Center for International Reproductive Health Training (CIRHT) Journal Article Writing Series

Module 2
Methods Section



Overview of module

- What the methods section should "do"
- Elements of methods and examples
 - First part setting up the study
 - Second part describe data collection and analysis
- Connecting your methods to your research question
- Formal guidelines on writing methods

Examples in this video



Writing methods section

Explain HOW study was done

Justify WHY you used methods

 Context to understand and interpret results

Enable replication

Orient readers to study "First Part"





Study design



The Data Program

Ethical considerations

Development of a context specific accreditation assessment tool for affirming quality midwifery education in Bangladesh

Malin Bogren, RN, RM, PhD International Midwifery Specialist^{a,*}, Sathyanarayanan Doraiswamy, MBBS, MD Chief Health^a, Kerstin Erlandsson, RNM,

Study setting

Setting

The questionnaire study was conducted at 25 public institutes/colleges (out of 38 in Bangladesh), covering seven out of eight geographical divisions in Bangladesh. Four nursing colleges were in urban areas with up to 9 million inhabitants, and 21 institutes were in remote areas with up to 2.6 million inhabitants (World Bank Statistics, 2015). Each institute/college enrolled 25–30 midwifery students per year. Sixty per cent of midwifery education took place in the clinical setting, mostly at tertiary and district hospitals.

Study design

Design

A questionnaire study was conducted at 25 public institutes/colleges (out of 38 in Bangladesh), covering seven out of eight geographical divisions in the country. The ICM Global Standards for Midwifery Education (ICM, 2013) was used as a conceptual framework to guide data collection, deductive content analysis and description of the quantitative results. In addition, the study design focused on a respectful participatory consensus approach to education and regulatory system levels inspired by Sidebotham et al. (2017). The findings of this study guided the development of a context-specific accreditation assessment tool for midwifery education in Bangladesh led by the Director General, Directorate General of Nursing and Midwifery, and Bangladesh Nursing and Midwifery Council. Ethical approval was obtained from the Directorate General of Nursing and Midwifery on 21 February 2017.

Participants

Data collection

Sample

One hundred and twenty-three midwifery educators at 25 institutes/colleges, teaching the 3-year diploma midwifery programme, were involved in this questionnaire study. The faculty members educated the midwifery students at educational institutes and in practical learning placements. The nursing experience of the faculty members varied from < 5 years to > 30 years; none of them were professional midwives. More than 50% of the faculty members were aged > 45 years, and held Master's degrees in nursing or public health.

Recruitment

Ethical considerations

Data were collected by 60 faculty members enrolled in a Swedish Master's programme 2016/2017 that aimed to increase the capacity of midwifery faculties in Bangladesh (Erlandsson et al., 2016). The 60 faculty members collected data from their own midwifery faculty colleagues over a 4-month period in 2017. As such, convenience sampling was used (Polit and Beck, 2012). The 60 faculty members formulated groups of four to five colleagues to answer the questionnaire. Working as a group to answer the questionnaire was deemed superior to data in order to avoid missing or conflicting information within the same institute/college. The invitation letters outlining the objective of the questionnaire study were distributed, oral information was provided, and signed consent forms were obtained. The groups gathered in a silent room at their respective institutes/colleges.

Bogren et al. Midwifery 61 (2018) 74–80

Original research article

"It is my business": A Mixed-Methods Analysis of Covert Contraceptive Use among Women in Rakai, Uganda

Craig J Heck a,*, Stephanie A Grilo a, Xiaoyu Song b, Tom Lutalo c, Neema Nakyanjo c, John S Santelli a

2. Materials and methods

Our study design uses data from two related studies, one quantitative and one qualitative, conducted in the Rakai district of Uganda. To capture the breadth of CCU, we examine survey responses from a demographic cohort—while the qualitative interviews elucidate the reasons why women in Rakai employ CCU.

We drew quantitative data from the Rakai Community Cohort Survey (RCCS), a longitudinal cohort in Rakai, Uganda tracked since 1994 by the Rakai Health Sciences Program (RHSP). The RCCS captures data about reproductive and sexual health decisions and outcomes, including HIV incidence and prevalence, sexual risk behaviors, relationship status, pregnancy history, contraceptive use, pregnancy intentions, and unmet need for contraception. Community members are offered the opportunity to participate in the dynamic community cohort by enrolling for free HIV testing and care at one of RHSP's mobile clinics. Previous RHSP studies have already extensively outlined the methods, logistics, and history of the RCCS [8,9]

Analytic sample

For our analysis, we selected women currently using contraception from Round 15 (2011–2013) of the RCCS, which included an additional question about CCU, and examined contraceptive methods that can be used without a male partner's knowledge—as operationalized by the RCCS. The examined contraceptive methods included oral contraceptives, implants, Depo, periodic abstinence, and IUDs. Since our focus is on current users of contraceptives, we excluded currently pregnant women. From 9233 females, 3264 used contraceptive methods, with 2301 (70%) of those females being current users of an examined contraceptive method. 93 women did not provide a response to the question pertaining to CCU, and 2 women provided invalid responses (i.e., they were asked about CCU without using one of the examined contraceptive methods), giving a final sample of 2206 women.

2.3. Ethics

Trained RHSP personnel obtained written informed consent and assent from all participants in both the qualitative and quantitative studies. Emancipated minors (i.e., individuals aged 15–17 who were married or lived outside of their familial household) provided consent without their parent's consultation. The protocols were reviewed and approved by IRBs at Columbia University Medical Center in the United States and the Uganda Virus Research Institute.

Ethical considerations

Does the addition of active body warming to in-line intravenous fluid warming prevent maternal hypothermia during elective caesarean section? A randomised controlled trial

R. Chebbout, R.S. Newton, M. Walters, I.J. Wrench, M. Woolnough The Medical School, University of Sheffield, Sheffield, UK Sheffield Teaching Hospitals NHS Foundation Trust, Jessop Wing, Sheffield, UK

The study received ethical approval from the local NHS research ethics committee (14/YH/0159) and was registered (www.clinicaltrials.gov) with the protocol published online (NCT02201095). It was a single-centre, three-arm parallel group, open-label, block-randomised superiority trial. The study was conducted at the Jessop Wing Hospital of the Short Ethical Hospitals NHS Trust, a tertiary-refer pital providing services to the South Considerations

Patients were randomised in a ratio of 1:1:1 to one of three parallel study groups: the control group who received standard care (SC); the SC plus forced air warming (FAW) group; and the SC plus conduction mattress warming (CMW) group. The random allocation sequence was generated in four fixed blocks of equal size using an electronic random number generator by an individual unrelated to the trial team and hospital staff. The sequence was recorded on cards which were individually concealed in sequentially numbered opaque, sealed envelopes. These were securely stored and opened in number order by the trial team.

Study design

Sample

Women presenting for elective CS, with or without tubal ligation surgery (sterilisation), under spinal anaesthesia, with a singleton uncomplicated pregnancy, were recruited. Potential participants were approached more than 24 h before their operation during routine preoperative assessments. Informed consent was sought on the morning of surgery. Exclusion criteria included: age <18 years; body mass index (BMI) ≤19 or ≥31 kg/m²; multiple pregnancy; coexisting maternal disease; pregnancy-induced disease; coagulation abnormality; thyroid disease; expected complex procedure; or grand multiparity.

Data collection and analysis

"Second Part"

Measures

- Describe
- Justify (valid, precise)

- Collection protocol
 - Timing? Training? Blinding?
- Storing of samples

Laboratory Analysis

- Sample storage
- Protocols
- Details about assays, etc.

Statistical Analysis

 Stat tests with justification, linked to study questions

Does the addition of active body warming to in-line intravenous fluid warming prevent maternal hypothermia during elective caesarean section? A randomised controlled trial

All participants were a hospital gown, dressing gown and anti-embolism stockings to the operating theatre. Theatre and recovery room ambient temperatures were centrally controlled by the hospital. For the trial, the operating table surface was covered (in ascending order) with a sponge mattress, an Inditherm® three-quarter conduction mattress, model OTM2 (Inspiration Medical, Rotherham, South Yorkshire, UK), a blue paper sheet, a white cotton bed sheet, a small square absorption pad and Bair Hugger™ adult underbody blanket, model 545 (3 M, Bracknell, Berks, UK). Before participants entered the theatre, the allocation envelope was opened and if allocated to the CMW group, the Inditherm® mattress was switched on and the Bair Hugger™ blanket remained switched off. If allocated to the SC or FAW groups, the Inditherm® mattress remained switched off.

Maternal T_c was measured orally using a SureTemp[®] Plus 690 thermometer (Welch Allyn, Aylesbury, Bucks, UK). The same thermometer was used for all participants and all measurements, with disposable covers for the measurement probe ensuring sterility. Maternal T_c was measured preoperatively, at the point at which spinal anaesthesia was delivered and every 15-min subsequently until transfer to the recovery room. It was then measured on entry to the recovery room and every 15-min until discharge from recovery.

Thermal comfort was measured using the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) scale.^{24–26} This is a seven-point Likert scale with the increments: Hot (+3), Warm (+2), Slightly warm (+1), Neutral "just right" (0), Slightly cool (-1), Cool (-2) and Cold (-3). Participants were shown the scale each time T_c was measured and asked which word on the scale best described their thermal comfort.



Chebbout et al. International Journal of Obstetric Anesthesia (2017) 31, 37–44

OBSTETRICS

Chronic hypertension: first-trimester blood pressure control and likelihood of severe hypertension, preeclampsia, and small for gestational age

Diane Nzelu, MD; Dan Dumitrascu-Biris, MD; Kypros H. Nicolaides, MD; Nikos A. Kametas, MD

preeclampsia was subdivided preterm preeclampsia with onset at <37 weeks of gestation and term preeclampsia with onset at \geq 37 weeks. SGA defined birthweight <5th as percentile for gestational age. 15 Because the International Society for the Study of Hypertension (2014) guidelines recognize that the inclusion of fetal growth restriction in the definition of preeclampsia is controversial, we present the data on prevalence of SGA separately from those of the maternal features of the disease.

Why

How organized

Missed opportunities for HPV immunization among young adult women



Carlos R. Oliveira, MD; Robert M. Rock, BA; Eugene D. Shapiro, MD; Xiao Xu, PhD; Lisbet Lundsberg, PhD; Liye B. Zhang, BA; Aileen Gariepy, MD; Jessica L. Illuzzi, MD, MHS; Sangini S. Sheth, MD, MPH

Statistical analysis

Logistic regression models were estimated to identify patient characteristics associated with at least 1 missed opportunity for HPV immunization during the 1 year study period. All patient characteristics were first evaluated individually for association with missed opportunities using simple regression models (ie, including 1 patient characteristic at a time). Connect statistical approach to study question

Organizing your methods section

- Author guidelines
- Examples from target journal (similar topic and study design)



http://www.icmje.org/recommendations/browse/manuscript-preparation/preparing-for-submission.html#d



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http://www.equator-network.org/

Summary

- Two parts of methods:
 - Orient your reader to the study
 - Carry out data collection and analysis
- Explain what you did
- Justify choices
- Type of information included should match the type of study
- Analytic description should be included for each of your research aims/ questions