you say that this has happened once, a few times or many times? (after answering C, go to D) (in total from all the persons she mentioned)			Has this happened during this pregnancy? (If YES ask Who was/were) And would you say that this has happened once, a few times, or many times? (in total from all the persons she mentioned) (choose "one", "few" or many" considering in total from all the persons she mentioned)					
	YES	NO	YES	Who did this to you? (multiple responses)	No	One	Few	Many (>5 times)	YES	Who did this to you? (multiple responses)	No	One	Few	Many (>5 times)
C25. Ever beaten you or physically mistreated you in any way ?	1	2	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3
C26. ¿forced you to have sex or to perform a sexual act when did you not want or to do something sexual that you found degrading or humiliating?	1	2	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3

C27. Have you ever been punched or kicked in the abdomen by anyone including your (ex or current) partner or other person(s) whilst you were pregnant?

1. No
2. Yes

C28 When (indicate year and which pregnancy) Year.....Which pregnancy.....

9. Don't know / Decline to answer

C29. Have any health care professionals asked you if you were affected by IPV or non-partner violence?

1 No
2 Yes
9 Do not know / Decline to answer

Continue with the questions C30, C31 and C32 for those participants who were affected by harm acts

Go to question C32 (Skip questions C29 and C30) for those participants who were NOT affected by harm acts

C30. Have you sought help to prevent or stop gender-based violence?

- 1 No
- 2 Yes
- 9 Do not know / Decline to answer

C31. Can you mention what type of help?

- 1 Family member
- 2 Friend
- 3 Community Social Services from the government
- 4 Police
- 5 Other (specify).....
- 9 Do not know / Decline to answer

Ask the following question to each participant

C32. Is there anything else do you want to tell me?
(Write down the exact words expressed by the participant)

Now give the information about free social support services available for domestic violence at this Institution and which are free of cost and are provided by the Peruvian government.

Thank you for your participation!!!!



- D6** Gestational age at first antenatal visit _____ weeks [999 = Not recorded]
- D7.** Number of antenatal visits _____ [999 = Not recorded]
- D8** Pre-pregnancy weight (weight before the participant became pregnant this time) _____ Kilograms [999 = Not recorded]
- D9** Pregnancy weight before delivery _____ Kilograms [999 = Not recorded]
- D10.** Weight gain during pregnant _____ Kilograms [999 = Not recorded]
- D11** Height _____ Centimeters [999 = Not recorded]
- D12.** Date of admission at this hospital ____ / ____ / ____
D D / M M / Y Y Y Y
- D13.** Indicate the diagnosis of the patient when she was hospitalized at this hospital:
1. _____
 2. _____
 3. _____
 4. _____
 5. _____
- D14** Socioeconomic level according to Social Services Department of this hospital:
1. Lower risk
 2. Medium risk
 3. High risk
 4. No category
- D15.** Was the participant admitted at the Intensive Care Unit?
1. No → **Skip to D26**
 2. Yes → **Continue to D16**
- D16.** Date of admission at the Intensive Care Unit ____ / ____ / ____ Time _____ (hour)
D D / M M / Y Y Y Y
- D17.** Indicate the diagnosis (ses) of the participant when she was admitted at the Intensive Care Unit:
1. _____
 2. _____
 3. _____
 4. _____
 5. _____
- D18.** Weeks of pregnancy at the moment of the event (s) (SAMM) which cause(s) her admission at the Intensive Care Unit:
_____ weeks
- D19.** Moment of such event (SAMM) in relation to the termination of pregnancy:
1. Before
 2. During
 3. After
- D20.** Did the woman received assistance with ventilation?
1. CPAP
 2. Non-invasive ventilation (e.g. BiPAP)
 3. Invasive mechanical ventilation
 4. None of the above
- D21.** Which management did the woman receive in the ICU (multiple responses)?
1. Inotrope or vasopressor therapy
 2. Renal replacement therapy (dialysis)
 3. Central venous access
 4. None of the above
- D22.** What was the severity of illness score on admission? _____ Score (APACHE)
- D23.** Date of discharge of the Intensive Care Unit: ____ / ____ / ____
D D / M M / Y Y Y Y
- D24.** Indicate the number of days in the Intensive Care Unit: _____ days

D25. Indicate the diagnosis (ses) of the patient when she was discharged from the Intensive Care Unit:

- 1. _____
- 2. _____
- 3. _____
- 4. _____
- 5. _____
- 6. _____

D26. Did the participant receive blood transfusion during her hospital stay?

- 1. No
- 2. Yes a. Indicate the numbers of red blood cell transfusion unit _____

D27. Did the participant receive other blood product transfusions during her hospital stay?

- 1. No → **Skip to D29**
- 2. Yes → **Continue to D28**

D28. What were these other transfusions (multiple responses)?

- 1. Plasma
- 2. Platelet
- 3. Cryoprecipitate
- 4. Other (specify) _____

D29. Date of discharge of this hospital ____ / ____ / ____ D D / M M / Y Y Y Y

D30. Diagnosis (ses) of the patient at discharge of this hospital:

- 1 _____
- 2 _____
- 3 _____
- 4 _____
- 5 _____
- 6 _____

D31. Indicate the number of hospital stay days _____ days

About clinical conditions during this pregnancy

D32. Clinical conditions during this pregnancy (multiple responses)

Clinical conditions	NO	YES	NOT RECORDED
1 Hypertensive related disease	1	2	99
a Severe Preeclampsia	1	2	99
Magnesium sulfate treatment	1	2	99
b Eclampsia	1	2	99
Magnesium sulfate treatment	1	2	99
c HELLP Syndrome	1	2	99
2 Antepartum hemorrhage in the second trimester of pregnancy because of (specify):	1	2	99
a Placenta previa	1	2	99
b Uterine rupture	1	2	99
c Abruptio placentae	1	2	99
d Other (specify)	1	2	99
3 Antepartum hemorrhage in the third trimester of pregnancy because of (specify):	1	2	99
a Placenta previa	1	2	99
b Uterine rupture	1	2	99
c Abruptio placentae	1	2	99
d Other (specify)	1	2	99
4 Postpartum hemorrhage complication	1	2	99
a Uterine atony	1	2	99
b Cervical laceration/tear	1	2	99
c Retained products/fetal membranes	1	2	99

d	Ruptured uterus	1	2	99
e	Accreta/increta/percreta placenta	1	2	99
f	Other (specify)	1	2	99
5	Miscarriage complication	1	2	99
a	Uterine perforation	1	2	99
b	Cervical laceration/tear	1	2	99
c	Infection	1	2	99
d	Other (specify)	1	2	99
6	Ectopic pregnancy	1	2	99
7	Sepsis (obstetric origin)	1	2	99
a	Chorioamnionitis	1	2	99
b	Surgical wound infection	1	2	99
c	Endometritis	1	2	99
d	Other (specify)	1	2	99
8	Sepsis (non-obstetric origin)	1	2	99
a	Urine infection	1	2	99
b	Other (specify)	1	2	99
9	Sepsis (pulmonary origin)	1	2	99
a	Pneumonia	1	2	99
b	Viral cause	1	2	99
b.1	Influenza (e.g. H1N1)	1	2	99
b.2	Varicella	1	2	99
b.3	Other (specify)	1	2	99
c	Other (specify)	1	2	99
10	Clinical condition	1	2	99
a	Oligohydramnios	1	2	99
b	Intrauterine growth restriction	1	2	99
c	Fetal macrosomy	1	2	99
d	Other (specify)	1	2	99
11	Other associated pathologies			
a	Premature rupture of fetal membranes	1	2	99
b	Disseminated intravascular coagulation (DIC)	1	2	99
c	Maternal pulmonary edema	1	2	99
d	Amniotic fluid embolism	1	2	99
e	Retroplacental clot	1	2	99
f	Septic shock.	1	2	99
g	Hypovolemic Shock	1	2	99
h	Other (specify)	1	2	99
12	Complications of pre-existent diseases	1	2	99
a	Tuberculosis	1	2	99
b	Diabetes Mellitus	1	2	99
c	Heart disease	1	2	99
d	Thyroid crisis	1	2	99
e	Chronic hypertension	1	2	99
f	HIV infection	1	2	99
g	Anemia	1	2	99
h	Cervical cancer	1	2	99
i	Ovarian cancer	1	2	99
j	Other (specify) _____	1	2	99

D33. Did the participant develop any organic dysfunctions?
1. No → Skip to D35
2. Yes → Continue to D34

D34. What were these organic dysfunctions?
(Information extracted from the epidemiological report, multiple responses)
1 Cardiovascular dysfunction
2 Respiratory dysfunction
3 Renal dysfunction
4 Coagulation/hematologic dysfunction
5 Hepatic dysfunction
6 Neurologic dysfunction
7 Uterine dysfunction/hysterectomy
8 Multiple organ dysfunction

About outcome of this pregnancy

D35. Type of pregnancy termination:
1 Abortion
i. Miscarriage
ii. Therapeutic
iii. Unsafe
2 Delivery
3 Laparotomy for ectopic pregnancy
4 Still pregnant

D36. Date of pregnancy termination (delivery, abortion, ectopic pregnancy) ____/____/____ Time ____ (hour)
D D / M M / Y Y Y Y

D37. Indicate the number of hospital stay days before pregnancy termination ____ days

D38. Gestational age at delivery or abortion (including ectopic pregnancy): ____ (Weeks)

D39. Mode of delivery or abortion
1 Vaginal, normal
a. Active management of the third stage of labor.
i. No
ii. Yes
2 Vaginal, vacuum/forceps
a. Active management of the third stage of labor.
i. No
ii. Yes
3 Emergency C-section
4 Scheduled C-section
5 Curettage (for a woman who had an abortion)

D40. Place of the delivery:
1. This hospital
2. Other hospital
3. Health Center
4. Home
5. Another (specify) _____

D41. Who attended the delivery?
1. Doctor
2. Midwifery
3. Another (specify) _____

About additional surgical treatment (s) performed during this pregnancy

D42. Was/were additional surgical treatment(s) performed?
1. No → Skip to D46
2. Yes → Continue to D43

D43. Report about additional first surgical treatment (s) performed (multiple responses):

- 1 Hysterectomy
- 2 Laparotomy
- 3 Curettage
- 4 Repair of cervical tears
- 5 Drainage of puerperal hematoma and repair of puerperal hematoma
- 6 Manual removal of placenta (after vaginal delivery)
- 7 Other (specify) _____

D44. Report about an additional second surgical treatment performed:

- 1 Hysterectomy
- 2 Laparotomy
- 3 Other (specify) _____

D45. Report about an additional third surgical treatment performed:

- 1 Hysterectomy
- 2 Laparotomy
- 3 Another (specify) _____

About surgical treatment (s) performed during this pregnancy, indicate the diagnosis (ses) for each procedures correspondingly:

D46. Uterine curettage indication:

- 1 _____
- 2 _____
- 3 _____
- 4 _____

D47. Cesarean indication:

- 1 _____
- 2 _____
- 3 _____
- 4 _____

D48. Laparotomy indication:

- 1 _____
- 2 _____
- 3 _____
- 4 _____
- 5 _____

D49. Hysterectomy indication:

- 1 _____
- 2 _____
- 3 _____
- 4 _____

About main delays (Information extracted from the epidemiological report if the participant was admitted at the Intensive Care Unit).

Go to the Neonatal information (Skip item D50, D51, D52 and D53) if the participant **was NOT** admitted at the Intensive Care Unit.

D50. Qualitative analysis of Delay I

- 1 No
- 2 Yes

D51. Qualitative analysis of Delay II

- 1 No
- 2 Yes

D52. Qualitative analysis of Delay III

- 1 No
- 2 Yes

D53. Qualitative analysis of Delay IV

- 1 No
- 2 Yes

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

E. NEONATAL INFORMATION

This information **is excluded** for those women **who had an abortion or an ectopic pregnancy**

Number _____

	Baby 1	Baby 2 (if applicable)	Baby 3 (if applicable)
E1. Birth weight	----- grams	----- grams	-----grams
E2. Age at birth (according to Neonatologist)	----- weeks	----- weeks	----- weeks
E3. Sex	1 Male 2 Female 3 Ambiguous	1 Male 2 Female 3 Ambiguous	1 Male 2 Female 3 Ambiguous
E4. Apgar score (1 minute)	-----	-----	-----
E5. Apgar score (5 minutes)	-----	-----	-----
E6. Baby outcome at birth:	1 Live birth 2 Stillborn	1 Live birth 2 Stillborn	1 Live birth 2 Stillborn
E7. Nursery of baby	1 Stay with mom (Regular nursery) 2 Other (specify) _____	1 Stay with mom (Regular nursery) 2 Other (specify) _____	1 Stay with mom (Regular nursery) 2 Other (specify) _____
E8. Breastfeeding	1 Breastfeeding 2 Formula 3 Both 4 Another(specify) _____	1 Breastfeeding 2 Formula 3 Both 4 Another(specify) _____	1. Breastfeeding 2. Formula 3. Both 4. Another(specify) _____
E9. Gross fetal/neonatal malformation	1 No 2 Yes 99 Do not know	1. No 2. Yes 99 Do not know	1. No 2. Yes 99 Do not know
E10. Neonatal Intensive Care Unit (NICU) Admission	1. No 2. Yes	1. No 2. Yes	1 No 2 Yes
E11. Indicate the diagnosis (ses) of the baby for NICU admission	1. _____ 2. _____ 3. _____ 4. _____	1. _____ 2. _____ 3. _____ 4. _____	1. _____ 2. _____ 3. _____ 4. _____
E12. Management of the baby at NICU (multiple responses)	1. CPAP 2. Non-invasive ventilation (e.g. BiPAP) 3. Invasive mechanical ventilation 4. Inotrope or vasopressor therapy 5. Blood transfusion 6. None of the above	1. CPAP 2. Non-invasive ventilation (e.g. BiPAP) 3. Invasive mechanical ventilation 4. Inotrope or vasopressor therapy 5. None of the above	1. CPAP 2. Non-invasive ventilation (e.g. BiPAP) 3. Invasive mechanical ventilation 4. Inotrope or vasopressor therapy 5. None of the above
E13. Indicate the diagnosis (ses) of the baby when was discharged from the NICU	1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____	1 _____ 2 _____ 3 _____ 4 _____ 5 _____ 6 _____	1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____
E14. Antibiotic use in NICU	1 No 2 Yes	1 No 2 Yes	1 No 2 Yes
E15. Days of stay at NICU	_____ days	_____ days	_____ days
E16. Days of stay at this hospital	_____ days	_____ days	_____ days

E17. Discharge status of baby from this hospital	1. Alive 2. Dead (Days after birth_____)	1. Alive 2. Dead (Days after birth_____)	1. Alive 2. Dead (Days after birth_____)
E18. Indicate the diagnosis of the baby when was discharged from this hospital	1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____	1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____	1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____

The End
Thank You!!!!!!!!!!!!!!

BMJ Open

The impact of violence against women on severe acute maternal morbidity in the intensive care unit, including neonatal outcomes: a case-control study protocol in a tertiary healthcare facility in Lima-Peru

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-020147.R1
Article Type:	Protocol
Date Submitted by the Author:	22-Dec-2017
Complete List of Authors:	Ayala Quintanilla, Beatriz; La Trobe University College of Science Health and Engineering, Judith Lumley Centre; Peruvian National Institute of Health, Lima Taft, Angela; La Trobe University, Mother and Child Health Research McDonald, SJ; Midwifery Professorial Unit, La Trobe University/Mercy Hospital for Women Pollock, Wendy; La Trobe University, The Judith Lumley Centre; Mercy Hospital for Women
Primary Subject Heading:	Public health
Secondary Subject Heading:	Intensive care, Obstetrics and gynaecology
Keywords:	Severe acute maternal morbidity, violence against women, intimate partner violence, intensive care unit, social determinants, near miss

SCHOLARONE™
Manuscripts

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

29

30

31

32

33

34

35

36

37

38

39

40

41

42

43

44

45

46

47

48

49

50

51

52

53

54

55

56

57

58

59

60

Title

The impact of violence against women on severe acute maternal morbidity in the intensive care unit, including neonatal outcomes: a case-control study protocol in a tertiary healthcare facility in Lima-Peru

Corresponding author:

Dr. Beatriz Paulina Ayala Quintanilla.

Address: 215 Franklin Street, Melbourne, Vic 3000, Victoria, Australia.

Telephone: +61 3 9479 8800. Fax: +61 3 9479 8811.

Email: ayalaquintanilla.b@students.latrobe.edu.au

Authors: Beatriz Paulina Ayala Quintanilla^{1, 2, 4}, Angela Taft¹, Susan McDonald^{1, 2}, Wendy Pollock^{1, 2, 3}

Author affiliations

- ¹ The Judith Lumley Centre, La Trobe University, Melbourne, Australia
- ² Mercy Hospital for Women, Melbourne, Australia
- ³ University of Melbourne, Melbourne, Australia
- ⁴ Peruvian National Institute of Health, Lima, Peru

Keywords: Severe acute maternal morbidity, violence against women, intimate partner violence, intensive care unit, social determinants, near miss.

Words in the abstract: 290 words.

Words in article: 3,451 words, excluding title page, abstract, references, authors’ contributions, funding and competing interest statement.

ABSTRACT

Introduction: Preventing and reducing violence against women (VAW) and maternal mortality are Sustainable Development Goals. Worldwide, the maternal mortality ratio has fallen about 44% in the last 25 years, and for one maternal death there are many women affected by severe acute maternal morbidity (SAMM) requiring management in the intensive care unit (ICU). These women represent the most critically ill obstetric patients of the maternal morbidity spectrum and should be studied to complement the review of maternal mortality. VAW has been associated with all-cause maternal deaths, and since many women (30%) endure violence usually exerted by their intimate partners and this abuse can be severe during pregnancy, it is important to determine whether it impacts SAMM. Thus, this study aims to investigate the impact of VAW on SAMM in the ICU.

Methods and analysis: This will be a prospective case-control study undertaken in a tertiary healthcare facility in Lima-Peru, with a sample size of 109 cases (obstetric patients admitted to the ICU) and 109 controls (obstetric patients not admitted to the ICU selected by systematic random sampling). Data on social determinants, medical and obstetric characteristics, VAW, pregnancy and neonatal outcome will be collected through interviews and by extracting information from the medical records using a pretested form. Main outcome will be VAW rate and neonatal mortality rate between cases and controls. VAW will be assessed by using the World Health Organization (WHO) instrument. Binary logistic regression model will assess any association between VAW and SAMM.

Ethics and dissemination: Ethical approval has been granted by the La Trobe University, Melbourne-Australia and the tertiary healthcare facility in Lima-Peru. This research follows the WHO ethical and safety recommendations for research on VAW. Findings will be presented at conferences, and published in peer-reviewed journals.

Strengths and limitations of this study

- This prospective study will examine for the first time the influence of violence against women on severe acute maternal morbidity (SAMM).
- Studying the stage before maternal death (SAMM) complements the review of maternal mortality.
- This study uses a standardised global instrument for the evaluation of violence against women and a pre-tested form for the assessment of other variables of interest.
- Studying violence against women can be challenging and may underestimate the rate of abuse due to recall and cultural bias.
- Findings should be interpreted cautiously because this study is within one very large tertiary hospital and further multi-centre and multi-country studies may be needed, based on these replicable methods.

INTRODUCTION

Preventing and reducing violence against women and maternal mortality are Sustainable Development Goals (SDG).¹ Worldwide, the maternal mortality ratio (MMR) has declined by 44% with a reduction from 385 to 216 maternal deaths per 100,000 live births between 1990 (532,000 maternal deaths) and 2015 (303,000 maternal deaths). This equates to approximately 830 women dying daily, of which 99% of maternal deaths occurred in developing countries.² However, maternal mortality is only a small proportion of the global burden of the maternal morbidity spectrum.³⁻⁵ This is because for one maternal death there are many women affected by severe acute maternal morbidity (SAMM) during pregnancy, childbirth and the postpartum period⁵⁻¹¹ including those obstetric patients who require multidisciplinary management in the intensive care unit (ICU).¹¹⁻¹⁷

ICU admission can be a marker for defining SAMM,^{12 18-25} and SAMM can be named as near miss; either term has been widely used to study this population of obstetric patients.^{15 19 21 25-28} There are no internationally accepted criteria for defining SAMM and its definition may differ across studies,^{19 20 25-34} and the use of ICU admission to identify severe maternal morbidity has high sensitivity (86.4%), specificity (87.8%) and positive predicted value (0.85).^{22 27 35-38} Women with SAMM treated in the ICU represent the most critically ill obstetric patients,^{11 19 39} and require timely managed care due to the physiologic changes of pregnancy and the care of the mother-baby dyad.^{11-17 40-46}

The incidence of maternal ICU admission varies from 0.04 to 4.54%, and the common causes are mainly direct obstetric clinical conditions.^{12 14 19 29} According to Pollock, et al.,¹⁴ hypertensive disorders were the leading cause of ICU admission (0.09% of deliveries), followed by obstetric haemorrhage (0.07%), and sepsis (0.02%); and, although the ICU admission profile was similar worldwide there were higher rates of maternal deaths in the ICUs of developing countries.

Violence against women is a global public health problem and many women of reproductive age endure violence usually exerted by their intimate partners (IPV). Globally, 30% of women have experienced partner abuse.⁴⁷⁻⁴⁹ However, the IPV rate varies across studies ranging from 15 to 71% and from 1 to 28% during pregnancy.⁵⁰ Diverse studies have also reported a wide range of IPV rate during pregnancy from 0.9 to 20.1% in high-income countries,⁵¹ 3 to 44% in Latin America and Caribbean countries⁵² and 2 to 57% in African countries.⁵³

Several studies have reported negative and mortal consequences of IPV on reproductive age women.⁵⁴⁻⁵⁷ During pregnancy, these adverse health outcomes affect the mother-baby dyad; and, can be augmented by consequent risky health behaviours (smoking, alcohol consumption, substance abuse, poor nutrition, lack of seeking health care, among others)⁵⁷⁻⁶⁰ and physiological mechanisms through neural, neuroendocrine, and immune responses to acute and/or chronic stress originating from exposure to violence.^{55 61} All of this may exacerbate pre-existing medical conditions and/or lead to diverse pregnancy complications.^{52 55 61 62} Even though women could be more vulnerable to IPV during the pregnancy and puerperium periods, no data on violence against women of obstetric patients in the ICU have been reported in Peru or elsewhere⁶³. Thus, it is important to examine whether violence against women is a risk factor for women with SAMM. We are conducting this study in Peru, an upper-middle income country⁶⁴ with a lifetime

IPV rate of 68.2% (emotional 64.2%, physical 31.7% and sexual 6.6%).⁶⁵ In Peru, there are about 9 cases of femicide monthly⁵⁶ and a MMR of 68, which fell 72.9% from 251 between 1990 and 2015.²

There has been increased concern about the negative influence of violence against women on maternal mortality,⁶⁶⁻⁷² and violence against women has been associated with all-cause maternal deaths.^{66 67} Although, this association was first analysed 16 years ago⁶⁷ there is still a paucity of studies investigating the influence of violence against women on SAMM⁶³, which can be considered as a complement to a review of maternal deaths.^{15 22 29 36 73-75} Thus, it is important to determine whether violence against women impacts SAMM, since many women endure violence usually exerted by their intimate partners and this abuse can be severe during pregnancy. Therefore, this research of the stage before maternal death (SAMM) will provide for the first time, a better understanding about what potential factors, such as violence against women, are affecting obstetric patients with SAMM in the ICU. This will make an important contribution to global knowledge of causes of maternal morbidity.

HYPOTHESIS

We hypothesise that violence against women is significantly associated with severe acute maternal morbidity in obstetric patients managed in the intensive care unit.

OBJECTIVES

- To investigate the impact of violence against women on obstetric patients with SAMM treated in the ICU (cases) by comparing them with obstetric patients not admitted to the ICU (controls), in a tertiary healthcare facility in Lima-Peru.
- To evaluate pregnancy and neonatal outcome of women with SAMM in the ICU of a tertiary healthcare facility in Lima-Peru.

METHODS

This is a prospective case-control study protocol and follows the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) criteria.^{76 77}

Study design

In this case-control study, cases will be obstetric patients experiencing SAMM in the ICU (s) including miscarriage, therapeutic abortion, unsafe abortion, and ectopic pregnancy prospectively identified from the ICU register. The inclusion criteria of cases include: i) a woman with a maternal ICU admission due to a complication (s) during pregnancy, delivery or within 42 days of the ending of pregnancy, with favourable evolution and who fulfils eligibility prior to hospital discharge; ii) 18-year-old or older; iii) Spanish speaker; and iv) gives written

informed consent. The exclusion criteria are: i) a woman with mental illness or disabilities or other similar disabling pathologies; ii) not able to provide informed consent; iii) an obstetric patient referred from other healthcare facilities for maternity care; and iv) ICU stay less than 24 hours. The controls are from the same source population that gives rise to the cases and their inclusion criteria consist of i) a woman admitted to this hospital during pregnancy, delivery or within 42 days of the ending of pregnancy, with favourable evolution and who fulfils eligibility prior to hospital discharge; ii) 18-year-old or older; iii) Spanish speaker; and iv) gives written informed consent. The exclusion criteria are: i) a woman with mental illness or disabilities or other similar disabling pathologies; ii) not able to provide informed consent; and iii) an obstetric patient referred from other healthcare facilities for maternity care. Favourable evolution means that an obstetric patient has received the required management for the condition responsible for her admission to the hospital or the ICU, is hemodynamically stable without requiring strict monitoring or specialized treatment, her life is not at risk, and is well enough to be discharge from the hospital to home (it implies that the maternal morbidity has resolved for the cases).

We plan to include all cases who meet the selection criteria during the study period, until we reach the estimated sample size of 109 obstetric patients admitted to the ICU. This is because there were 263 ICU admissions (pregnant and non-pregnant women) in 2012, 230 in 2013 and 274 in 2014 according to the Department of Epidemiology of this hospital⁷⁸; and, approximately 48% of the ICU admissions are referred from other healthcare facilities (as indicated by the Chief of the ICU). We expect that cases will be recruited during a period of twelve (12) months, though recruitment will continue for longer if necessary for the minimum sample sizes to be achieved. Controls will be selected by using a probability sampling method, specifically a systematic random sampling (without replacement) starting with 18 and with a value of $k = 131$ as the sampling interval.

Setting

This study is being undertaken in a tertiary hospital located in the capital city of Peru (where about one third of the Peruvian population live). This institution is the main national referral hospital for high risk maternal and neonatal patients throughout Peru, where there are over 22,000 deliveries yearly, which equates to approximately 1 delivery every 25 minutes.⁷⁹

Sample size

The sample size will comprise 218 participants (109 controls and 109 cases) which has been calculated by using the Sample Size Calculation for Unmatched Case-Control Studies of the software open Epi⁸⁰ with a confidence level of 95% and a power of 80% to detect a (18.8%) difference in the exposure of violence against women (rate) between cases and controls. There are not preceding studies assessing the prevalence of violence against women among obstetric patients with SAMM in the ICU. We estimated an IPV rate of 24.3% for controls and 43.1% for cases in accordance with previous research investigating the relationship between IPV and preeclampsia in Peruvian pregnant women at this maternity hospital.⁸¹

Recruitment Method

Participants will be invited to participate and recruited during their hospital stay once their acute medical condition (s) have been resolved (this will be after they were discharged from the ICU for the case women), and before they are discharged from hospital to going home. Women in the

control group will be invited to participate within one week of a case woman being interviewed. The researcher (interviewer), a Spanish speaking midwife, has been trained and has research experience working on violence against women studies and research ethics. The researcher will check with the hospital staff regarding eligibility (selection criteria, e.g. mental illness and others), prior to approaching and inviting potential participants to the study. She will also ensure that the potential participants understand the participant information statement and answer all their questions, and explain to the participants that they can refuse or withdraw their participation at any time without affecting their health care and rights.

Data Collection

Data collection commenced on 23rd October 2015 and is still ongoing. We expect to finish by the end of March 2018. Currently, we are collecting data from the medical records. Women who give consent will be interviewed once in private using a structured questionnaire (Appendix 1). We will also extract information from their medical records using a pretested form developed by the team members (Appendix 2).

Interview

The following information will be obtained during the face to face interview: socio-demographic characteristics (age, place of residence, educational level, marital status, occupation and type of health insurance) of the participant and her partner; behavioural factors (smoking, use of alcohol or drugs); medical (previous and current diseases) and obstetric characteristics (number of pregnancies, previous abortions, prenatal care visits, previous caesarean sections, and vaginal births; use of family planning methods; anaemia during pregnancy and use of iron supplements during pregnancy); and violence against women evaluation.

Violence against women will be assessed by using questions from a standardised instrument of the WHO.⁵⁰ These questions were validated, translated and adapted rigorously, since Peru was one of the countries selected in the WHO Multi-country study instrument.⁵⁰ They have been also used by other researchers for investigating violence against women in Peru, and an adapted version was applied in the Peruvian Demographic and Family Health Survey.⁶⁵

Violence against women evaluation will comprise emotional (including controlling behaviours), physical and sexual abuse exerted by intimate-partners and by non-intimate partners (relatives, friends or others) assessed 12 months before and during pregnancy. The participants will answer the frequency (once or twice or many) for each act of emotional, physical or sexual violence. Violence against women will be examined in an empathetic, supportive and non-judgmental manner, giving the participants the opportunity not to answer any questions that make them feel uncomfortable or to reschedule or terminate the interview at any time. The interview will only be conducted with the woman alone and in private. If the interview is interrupted, the interviewer will change the topic or may terminate the interview correspondingly. It is expected that the interview will take approximately 25 to 30 minutes. After the interview, information about free social support services for domestic violence (available at this maternity hospital) will be offered to every participant including a referral if they wish. There will be also debriefing sessions for the well-being of the interviewer. Individual support/counselling can be arranged at the hospital for the interviewer or participant if it is needed.

Extracting data from medical records

We will extract data from the medical reports of the mothers and newborns (if applicable) related to SAMM, pregnancy outcome, fetal and neonatal characteristics and outcome.

SAMM data will include hospital admission date, clinical causes for hospitalisation and/or ICU admission, diagnoses after being discharged from the ICU and/or the hospital, number of hospital stay days and ICU stay days, type of delivery, additional procedures, weeks of pregnancy when SAMM occurs, organ failure (s), use of technologies (mechanical ventilation, transfusion, use of inotropic support and renal replacement therapies), main delays (in relation to the three delays model framework used to study maternal mortality⁸²), and pregnancy outcome (Appendix 2).

Fetal and neonatal data will include: birth weight; birth age; sex; Apgar score (at 1 and 5 minutes); outcome at birth; clinical cause (s) for Neonatal ICU (NICU); number of days at the NICU (if applicable) or at the hospital; use of technologies and/or antibiotics at the NICU; feeding type (breastfeeding, formula or both); discharge status; and diagnoses from the hospital and/or the NICU (Appendix 2).

Data entry and analysis

Data will be entered using SPSS V.24.0. Univariate analysis will be carried out to describe the characteristics of SAMM, social determinants, violence against women and pregnancy and neonatal outcomes. Quantitative variables will be displayed as the mean ± SD and/or median (interquartile rate) after verifying their normal or asymmetrical distribution. Difference of means analyses between variables will be performed using appropriate statistical tests (Student's t-test or Mann–Whitney U test or other similar). Qualitative variables will be displayed as frequencies.

We will apply a bivariate analysis to evaluate the association of violence against women (partner and non-partner) as an independent variable with SAMM; and we will also evaluate this association with partner violence only; and, with non-partner violence only.

We will fully assess violence against women as a risk factor by using a multivariate logistic regression modelling considering an Odds Ratio (OR) with 95% CI. Crude ORs will also be calculated. Statistical significance will be set at $p < 0.05$ for all analyses. We will identify effect modification for age, level of education, alcohol consumption and use of drugs by performing a stratified analysis of these variables that could potentially modify the effect of violence against women on SAMM. This will be assessed by the calculation of crude ORs within every level of each variable that is stratified. The final model will include the socio-demographic characteristics of the participants, other variables of interest (such as household income, partner's educational level, partner's occupation, etc.) according to the literature review, and modifiers (we will remove the least significant modifiers one at a time until only those with $p < 0.05$ remain). Those variables with p values of < 0.25 will be initially chosen to be included in the model,⁸³ and the Hosmer-Lemeshow's goodness-of-fit test will be used to assess model adequacy

and stepwise multiple regression analysis performed to select and identify the predictive factors in the final model.⁸³

ETHICS AND DISSEMINATION

Ethical approval has been granted by the La Trobe University Human Ethics committee (HEC15-023), Melbourne, Australia and the Institutional Review Board of the tertiary healthcare hospital in Lima, Peru. Individual written informed consent will be obtained from participants prior to data collection. The present research follows the WHO and other ethical and safety recommendations for research on gender-based violence to ensure the safety of the participants and the interviewer.^{50 84-88}

It is planned that the findings of this case-control study will be presented at La Trobe University and national and/or international conferences, and it will be also published in a peer review journal. It is expected that these finding will inform policymakers, patients, and the public through these presentations.

PRESENTING AND REPORTING RESULTS

This prospective case-control study will examine for the first time the influence of violence against women on obstetric patients affected by severe acute maternal morbidity who require management in the ICU, and evaluate their pregnancy and neonatal outcomes. We will present major findings in tables and also describe results in narrative format outlining effect sizes and their parameters. The findings and further publications will be reported following the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) criteria,^{76 77} which is part of the Enhancing the quality and transparency of health research (EQUATOR) Network website.

DISCUSSION

The influence of violence against pregnant women on the incidence of or type of SAMM is not known and worthy of study. Although, the negative contribution of violence against women to maternal deaths was described in the 1997-1999 Confidential Enquiry into Maternal Death,⁶⁷ and many studies have reported negative and fatal repercussions of IPV on women's health including during all stages of pregnancy,⁵²⁻⁶² there is a paucity of studies assessing the relationship between violence against women and SAMM.⁶³ Investigating women affected by SAMM could complement the review of maternal deaths^{15 22 29 36 73-75} to understand which underlying factors are influencing the sequence of events from a healthy pregnancy through minor complications to life threatening obstetric conditions and even death in childbearing women.^{26 89 90}

This case-control study will contribute to evidence about the potential negative consequences of violence against women of obstetric patients with SAMM in the ICU, who represent the most critically ill patients^{11 19 39} and have been shown to be an important component of the maternal morbidity spectrum requiring timely managed care.^{11-17 40-46} This may help to highlight that non-biological factors (violence against women), which are potentially modifiable, may be associated with SAMM and are important to address to reduce maternal morbidity-mortality in Peru and in other low and middle-income countries. Acute or chronic exposure to violence adversely affects both the mothers and their babies and can be augmented by any risky health behaviors⁵⁷⁻⁶⁰ and

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

through physiological (neural, neuroendocrine, and immune) mechanisms in response to this abuse.^{55 61} All of this may exacerbate pre-existing medical conditions and/or lead to diverse pregnancy complications.^{52 55 61 62} Thus, it would be important to know if violence against women is a risk factor for SAMM in the ICU, and to understand the complete picture of the global burden of maternal morbidity-mortality to improve mother-baby dyad health and women’s well-being.

This study may also help participants affected by violence to disclose abuse in a safe and supportive environment; and, provide an opportunity for those abused women to understand that it is possible to prevent violence and improve their and other women’s lives, since they will be informed and/or referred to the free social support services available for domestic violence provided by the Peruvian government.

We understand that the findings of this study should be interpreted cautiously and some limitations should be noted. Firstly, this research will be undertaken in a single centre. It will be important to carry out further multi-centre and multi-country studies. Other limitations may include recall, cultural and measurement bias which can underestimated or overestimate the exposure.^{50 91} This is because the assessment of violence against women is complex and challenging. Accordingly, this research follows the ethical and safety recommendations for research on violence against women;^{50 84-88} and uses standardized questions for the assessment of violence against women (WHO instrument) and a pretested questionnaire for the evaluation of other factors. Amendments to this protocol are not expected. However, if any are required, these amendments will be reported transparently.

Notwithstanding these limitations, we hope that this study will contribute to the global effort towards achieving SDGs by providing valuable information for a better understanding of SAMM and violence against women in Peru. This will make an important contribution to global knowledge of causes of maternal morbidity by providing evidence of the relationship between violence against women and SAMM, which is important for preventing and/or reducing maternal morbidity-mortality and improve maternal health. Therefore, we expect that this research will extend knowledge in an identified research gap, and may provide direction for further studies in obstetric women affected by SAMM in the ICU.

REFERENCES

1. United Nations. Transforming our world: the 2030 Agenda for Sustainable Development. Resolution adopted by the General Assembly on 25 September 2015. 2015. <https://sustainabledevelopment.un.org/post2015/transformingourworld> (accessed 6 May 2017).
2. World Health Organization. Trends in maternal mortality: 1990 to 2015. Estimates by WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division. Secondary Trends in maternal mortality: 1990 to 2015. Estimates by WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division. 2015. <http://www.who.int/classifications/icd/factsheet/en/> (accessed 15 Feb 2016).
3. Mantel GD, Buchmann E, Rees H, et al. Severe acute maternal morbidity: a pilot study of a definition for a near-miss. *Br J Obstet Gynaecol* 1998;105:985-90.
4. Geller SE, Cox SM, Callaghan WM, et al. Morbidity and mortality in pregnancy: laying the groundwork for safe motherhood. *Womens Health Issues* 2006;16:176-88.
5. Firoz T, Chou D, von Dadelszen P, et al. Measuring maternal health: focus on maternal morbidity. *Bull World Health Organ* 2013;91:794-6.
6. Ashford L. Hidden suffering: disabilities from pregnancy and childbirth in less developed countries. Secondary Hidden suffering: disabilities from pregnancy and childbirth in less developed countries. 2002. <http://www.prb.org/pdf/hiddensufferingeng.pdf> (accessed 23 Jul 2014).
7. Fottrell E, Kanhonou L, Goufodji S, et al. Risk of psychological distress following severe obstetric complications in Benin: the role of economics, physical health and spousal abuse. *Br J Psychiatry* 2010;196:18-25.
8. Pacagnella RC, Cecatti JG, Camargo RP, et al. Rationale for a long-term evaluation of the consequences of potentially life-threatening maternal conditions and maternal "near-miss" incidents using a multidimensional approach. *J Obstet Gynaecol Can* 2010;32:730-8.
9. Wilson RE, Salihu HM. The paradox of obstetric "near misses": converting maternal mortality into morbidity. *Int J Fertil Womens Med* 2007;52:121-7.
10. Storeng KT, Drabo S, Ganaba R, et al. Mortality after near-miss obstetric complications in Burkina Faso: medical, social and health-care factors. *Bull World Health Organ* 2012;90:418-25B.
11. Plaat F, Naik M. Critical care in pregnancy. *Crit Care* 2011;15:1014 doi: <http://dx.doi.org/10.1186/cc10479> [published Online First: 22 December 2013].
12. Zieleskiewicz L, Chantry A, Duclos G, et al. Intensive care and pregnancy: Epidemiology and general principles of management of obstetrics ICU patients during pregnancy. *Anaesth Crit Care Pain Med* 2016;35 (Suppl 1):S51-7 doi: 10.1016/j.accpm.2016.06.005 [published Online First: 5 July 2016].
13. Guntupalli KK, Hall N, Karnad DR, et al. Critical illness in pregnancy Part I: an approach to a pregnant patient in the ICU and common obstetric disorders. *Chest* 2015;148:1093-104.
14. Pollock W, Rose L, Dennis C. Pregnant and postpartum admissions to the intensive care unit: a systematic review. *Intensive Care Med* 2010;36:1465-74.
15. Baskett TF. Epidemiology of obstetric critical care. *Best Pract Res Clin Obstet Gynaecol* 2008;22:763-74. Complement to maternal deaths
16. Martin SR, Foley MR. Intensive care in obstetrics: an evidence-based review. *Am J Obstet Gynecol* 2006;195:673-89.
17. Germain S, Wyncoll D, Nelson-Piercy C. Management of the critically ill obstetric patient. *Curr Obstet Gynaecol* 2006;16:125-33.
18. Oud L. Epidemiology of Pregnancy-Associated ICU Utilization in Texas: 2001 - 2010. *J Clin Med Res* 2017;9:143-53 doi: 10.14740/jocmr2854w [published Online First: 17 January 2017]. ICUproxi of ICU
19. Senanayake H, Dias T, Jayawardena A. Maternal mortality and morbidity: Epidemiology of intensive care admissions in pregnancy. *Best Pract Res Clin Obstet Gynaecol* 2013;27:811-20. ICUproxi of ICU

20. Bouvier-Colle MH, Mohangoo AD, Gissler M, et al. What about the mothers? An analysis of maternal mortality and morbidity in perinatal health surveillance systems in Europe. *BJOG* 2012;119:880-9; discussion 90.

21. Reichenheim ME, Zylbersztajn F, Moraes CL, et al. Severe acute obstetric morbidity (near-miss): a review of the relative use of its diagnostic indicators. *Arch Gynecol Obstet* 2009;280:337-43.

22. Hirshberg A, Srinivas SK. Epidemiology of maternal morbidity and mortality. *Semin Perinatol* Published Online First: 17 August 2017. doi: 10.1053/j.semperi.2017.07.007.

23. Brace V, Penney G, Hall M. Quantifying severe maternal morbidity: a Scottish population study. *BJOG* 2004;111:481-4.

24. Lawton BA, Wilson LF, Dinsdale RA, et al. Audit of severe acute maternal morbidity describing reasons for transfer and potential preventability of admissions to ICU. *Aust N Z J Obstet Gynaecol* 2010;50:346-51.

25. Chantry AA, Deneux-Tharoux C, Bonnet MP, et al. Pregnancy-related ICU admissions in France: Trends in rate and severity, 2006-2009. *Crit Care Med* 2015;43:78-86.

26. Say L, Souza JP, Pattinson RC. Maternal near miss--towards a standard tool for monitoring quality of maternal health care. *Best Pract Res Clin Obstet Gynaecol* 2009;23:287-96.

27. Callaghan WM, Grobman WA, Kilpatrick SJ, et al. Facility-based identification of women with severe maternal morbidity: it is time to start. *Obstet Gynecol* 2014;123:978-81.

28. Donati S, Senatore S, Ronconi A, et al. Obstetric near-miss cases among women admitted to intensive care units in Italy. *Acta Obstet Gynecol Scand* 2012;91:452-57.

29. Tuncalp O, Hindin MJ, Souza JP, et al. The prevalence of maternal near miss: a systematic review. *BJOG* 2012;119:653-61. Complement/ diverse criteria

30. Lewis G. Reviewing maternal deaths to make pregnancy safer. *Best Pract Res Clin Obstet Gynaecol* 2008;22:447-63.

31. Souza JP, Cecatti JG, Parpinelli MA, et al. Appropriate criteria for identification of near-miss maternal morbidity in tertiary care facilities: a cross sectional study. *BMC Pregnancy Childbirth* 2007;7:20 doi: 10.1186/1471-2393-7-20 [published Online First: 11 September 2007]

32. van Roosmalen J, Zwart J. Severe acute maternal morbidity in high-income countries. *Best Pract Res Clin Obstet Gynaecol* 2009;23:297-304.

33. David E, Machungo F, Zanconato G, et al. Maternal near miss and maternal deaths in Mozambique: a cross-sectional, region-wide study of 635 consecutive cases assisted in health facilities of Maputo province. *BMC Pregnancy Childbirth* 2014;14:401 doi: 10.1186/s12884-014-0401-3 [published Online First: 10 December 2014].

34. You WB, Chandrasekaran S, Sullivan J, et al. Validation of a scoring system to identify women with near-miss maternal morbidity. *Am J Perinatol* 2013;30:21-4.

35. Kilpatrick SJ, Berg C, Bernstein P, et al. Standardized severe maternal morbidity review: rationale and process. *Obstet Gynecol* 2014;124:361-6.

36. Kilpatrick SK, Ecker JL. Severe maternal morbidity: screening and review. *Am J Obstet Gynecol* 2016;215:B17-22.

37. Geller SE, Rosenberg D, Cox S, et al. A scoring system identified near-miss maternal morbidity during pregnancy. *J Clin Epidemiol* 2004;57:716-20.

38. Main EK, Abreo A, McNulty J, et al. Measuring severe maternal morbidity: validation of potential measures. *Am J Obstet Gynecol* 2016;214:643.e1-10 doi: 10.1016/j.ajog.2015.11.004 [published Online First:12 November 2015].

39. Zwart JJ, Dupuis JR, Richters A, et al. Obstetric intensive care unit admission: a 2-year nationwide population-based cohort study. *Intensive Care Med* 2010;36:256-63.

40. Shapiro JM. Critical care of the obstetric patient. *J Intensive Care Med* 2006;21:278-86.

41. Honiden S, Abdel-Razeq SS, Siegel MD. The management of the critically ill obstetric patient. *J Intensive Care Med* 2013;28:93-106.

42. Neligan PJ, Laffey JG. Clinical review: Special populations--critical illness and pregnancy. *Crit Care* 2011;15:227.

43. Soubra SH, Guntupalli KK. Critical illness in pregnancy: An overview. *Crit Care Med* 2005;33(Suppl 10):S248-55.

44. Trikha A, Singh P. The critically ill obstetric patient - Recent concepts. *Indian J Anaesth* 2010;54(5):421-7.

45. Aoyama K, Seaward PG, Lapinsky SE. Fetal outcome in the critically ill pregnant woman. *Crit Care* 2014;18(3):307 doi: 10.1186/cc13895 [published Online First:27 May 2014].

46. Munnur U, Bandi V, Guntupalli KK. Management Principles of the Critically Ill Obstetric Patient. *Clin Chest Med* 2011;32:53-60.
47. World Health Organization. Global and regional estimates of violence against women: prevalence and health effects of intimate partner violence and non-partner sexual violence. 2013. http://apps.who.int/iris/bitstream/10665/85239/1/9789241564625_eng.pdf?ua=1 (accessed 13 Nov 2014).
48. Devries KM, Mak JY, Garcia-Moreno C, et al. Global health. The global prevalence of intimate partner violence against women. *Science* 2013;340:1527-8 doi:10.1126/science.12409373042 [published Online First: 28 June 2013].
49. World Health Organization. The Global status report on violence prevention 2014. 2014. http://www.who.int/violence_injury_prevention/violence/status_report/2014/en/ (accessed 28 May 2015).
50. Garcia-Moreno C, Jansen HAFM, Ellsberg M, et al. Prevalence of intimate partner violence: findings from the WHO multi-country study on women's health and domestic violence. *Lancet* 2006;368:1260-9.
51. Gazmararian JA, Lazorick S, Spitz AM, et al. Prevalence of violence against pregnant women. *JAMA* 1996;275:1915-20.
52. Han A, Stewart DE. Maternal and fetal outcomes of intimate partner violence associated with pregnancy in the Latin American and Caribbean region. *Int J Gynaecol Obstet* 2014;124:6-11.
53. Shamu S, Abrahams N, Temmerman M, et al. A systematic review of African studies on intimate partner violence against pregnant women: prevalence and risk factors. *PloS One* 2011;6(3):e17591 doi: 10.1371/journal.pone.0017591 [published Online First: 8 March 2011].
54. Stockl H, Devries K, Rotstein A, et al. The global prevalence of intimate partner homicide: a systematic review. *Lancet* 2013;382:859-65.
55. Black MC. Intimate Partner Violence and Adverse Health Consequences: Implications for Clinicians. *J Womens Health (Larchmt)* 2011;5:428-39.
56. Ayala Quintanilla BP, Taft A, McDonald S, et al. An examination of femicides in Peru between 2009 and 2014. *Int J Gynaecol Obstet* 2016;134:342-3 doi: 10.1016/j.ijgo.2016.03.020 [published Online First: 4 June 2016].
57. Sugg N. Intimate partner violence: prevalence, health consequences, and intervention. *Med Clin North Am* 2015;99(3):629-49.
58. Sarkar NN. The impact of intimate partner violence on women's reproductive health and pregnancy outcome. *J Obstet Gynaecol* 2008;28:266-71.
59. Chambliss LR. Intimate partner violence and its implication for pregnancy. *Clin Obstet Gynecol* 2008;51(2):385-97.
60. Chisholm CA, Bullock L, Ferguson JEJ, 2nd. Intimate partner violence and pregnancy: epidemiology and impact. *Am J Obstet Gynecol* 2017;217(2):141-4.
61. Alhusen JL, Ray E, Sharps P, et al. Intimate partner violence during pregnancy: maternal and neonatal outcomes. *J Womens Health (Larchmt)* 2015;24:100-6.
62. Hill A, Pallitto C, McCleary-Sills J, et al. A systematic review and meta-analysis of intimate partner violence during pregnancy and selected birth outcomes. *Int J Gynaecol Obstet* 2016; 133:269-76 doi:10.1016/j.ijgo.2015.10.023 [published Online First: 11 March 2013].
63. Ayala Quintanilla, B. P., Taft, A., McDonald, et al. Social determinants and maternal exposure to intimate partner violence of obstetric patients with severe maternal morbidity in the intensive care unit: a systematic review protocol *BMJ Open* 2016;6(11):e013270 doi:10.1136/bmjopen-2016-013270 [published Online First: 28 November 2016].
64. World Bank. Data 2017. <http://data.worldbank.org/about/country-and-lending-groups> (accessed 4 Jun 2017).
65. INSTITUTO NACIONAL DE ESTADISTICA E INFORMATICA. Encuesta Demografica y de Salud Familiar 2016 - Nacional y Regional 2016. 2017. https://www.inei.gob.pe/media/MenuRecursivo/publicaciones_digitales/Est/Lib1356/. (accessed 12 Jun 2017).
66. Lewis G. (2007). The Confidential Enquiry into Maternal and Child Health (CEMACH). Saving Mothers' Lives: reviewing maternal deaths to make motherhood safer - 2003-2005. The Seventh Report on Confidential Enquiries into Maternal Deaths in the United Kingdom. London: CEMACH. <http://www.publichealth.hscni.net/sites/default/files/Saving%20Mothers%27%20Lives%202003-05%20.pdf> (accessed 12 Dec 2017).
67. The Confidential Enquiries into Maternal Deaths in the United Kingdom. 2001. Why mothers die 1997-1999. The fifth report of the Confidential Enquiries into Maternal Deaths. <http://www.hqip.org.uk/national-programmes/a-z-of-clinical-outcome-review-programmes/cmace-reports/> (accessed 2 Aug 2014).

68. Knight M, Tuffnell DJ, Kenyon S, et al. Saving Lives, Improving Mothers' Care - Surveillance of maternal deaths in the UK 2011-13 and lessons learned to inform maternity care from the UK and Ireland Confidential Enquiries into Maternal Deaths and Morbidity 2009-13. Oxford: National Perinatal Epidemiology Unit, University of Oxford. 2015. <https://www.npeu.ox.ac.uk/> (accessed 15 Apr 2016).

69. Knight M., Kenyon S., Brocklehurst P., et al. Saving Lives, Improving Mothers' Care - Lessons learned to inform future maternity care from the UK and Ireland Confidential Enquiries into Maternal Deaths and Morbidity 2009 -12. Oxford: National Perinatal Epidemiology Unit, University of Oxford. 2014. <https://www.npeu.ox.ac.uk/downloads/files/mbrrace-uk/reports/Saving%20Lives%20Improving%20Mothers%20Care%20report%202014%20Full.pdf> (accessed 27 Apr 2016).

70. United Nation, Every Woman Every Child. EVERY NEWBORN. An Action Plan To End Preventable Deaths. Secondary EVERY NEWBORN. An Action Plan To End Preventable Deaths 2014. http://apps.who.int/iris/bitstream/10665/127938/1/9789241507448_eng.pdf?ua=1 (accessed 14 Mar 2016).

71. Farquhar C, Sadler L, Masson V, et al. Beyond the numbers: classifying contributory factors and potentially avoidable maternal deaths in New Zealand, 2006-2009. *Am J Obstet Gynecol* 2011;205:331.e1-31e-8 doi:10.1016/j.ajog.2011.07.044 [published Online First: 30 July 2011].

72. Murphy NJ, Quinlan JD. Trauma in pregnancy: assessment, management, and prevention. *Am Fam Physician* 2014;90(10):717-22.

73. Knight M, Lewis G, Acosta CD, et al. Maternal near-miss case reviews: the UK approach. *BJOG* 2014;121 Suppl 4:112-6.

74. Ananth CV, Smulian JC. Chapter 1 Epidemiology of Critical Illness in Pregnancy. In Belfort MA, Saade G, Foley MR, et al., eds. *Critical Care Obstetrics* Fifth Edition 2011:1-10.

75. Knight M, Acosta C, Brocklehurst P, et al. Beyond maternal death: improving the quality of maternal care through national studies of 'near-miss' maternal morbidity. *Programme Grants Appl Res* 2016;4(9).

76. von Elm E, Altman DG, Egger M, et al. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *The Lancet* 2007;370(9596):1453-57.

77. von Elm E, Altman DG, Egger M, et al. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies. *Int J Surg* 2014;12:1495-9.

78. Instituto Nacional Materno Perinatal. Boletín Estadístico 2014. 2014. <http://www.inmp.gob.pe/institucional/sala-situacional/1421334856> (accessed 28 Jan 2015).

79. Instituto Nacional Materno Perinatal. Boletín Estadístico 2015 - 2016. 2016. <http://www.inmp.gob.pe/institucional/boletines-estadisticos/1422371837> (accessed 28 May 2017).

80. Open Epi. Sample Size Calculation for Unmatched Case-Control Studies. Version 3.03.17. 2014. <http://web1.sph.emory.edu/cdckms/sample%20size%20%20grps%20case%20control.html> (accessed 2 Jul 2015).

81. Sanchez SE, Qiu C, Perales MT, et al. Intimate partner violence (IPV) and preeclampsia among Peruvian women. *Eur J Obstet Gynecol Reprod Biol* 2008;137:50-5 doi: 10.1016/j.ejogrb.2007.05.013 [published Online First: 27 Jun 2007].

82. Thaddeus S, Maine D. Too far to walk: Maternal mortality in context. *Soc Sci Med* 1994;38:1091-110.

83. Hosmer DV, Lemeshow S. *Applied Logistic Regression*. Second Edition ed. USA: A Wiley-Interscience Publication. 2000:375.

84. Jewkes R, Dartnall E, Sikweyiya Y. *Ethical and Safety Recommendations for Research on the Perpetration of Sexual Violence*. Sexual Violence Research Initiative Pretoria, South Africa: Medical Research Council. 2012. <http://www.svri.org/EthicalRecommendations.pdf> (accessed 28 May 2015).

85. Ellsberg M, Heise L. *Researching Violence Against Women: A Practical Guide for Researchers and Activists* Washington DC, United States: World Health Organizationb PATH. 2005. http://whqlibdoc.who.int/publications/2005/9241546476_eng.pdf?ua=1 (accessed 26 May 2015).

86. World Health Organization. *Putting Women First: Ethical and Safety Recommendations for Research on Domestic Violence Against Women*. 2001. <http://www.who.int/gender/violence/womenfirtseng.pdf> (accessed 27 May 2015).

87. Jansen HAFM, Watts C, Ellsberg M, et al. *Interviewer Training in the WHO Multi-Country Study on Women's Health and Domestic Violence*. 2004. http://www.who.int/gender/documents/Interviewer_training.pdf (accessed 27 May 2015).

88. Garcia-Moreno C, Jansen HAFM, Ellsberg M, et al. WHO Multi-country Study on Women's Health and Domestic Violence Against Women. Initial results on prevalence, health outcomes and women's responses. 2005. <http://www.who.int/reproductivehealth/publications/violence/24159358X/en/> (accessed 2 Jul 2014).
89. Karolinski A, Mercer R, Micone P, et al. The epidemiology of life-threatening complications associated with reproductive process in public hospitals in Argentina. *BJOG* 2013;120:1685-95.
90. Filippi V, Chou D, Ronsmans C, et al. Levels and Causes of Maternal Mortality and Morbidity. In: Black RE, Laxminarayan R, Temmerman M, et al., eds. 2016. Reproductive, Maternal, Newborn, and Child Health. Disease Control Priorities, third edition, volume 2. Washington, DC: World Bank. doi:10.1596/978-1-4648-0348-2. License: Creative Commons Attribution CC BY 3.0 IGO.
91. Pandis, N. Case-control studies: part 2. *Am J Orthod Dentofacial Orthop* 2014;146:402-3.

Authors' contributions

BPAQ, AT, SMC and WP conceived and designed the study protocol. This study is part of the first's author PhD thesis. BPAQ drafted the manuscript and all authors edited following versions of the draft. BA, AT, SMC, and WP revised critically the methodological and clinical content of the protocol to make contributions. All authors reviewed and approved the final manuscript.

Funding

This study is part of a doctoral study at La Trobe University was supported by the Peruvian Government through PRONABEC (National Program of Scholarship and Educational Loan) and La Trobe University. No funding bodies will have any role in study design, collecting data, analysing data, interpreting findings, and writing, reviewing or deciding to publish the manuscript.

Competing interest statement

The authors declare that they have no competing interest.



Appendix 1

Judith Lumley Centre for mother, infant and family health research

College of Science, Health and Engineering

La Trobe University

Maternal health research in a tertiary health care facility in Lima, Peru

Structured questionnaire for face to face interview

Code number: 

Interview Date: / /
D D M M Y Y Y Y

Thank you for agreeing to participate in this study.

You are free to not answer any questions. If any of the questions are unclear, or you need more information the interviewer will be happy to provide you with the information you need.

Before I start, do you have any questions?

SECTION A. GENERAL INFORMATION

WOMAN INFORMATION

First I would like to ask you some questions about your background.

A1.How old are you? _____ (Years)

A2. Place of residence

1. **Lima Norte**
(Ancón, Carabayillo, Comas, Independencia, Los Olivos, Puente Piedra, San Juan de Lurigancho, San Martín de Porres, Santa Rosa)
2. **Lima Este**
(Ate, Cieneguilla, Chaclacayo, El Agustino, Lurigancho, San Luis, Santa Anita)
3. **Lima Sur**
(Chorrillos, Lurín, Pachacamac, Pucusana, Punta Hermosa, Punta Negra, San Bartolo, San Juan de Miraflores, Santa María del Mar, Villa el Salvador, Villa María del Triunfo)
4. **Residencial Lima**
(Barranco, Jesús María, La Molina, Lince, Magdalena, Miraflores, Pueblo Libre, San Borja, San Isidro, San Miguel, Santiago de Surco, Surquillo)
5. **Callao**
(Bellavista, Callao District, Carmen de la Legua Reynoso, La Perla, La Punta, Ventanilla District)
6. **Central Lima**
(Breña, La Victoria, Downtown Lima, Rimac)

A3. What is your level of education? Would you say?

1. Primary level
2. Secondary level
3. Technical studies
4. University level
5. Other (Specify) _____
- 9 Do not know / Not Sure

A4. What is your current marital status?

1. Single
2. Married
3. Cohabitant
4. Separated/Divorced
5. Widowed
9. Do not know / Not Sure

A5. What is your occupation?

1. Unemployed
2. Student
3. Employed
4. Self-employed
5. Housewife
6. Other (specify) _____
7. Do not know / Not Sure

A6. How hard is it for you (and your family) to pay for the very basics like food?

- 1 Very hard
- 2 Hard
- 3 Somewhat hard
- 4 Not very hard
- 9 Do not know / Not Sure

A7. How hard is it for you (and your family) to pay for medical care?

- 1 Very Hard
- 2 Hard
- 3 Somewhat hard
- 4 Not very hard
- 9 Do not know / Not Sure

A8. How much is the estimated monthly income of your nuclear family?**A9. How many household members are dependent on this monthly income (specify)?****A10. Are you a SIS beneficiary?**

- 1 No
- 2 Yes
- 9 Do not know / Declined to answer

A11. Can you tell me your SIS category?

- 1 Low risk
- 2 Medium risk
- 3 High risk
- 9 Do not know / Declined to answer

A12. If you do not have SIS, which health insurance do you have?

- 1 Private company
- 2 Other (specify) _____
- 3 Do not have any health insurance
- 9 Do not know / Declined to answer

A13. What about smoking, do you smoke during this pregnancy?

- 1 No → **Skip to A15**
- 2 Yes → **Continue to A14**
- 9 Do not know / Declined to answer

A14. If yes, would you say?

1. Daily
2. Occasionally
3. Not at all
- 9 Do not know / Declined to answer

A15. What about alcohol use, do you drink alcohol during this pregnancy?

- 1 No → **Skip to A17**
- 2 Yes → **Continue to A16**
- 9 Do not know / Declined to answer

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- 13
- 14
- 15
- 16
- 17
- 18
- 19
- 20
- 21
- 22
- 23
- 24
- 25
- 26
- 27
- 28
- 29
- 30
- 31
- 32
- 33
- 34
- 35
- 36
- 37
- 38
- 39
- 40
- 41
- 42
- 43
- 44
- 45
- 46
- 47
- 48
- 49
- 50
- 51
- 52
- 53
- 54
- 55
- 56
- 57
- 58
- 59
- 60
- A16. If yes, would you say?
1. Every day or nearly every day
2. Once or twice a week
3. 1 – 3 times a month
4. Occasionally, less than once a month
5. Never
- 9 Do not know / Declined to answer
- A17. What about drug use, do you use any illegal drugs during this pregnancy?
1. No
2. Yes
- 9 Do not know / Declined to answer

PARTNER INFORMATION

- 15
- 16
- 17
- 18
- 19
- 20
- 21
- 22
- 23
- 24
- 25
- 26
- 27
- 28
- 29
- 30
- 31
- 32
- 33
- 34
- 35
- 36
- 37
- 38
- 39
- 40
- 41
- 42
- 43
- 44
- 45
- 46
- 47
- 48
- 49
- 50
- 51
- 52
- 53
- 54
- 55
- 56
- 57
- 58
- 59
- 60
- A18. What is the age of your partner _____ (Years)
- A19. What is the level of education of your husband/partner?
1. Primary level
2. Secondary level
3. Technical studies
4. University level
5. Other (Specify) _____
- 9 Do not know / Declined to answer
- A20. What is the occupation of your husband/partner?
1. Unemployed
2. Student
3. Employed
4. Self-employed
5. Other (specify) _____
- 9 Do not know / Declined to answer
- A21. What about alcohol use, does/did your husband/partner drink alcohol during your pregnancy?
- 1 No → Skip to A25
- 2 Yes → Continue to A22
- A22. If yes, would you say?
1. Every day or nearly every day
2. Once or twice a week
3. 1 – 3 times a month
4. Occasionally, less than once a month
5. Never
- 9 Do not know / Declined to answer
- A23. Does/did your husband/partner get drunk during your pregnancy?
1. No → Skip to A25
2. Yes → Continue to A24
- 9 Do not know/Declined to answer
- A24. If yes, would you say?
1. Most days
2. Weekly
3. Once a month
4. Less than once a month
5. Never
- 9 Do not know / Declined to answer
- A25. What about drug use, does/did your partner use any illegal drugs during your pregnancy?
1. No
2. Yes
- 9 Do not know / Declined to answer

B. PREGNANCY AND PRENATAL CHARACTERISTICS

Now I would like to ask you some questions about your pregnancy history

- B1. How many weeks of pregnancy were you at your first prenatal visit? ____ (Weeks)
- B2. Did you receive prenatal care during this pregnancy?
1. No → **Skip to B4**
 2. Yes → **Continue to B3**
 - 9 Do not know / Not sure
- B3. How many antenatal care visits did you receive during pregnancy? _____ times [999 = Do not know]
- B4. How much was your weight before you became pregnant this time? _____ Kilograms [999 = Do not know]
- B5. How much weight did you gain since becoming pregnant? _____ Kilograms [999 = Do not know]
- B6. What is your height? _____ Centimeters [999 = Do not know]
- B7. GRAVIDITY = Number of pregnancies (including this pregnancy) ____
- B8. PARITY = Number of live births >22 weeks (including this pregnancy) ____
- B9. Number of vaginal deliveries (including this pregnancy) ____
- B10. Number of cesarean sections (including this pregnancy) ____
- B11. Number of total previous abortions ____
- B12. Miscarriages ____
- B13. Unsafe abortions ____
- B14. Therapeutic abortions ____
- B15. Number of Molas ____
- B16. Number of ectopic pregnancies ____
- B17. Number of alive children ____
- B18. Number of stillborns ____
- B19. Number of dead children ____
- B20. Did you plan to become pregnant this time?
- 1 No
 - 2 Yes
 - 9 Do not know / Declined to answer
- B21. Are you aware of family planning methods to avoid getting pregnant?
1. No → **Skip to B24**
 2. Yes → **Continue to B22**
 - 9 Do not know / Declined to answer
- B22. Which family planning methods do you use to avoid getting pregnant (if it is more than one, only consider the main method)?
- 1 Pills/Tablets
 - 2 Injectable
 - 3 Diaphragm/foam/jelly
 - 4 IUD
 - 5 Condoms
 - 6 Natural Method (calendar/mucus method)
 - 7 Withdrawal
 - 8 Other (specify) _____
- B23. How often do you use family planning methods?
1. Often
 2. Rarely
 3. Never (because of)
 - 3.1. Because of ignorance about them
 - 3.2. Because of logistic/administrative issues
 - 3.3. Because of unwillingness to use them
 - 3.4. Because of partner unwillingness to use them
 - 3.5. Because of the cost
 - 3.6. Other (specify) _____
 9. Do not know / Declined to answer

B24. Did you receive vaccination against tetanus in the last 10 years?

- 1. No
- 2. Yes
- 9 Do not know / Not sure

B25. Did a doctor ever tell you that you have anemia during this pregnancy?

- 1. No → **Skip to B30**
- 2. Yes → **Continue to B26**
- 9 Do not know / Not sure

B26. Which trimester, did a doctor tell you that you have anemia during this pregnancy?

- 1 I Trimester
- 2 II Trimester
- 3 III Trimester
- 9 Do not know / Not sure

B27. Did you take any ferrous iron supplement during this pregnancy?

- 1. No → **Skip to B30**
- 2. Yes → **Continue to B28**
- 9 Do not know / Not sure

B28. If yes, how many pills/tablets per day? _____ pills per day [99: Do not know / not sure]

B29. And, how many months did you drink these pills/tablets? _____ months [99: Do not know / not sure]

B30. How many times did you visit the emergency room during this pregnancy? _____ time/times [99: Do not know / not sure]

B31. Has a doctor ever told you that you have or do you have?

Diseases	You have had			You have		
	No	Yes	Do not know / not sure	No	Yes	Do not know / not sure
a Chronic hypertension	1	2	99	1	2	99
b Anemia	1	2	99	1	2	99
c Tuberculosis	1	2	99	1	2	99
d Diabetes Mellitus	1	2	99	1	2	99
e Heart disease	1	2	99	1	2	99
f Thyroid disease	1	2	99	1	2	99
g HIV infection	1	2	99	1	2	99
h Other (specify) _____	1	2	99	1	2	99

B32. Did you ever have one or more of the following condition (s) during **previous pregnancy (es)**?

Clinical conditions	NO	YES	Do not know / not sure
1 Hypertensive related disease	1	2	99
a Severe Preeclampsia	1	2	99
b Eclampsia	1	2	99
c HELLP Syndrome	1	2	99
2 Antepartum hemorrhage in the second trimester of pregnancy because of (specify):	1	2	99
a Placenta previa	1	2	99
b Uterine rupture	1	2	99
c Abruptio placentae			
d Other (specify)	1	2	99
3 Antepartum hemorrhage in the third trimester of pregnancy because of (specify):	1	2	99
a Placenta previa	1	2	99
b Uterine rupture	1	2	99
c Abruptio placentae	1	2	99

d Other (specify)	1	2	99
4 Postpartum hemorrhage complication	1	2	99
a Uterine atony	1	2	99
b Cervical laceration/tear	1	2	99
c Retained products/fetal membranes	1	2	99
d Ruptured uterus	1	2	99
e Accreta placenta	1	2	99
f Other (specify)	1	2	99
5 Sepsis (obstetric origin)	1	2	99
a Chorioamnionitis	1	2	99
b Surgical wound infection	1	2	99
c Endometritis	1	2	99
d Other (specify)	1	2	99
6 Sepsis (non-obstetric origin)	1	2	99
a Urine infection	1	2	99
b Other (specify)	1	2	99
7 Sepsis (pulmonary origin)	1	2	99
a Pneumonia	1	2	99
b Viral cause	1	2	99
b.1 H1N1	1	2	99
b.2 Varicella	1	2	99
b.3 Other (specify)	1	2	99
c Other (specify)	1	2	99
8 Clinical condition	1	2	99
a Oligohydramnios	1	2	99
b Intrauterine growth restriction	1	2	99
c Fetal macrosomy	1	2	99
d Other (specify)	1	2	99
9 Other associated pathologies			
a Premature rupture of fetal membranes	1	2	99
b Disseminated intravascular coagulation (DIC)	1	2	99
c Maternal pulmonary edema	1	2	99
d Amniotic fluid embolism	1	2	99
e Retroplacental clot	1	2	99
f Septic shock.	1	2	99
g Hypovolemic Shock	1	2	99
h Cervical cancer	1	2	99
i Other (specify)	1	2	99

C. ASSESSMENT OF VAW (IPV AND NON-IPV)

When two people marry or live together, they usually share both good and bad moments. I would now like to ask you some questions about your current and past relationships and how your husband / partner treats (treated) you. If anyone interrupts us I will change the topic of conversation. I would again like to assure you that your answers will be kept secret, and that you do not have to answer any questions that you do not want to. May I continue?

Assessing IPV			BEFORE PREGNANCY					DURING PREGNANCY					
			(In the past 12 months before pregnancy)										
I am going to ask you about some situations that are true for many women. Would you say it is generally true that he:	(A) (If YES continue with B. If NO, ask during pregnancy and if NO skip to next item)		(B) Has this happened in the past 12 months before this pregnancy? (If YES ask C, if NO ask D)		(C) In the past 12 months before this pregnancy, would you say that this has happened once, a few times or many times? (after answering C, go to D)			(D) Has this happened during this pregnancy? (If YES ask E)		(E) During Pregnancy, would you say that this has happened once, a few times, or many times?			
	YES	NO	YES	NO	One	Few	Many (>5 times)	YES	NO	One	Few	Many (>5 times)	
	C1. Tries to keep you from seeing your friends?	1	2	1	2	1	2	3	1	2	1	2	3
	C2. Tries to restrict contact with your family of birth?	1	2	1	2	1	2	3	1	2	1	2	3
	C3. Insists on knowing where you are at all times?	1	2	1	2	1	2	3	1	2	1	2	3
	C4. Ignores you and treats you indifferently?	1	2	1	2	1	2	3	1	2	1	2	3
	C5. Gets angry if you speak with another man?	1	2	1	2	1	2	3	1	2	1	2	3
	C6. Is often suspicious that you are unfaithful?	1	2	1	2	1	2	3	1	2	1	2	3
	C7. Expects you to ask his permission before seeking health care for yourself?	1	2	1	2	1	2	3	1	2	1	2	3

The next questions are about things that happen to many women, and that your current partner, or any other partner may have done to you.

Assessing IPV			BEFORE PREGNANCY						DURING PREGNANCY				
			(In the past 12 months before pregnancy)										
Has your <u>current</u> husband/partner or <u>any</u> other partner ever	(A) (If YES continue with B. If NO, ask during pregnancy and if NO skip to next item)		(B) Has this happened in the <u>past 12 months before this pregnancy?</u> (If YES ask C, if NO ask D)		(C) <u>In the past 12 months before this pregnancy</u> , would you say that this has happened once, a few times or many times? (after answering C, go to D)			(D) Has this happened <u>during this pregnancy?</u> (If YES ask E)		(E) <u>During Pregnancy</u> would you say that this has happened once, a few times, or many times?			
	YES	NO	YES	NO	One	Few	Many (>5 times)	YES	NO	One	Few	Many (>5 times)	
C8. Insulted you or made you feel bad about yourself?	1	2	1	2	1	2	3	1	2	1	2	3	
C9. Belittled or humiliated you in front of other people?	1	2	1	2	1	2	3	1	2	1	2	3	
C10. Done things to scare or intimidate you on purpose (e.g., by the way he looked at you, by yelling and smashing things)?	1	2	1	2	1	2	3	1	2	1	2	3	
C11. Threatened to hurt you or someone you care about	1	2	1	2	1	2	3	1	2	1	2	3	

Assessing IPV			BEFORE PREGNANCY						DURING PREGNANCY				
			(In the past 12 months before pregnancy)										
Has your <u>current</u> husband/partner or <u>any</u> other partner ever	(A)		(B)		(C)			(D)		(E)			
	(If YES continue with B. If NO, ask during pregnancy and if NO skip to next item)		Has this happened in the past 12 months before this pregnancy? (If YES ask C, if NO ask D)		In the past 12 months before this pregnancy, would you say that this has happened once, a few times or many times? (after answering C, go to D)			Has this happened during this pregnancy? (If YES ask E)		During Pregnancy, would you say that this has happened once, a few times, or many times?			
	YES	NO	YES	NO	One	Few	Many (>5 times)	YES	NO	One	Few	Many (>5 times)	
	C12. Slapped you or thrown something at you that could hurt you?	1	2	1	2	1	2	3	1	2	1	2	3
	C13. Pushed you or shoved you or pulled your hair?	1	2	1	2	1	2	3	1	2	1	2	3
	C14. Hit you with his fist or with something else that could hurt you?	1	2	1	2	1	2	3	1	2	1	2	3
	C15. Kicked you, dragged you or beat you up?	1	2	1	2	1	2	3	1	2	1	2	3
	C16. Choked or burnt you on purpose?	1	2	1	2	1	2	3	1	2	1	2	3
C17. Threatened to use or actually used a gun, knife or other weapon against you?	1	2	1	2	1	2	3	1	2	1	2	3	

Assessing IPV			BEFORE PREGNANCY					DURING PREGNANCY				
			(In the past 12 months before pregnancy)									
	(A)		(B)		(C)			(D)		(E)		
Has your <u>current</u> husband/partner or <u>any</u> other <u>partner</u> ever	(If YES continue with B. If NO ask during pregnancy, and if NO skip to next item)		Has this happened <u>in the past 12 months before this pregnancy?</u> (If YES ask C, if NO ask D)		<u>In the past 12 months before this pregnancy</u> , would you say that this has happened once, a few times or many times? (after answering C, go to D)			Has this happened <u>during this pregnancy?</u> (If YES ask E)		<u>During Pregnancy</u> , would you say that this has happened once, a few times, or many times?		
	YES	NO	YES	NO	One	Few	Many (>5 times)	YES	NO	One	Few	Many (>5 times)
C18. Did your <u>current</u> husband/partner or <u>any</u> other <u>partner</u> ever physically force you to have sexual intercourse when you did not want to?	1	2	1	2	1	2	3	1	2	1	2	3
C19. Did you ever have sexual intercourse you did not want to because you were afraid of what your partner or any other partner might do?	1	2	1	2	1	2	3	1	2	1	2	3
C20. Did your partner or any other partner ever force you to do something sexual that you found degrading or humiliating?	1	2	1	2	1	2	3	1	2	1	2	3

NON-IPV

In their lives, may women experience different forms of violence from relatives, other people that they know, and/or from strangers. If you don't mind. I would like to briefly ask you about some of these situations. If anyone interrupts us I will change the topic of conversation. Everything that you say will be kept private. May I continue?

Assessing Non-IPV		BEFORE PREGNANCY							DURING PREGNANCY						
		(In the past 12 months before pregnancy)													
	(A) (If YES continue with B. If NO, ask during pregnancy and if NO skip to next item)	(B) Has this happened in the past 12 months before this pregnancy? (If YES ask C, if NO ask D)		(C) In the past 12 months before this pregnancy, would you say that this has happened once, a few times or many times? (after answering C, go to D) (in total from all the persons she mentioned)				(D) Has this happened during this pregnancy? (If YES ask Who was/were) And would you say that this has happened once, a few times, or many times? (in total from all the persons she mentioned) (choose "one", "few" or many" considering in total from all the persons she mentioned)							
	YES	NO	YES	Who did this to you? (multiple responses)	No	One	Few	Many (>5 times)	YES	Who did this to you? (multiple responses)	No	One	Few	Many (>5 times)	
C21. Insulted you or made you feel bad about yourself?	1	2	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3	
C22. Belittled or humiliated you in front of other people?	1	2	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3	
C23. Done things to scare or intimidate you on purpose (e.g., by the way he looked at you, by yelling and smashing things)?	1	2	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3	
C24. Threatened to hurt you or someone you care about?	1	2	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3	

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Continue with the following questions.....

Assessing Non-IPV			BEFORE PREGNANCY						DURING PREGNANCY					
			(In the past 12 months before pregnancy)											
	(A)		(B)		(C)			(D)						
Since the age of 15 years, has anyone (other than your partner/husband):	(If YES continue with B. If NO, ask during pregnancy and if NO skip to next item)		Has this happened in the past 12 months before this pregnancy? (If YES ask C, if NO ask D)		In the past 12 months before this pregnancy, would you say that this has happened once, a few times or many times? (after answering C, go to D) (in total from all the persons she mentioned)			Has this happened during this pregnancy? (If YES ask Who was/were) And would you say that this has happened once, a few times, or many times? (in total from all the persons she mentioned) (choose "one", "few" or many" considering in total from all the persons she mentioned)						
	YES	NO	YES	Who did this to you? (multiple responses)	No	One	Few	Many (>5 times)	YES	Who did this to you? (multiple responses)	No	One	Few	Many (>5 times)
C25. Ever beaten you or physically mistreated you in any way ?	1	2	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3
C26. ¿forced you to have sex or to perform a sexual act when did you not want or to do something sexual that you found degrading or humiliating?	1	2	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3

C27. Have you ever been punched or kicked in the abdomen by anyone including your (ex or current) partner or other person(s) whilst you were pregnant?

1. No
2. Yes

C28 When (indicate year and which pregnancy) Year.....Which pregnancy.....

9. Don't know / Decline to answer

C29. Have any health care professionals asked you if you were affected by IPV or non-partner violence?

1 No
2 Yes
9 Do not know / Decline to answer

Continue with the questions C30, C31 and C32 for those participants who were affected by harm acts

Go to question C32 (Skip questions C29 and C30) for those participants who were NOT affected by harm acts

C30. Have you sought help to prevent or stop gender-based violence?

- 1 No
- 2 Yes
- 9 Do not know / Decline to answer

C31. Can you mention what type of help?

- 1 Family member
- 2 Friend
- 3 Community Social Services from the government
- 4 Police
- 5 Other (specify).....
- 9 Do not know / Decline to answer

Ask the following question to each participant

C32. Is there anything else do you want to tell me?
(Write down the exact words expressed by the participant)

Now give the information about free social support services available for domestic violence at this Institution and which are free of cost and are provided by the Peruvian government.

Thank you for your participation!!!!



Appendix 2

Judith Lumley Centre for mother, infant and family health research centre

College of Science, Health and Engineering

La Trobe University

Maternal health research in a tertiary health care facility in Lima, Peru

Form for data collection of medical records

Code number: _____ Date: ____/____/____
D D M M Y Y Y Y

D. MATERNAL MORBIDITY AND PREGNANCY OUTCOME INFORMATION

Number

About previous pathologies during this pregnancy

In the First Trimester (< 13 weeks of gestation)

D1. Indicate which pathologies are described in the medical chart:

1. Anemia
2. Urine Infection
3. Threatened abortion
4. Other (specify) _____
5. No pathologies
6. No pathologies because first antenatal care was after 13 weeks of pregnancy

In the Second Trimester (≥ 13 and < 24 weeks of pregnancy)

D2. Indicate which pathologies are described in the medical chart:

1. Anemia
2. Urine Infection
3. Preeclampsia
4. Threatened abortion
5. Antepartum hemorrhage
6. Other (specify) _____
7. No pathologies
8. No pathologies because first antenatal care was after 24 weeks of pregnancy

In the Third Trimester (≥ 24 weeks of pregnancy)

D3. Indicate which pathologies are described in the medical chart:

1. Anemia
2. Urine Infection
3. Preeclampsia
4. Antepartum hemorrhage
5. Other (specify) _____
6. No pathologies

About hospital stay of the participant (including Intensive Care Unit admission if applicable)

D4. 1st day of the last normal menstrual period _ _ / _ _ / _ _ _ _
D D / M M / Y Y Y Y

[illegible]

- D6** Gestational age at first antenatal visit _____ weeks [999 = Not recorded]
- D7.** Number of antenatal visits _____ [999 = Not recorded]
- D8** Pre-pregnancy weight (weight before the participant became pregnant this time) _____ Kilograms [999 = Not recorded]
- D9** Pregnancy weight before delivery _____ Kilograms [999 = Not recorded]
- D10.** Weight gain during pregnant _____ Kilograms [999 = Not recorded]
- D11** Height _____ Centimeters [999 = Not recorded]
- D12.** Date of admission at this hospital ____ / ____ / ____
D D / M M / Y Y Y Y
- D13.** Indicate the diagnosis of the patient when she was hospitalized at this hospital:
1. _____
 2. _____
 3. _____
 4. _____
 5. _____
- D14** Socioeconomic level according to Social Services Department of this hospital:
1. Lower risk
 2. Medium risk
 3. High risk
 4. No category
- D15.** Was the participant admitted at the Intensive Care Unit?
1. No → **Skip to D26**
 2. Yes → **Continue to D16**
- D16.** Date of admission at the Intensive Care Unit ____ / ____ / ____ Time _____ (hour)
D D / M M / Y Y Y Y
- D17.** Indicate the diagnosis (ses) of the participant when she was admitted at the Intensive Care Unit:
1. _____
 2. _____
 3. _____
 4. _____
 5. _____
- D18.** Weeks of pregnancy at the moment of the event (s) (SAMM) which cause(s) her admission at the Intensive Care Unit:
_____ weeks
- D19.** Moment of such event (SAMM) in relation to the termination of pregnancy:
1. Before
 2. During
 3. After
- D20.** Did the woman received assistance with ventilation?
1. CPAP
 2. Non-invasive ventilation (e.g. BiPAP)
 3. Invasive mechanical ventilation
 4. None of the above
- D21.** Which management did the woman receive in the ICU (multiple responses)?
1. Inotrope or vasopressor therapy
 2. Renal replacement therapy (dialysis)
 3. Central venous access
 4. None of the above
- D22.** What was the severity of illness score on admission? _____ Score (APACHE)
- D23.** Date of discharge of the Intensive Care Unit: ____ / ____ / ____
D D / M M / Y Y Y Y
- D24.** Indicate the number of days in the Intensive Care Unit: _____ days

D25. Indicate the diagnosis (ses) of the patient when she was discharged from the Intensive Care Unit:

- 1. _____
- 2. _____
- 3. _____
- 4. _____
- 5. _____
- 6. _____

D26. Did the participant receive blood transfusion during her hospital stay?

- 1. No
- 2. Yes a. Indicate the numbers of red blood cell transfusion unit _____

D27. Did the participant receive other blood product transfusions during her hospital stay?

- 1. No → **Skip to D29**
- 2. Yes → **Continue to D28**

D28. What were these other transfusions (multiple responses)?

- 1. Plasma
- 2. Platelet
- 3. Cryoprecipitate
- 4. Other (specify) _____

D29. Date of discharge of this hospital ____ / ____ / ____ D D / M M / Y Y Y Y

D30. Diagnosis (ses) of the patient at discharge of this hospital:

- 1 _____
- 2 _____
- 3 _____
- 4 _____
- 5 _____
- 6 _____

D31. Indicate the number of hospital stay days _____ days

About clinical conditions during this pregnancy

D32. Clinical conditions during this pregnancy (multiple responses)

Clinical conditions	NO	YES	NOT RECORDED
1 Hypertensive related disease	1	2	99
a Severe Preeclampsia	1	2	99
Magnesium sulfate treatment	1	2	99
b Eclampsia	1	2	99
Magnesium sulfate treatment	1	2	99
c HELLP Syndrome	1	2	99
2 Antepartum hemorrhage in the second trimester of pregnancy because of (specify):	1	2	99
a Placenta previa	1	2	99
b Uterine rupture	1	2	99
c Abruptio placentae	1	2	99
d Other (specify)	1	2	99
3 Antepartum hemorrhage in the third trimester of pregnancy because of (specify):	1	2	99
a Placenta previa	1	2	99
b Uterine rupture	1	2	99
c Abruptio placentae	1	2	99
d Other (specify)	1	2	99
4 Postpartum hemorrhage complication	1	2	99
a Uterine atony	1	2	99
b Cervical laceration/tear	1	2	99
c Retained products/fetal membranes	1	2	99

d	Ruptured uterus	1	2	99
e	Accreta/increta/percreta placenta	1	2	99
f	Other (specify)	1	2	99
5	Miscarriage complication	1	2	99
a	Uterine perforation	1	2	99
b	Cervical laceration/tear	1	2	99
c	Infection	1	2	99
d	Other (specify)	1	2	99
6	Ectopic pregnancy	1	2	99
7	Sepsis (obstetric origin)	1	2	99
a	Chorioamnionitis	1	2	99
b	Surgical wound infection	1	2	99
c	Endometritis	1	2	99
d	Other (specify)	1	2	99
8	Sepsis (non-obstetric origin)	1	2	99
a	Urine infection	1	2	99
b	Other (specify)	1	2	99
9	Sepsis (pulmonary origin)	1	2	99
a	Pneumonia	1	2	99
b	Viral cause	1	2	99
b.1	Influenza (e.g. H1N1)	1	2	99
b.2	Varicella	1	2	99
b.3	Other (specify)	1	2	99
c	Other (specify)	1	2	99
10	Clinical condition	1	2	99
a	Oligohydramnios	1	2	99
b	Intrauterine growth restriction	1	2	99
c	Fetal macrosomy	1	2	99
d	Other (specify)	1	2	99
11	Other associated pathologies			
a	Premature rupture of fetal membranes	1	2	99
b	Disseminated intravascular coagulation (DIC)	1	2	99
c	Maternal pulmonary edema	1	2	99
d	Amniotic fluid embolism	1	2	99
e	Retroplacental clot	1	2	99
f	Septic shock.	1	2	99
g	Hypovolemic Shock	1	2	99
h	Other (specify)	1	2	99
12	Complications of pre-existent diseases	1	2	99
a	Tuberculosis	1	2	99
b	Diabetes Mellitus	1	2	99
c	Heart disease	1	2	99
d	Thyroid crisis	1	2	99
e	Chronic hypertension	1	2	99
f	HIV infection	1	2	99
g	Anemia	1	2	99
h	Cervical cancer	1	2	99
i	Ovarian cancer	1	2	99
j	Other (specify) _____	1	2	99

D33. Did the participant develop any organic dysfunctions?
1. No → Skip to D35
2. Yes → Continue to D34

D34. What were these organic dysfunctions?
(Information extracted from the epidemiological report, multiple responses)
1 Cardiovascular dysfunction
2 Respiratory dysfunction
3 Renal dysfunction
4 Coagulation/hematologic dysfunction
5 Hepatic dysfunction
6 Neurologic dysfunction
7 Uterine dysfunction/hysterectomy
8 Multiple organ dysfunction

About outcome of this pregnancy

D35. Type of pregnancy termination:
1 Abortion
i. Miscarriage
ii. Therapeutic
iii. Unsafe
2 Delivery
3 Laparotomy for ectopic pregnancy
4 Still pregnant

D36. Date of pregnancy termination (delivery, abortion, ectopic pregnancy) ____/____/____ Time ____ (hour)
D D / M M / Y Y Y Y

D37. Indicate the number of hospital stay days before pregnancy termination ____ days

D38. Gestational age at delivery or abortion (including ectopic pregnancy): ____ (Weeks)

D39. Mode of delivery or abortion
1 Vaginal, normal
a. Active management of the third stage of labor.
i. No
ii. Yes
2 Vaginal, vacuum/forceps
a. Active management of the third stage of labor.
i. No
ii. Yes
3 Emergency C-section
4 Scheduled C-section
5 Curettage (for a woman who had an abortion)

D40. Place of the delivery:
1. This hospital
2. Other hospital
3. Health Center
4. Home
5. Another (specify) _____

D41. Who attended the delivery?
1. Doctor
2. Midwifery
3. Another (specify) _____

About additional surgical treatment (s) performed during this pregnancy

D42. Was/were additional surgical treatment(s) performed?
1. No → Skip to D46
2. Yes → Continue to D43

D43. Report about additional first surgical treatment (s) performed (multiple responses):

- 1 Hysterectomy
- 2 Laparotomy
- 3 Curettage
- 4 Repair of cervical tears
- 5 Drainage of puerperal hematoma and repair of puerperal hematoma
- 6 Manual removal of placenta (after vaginal delivery)
- 7 Other (specify) _____

D44. Report about an additional second surgical treatment performed:

- 1 Hysterectomy
- 2 Laparotomy
- 3 Other (specify) _____

D45. Report about an additional third surgical treatment performed:

- 1 Hysterectomy
- 2 Laparotomy
- 3 Another (specify) _____

About surgical treatment (s) performed during this pregnancy, indicate the diagnosis (ses) for each procedures correspondingly:

D46. Uterine curettage indication:

- 1 _____
- 2 _____
- 3 _____
- 4 _____

D47. Cesarean indication:

- 1 _____
- 2 _____
- 3 _____
- 4 _____

D48. Laparotomy indication:

- 1 _____
- 2 _____
- 3 _____
- 4 _____
- 5 _____

D49. Hysterectomy indication:

- 1 _____
- 2 _____
- 3 _____
- 4 _____

About main delays (Information extracted from the epidemiological report if the participant was admitted at the Intensive Care Unit).

Go to the Neonatal information (Skip item D50, D51, D52 and D53) if the participant **was NOT** admitted at the Intensive Care Unit.

D50. Qualitative analysis of Delay I

- 1 No
- 2 Yes

D51. Qualitative analysis of Delay II

- 1 No
- 2 Yes

D52. Qualitative analysis of Delay III

- 1 No
- 2 Yes

D53. Qualitative analysis of Delay IV

- 1 No
- 2 Yes

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

E. NEONATAL INFORMATION

This information **is excluded** for those women **who had an abortion or an ectopic pregnancy**

Number _____

	Baby 1	Baby 2 (if applicable)	Baby 3 (if applicable)
E1. Birth weight	----- grams	----- grams	-----grams
E2. Age at birth (according to Neonatologist)	----- weeks	----- weeks	----- weeks
E3. Sex	1 Male 2 Female 3 Ambiguous	1 Male 2 Female 3 Ambiguous	1 Male 2 Female 3 Ambiguous
E4. Apgar score (1 minute)	-----	-----	-----
E5. Apgar score (5 minutes)	-----	-----	-----
E6. Baby outcome at birth:	1 Live birth 2 Stillborn	1 Live birth 2 Stillborn	1 Live birth 2 Stillborn
E7. Nursery of baby	1 Stay with mom (Regular nursery) 2 Other (specify) _____	1 Stay with mom (Regular nursery) 2 Other (specify) _____	1 Stay with mom (Regular nursery) 2 Other (specify) _____
E8. Breastfeeding	1 Breastfeeding 2 Formula 3 Both 4 Another(specify) _____	1 Breastfeeding 2 Formula 3 Both 4 Another(specify) _____	1. Breastfeeding 2. Formula 3. Both 4. Another(specify) _____
E9. Gross fetal/neonatal malformation	1 No 2 Yes 99 Do not know	1. No 2. Yes 99 Do not know	1. No 2. Yes 99 Do not know
E10. Neonatal Intensive Care Unit (NICU) Admission	1. No 2. Yes	1. No 2. Yes	1 No 2 Yes
E11. Indicate the diagnosis (ses) of the baby for NICU admission	1. _____ 2. _____ 3. _____ 4. _____	1. _____ 2. _____ 3. _____ 4. _____	1. _____ 2. _____ 3. _____ 4. _____
E12. Management of the baby at NICU (multiple responses)	1. CPAP 2. Non-invasive ventilation (e.g. BiPAP) 3. Invasive mechanical ventilation 4. Inotrope or vasopressor therapy 5. Blood transfusion 6. None of the above	1. CPAP 2. Non-invasive ventilation (e.g. BiPAP) 3. Invasive mechanical ventilation 4. Inotrope or vasopressor therapy 5. None of the above	1. CPAP 2. Non-invasive ventilation (e.g. BiPAP) 3. Invasive mechanical ventilation 4. Inotrope or vasopressor therapy 5. None of the above
E13. Indicate the diagnosis (ses) of the baby when was discharged from the NICU	1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____	1 _____ 2 _____ 3 _____ 4 _____ 5 _____ 6 _____	1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____
E14. Antibiotic use in NICU	1 No 2 Yes	1 No 2 Yes	1 No 2 Yes
E15. Days of stay at NICU	_____ days	_____ days	_____ days
E16. Days of stay at this hospital	_____ days	_____ days	_____ days

E17. Discharge status of baby from this hospital	1. Alive 2. Dead (Days after birth_____)	1. Alive 2. Dead (Days after birth_____)	1. Alive 2. Dead (Days after birth_____)
E18. Indicate the diagnosis of the baby when was discharged from this hospital	1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____	1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____	1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____

The End
Thank You!!!!!!!!!!!!!!

BMJ Open

The impact of violence against women on severe acute maternal morbidity in the intensive care unit, including neonatal outcomes: a case-control study protocol in a tertiary healthcare facility in Lima-Peru

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-020147.R2
Article Type:	Protocol
Date Submitted by the Author:	12-Feb-2018
Complete List of Authors:	Ayala Quintanilla, Beatriz; La Trobe University College of Science Health and Engineering, Judith Lumley Centre; Peruvian National Institute of Health, Lima Pollock, Wendy; La Trobe University, The Judith Lumley Centre; Mercy Hospital for Women McDonald, SJ; Midwifery Professorial Unit, La Trobe University/Mercy Hospital for Women Taft, Angela; La Trobe University, Mother and Child Health Research
Primary Subject Heading:	Public health
Secondary Subject Heading:	Intensive care, Obstetrics and gynaecology
Keywords:	Severe acute maternal morbidity, violence against women, intimate partner violence, intensive care unit, social determinants, near miss

SCHOLARONE™
Manuscripts

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

29

30

31

32

33

34

35

36

37

38

39

40

41

42

43

44

45

46

47

48

49

50

51

52

53

54

55

56

57

58

59

60

Title

The impact of violence against women on severe acute maternal morbidity in the intensive care unit, including neonatal outcomes: a case-control study protocol in a tertiary healthcare facility in Lima-Peru

Corresponding author:

Dr. Beatriz Paulina Ayala Quintanilla.

Address: 215 Franklin Street, Melbourne, Vic 3000, Victoria, Australia.

Telephone: +61 3 9479 8800. Fax: +61 3 9479 8811.

Email: ayalaquintanilla.b@students.latrobe.edu.au

Authors: Beatriz Paulina Ayala Quintanilla^{1, 2, 4}, Wendy Pollock^{1, 2, 3}, Susan McDonald^{1, 2}, Angela Taft¹

Author affiliations

- ¹ The Judith Lumley Centre, La Trobe University, Melbourne, Australia
- ² Mercy Hospital for Women, Melbourne, Australia
- ³ University of Melbourne, Melbourne, Australia
- ⁴ Peruvian National Institute of Health, Lima, Peru

Keywords: Severe acute maternal morbidity, violence against women, intimate partner violence, intensive care unit, social determinants, near miss.

Words in the abstract: 298 words.

Words in article: 3,451 words, excluding title page, abstract, references, authors’ contributions, funding and competing interest statement.

ABSTRACT

Introduction: Preventing and reducing violence against women (VAW) and maternal mortality are Sustainable Development Goals. Worldwide, the maternal mortality ratio has fallen about 44% in the last 25 years, and for one maternal death there are many women affected by severe acute maternal morbidity (SAMM) requiring management in the intensive care unit (ICU). These women represent the most critically ill obstetric patients of the maternal morbidity spectrum and should be studied to complement the review of maternal mortality. VAW has been associated with all-cause maternal deaths, and since many women (30%) endure violence usually exerted by their intimate partners and this abuse can be severe during pregnancy, it is important to determine whether it impacts SAMM. Thus, this study aims to investigate the impact of VAW on SAMM in the ICU.

Methods and analysis: This will be a prospective case-control study undertaken in a tertiary healthcare facility in Lima-Peru, with a sample size of 109 cases (obstetric patients admitted to the ICU) and 109 controls (obstetric patients not admitted to the ICU selected by systematic random sampling). Data on social determinants, medical and obstetric characteristics, VAW, pregnancy and neonatal outcome will be collected through interviews and by extracting information from the medical records using a pretested form. Main outcome will be VAW rate and neonatal mortality rate between cases and controls. VAW will be assessed by using the World Health Organization (WHO) instrument. Binary logistic followed by stepwise multivariate regression and goodness of fit test will assess any association between VAW and SAMM.

Ethics and dissemination: Ethical approval has been granted by the La Trobe University, Melbourne-Australia and the tertiary healthcare facility in Lima-Peru. This research follows the WHO ethical and safety recommendations for research on VAW. Findings will be presented at conferences, and published in peer-reviewed journals.

Strengths and limitations of this study

- This prospective study will examine for the first time the influence of violence against women on severe acute maternal morbidity (SAMM).
- Studying the stage before maternal death (SAMM) complements the review of maternal mortality.
- This study uses a standardised global instrument for the evaluation of violence against women and a pre-tested form for the assessment of other variables of interest.
- Studying violence against women can be challenging and may underestimate the rate of abuse due to recall and cultural bias.
- Findings should be interpreted cautiously because this study is within one very large tertiary hospital and further multi-centre and multi-country studies may be needed, based on these replicable methods.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

29

30

31

32

33

34

35

36

37

38

39

40

41

42

43

44

45

46

47

48

49

50

51

52

53

54

55

56

57

58

59

60

INTRODUCTION

Preventing and reducing violence against women and maternal mortality are Sustainable Development Goals (SDG).¹ Worldwide, the maternal mortality ratio (MMR) has declined by 44% with a reduction from 385 to 216 maternal deaths per 100,000 live births between 1990 (532,000 maternal deaths) and 2015 (303,000 maternal deaths). This equates to approximately 830 women dying daily, of which 99% of maternal deaths occurred in developing countries.² However, maternal mortality is only a small proportion of the global burden of the maternal morbidity spectrum.³⁻⁵ This is because for one maternal death there are many women affected by severe acute maternal morbidity (SAMM) during pregnancy, childbirth and the postpartum period⁵⁻¹¹ including those obstetric patients who require multidisciplinary management in the intensive care unit (ICU).¹¹⁻¹⁷

ICU admission can be a marker for defining SAMM,^{12 18-25} and SAMM can be named as near miss; either term has been widely used to study this population of obstetric patients.^{15 19 21 25-28} There are no internationally accepted criteria for defining SAMM and its definition may differ across studies,^{19 20 25-34} and the use of ICU admission to identify severe maternal morbidity has high sensitivity (86.4%), specificity (87.8%) and positive predicted value (0.85).^{22 27 35-38} Women with SAMM treated in the ICU represent the most critically ill obstetric patients,^{11 19 39} and require timely managed care due to the physiologic changes of pregnancy and the care of the mother-baby dyad.^{11-17 40-46}

The incidence of maternal ICU admission varies from 0.04 to 4.54%, and the common causes are mainly direct obstetric clinical conditions.^{12 14 19 29} According to Pollock, et al.,¹⁴ hypertensive disorders were the leading cause of ICU admission (0.09% of deliveries), followed by obstetric haemorrhage (0.07%), and sepsis (0.02%); and, although the ICU admission profile was similar worldwide there were higher rates of maternal deaths in the ICUs of developing countries.

Violence against women is a global public health problem and many women of reproductive age endure violence usually exerted by their intimate partners (IPV). Globally, 30% of women have experienced partner abuse.⁴⁷⁻⁴⁹ However, the IPV rate varies across studies ranging from 15 to 71% and from 1 to 28% during pregnancy.⁵⁰ Diverse studies have also reported a wide range of IPV rate during pregnancy from 0.9 to 20.1% in high-income countries,⁵¹ 3 to 44% in Latin America and Caribbean countries⁵² and 2 to 57% in African countries.⁵³

Several studies have reported negative and mortal consequences of IPV on reproductive age women.⁵⁴⁻⁵⁷ During pregnancy, these adverse health outcomes affect the mother-baby dyad; and, can be augmented by consequent risky health behaviours (smoking, alcohol consumption, substance abuse, poor nutrition, lack of seeking health care, among others)⁵⁷⁻⁶⁰ and physiological mechanisms through neural, neuroendocrine, and immune responses to acute and/or chronic stress originating from exposure to violence.^{55 61} All of this may exacerbate pre-existing medical conditions and/or lead to diverse pregnancy complications.^{52 55 61 62} Even though women could be more vulnerable to IPV during the pregnancy and puerperium periods, no data on violence against women of obstetric patients in the ICU have been reported in Peru or elsewhere⁶³. Thus, it is important to examine whether violence against women is a risk factor for women with

SAMM. We are conducting this study in Peru, an upper-middle income country⁶⁴ with a lifetime IPV rate of 68.2% (emotional 64.2%, physical 31.7% and sexual 6.6%).⁶⁵ In Peru, there are about 9 cases of femicide monthly⁵⁶ and a MMR of 68, which fell 72.9% from 251 between 1990 and 2015.²

There has been increased concern about the negative influence of violence against women on maternal mortality,⁶⁶⁻⁷² and violence against women has been associated with all-cause maternal deaths.^{66 67} Although, this association was first analysed 16 years ago⁶⁷ there is still a paucity of studies investigating the influence of violence against women on SAMM⁶³, which can be considered as a complement to a review of maternal deaths.^{15 22 29 36 73-75} Thus, it is important to determine whether violence against women impacts SAMM, since many women endure violence usually exerted by their intimate partners and this abuse can be severe during pregnancy. Therefore, this research of the stage before maternal death (SAMM) will provide for the first time, a better understanding about what potential factors, such as violence against women, are affecting obstetric patients with SAMM in the ICU. This will make an important contribution to global knowledge of causes of maternal morbidity.

HYPOTHESIS

We hypothesise that violence against women is significantly associated with severe acute maternal morbidity in obstetric patients managed in the intensive care unit.

OBJECTIVES

- To investigate the impact of violence against women on obstetric patients with SAMM treated in the ICU (cases) by comparing them with obstetric patients not admitted to the ICU (controls), in a tertiary healthcare facility in Lima-Peru.
- To evaluate pregnancy and neonatal outcome of women with SAMM in the ICU of a tertiary healthcare facility in Lima-Peru.

METHODS

This is a prospective case-control study protocol and follows the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) criteria.^{76 77}

Study design

In this case-control study, cases will be obstetric patients experiencing SAMM in the ICU (s) including miscarriage, therapeutic abortion, unsafe abortion, and ectopic pregnancy prospectively identified from the ICU register. The inclusion criteria of cases include: i) a woman with a maternal ICU admission due to a complication (s) during pregnancy, delivery or within 42 days of the ending of pregnancy, with favourable evolution and who fulfils eligibility

prior to hospital discharge; ii) 18-year-old or older; iii) Spanish speaker; and iv) gives written informed consent. The exclusion criteria are: i) a woman with mental illness or disabilities or other similar disabling pathologies; ii) not able to provide informed consent; iii) an obstetric patient referred from other healthcare facilities for maternity care; and iv) ICU stay less than 24 hours. The controls are from the same source population that gives rise to the cases and their inclusion criteria consist of i) a woman admitted to this hospital during pregnancy, delivery or within 42 days of the ending of pregnancy, with favourable evolution and who fulfils eligibility prior to hospital discharge; ii) 18-year-old or older; iii) Spanish speaker; and iv) gives written informed consent. The exclusion criteria are: i) a woman with mental illness or disabilities or other similar disabling pathologies; ii) not able to provide informed consent; and iii) an obstetric patient referred from other healthcare facilities for maternity care. Favourable evolution means that an obstetric patient has received the required management for the condition responsible for her admission to the hospital or the ICU, is hemodynamically stable without requiring strict monitoring or specialized treatment, her life is not at risk, and is well enough to be discharge from the hospital to home (it implies that the maternal morbidity has resolved for the cases).

We plan to include all cases who meet the selection criteria during the study period, until we reach the estimated sample size of 109 obstetric patients admitted to the ICU. This is because there were 263 ICU admissions (pregnant and non-pregnant women) in 2012, 230 in 2013 and 274 in 2014 according to the Department of Epidemiology of this hospital⁷⁸; and, approximately 48% of the ICU admissions are referred from other healthcare facilities (as indicated by the Chief of the ICU). We expect that cases will be recruited during a period of twelve (12) months, though recruitment will continue for longer if necessary for the minimum sample sizes to be achieved. Controls will be selected by using a probability sampling method, specifically a systematic random sampling (without replacement) starting with 18 and with a value of $k = 131$ as the sampling interval.

Setting

This study is being undertaken in a tertiary hospital located in the capital city of Peru (where about one third of the Peruvian population live). This institution is the main national referral hospital for high risk maternal and neonatal patients throughout Peru, where there are over 22,000 deliveries yearly, which equates to approximately 1 delivery every 25 minutes.⁷⁹

Sample size

The sample size will comprise 218 participants (109 controls and 109 cases) which has been calculated by using the Sample Size Calculation for Unmatched Case-Control Studies of the software open Epi⁸⁰ with a confidence level of 95% and a power of 80% to detect a (18.8%) difference in the exposure of violence against women (rate) between cases and controls. There are not preceding studies assessing the prevalence of violence against women among obstetric patients with SAMM in the ICU. We estimated an IPV rate of 24.3% for controls and 43.1% for cases in accordance with previous research investigating the relationship between IPV and preeclampsia in Peruvian pregnant women at this maternity hospital.⁸¹

Recruitment Method

Participants will be invited to participate and recruited during their hospital stay once their acute medical condition (s) have been resolved (this will be after they were discharged from the ICU

for the case women), and before they are discharged from hospital to going home. Women in the control group will be invited to participate within one week of a case woman being interviewed. The researcher (interviewer), a Spanish speaking midwife, has been trained and has research experience working on violence against women studies and research ethics. The researcher will check with the hospital staff regarding eligibility (selection criteria, e.g. mental illness and others), prior to approaching and inviting potential participants to the study. She will also ensure that the potential participants understand the participant information statement and answer all their questions, and explain to the participants that they can refuse or withdraw their participation at any time without affecting their health care and rights.

Data Collection

Data collection commenced on 23rd October 2015 and is still ongoing. We expect to finish by the end of March 2018. Currently, we are collecting data from the medical records. Women who give consent will be interviewed once in private using a structured questionnaire (Appendix 1). We will also extract information from their medical records using a pretested form developed by the team members (Appendix 2).

Interview

The following information will be obtained during the face to face interview: socio-demographic characteristics (age, place of residence, educational level, marital status, occupation and type of health insurance) of the participant and her partner; behavioural factors (smoking, use of alcohol or drugs); medical (previous and current diseases) and obstetric characteristics (number of pregnancies, previous abortions, prenatal care visits, previous caesarean sections, and vaginal births; use of family planning methods; anaemia during pregnancy and use of iron supplements during pregnancy); and violence against women evaluation.

Violence against women will be assessed by using questions from a standardised instrument of the WHO.⁵⁰ These questions were validated, translated and adapted rigorously, since Peru was one of the countries selected in the WHO Multi-country study instrument.⁵⁰ They have been also used by other researchers for investigating violence against women in Peru, and an adapted version was applied in the Peruvian Demographic and Family Health Survey.⁶⁵

Violence against women evaluation will comprise emotional (including controlling behaviours), physical and sexual abuse exerted by intimate-partners and by non-intimate partners (relatives, friends or others) assessed 12 months before and during pregnancy. The participants will answer the frequency (once or twice or many) for each act of emotional, physical or sexual violence. Violence against women will be examined in an empathetic, supportive and non-judgmental manner, giving the participants the opportunity not to answer any questions that make them feel uncomfortable or to reschedule or terminate the interview at any time. The interview will only be conducted with the woman alone and in private. If the interview is interrupted, the interviewer will change the topic or may terminate the interview correspondingly. It is expected that the interview will take approximately 25 to 30 minutes. After the interview, information about free social support services for domestic violence (available at this maternity hospital) will be offered to every participant including a referral if they wish. There will be also debriefing sessions for

the well-being of the interviewer. Individual support/counselling can be arranged at the hospital for the interviewer or participant if it is needed.

Extracting data from medical records

We will extract data from the medical reports of the mothers and newborns (if applicable) related to SAMM, pregnancy outcome, fetal and neonatal characteristics and outcome.

SAMM data will include hospital admission date, clinical causes for hospitalisation and/or ICU admission, diagnoses after being discharged from the ICU and/or the hospital, number of hospital stay days and ICU stay days, type of delivery, additional procedures, weeks of pregnancy when SAMM occurs, organ failure (s), use of technologies (mechanical ventilation, transfusion, use of inotropic support and renal replacement therapies), main delays (in relation to the three delays model framework used to study maternal mortality⁸²), and pregnancy outcome (Appendix 2).

Fetal and neonatal data will include: birth weight; birth age; sex; Apgar score (at 1 and 5 minutes); outcome at birth; clinical cause (s) for Neonatal ICU (NICU); number of days at the NICU (if applicable) or at the hospital; use of technologies and/or antibiotics at the NICU; feeding type (breastfeeding, formula or both); discharge status; and diagnoses from the hospital and/or the NICU (Appendix 2).

Data entry and analysis

Data will be entered using SPSS V.24.0. Univariate analysis will be carried out to describe the characteristics of SAMM, social determinants, violence against women and pregnancy and neonatal outcomes. Quantitative variables will be displayed as the mean ± SD and/or median (interquartile rate) after verifying their normal or asymmetrical distribution. Difference of means analyses between variables will be performed using appropriate statistical tests (Student's t-test or Mann–Whitney U test or other similar). Qualitative variables will be displayed as frequencies.

We will apply a bivariate analysis to evaluate the association of violence against women (partner and non-partner) as an independent variable with SAMM; and we will also evaluate this association with partner violence only; and, with non-partner violence only.

We will fully assess violence against women as a risk factor by using a multivariate logistic regression modelling considering an Odds Ratio (OR) with 95% CI. Crude ORs will also be calculated. Statistical significance will be set at $p < 0.05$ for all analyses. We will identify effect modification for age, level of education, alcohol consumption and use of drugs by performing a stratified analysis of these variables that could potentially modify the effect of violence against women on SAMM. This will be assessed by the calculation of crude ORs within every level of each variable that is stratified. The final model will include the socio-demographic characteristics of the participants, other variables of interest (such as household income, partner's educational level, partner's occupation, etc.) according to the literature review, and modifiers (we will remove the least significant modifiers one at a time until only those with $p < 0.05$

remain). Those variables with p values of < 0.25 will be initially chosen to be included in the model,⁸³ and the Hosmer-Lemeshow's goodness-of-fit test will be used to assess model adequacy and stepwise multiple regression analysis performed to select and identify the predictive factors in the final model.⁸³

ETHICS AND DISSEMINATION

Ethical approval has been granted by the La Trobe University Human Ethics committee (HEC15-023), Melbourne, Australia and the Institutional Review Board of the tertiary healthcare hospital in Lima, Peru. Individual written informed consent will be obtained from participants prior to data collection. The present research follows the WHO and other ethical and safety recommendations for research on gender-based violence to ensure the safety of the participants and the interviewer.^{50 84-88}

It is planned that the findings of this case-control study will be presented at La Trobe University and national and/or international conferences, and it will be also published in a peer review journal. It is expected that these finding will inform policymakers, patients, and the public through these presentations.

PRESENTING AND REPORTING RESULTS

This prospective case-control study will examine for the first time the influence of violence against women on obstetric patients affected by severe acute maternal morbidity who require management in the ICU, and evaluate their pregnancy and neonatal outcomes. We will present major findings in tables and also describe results in narrative format outlining effect sizes and their parameters. The findings and further publications will be reported following the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) criteria,^{76 77} which is part of the Enhancing the quality and transparency of health research (EQUATOR) Network website.

DISCUSSION

The influence of violence against pregnant women on the incidence of or type of SAMM is not known and worthy of study. Although, the negative contribution of violence against women to maternal deaths was described in the 1997-1999 Confidential Enquiry into Maternal Death,⁶⁷ and many studies have reported negative and fatal repercussions of IPV on women's health including during all stages of pregnancy,⁵²⁻⁶² there is a paucity of studies assessing the relationship between violence against women and SAMM⁶³. Investigating women affected by SAMM could complement the review of maternal deaths^{15 22 29 36 73-75} to understand which underlying factors are influencing the sequence of events from a healthy pregnancy through minor complications to life threatening obstetric conditions and even death in childbearing women.^{26 89 90}

This case-control study will contribute to evidence about the potential negative consequences of violence against women of obstetric patients with SAMM in the ICU, who represent the most critically ill patients^{11 19 39} and have been shown to be an important component of the maternal morbidity spectrum requiring timely managed care.^{11-17 40-46} This may help to highlight that non-biological factors (violence against women), which are potentially modifiable, may be associated with SAMM and are important to address to reduce maternal morbidity-mortality in Peru and in

other low and middle-income countries. Acute or chronic exposure to violence adversely affects both the mothers and their babies and can be augmented by any risky health behaviors⁵⁷⁻⁶⁰ and through physiological (neural, neuroendocrine, and immune) mechanisms in response to this abuse.^{55 61} All of this may exacerbate pre-existing medical conditions and/or lead to diverse pregnancy complications.^{52 55 61 62} Thus, it would be important to know if violence against women is a risk factor for SAMM in the ICU, and to understand the complete picture of the global burden of maternal morbidity-mortality to improve mother-baby dyad health and women’s well-being.

This study may also help participants affected by violence to disclose abuse in a safe and supportive environment; and, provide an opportunity for those abused women to understand that it is possible to prevent violence and improve their and other women’s lives, since they will be informed and/or referred to the free social support services available for domestic violence provided by the Peruvian government.

We understand that the findings of this study should be interpreted cautiously and some limitations should be noted. Firstly, this research will be undertaken in a single centre. It will be important to carry out further multi-centre and multi-country studies. Other limitations may include recall, cultural and measurement bias which can underestimated or overestimate the exposure.^{50 91} This is because the assessment of violence against women is complex and challenging. Accordingly, this research follows the ethical and safety recommendations for research on violence against women;^{50 84-88} and uses standardized questions for the assessment of violence against women (WHO instrument) and a pretested questionnaire for the evaluation of other factors. Amendments to this protocol are not expected. However, if any are required, these amendments will be reported transparently.

Notwithstanding these limitations, we hope that this study will contribute to the global effort towards achieving SDGs by providing valuable information for a better understanding of SAMM and violence against women in Peru. This will make an important contribution to global knowledge of causes of maternal morbidity by providing evidence of the relationship between violence against women and SAMM, which is important for preventing and/or reducing maternal morbidity-mortality and improve maternal health. Therefore, we expect that this research will extend knowledge in an identified research gap, and may provide direction for further studies in obstetric women affected by SAMM in the ICU.

REFERENCES

1. United Nations. Transforming our world: the 2030 Agenda for Sustainable Development. Resolution adopted by the General Assembly on 25 September 2015. 2015. <https://sustainabledevelopment.un.org/post2015/transformingourworld> (accessed 6 May 2017).
2. World Health Organization. Trends in maternal mortality: 1990 to 2015. Estimates by WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division. Secondary Trends in maternal mortality: 1990 to 2015. Estimates by WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division. 2015. <http://www.who.int/classifications/icd/factsheet/en/> (accessed 15 Feb 2016).
3. Mantel GD, Buchmann E, Rees H, et al. Severe acute maternal morbidity: a pilot study of a definition for a near-miss. *Br J Obstet Gynaecol* 1998;105:985-90.
4. Geller SE, Cox SM, Callaghan WM, et al. Morbidity and mortality in pregnancy: laying the groundwork for safe motherhood. *Womens Health Issues* 2006;16:176-88.
5. Firoz T, Chou D, von Dadelszen P, et al. Measuring maternal health: focus on maternal morbidity. *Bull World Health Organ* 2013;91:794-6.
6. Ashford L. Hidden suffering: disabilities from pregnancy and childbirth in less developed countries. Secondary Hidden suffering: disabilities from pregnancy and childbirth in less developed countries. 2002. <http://www.prb.org/pdf/hiddensufferingeng.pdf> (accessed 23 Jul 2014).
7. Fottrell E, Kanhonou L, Goufodji S, et al. Risk of psychological distress following severe obstetric complications in Benin: the role of economics, physical health and spousal abuse. *Br J Psychiatry* 2010;196:18-25.
8. Pacagnella RC, Cecatti JG, Camargo RP, et al. Rationale for a long-term evaluation of the consequences of potentially life-threatening maternal conditions and maternal "near-miss" incidents using a multidimensional approach. *J Obstet Gynaecol Can* 2010;32:730-8.
9. Wilson RE, Salihu HM. The paradox of obstetric "near misses": converting maternal mortality into morbidity. *Int J Fertil Womens Med* 2007;52:121-7.
10. Storeng KT, Drabo S, Ganaba R, et al. Mortality after near-miss obstetric complications in Burkina Faso: medical, social and health-care factors. *Bull World Health Organ* 2012;90:418-25B.
11. Plaat F, Naik M. Critical care in pregnancy. *Crit Care* 2011;15:1014 doi: <http://dx.doi.org/10.1186/cc10479> [published Online First: 22 December 2013].
12. Zieleskiewicz L, Chantry A, Duclos G, et al. Intensive care and pregnancy: Epidemiology and general principles of management of obstetrics ICU patients during pregnancy. *Anaesth Crit Care Pain Med* 2016;35 (Suppl 1):S51-7 doi: 10.1016/j.accpm.2016.06.005 [published Online First: 5 July 2016].
13. Guntupalli KK, Hall N, Karnad DR, et al. Critical illness in pregnancy Part I: an approach to a pregnant patient in the ICU and common obstetric disorders. *Chest* 2015;148:1093-104.
14. Pollock W, Rose L, Dennis C. Pregnant and postpartum admissions to the intensive care unit: a systematic review. *Intensive Care Med* 2010;36:1465-74.
15. Baskett TF. Epidemiology of obstetric critical care. *Best Pract Res Clin Obstet Gynaecol* 2008;22:763-74. Complement to maternal deaths
16. Martin SR, Foley MR. Intensive care in obstetrics: an evidence-based review. *Am J Obstet Gynecol* 2006;195:673-89.
17. Germain S, Wyncoll D, Nelson-Piercy C. Management of the critically ill obstetric patient. *Curr Obstet Gynaecol* 2006;16:125-33.

18. Oud L. Epidemiology of Pregnancy-Associated ICU Utilization in Texas: 2001 - 2010. *J Clin Med Res* 2017;9:143-53 doi: 10.14740/jocmr2854w [published Online First: 17 January 2017]. ICUproxi of ICU

19. Senanayake H, Dias T, Jayawardena A. Maternal mortality and morbidity: Epidemiology of intensive care admissions in pregnancy. *Best Pract Res Clin Obstet Gynaecol* 2013;27:811-20. ICUproxi of ICU

20. Bouvier-Colle MH, Mohangoo AD, Gissler M, et al. What about the mothers? An analysis of maternal mortality and morbidity in perinatal health surveillance systems in Europe. *BJOG* 2012;119:880-9; discussion 90.

21. Reichenheim ME, Zylbersztajn F, Moraes CL, et al. Severe acute obstetric morbidity (near-miss): a review of the relative use of its diagnostic indicators. *Arch Gynecol Obstet* 2009;280:337-43.

22. Hirshberg A, Srinivas SK. Epidemiology of maternal morbidity and mortality. *Semin Perinatol* Published Online First: 17 August 2017. doi: 10.1053/j.semperi.2017.07.007.

23. Brace V, Penney G, Hall M. Quantifying severe maternal morbidity: a Scottish population study. *BJOG* 2004;111:481-4.

24. Lawton BA, Wilson LF, Dinsdale RA, et al. Audit of severe acute maternal morbidity describing reasons for transfer and potential preventability of admissions to ICU. *Aust N Z J Obstet Gynaecol* 2010;50:346-51.

25. Chantry AA, Deneux-Tharaux C, Bonnet MP, et al. Pregnancy-related ICU admissions in France: Trends in rate and severity, 2006-2009. *Crit Care Med* 2015;43:78-86.

26. Say L, Souza JP, Pattinson RC. Maternal near miss--towards a standard tool for monitoring quality of maternal health care. *Best Pract Res Clin Obstet Gynaecol* 2009;23:287-96.

27. Callaghan WM, Grobman WA, Kilpatrick SJ, et al. Facility-based identification of women with severe maternal morbidity: it is time to start. *Obstet Gynecol* 2014;123:978-81.

28. Donati S, Senatore S, Ronconi A, et al. Obstetric near-miss cases among women admitted to intensive care units in Italy. *Acta Obstet Gynecol Scand* 2012;91:452-57.

29. Tuncalp O, Hindin MJ, Souza JP, et al. The prevalence of maternal near miss: a systematic review. *BJOG* 2012;119:653-61. Complement/ diverse criteria

30. Lewis G. Reviewing maternal deaths to make pregnancy safer. *Best Pract Res Clin Obstet Gynaecol* 2008;22:447-63.

31. Souza JP, Cecatti JG, Parpinelli MA, et al. Appropriate criteria for identification of near-miss maternal morbidity in tertiary care facilities: a cross sectional study. *BMC Pregnancy Childbirth* 2007;7:20 doi: 10.1186/1471-2393-7-20 [published Online First: 11 September 2007]

32. van Roosmalen J, Zwart J. Severe acute maternal morbidity in high-income countries. *Best Pract Res Clin Obstet Gynaecol* 2009;23:297-304.

33. David E, Machungo F, Zanconato G, et al. Maternal near miss and maternal deaths in Mozambique: a cross-sectional, region-wide study of 635 consecutive cases assisted in health facilities of Maputo province. *BMC Pregnancy Childbirth* 2014;14:401 doi: 10.1186/s12884-014-0401-3 [published Online First: 10 December 2014].

34. You WB, Chandrasekaran S, Sullivan J, et al. Validation of a scoring system to identify women with near-miss maternal morbidity. *Am J Perinatol* 2013;30:21-4.

35. Kilpatrick SJ, Berg C, Bernstein P, et al. Standardized severe maternal morbidity review: rationale and process. *Obstet Gynecol* 2014;124:361-6.

36. Kilpatrick SK, Ecker JL. Severe maternal morbidity: screening and review. *Am J Obstet Gynecol* 2016;215:B17-22.

37. Geller SE, Rosenberg D, Cox S, et al. A scoring system identified near-miss maternal morbidity during pregnancy. *J Clin Epidemiol* 2004;57:716-20.

38. Main EK, Abreo A, McNulty J, et al. Measuring severe maternal morbidity: validation of potential measures. *Am J Obstet Gynecol* 2016;214:643.e1-10 doi: 10.1016/j.ajog.2015.11.004 [published Online First: 12 November 2015].

39. Zwart JJ, Dupuis JR, Richters A, et al. Obstetric intensive care unit admission: a 2-year nationwide population-based cohort study. *Intensive Care Med* 2010;36:256-63.

40. Shapiro JM. Critical care of the obstetric patient. *J Intensive Care Med* 2006;21:278-86.

41. Honiden S, Abdel-Razeq SS, Siegel MD. The management of the critically ill obstetric patient. *J Intensive Care Med* 2013;28:93-106.

42. Neligan PJ, Laffey JG. Clinical review: Special populations--critical illness and pregnancy. *Crit Care* 2011;15:227.

43. Soubra SH, Guntupalli KK. Critical illness in pregnancy: An overview. *Crit Care Med* 2005;33(Suppl 10):S248-55.

44. Trikha A, Singh P. The critically ill obstetric patient - Recent concepts. *Indian J Anaesth* 2010;54(5):421-7.
45. Aoyama K, Seaward PG, Lapinsky SE. Fetal outcome in the critically ill pregnant woman. *Crit Care* 2014;18(3):307 doi: [10.1186/cc13895](https://doi.org/10.1186/cc13895) [published Online First:27 May 2014].
46. Munnur U, Bandi V, Guntupalli KK. Management Principles of the Critically Ill Obstetric Patient. *Clin Chest Med* 2011;32:53-60.
47. World Health Organization. Global and regional estimates of violence against women: prevalence and health effects of intimate partner violence and non-partner sexual violence. 2013. http://apps.who.int/iris/bitstream/10665/85239/1/9789241564625_eng.pdf?ua=1 (accessed 13 Nov 2014).
48. Devries KM, Mak JY, Garcia-Moreno C, et al. Global health. The global prevalence of intimate partner violence against women. *Science* 2013;340:1527-8 doi:10.1126/science.12409373042 [published Online First: 28 June 2013].
49. World Health Organization. The Global status report on violence prevention 2014. 2014. http://www.who.int/violence_injury_prevention/violence/status_report/2014/en/ (accessed 28 May 2015).
50. Garcia-Moreno C, Jansen HAFM, Ellsberg M, et al. Prevalence of intimate partner violence: findings from the WHO multi-country study on women's health and domestic violence. *Lancet* 2006;368:1260-9.
51. Gazmararian JA, Lazorick S, Spitz AM, et al. Prevalence of violence against pregnant women. *JAMA* 1996;275:1915-20.
52. Han A, Stewart DE. Maternal and fetal outcomes of intimate partner violence associated with pregnancy in the Latin American and Caribbean region. *Int J Gynaecol Obstet* 2014;124:6-11.
53. Shamu S, Abrahams N, Temmerman M, et al. A systematic review of African studies on intimate partner violence against pregnant women: prevalence and risk factors. *PloS One* 2011;6(3):e17591 doi: 10.1371/journal.pone.0017591 [published Online First: 8 March 2011].
54. Stockl H, Devries K, Rotstein A, et al. The global prevalence of intimate partner homicide: a systematic review. *Lancet* 2013;382:859-65.
55. Black MC. Intimate Partner Violence and Adverse Health Consequences: Implications for Clinicians. *J Womens Health (Larchmt)* 2011;5:428-39.
56. Ayala Quintanilla BP, Taft A, McDonald S, et al. An examination of femicides in Peru between 2009 and 2014. *Int J Gynaecol Obstet* 2016;134:342-3 doi: 10.1016/j.ijgo.2016.03.020 [published Online First: 4 June 2016].
57. Sugg N. Intimate partner violence: prevalence, health consequences, and intervention. *Med Clin North Am* 2015;99(3):629-49.
58. Sarkar NN. The impact of intimate partner violence on women's reproductive health and pregnancy outcome. *J Obstet Gynaecol* 2008;28:266-71.
59. Chambliss LR. Intimate partner violence and its implication for pregnancy. *Clin Obstet Gynecol* 2008;51(2):385-97.
60. Chisholm CA, Bullock L, Ferguson JEJ, 2nd. Intimate partner violence and pregnancy: epidemiology and impact. *Am J Obstet Gynecol* 2017;217(2):141-4.
61. Alhusen JL, Ray E, Sharps P, et al. Intimate partner violence during pregnancy: maternal and neonatal outcomes. *J Womens Health (Larchmt)* 2015;24:100-6.
62. Hill A, Pallitto C, McCleary-Sills J, et al. A systematic review and meta-analysis of intimate partner violence during pregnancy and selected birth outcomes. *Int J Gynaecol Obstet* 2016; 133:269-76 doi:10.1016/j.ijgo.2015.10.023 [published Online First: 11 March 2013].
63. Ayala Quintanilla, B. P., Taft, A., McDonald, et al. Social determinants and maternal exposure to intimate partner violence of obstetric patients with severe maternal morbidity in the intensive care unit: a systematic review protocol *BMJ Open* 2016;6(11):e013270 doi:10.1136/bmjopen-2016-013270 [published Online First: 28 November 2016].
64. World Bank. Data 2017. <http://data.worldbank.org/about/country-and-lending-groups> (accessed 4 Jun 2017).
65. INSTITUTO NACIONAL DE ESTADISTICA E INFORMATICA. Encuesta Demografica y de Salud Familiar 2016 - Nacional y Regional 2016. 2017. https://www.inei.gob.pe/media/MenuRecursivo/publicaciones_digitales/Est/Lib1356/. (accessed 12 Jun 2017).
66. Lewis G. (2007). The Confidential Enquiry into Maternal and Child Health (CEMACH). Saving Mothers' Lives: reviewing maternal deaths to make motherhood safer - 2003-2005. The Seventh Report on Confidential Enquiries into Maternal Deaths in the United Kingdom. London: CEMACH. <http://www.publichealth.hscni.net/sites/default/files/Saving%20Mothers%27%20Lives%202003-05%20.pdf> (accessed 12 Dec 2017).

67. The Confidential Enquiries into Maternal Deaths in the United Kingdom. 2001. Why mothers die 1997–1999. The fifth report of the Confidential Enquiries into Maternal Deaths. <http://www.hqip.org.uk/national-programmes/a-z-of-clinical-outcome-review-programmes/cmace-reports/> (accessed 2 Aug 2014).

68. Knight M, Tuffnell DJ, Kenyon S, et al. Saving Lives, Improving Mothers' Care - Surveillance of maternal deaths in the UK 2011-13 and lessons learned to inform maternity care from the UK and Ireland Confidential Enquiries into Maternal Deaths and Morbidity 2009-13. Oxford: National Perinatal Epidemiology Unit, University of Oxford. 2015. <https://www.npeu.ox.ac.uk/> (accessed 15 Apr 2016).

69. Knight M., Kenyon S., Brocklehurst P., et al. Saving Lives, Improving Mothers' Care - Lessons learned to inform future maternity care from the UK and Ireland Confidential Enquiries into Maternal Deaths and Morbidity 2009 –12. Oxford: National Perinatal Epidemiology Unit, University of Oxford. 2014. <https://www.npeu.ox.ac.uk/downloads/files/mbrace-uk/reports/Saving%20Lives%20Improving%20Mothers%20Care%20report%202014%20Full.pdf> (accessed 27 Apr 2016).

70. United Nation, Every Woman Every Child. EVERY NEWBORN. An Action Plan To End Preventable Deaths. Secondary EVERY NEWBORN. An Action Plan To End Preventable Deaths 2014. http://apps.who.int/iris/bitstream/10665/127938/1/9789241507448_eng.pdf?ua=1 (accessed 14 Mar 2016).

71. Farquhar C, Sadler L, Masson V, et al. Beyond the numbers: classifying contributory factors and potentially avoidable maternal deaths in New Zealand, 2006–2009. *Am J Obstet Gynecol* 2011;205:331.e1-31e-8 doi:10.1016/j.ajog.2011.07.044 [published Online First: 30 July 2011].

72. Murphy NJ, Quinlan JD. Trauma in pregnancy: assessment, management, and prevention. *Am Fam Physician* 2014;90(10):717-22.

73. Knight M, Lewis G, Acosta CD, et al. Maternal near-miss case reviews: the UK approach. *BJOG* 2014;121 Suppl 4:112-6.

74. Ananth CV, Smulian JC. Chapter 1 Epidemiology of Critical Illness in Pregnancy. In Belfort MA, Saade G, Foley MR, et al., eds. *Critical Care Obstetrics Fifth Edition* 2011:1-10.

75. Knight M, Acosta C, Brocklehurst P, et al. Beyond maternal death: improving the quality of maternal care through national studies of 'near-miss' maternal morbidity. *Programme Grants Appl Res* 2016;4(9).

76. von Elm E, Altman DG, Egger M, et al. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *The Lancet* 2007;370(9596):1453-57.

77. von Elm E, Altman DG, Egger M, et al. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies. *Int J Surg* 2014;12:1495-9.

78. Instituto Nacional Materno Perinatal. Boletín Estadístico 2014. 2014. <http://www.inmp.gob.pe/institucional/sala-situacional/1421334856> (accessed 28 Jan 2015).

79. Instituto Nacional Materno Perinatal. Boletín Estadístico 2015 - 2016. 2016. <http://www.inmp.gob.pe/institucional/boletines-estadisticos/1422371837> (accessed 28 May 2017).

80. Open Epi. Sample Size Calculation for Unmatched Case-Control Studies. Version 3.03.17. 2014. <http://web1.sph.emory.edu/cdckms/sample%20size%20%20grps%20case%20control.html> (accessed 2 Jul 2015).

81. Sanchez SE, Qiu C, Perales MT, et al. Intimate partner violence (IPV) and preeclampsia among Peruvian women. *Eur J Obstet Gynecol Reprod Biol* 2008;137:50-5 doi: 10.1016/j.ejogrb.2007.05.013 [published Online First: 27 Jun 2007].

82. Thaddeus S, Maine D. Too far to walk: Maternal mortality in context. *Soc Sci Med* 1994;38:1091-110.

83. Hosmer DV, Lemeshow S. *Applied Logistic Regression*. Second Edition ed. USA: A Wiley-Interscience Publication. 2000:375.

84. Jewkes R, Dartnall E, Sikweyiya Y. *Ethical and Safety Recommendations for Research on the Perpetration of Sexual Violence*. Sexual Violence Research Initiative Pretoria, South Africa: Medical Research Council. 2012. <http://www.svri.org/EthicalRecommendations.pdf> (accessed 28 May 2015).

85. Ellsberg M, Heise L. *Researching Violence Against Women: A Practical Guide for Researchers and Activists* Washington DC, United States: World Health Organizationb PATH. 2005. http://whqlibdoc.who.int/publications/2005/9241546476_eng.pdf?ua=1 (accessed 26 May 2015).

86. World Health Organization. *Putting Women First: Ethical and Safety Recommendations for Research on Domestic Violence Against Women*. 2001. <http://www.who.int/gender/violence/womenfirstseng.pdf> (accessed 27 May 2015).

87. Jansen HAFM, Watts C, Ellsberg M, et al. Interviewer Training in the WHO Multi-Country Study on Women's Health and Domestic Violence. 2004. http://www.who.int/gender/documents/Interviewer_training.pdf (accessed 27 May 2015).
88. Garcia-Moreno C, Jansen HAFM, Ellsberg M, et al. WHO Multi-country Study on Women's Health and Domestic Violence Against Women. Initial results on prevalence, health outcomes and women's responses. 2005. <http://www.who.int/reproductivehealth/publications/violence/24159358X/en/> (accessed 2 Jul 2014).
89. Karolinski A, Mercer R, Micone P, et al. The epidemiology of life-threatening complications associated with reproductive process in public hospitals in Argentina. *BJOG* 2013;120:1685-95.
90. Filippi V, Chou D, Ronsmans C, et al. Levels and Causes of Maternal Mortality and Morbidity. In: Black RE, Laxminarayan R, Temmerman M, et al., eds. 2016. Reproductive, Maternal, Newborn, and Child Health. Disease Control Priorities, third edition, volume 2. Washington, DC: World Bank. doi:10.1596/978-1-4648-0348-2. License: Creative Commons Attribution CC BY 3.0 IGO.
91. Pandis, N. Case-control studies: part 2. *Am J Orthod Dentofacial Orthop* 2014;146:402-3.

Authors' contributions

BPAQ, AT, SMC and WP conceived and designed the study protocol. This study is part of the first's author PhD thesis. BPAQ drafted the manuscript and all authors edited following versions of the draft. BA, AT, SMC, and WP revised critically the methodological and clinical content of the protocol to make contributions. All authors reviewed and approved the final manuscript.

Funding

This study is part of a doctoral study at La Trobe University was supported by the Peruvian Government through PRONABEC (National Program of Scholarship and Educational Loan) and La Trobe University. No funding bodies will have any role in study design, collecting data, analysing data, interpreting findings, and writing, reviewing or deciding to publish the manuscript.

Competing interest statement

The authors declare that they have no competing interest.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60



Appendix 1

Judith Lumley Centre for mother, infant and family health research

College of Science, Health and Engineering

La Trobe University

Maternal health research in a tertiary health care facility in Lima, Peru

Structured questionnaire for face to face interview

Code number: _____ Interview Date: ____/____/____

D D M M Y Y Y Y

Thank you for agreeing to participate in this study.

You are free to not answer any questions. If any of the questions are unclear, or you need more information the interviewer will be happy to provide you with the information you need.

Before I start, do you have any questions?

SECTION A. GENERAL INFORMATION

WOMAN INFORMATION

First I would like to ask you some questions about your background.

- A1.How old are you? _____ (Years)
- A2. Place of residence
1. Lima Norte

(Ancón, Carabayllo, Comas, Independencia, Los Olivos, Puente Piedra, San Juan de Lurigancho, San Martín de Porres, Santa Rosa)
2. Lima Este

(Ate, Cieneguilla, Chaclacayo, El Agustino, Lurigancho, San Luis, Santa Anita)
3. Lima Sur

(Chorrillos, Lurín, Pachacamac, Pucusana, Punta Hermosa, Punta Negra, San Bartolo, San Juan de Miraflores, Santa María del Mar, Villa el Salvador, Villa María del Triunfo)
4. Residential Lima

(Barranco, Jesús María, La Molina, Lince, Magdalena, Miraflores, Pueblo Libre, San Borja, San Isidro, San Miguel, Santiago de Surco, Surquillo)
5. Callao

(Bellavista, Callao District, Carmen de la Legua Reynoso, La Perla, La Punta, Ventanilla District)
6. Central Lima

(Breña, La Victoria, Downtown Lima, Rimac)
- A3. What is your level of education? Would you say?
1. Primary level

2. Secondary level

3. Technical studies

4. University level

5. Other (Specify) _____

9 Do not know / Not Sure
- A4. What is your current marital status?
1. Single

2. Married

3. Cohabitant

4. Separated/Divorced

5. Widowed

9. Do not know / Not Sure

A5. What is your occupation?

1. Unemployed
2. Student
3. Employed
4. Self-employed
5. Housewife
6. Other (specify) _____
7. Do not know / Not Sure

A6. How hard is it for you (and your family) to pay for the very basics like food?

- 1 Very hard
- 2 Hard
- 3 Somewhat hard
- 4 Not very hard
- 9 Do not know / Not Sure

A7. How hard is it for you (and your family) to pay for medical care?

- 1 Very Hard
- 2 Hard
- 3 Somewhat hard
- 4 Not very hard
- 9 Do not know / Not Sure

A8. How much is the estimated monthly income of your nuclear family?**A9. How many household members are dependent on this monthly income (specify)?****A10. Are you a SIS beneficiary?**

- 1 No
- 2 Yes
- 9 Do not know / Declined to answer

A11. Can you tell me your SIS category?

- 1 Low risk
- 2 Medium risk
- 3 High risk
- 9 Do not know / Declined to answer

A12. If you do not have SIS, which health insurance do you have?

- 1 Private company
- 2 Other (specify) _____
- 3 Do not have any health insurance
- 9 Do not know / Declined to answer

A13. What about smoking, do you smoke during this pregnancy?

- 1 No → **Skip to A15**
- 2 Yes → **Continue to A14**
- 9 Do not know / Declined to answer

A14. If yes, would you say?

1. Daily
2. Occasionally
3. Not at all
- 9 Do not know / Declined to answer

A15. What about alcohol use, do you drink alcohol during this pregnancy?

- 1 No → **Skip to A17**
- 2 Yes → **Continue to A16**
- 9 Do not know / Declined to answer

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- 13
- 14
- 15
- 16
- 17
- 18
- 19
- 20
- 21
- 22
- 23
- 24
- 25
- 26
- 27
- 28
- 29
- 30
- 31
- 32
- 33
- 34
- 35
- 36
- 37
- 38
- 39
- 40
- 41
- 42
- 43
- 44
- 45
- 46
- 47
- 48
- 49
- 50
- 51
- 52
- 53
- 54
- 55
- 56
- 57
- 58
- 59
- 60
- A16. If yes, would you say?
1. Every day or nearly every day
2. Once or twice a week
3. 1 – 3 times a month
4. Occasionally, less than once a month
5. Never
9. Do not know / Declined to answer
- A17. What about drug use, do you use any illegal drugs during this pregnancy?
1. No
2. Yes
9. Do not know / Declined to answer

PARTNER INFORMATION

- 15
- 16
- 17
- 18
- 19
- 20
- 21
- 22
- 23
- 24
- 25
- 26
- 27
- 28
- 29
- 30
- 31
- 32
- 33
- 34
- 35
- 36
- 37
- 38
- 39
- 40
- 41
- 42
- 43
- 44
- 45
- 46
- 47
- 48
- 49
- 50
- 51
- 52
- 53
- 54
- 55
- 56
- 57
- 58
- 59
- 60
- A18. What is the age of your partner _____ (Years)
- A19. What is the level of education of your husband/partner?
1. Primary level
2. Secondary level
3. Technical studies
4. University level
5. Other (Specify) _____
9. Do not know / Declined to answer
- A20. What is the occupation of your husband/partner?
1. Unemployed
2. Student
3. Employed
4. Self-employed
5. Other (specify) _____
9. Do not know / Declined to answer
- A21. What about alcohol use, does/did your husband/partner drink alcohol during your pregnancy?
1. No → Skip to A25
2. Yes → Continue to A22
- A22. If yes, would you say?
1. Every day or nearly every day
2. Once or twice a week
3. 1 – 3 times a month
4. Occasionally, less than once a month
5. Never
9. Do not know / Declined to answer
- A23. Does/did your husband/partner get drunk during your pregnancy?
1. No → Skip to A25
2. Yes → Continue to A24
9. Do not know/Declined to answer
- A24. If yes, would you say?
1. Most days
2. Weekly
3. Once a month
4. Less than once a month
5. Never
9. Do not know / Declined to answer
- A25. What about drug use, does/did your partner use any illegal drugs during your pregnancy?
1. No
2. Yes
9. Do not know / Declined to answer

B. PREGNANCY AND PRENATAL CHARACTERISTICS

Now I would like to ask you some questions about your pregnancy history

B1. How many weeks of pregnancy were you at your first prenatal visit? ____ (Weeks)

B2. Did you receive prenatal care during this pregnancy?

1. No → **Skip to B4**
2. Yes → **Continue to B3**
- 9 Do not know / Not sure

B3. How many antenatal care visits did you receive during pregnancy? _____ times [999 = Do not know]

B4. How much was your weight before you became pregnant this time? _____ Kilograms [999 = Do not know]

B5. How much weight did you gain since becoming pregnant? _____ Kilograms [999 = Do not know]

B6. What is your height? _____ Centimeters [999 = Do not know]

B7. GRAVIDITY = Number of pregnancies (including this pregnancy) ____

B8. PARITY = Number of live births >22 weeks (including this pregnancy) ____

B9. Number of vaginal deliveries (including this pregnancy) ____

B10. Number of cesarean sections (including this pregnancy) ____

B11. Number of total previous abortions ____

B12. Miscarriages ____

B13. Unsafe abortions ____

B14. Therapeutic abortions ____

B15. Number of Molas ____

B16. Number of ectopic pregnancies ____

B17. Number of alive children ____

B18. Number of stillborns ____

B19. Number of dead children ____

B20. Did you plan to become pregnant this time?

- 1 No
- 2 Yes
- 9 Do not know / Declined to answer

B21. Are you aware of family planning methods to avoid getting pregnant?

1. No → **Skip to B24**
2. Yes → **Continue to B22**
- 9 Do not know / Declined to answer

B22. Which family planning methods do you use to avoid getting pregnant (if it is more than one, only consider the main method)?

- 1 Pills/Tablets
- 2 Injectable
- 3 Diaphragm/foam/jelly
- 4 IUD
- 5 Condoms
- 6 Natural Method (calendar/mucus method)
- 7 Withdrawal
- 8 Other (specify) _____

B23. How often do you use family planning methods?

1. Often
2. Rarely
3. Never (because of)
 - 3.1. Because of ignorance about them
 - 3.2. Because of logistic/administrative issues
 - 3.3. Because of unwillingness to use them
 - 3.4. Because of partner unwillingness to use them
 - 3.5. Because of the cost
 - 3.6. Other (specify) _____
9. Do not know / Declined to answer

B24. Did you receive vaccination against tetanus in the last 10 years?

- 1. No
- 2. Yes
- 9 Do not know / Not sure

B25. Did a doctor ever tell you that you have anemia during this pregnancy?

- 1. No → **Skip to B30**
- 2. Yes → **Continue to B26**
- 9 Do not know / Not sure

B26. Which trimester, did a doctor tell you that you have anemia during this pregnancy?

- 1 I Trimester
- 2 II Trimester
- 3 III Trimester
- 9 Do not know / Not sure

B27. Did you take any ferrous iron supplement during this pregnancy?

- 1. No → **Skip to B30**
- 2. Yes → **Continue to B28**
- 9 Do not know / Not sure

B28. If yes, how many pills/tablets per day? _____ pills per day [99: Do not know / not sure]

B29. And, how many months did you drink these pills/tablets? _____ months [99: Do not know / not sure]

B30. How many times did you visit the emergency room during this pregnancy? _____ time/times [99: Do not know / not sure]

B31. Has a doctor ever told you that you have or do you have?

Diseases	You have had			You have		
	No	Yes	Do not know / not sure	No	Yes	Do not know / not sure
a Chronic hypertension	1	2	99	1	2	99
b Anemia	1	2	99	1	2	99
c Tuberculosis	1	2	99	1	2	99
d Diabetes Mellitus	1	2	99	1	2	99
e Heart disease	1	2	99	1	2	99
f Thyroid disease	1	2	99	1	2	99
g HIV infection	1	2	99	1	2	99
h Other (specify) _____	1	2	99	1	2	99

B32. Did you ever have one or more of the following condition (s) during previous pregnancy (es)?

Clinical conditions	NO	YES	Do not know / not sure
1 Hypertensive related disease	1	2	99
a Severe Preeclampsia	1	2	99
b Eclampsia	1	2	99
c HELLP Syndrome	1	2	99
2 Antepartum hemorrhage in the second trimester of pregnancy because of (specify):	1	2	99
a Placenta previa	1	2	99
b Uterine rupture	1	2	99
c Abruptio placentae			
d Other (specify)	1	2	99
3 Antepartum hemorrhage in the third trimester of pregnancy because of (specify):	1	2	99
a Placenta previa	1	2	99
b Uterine rupture	1	2	99
c Abruptio placentae	1	2	99

d Other (specify)	1	2	99
4 Postpartum hemorrhage complication	1	2	99
a Uterine atony	1	2	99
b Cervical laceration/tear	1	2	99
c Retained products/fetal membranes	1	2	99
d Ruptured uterus	1	2	99
e Accreta placenta	1	2	99
f Other (specify)	1	2	99
5 Sepsis (obstetric origin)	1	2	99
a Chorioamnionitis	1	2	99
b Surgical wound infection	1	2	99
c Endometritis	1	2	99
d Other (specify)	1	2	99
6 Sepsis (non-obstetric origin)	1	2	99
a Urine infection	1	2	99
b Other (specify)	1	2	99
7 Sepsis (pulmonary origin)	1	2	99
a Pneumonia	1	2	99
b Viral cause	1	2	99
b.1 H1N1	1	2	99
b.2 Varicella	1	2	99
b.3 Other (specify)	1	2	99
c Other (specify)	1	2	99
8 Clinical condition	1	2	99
a Oligohydramnios	1	2	99
b Intrauterine growth restriction	1	2	99
c Fetal macrosomy	1	2	99
d Other (specify)	1	2	99
9 Other associated pathologies			
a Premature rupture of fetal membranes	1	2	99
b Disseminated intravascular coagulation (DIC)	1	2	99
c Maternal pulmonary edema	1	2	99
d Amniotic fluid embolism	1	2	99
e Retroplacental clot	1	2	99
f Septic shock.	1	2	99
g Hypovolemic Shock	1	2	99
h Cervical cancer	1	2	99
i Other (specify)	1	2	99

C. ASSESSMENT OF VAW (IPV AND NON-IPV)

When two people marry or live together, they usually share both good and bad moments. I would now like to ask you some questions about your current and past relationships and how your husband / partner treats (treated) you. If anyone interrupts us I will change the topic of conversation. I would again like to assure you that your answers will be kept secret, and that you do not have to answer any questions that you do not want to. May I continue?

Assessing IPV			BEFORE PREGNANCY						DURING PREGNANCY				
			(In the past 12 months before pregnancy)										
I am going to ask you about some situations that are true for many women. Would you say it is generally true that he:	(A) (If YES continue with B. If NO, ask during pregnancy and if NO skip to next item)		(B) Has this happened <u>in the past 12 months before this pregnancy?</u> (If YES ask C, if NO ask D)		(C) <u>In the past 12 months before this pregnancy</u> , would you say that this has happened once, a few times or many times? (after answering C, go to D)			(D) Has this happened <u>during this pregnancy?</u> (If YES ask E)		(E) <u>During Pregnancy</u> , would you say that this has happened once, a few times, or many times?			
	YES	NO	YES	NO	One	Few	Many (>5 times)	YES	NO	One	Few	Many (>5 times)	
	C1. Tries to keep you from seeing your friends?	1	2	1	2	1	2	3	1	2	1	2	3
	C2. Tries to restrict contact with your family of birth?	1	2	1	2	1	2	3	1	2	1	2	3
	C3. Insists on knowing where you are at all times?	1	2	1	2	1	2	3	1	2	1	2	3
	C4. Ignores you and treats you indifferently?	1	2	1	2	1	2	3	1	2	1	2	3
	C5. Gets angry if you speak with another man?	1	2	1	2	1	2	3	1	2	1	2	3
	C6. Is often suspicious that you are unfaithful?	1	2	1	2	1	2	3	1	2	1	2	3
	C7. Expects you to ask his permission before seeking health care for yourself?	1	2	1	2	1	2	3	1	2	1	2	3

The next questions are about things that happen to many women, and that your current partner, or any other partner may have done to you.

Assessing IPV			BEFORE PREGNANCY						DURING PREGNANCY				
			(In the past 12 months before pregnancy)										
Has your <u>current</u> husband/partner or <u>any</u> other <u>partner</u> ever	(A)		(B)		(C)			(D)		(E)			
	(If YES continue with B. If NO, ask during pregnancy and if NO skip to next item)		Has this happened in the <u>past 12 months before this pregnancy?</u> (If YES ask C, if NO ask D)		In the past 12 months before <u>this pregnancy</u> , would you say that this has happened once, a few times or many times? (after answering C, go to D)			Has this happened <u>during this pregnancy?</u> (If YES ask E)		During Pregnancy would you say that this has happened once, a few times, or many times?			
	YES	NO	YES	NO	One	Few	Many (>5 times)	YES	NO	One	Few	Many (>5 times)	
C8. Insulted you or made you feel bad about yourself?	1	2	1	2	1	2	3	1	2	1	2	3	
C9. Belittled or humiliated you in front of other people?	1	2	1	2	1	2	3	1	2	1	2	3	
C10. Done things to scare or intimidate you on purpose (e.g., by the way he looked at you, by yelling and smashing things)?	1	2	1	2	1	2	3	1	2	1	2	3	
C11. Threatened to hurt you or someone you care about	1	2	1	2	1	2	3	1	2	1	2	3	

Assessing IPV			BEFORE PREGNANCY						DURING PREGNANCY				
			(In the past 12 months before pregnancy)										
Has your <u>current</u> husband/partner or <u>any</u> other <u>partner</u> ever	(A)		(B)		(C)			(D)		(E)			
	(If YES continue with B. If NO, ask during pregnancy and if NO skip to next item)		Has this happened in the past 12 months before this pregnancy? (If YES ask C, if NO ask D)		In the past 12 months before this pregnancy, would you say that this has happened once, a few times or many times? (after answering C, go to D)			Has this happened during this pregnancy? (If YES ask E)		During Pregnancy, would you say that this has happened once, a few times, or many times?			
	YES	NO	YES	NO	One	Few	Many (>5 times)	YES	NO	One	Few	Many (>5 times)	
	C12. Slapped you or thrown something at you that could hurt you?	1	2	1	2	1	2	3	1	2	1	2	3
	C13. Pushed you or shoved you or pulled your hair?	1	2	1	2	1	2	3	1	2	1	2	3
	C14. Hit you with his fist or with something else that could hurt you?	1	2	1	2	1	2	3	1	2	1	2	3
	C15. Kicked you, dragged you or beat you up?	1	2	1	2	1	2	3	1	2	1	2	3
	C16. Choked or burnt you on purpose?	1	2	1	2	1	2	3	1	2	1	2	3
C17. Threatened to use or actually used a gun, knife or other weapon against you?	1	2	1	2	1	2	3	1	2	1	2	3	

Assessing IPV			BEFORE PREGNANCY					DURING PREGNANCY				
			(In the past 12 months before pregnancy)									
	(A)		(B)		(C)			(D)		(E)		
Has your <u>current</u> husband/partner or <u>any</u> other <u>partner</u> ever	(If YES continue with B. If NO ask during pregnancy, and if NO skip to next item)		Has this happened <u>in the past 12 months before this pregnancy?</u> (If YES ask C, if NO ask D)		<u>In the past 12 months before this pregnancy</u> , would you say that this has happened once, a few times or many times? (after answering C, go to D)			Has this happened <u>during this pregnancy?</u> (If YES ask E)		<u>During Pregnancy</u> , would you say that this has happened once, a few times, or many times?		
	YES	NO	YES	NO	One	Few	Many (>5 times)	YES	NO	One	Few	Many (>5 times)
C18. Did your <u>current</u> husband/partner or <u>any</u> other <u>partner</u> ever physically force you to have sexual intercourse when you did not want to?	1	2	1	2	1	2	3	1	2	1	2	3
C19. Did you ever have sexual intercourse you did not want to because you were afraid of what your partner or any other partner might do?	1	2	1	2	1	2	3	1	2	1	2	3
C20. Did your partner or any other partner ever force you to do something sexual that you found degrading or humiliating?	1	2	1	2	1	2	3	1	2	1	2	3

NON-IPV

In their lives, may women experience different forms of violence from relatives, other people that they know, and/or from strangers. If you don't mind. I would like to briefly ask you about some of these situations. If anyone interrupts us I will change the topic of conversation. Everything that you say will be kept private. May I continue?

Assessing Non-IPV	BEFORE PREGNANCY								DURING PREGNANCY							
	(In the past 12 months before pregnancy)															
	(A)		(B)		(C)				(D)							
Since the age of 15 years, has anyone (other than your partner/husband):	(If YES continue with B. If NO, ask during pregnancy and if NO skip to next item)		Has this happened in the past 12 months before this pregnancy? (If YES ask C, if NO ask D)		In the past 12 months before this pregnancy, would you say that this has happened once, a few times or many times? (after answering C, go to D) (in total from all the persons she mentioned)				Has this happened during this pregnancy? (If YES ask Who was/were) And would you say that this has happened once, a few times, or many times? (in total from all the persons she mentioned) (choose "one", "few" or "many" considering in total from all the persons she mentioned)							
	YES	NO	YES	Who did this to you? (multiple responses)	No	One	Few	Many (>5 times)	YES	Who did this to you? (multiple responses)	No	One	Few	Many (>5 times)		
C21. Insulted you or made you feel bad about yourself?	1	2	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3		
C22. Belittled or humiliated you in front of other people?	1	2	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3		
C23. Done things to scare or intimidate you on purpose (e.g., by the way he looked at you, by yelling and smashing things)?	1	2	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3		
C24. Threatened to hurt you or someone you care about?	1	2	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3		

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Continue with the following questions.....

Assessing Non-IPV			BEFORE PREGNANCY						DURING PREGNANCY					
			(In the past 12 months before pregnancy)											
	(A)		(B)			(C)			(D)					
Since the age of 15 years, has anyone (other than your partner/husband):	(If YES continue with B. If NO, ask during pregnancy and if NO skip to next item)		Has this happened in the past 12 months before this pregnancy? (If YES ask C, if NO ask D)			In the past 12 months before this pregnancy, would you say that this has happened once, a few times or many times? (after answering C, go to D) (in total from all the persons she mentioned)			Has this happened during this pregnancy? (If YES ask Who was/were) And would you say that this has happened once, a few times, or many times? (in total from all the persons she mentioned) (choose "one", "few" or many" considering in total from all the persons she mentioned)					
	YES	NO	YES	Who did this to you? (multiple responses)	No	One	Few	Many (>5 times)	YES	Who did this to you? (multiple responses)	No	One	Few	Many (>5 times)
C25. Ever beaten you or physically mistreated you in any way ?	1	2	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3
C26. ¿forced you to have sex or to perform a sexual act when did you not want or to do something sexual that you found degrading or humiliating?	1	2	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3	1	B Father C Mother D Father in law E Mother in law F Other family member G Friend of family H Neighbor I Someone at work J Stranger K Other (specify)	2	1	2	3

C27. Have you ever been punched or kicked in the abdomen by anyone including your (ex or current) partner or other person(s) whilst you were pregnant?

1. No

2. Yes

C28 When (indicate year and which pregnancy) Year.....Which pregnancy.....

9. Don't know / Decline to answer

C29. Have any health care professionals asked you if you were affected by IPV or non-partner violence?

1 No

2 Yes

9 Do not know / Decline to answer

Continue with the questions C30, C31 and C32 for those participants who were affected by harm acts

Go to question C32 (Skip questions C29 and C30) for those participants who were NOT affected by harm acts

C30. Have you sought help to prevent or stop gender-based violence?

- 1 No
- 2 Yes
- 9 Do not know / Decline to answer

C31. Can you mention what type of help?

- 1 Family member
- 2 Friend
- 3 Community Social Services from the government
- 4 Police
- 5 Other (specify).....
- 9 Do not know / Decline to answer

Ask the following question to each participant

C32. Is there anything else do you want to tell me?
(Write down the exact words expressed by the participant)

Now give the information about free social support services available for domestic violence at this Institution and which are free of cost and are provided by the Peruvian government.

Thank you for your participation!!!!



- D6** Gestational age at first antenatal visit _____ weeks [999 = Not recorded]
- D7.** Number of antenatal visits _____ [999 = Not recorded]
- D8** Pre-pregnancy weight (weight before the participant became pregnant this time) _____ Kilograms [999 = Not recorded]
- D9** Pregnancy weight before delivery _____ Kilograms [999 = Not recorded]
- D10.** Weight gain during pregnant _____ Kilograms [999 = Not recorded]
- D11** Height _____ Centimeters [999 = Not recorded]
- D12.** Date of admission at this hospital ____ / ____ / ____
D D / M M / Y Y Y Y
- D13.** Indicate the diagnosis of the patient when she was hospitalized at this hospital:
1. _____
 2. _____
 3. _____
 4. _____
 5. _____
- D14** Socioeconomic level according to Social Services Department of this hospital:
1. Lower risk
 2. Medium risk
 3. High risk
 4. No category
- D15.** Was the participant admitted at the Intensive Care Unit?
1. No → **Skip to D26**
 2. Yes → **Continue to D16**
- D16.** Date of admission at the Intensive Care Unit ____ / ____ / ____ Time _____ (hour)
D D / M M / Y Y Y Y
- D17.** Indicate the diagnosis (ses) of the participant when she was admitted at the Intensive Care Unit:
1. _____
 2. _____
 3. _____
 4. _____
 5. _____
- D18.** Weeks of pregnancy at the moment of the event (s) (SAMM) which cause(s) her admission at the Intensive Care Unit:
_____ weeks
- D19.** Moment of such event (SAMM) in relation to the termination of pregnancy:
1. Before
 2. During
 3. After
- D20.** Did the woman received assistance with ventilation?
1. CPAP
 2. Non-invasive ventilation (e.g. BiPAP)
 3. Invasive mechanical ventilation
 4. None of the above
- D21.** Which management did the woman receive in the ICU (multiple responses)?
1. Inotrope or vasopressor therapy
 2. Renal replacement therapy (dialysis)
 3. Central venous access
 4. None of the above
- D22.** What was the severity of illness score on admission? _____ Score (APACHE)
- D23.** Date of discharge of the Intensive Care Unit: ____ / ____ / ____
D D / M M / Y Y Y Y
- D24.** Indicate the number of days in the Intensive Care Unit: _____ days

D25. Indicate the diagnosis (ses) of the patient when she was discharged from the Intensive Care Unit:

- 1. _____
- 2. _____
- 3. _____
- 4. _____
- 5. _____
- 6. _____

D26. Did the participant receive blood transfusion during her hospital stay?

- 1. No
- 2. Yes a. Indicate the numbers of red blood cell transfusion unit _____

D27. Did the participant receive other blood product transfusions during her hospital stay?

- 1. No → Skip to D29
- 2. Yes → Continue to D28

D28. What were these other transfusions (multiple responses)?

- 1. Plasma
- 2. Platelet
- 3. Cryoprecipitate
- 4. Other (specify) _____

D29. Date of discharge of this hospital ____ / ____ / ____ D D / M M / Y Y Y Y

D30. Diagnosis (ses) of the patient at discharge of this hospital:

- 1 _____
- 2 _____
- 3 _____
- 4 _____
- 5 _____
- 6 _____

D31. Indicate the number of hospital stay days _____ days

About clinical conditions during this pregnancy

D32. Clinical conditions during this pregnancy (multiple responses)

Clinical conditions	NO	YES	NOT RECORDED
1 Hypertensive related disease	1	2	99
a Severe Preeclampsia	1	2	99
Magnesium sulfate treatment	1	2	99
b Eclampsia	1	2	99
Magnesium sulfate treatment	1	2	99
c HELLP Syndrome	1	2	99
2 Antepartum hemorrhage in the second trimester of pregnancy because of (specify):	1	2	99
a Placenta previa	1	2	99
b Uterine rupture	1	2	99
c Abruptio placentae	1	2	99
d Other (specify)	1	2	99
3 Antepartum hemorrhage in the third trimester of pregnancy because of (specify):	1	2	99
a Placenta previa	1	2	99
b Uterine rupture	1	2	99
c Abruptio placentae	1	2	99
d Other (specify)	1	2	99
4 Postpartum hemorrhage complication	1	2	99
a Uterine atony	1	2	99
b Cervical laceration/tear	1	2	99
c Retained products/fetal membranes	1	2	99

d	Ruptured uterus	1	2	99
e	Accreta/increta/percreta placenta	1	2	99
f	Other (specify)	1	2	99
5	Miscarriage complication	1	2	99
a	Uterine perforation	1	2	99
b	Cervical laceration/tear	1	2	99
c	Infection	1	2	99
d	Other (specify)	1	2	99
6	Ectopic pregnancy	1	2	99
7	Sepsis (obstetric origin)	1	2	99
a	Chorioamnionitis	1	2	99
b	Surgical wound infection	1	2	99
c	Endometritis	1	2	99
d	Other (specify)	1	2	99
8	Sepsis (non-obstetric origin)	1	2	99
a	Urine infection	1	2	99
b	Other (specify)	1	2	99
9	Sepsis (pulmonary origin)	1	2	99
a	Pneumonia	1	2	99
b	Viral cause	1	2	99
b.1	Influenza (e.g. H1N1)	1	2	99
b.2	Varicella	1	2	99
b.3	Other (specify)	1	2	99
c	Other (specify)	1	2	99
10	Clinical condition	1	2	99
a	Oligohydramnios	1	2	99
b	Intrauterine growth restriction	1	2	99
c	Fetal macrosomy	1	2	99
d	Other (specify)	1	2	99
11	Other associated pathologies			
a	Premature rupture of fetal membranes	1	2	99
b	Disseminated intravascular coagulation (DIC)	1	2	99
c	Maternal pulmonary edema	1	2	99
d	Amniotic fluid embolism	1	2	99
e	Retroplacental clot	1	2	99
f	Septic shock	1	2	99
g	Hypovolemic Shock	1	2	99
h	Other (specify)	1	2	99
12	Complications of pre-existent diseases	1	2	99
a	Tuberculosis	1	2	99
b	Diabetes Mellitus	1	2	99
c	Heart disease	1	2	99
d	Thyroid crisis	1	2	99
e	Chronic hypertension	1	2	99
f	HIV infection	1	2	99
g	Anemia	1	2	99
h	Cervical cancer	1	2	99
i	Ovarian cancer	1	2	99
j	Other (specify)	1	2	99

D33. Did the participant develop any organic dysfunctions?

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

- 1. No → Skip to D35
- 2. Yes → Continue to D34

D34. What were these organic dysfunctions?
(Information extracted from the epidemiological report, multiple responses)

- 1 Cardiovascular dysfunction
- 2 Respiratory dysfunction
- 3 Renal dysfunction
- 4 Coagulation/hematologic dysfunction
- 5 Hepatic dysfunction
- 6 Neurologic dysfunction
- 7 Uterine dysfunction/hysterectomy
- 8 Multiple organ dysfunction

About outcome of this pregnancy

D35. Type of pregnancy termination:

- 1 Abortion
 - i. Miscarriage
 - ii. Therapeutic
 - iii. Unsafe
- 2 Delivery
- 3 Laparotomy for ectopic pregnancy
- 4 Still pregnant

D36. Date of pregnancy termination (delivery, abortion, ectopic pregnancy) ____/____/____ Time ____ (hour)
D D / M M / Y Y Y Y

D37. Indicate the number of hospital stay days before pregnancy termination ____ days

D38. Gestational age at delivery or abortion (including ectopic pregnancy): ____ (Weeks)

D39. Mode of delivery or abortion

- 1 Vaginal, normal
 - a. Active management of the third stage of labor.
 - i. No
 - ii. Yes
- 2 Vaginal, vacuum/forceps
 - a. Active management of the third stage of labor.
 - i. No
 - ii. Yes
- 3 Emergency C-section
- 4 Scheduled C-section
- 5 Curettage (for a woman who had an abortion)

D40. Place of the delivery:

- 1. This hospital
- 2. Other hospital
- 3. Health Center
- 4. Home
- 5. Another (specify) _____

D41. Who attended the delivery?

- 1. Doctor
- 2. Midwifery
- 3. Another (specify) _____

About additional surgical treatment (s) performed during this pregnancy

D42. Was/were additional surgical treatment(s) performed?

- 1. No → Skip to D46
- 2. Yes → Continue to D43

D43. Report about additional first surgical treatment (s) performed (multiple responses):

- 1 Hysterectomy
- 2 Laparotomy
- 3 Curettage
- 4 Repair of cervical tears
- 5 Drainage of puerperal hematoma and repair of puerperal hematoma
- 6 Manual removal of placenta (after vaginal delivery)
- 7 Other (specify)_____

D44. Report about an additional second surgical treatment performed:

- 1 Hysterectomy
- 2 Laparotomy
- 3 Other (specify)_____

D45. Report about an additional third surgical treatment performed:

- 1 Hysterectomy
- 2 Laparotomy
- 3 Another (specify)_____

About surgical treatment (s) performed during this pregnancy, indicate the diagnosis (ses) for each procedures correspondingly:

D46. Uterine curettage indication:

- 1 _____
- 2 _____
- 3 _____
- 4 _____

D47. Cesarean indication:

- 1 _____
- 2 _____
- 3 _____
- 4 _____

D48. Laparotomy indication:

- 1 _____
- 2 _____
- 3 _____
- 4 _____
- 5 _____

D49. Hysterectomy indication:

- 1 _____
- 2 _____
- 3 _____
- 4 _____

About main delays (Information extracted from the epidemiological report if the participant was admitted at the Intensive Care Unit).

Go to the Neonatal information (Skip item D50, D51, D52 and D53) if the participant was NOT admitted at the Intensive Care Unit.

D50. Qualitative analysis of Delay I

- 1 No
- 2 Yes

D51. Qualitative analysis of Delay II

- 1 No
- 2 Yes

D52. Qualitative analysis of Delay III

- 1 No
- 2 Yes

D53. Qualitative analysis of Delay IV

- 1 No
- 2 Yes

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

E. NEONATAL INFORMATION

This information **is excluded** for those women **who had an abortion or an ectopic pregnancy**

Number _____

	Baby 1	Baby 2 (if applicable)	Baby 3 (if applicable)
E1. Birth weight	----- grams	----- grams	-----grams
E2. Age at birth (according to Neonatologist)	----- weeks	----- weeks	----- weeks
E3. Sex	1 Male 2 Female 3 Ambiguous	1 Male 2 Female 3 Ambiguous	1 Male 2 Female 3 Ambiguous
E4. Apgar score (1 minute)	-----	-----	-----
E5. Apgar score (5 minutes)	-----	-----	-----
E6. Baby outcome at birth:	1 Live birth 2 Stillborn	1 Live birth 2 Stillborn	1 Live birth 2 Stillborn
E7. Nursery of baby	1 Stay with mom (Regular nursery) 2 Other (specify)	1 Stay with mom (Regular nursery) 2 Other (specify)	1 Stay with mom (Regular nursery) 2 Other (specify)
E8. Breastfeeding	1 Breastfeeding 2 Formula 3 Both 4 Another(specify)	1 Breastfeeding 2 Formula 3 Both 4 Another(specify)	1. Breastfeeding 2. Formula 3. Both 4. Another(specify)
E9. Gross fetal/neonatal malformation	1 No 2 Yes 99 Do not know	1. No 2. Yes 99 Do not know	1. No 2. Yes 99 Do not know
E10. Neonatal Intensive Care Unit (NICU) Admission	1. No 2. Yes	1. No 2. Yes	1 No 2 Yes
E11. Indicate the diagnosis (ses) of the baby for NICU admission	1. _____ 2. _____ 3. _____ 4. _____	1. _____ 2. _____ 3. _____ 4. _____	1. _____ 2. _____ 3. _____ 4. _____
E12. Management of the baby at NICU (multiple responses)	1. CPAP 2. Non-invasive ventilation (e.g. BiPAP) 3. Invasive mechanical ventilation 4. Inotrope or vasopressor therapy 5. Blood transfusion 6. None of the above	1. CPAP 2. Non-invasive ventilation (e.g. BiPAP) 3. Invasive mechanical ventilation 4. Inotrope or vasopressor therapy 5. None of the above	1. CPAP 2. Non-invasive ventilation (e.g. BiPAP) 3. Invasive mechanical ventilation 4. Inotrope or vasopressor therapy 5. None of the above
E13. Indicate the diagnosis (ses) of the baby when was discharged from the NICU	1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____	1 _____ 2 _____ 3 _____ 4 _____ 5 _____ 6 _____	1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____
E14. Antibiotic use in NICU	1 No 2 Yes	1 No 2 Yes	1 No 2 Yes
E15. Days of stay at NICU	_____ days	_____ days	_____ days
E16. Days of stay at this hospital	_____ days	_____ days	_____ days
E17. Discharge status of baby from this hospital	1. Alive 2. Dead (Days after birth_____)	1 Alive 2 Dead (Days after birth_____)	1. Alive 2. Dead (Days after birth_____)

BMJ Open: first published as 10.1136/bmjopen-2017-020147 on 14 March 2018. Downloaded from <http://bmjopen.bmj.com/> on April 10, 2024 by guest. Protected by copyright.

E18. Indicate the diagnosis of the baby when was discharged from this hospital	1.	_____	1	_____	1	_____
	2.	_____	2	_____	2	_____
	3.	_____	3	_____	3	_____
	4.	_____	4	_____	4	_____
	5.	_____	5	_____	5	_____
	6.	_____	6	_____	6	_____

The End
Thank You!!!!!!!!!!!!!!

For peer review only