

Kusum Poudel

Current vaginal discharge management at a tertiary referral hospital in Nepal, patient reported outcomes

Master's thesis in Public Health, specialization in Global Health
Supervisor: Risa Lonnée-Hoffmann
Co-supervisor: Sunila Shakya
November 2022

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ACKNOWLEDGEMENT

Behind the successful accomplishment of research lie the sincere contributions and precious support of many luminaries. This research is therefore, not the exclusive product of mine. I owe much of the credit to the support and assistance of many helping hands. I am grateful to conduct this study under the supervision of Dr. Risa Lonnèe-Hoffmann, who helped me immensely; whose valuable guidance, helpful suggestions as well as timely and continuous encouragement helped me successfully accomplish this research study. I am thankful to Dr. Sunila Shakya for mentoring me at Dhulikhel hospital as a field supervisor and grooming my work throughout this period. I am also grateful to Hilsen Melanie who helped me in doing power calculation of sample size for this study. I also wish to express my profound gratitude to the Department of Global Health, NTNU who provided full support during my research. At the same time, I would be happy to acknowledge my gratitude to all the faculty members for their kind support and guidance at each and every step of my research work. I cordially gratify the Regional Committee for Medical and Health Research Ethics (REC) in Norway, Nepal Health Research Council (NHRC) in Nepal and Ethics and Research Committee in Dhulikhel hospital, Nepal for providing the approval to carry out the study. Further, I cannot express my enough gratitude to Dr. Suman Raj Tamrakar HOD of the OBGYN department of Dhulikhel Hospital who gave approval for my data collection and to the respondents who participated in this study. Without their co-operative and enthusiastic participation, it would be impossible to accomplish this study. Last but not the least I would like to thank all those who helped me directly or indirectly to make this research a success.

Kusum Poudel

CLEARANCE CERTIFICATE FROM IRC



Region: REK nord **Saksbehandler:** Susanne Ramstad **Telefon:** 77660388 **Vår dato:** 07.12.2021 **Vår referanse:** 375616

Risa Lonnee-Hoffmann

Prosjektsøknad: Kvinner med plagsom vaginal utflod i primær og tertiær helsetjenesten i Nepal: Hvilken andel får behandling med antibiotika? Er kvinner fornøyde?

Søknadsnummer: 375616

Forskningsansvarlig institusjon: Norges teknisk-naturvitenskapelige universitet

Prosjektsøknad vurderes som utenfor helseforskningslovens virkeområde

Søkers beskrivelse

Også i et lav-mellom inkomst land som Nepal er plagsom vaginal utflod et svært hyppig problem, mange kvinner oppsøker helsevesenet for. I høy inkomst land undersøkes som vanlig kvinner gynekologisk og man tar mikrobiologiske prøver ved mistanke om infeksjon. I lav- og mellom-lav inkomst land brukes antibiotika hos de aller fleste kvinner, ofte uten undersøkelse. Det er på grunn av mangel på tilgang til labor baserte tester, økonomiske, logistiske og kulturelle barrierer. Det er ikke kjent, hvilken andel av kvinner som oppsøker helse tjeneste i Sør Asia plages med vaginal utflod, hvilke undersøkelser gjennomføres, hvilken behandlingen gis, spesielt hvor høy er andel av kvinner som får antibiotikabehandling, om symptomer er forandret etter behandlingen samt kvinnenes fornøydhet med konsultasjonen og behandlingen. Problemstilling angående fornøydhet av kvinner, kom frem i konsultasjonen med brukerrepresentanter under planleggingen av et PhD prosjekt i Nepal.

Denne masteroppgaven er en oppfølgende observasjonsstudie som finner sted i et tertiær og to primer helse institusjoner i Nepal. For datainnsamling brukes en spørreundersøkelse, spørsmålene er utviklet spesifikt for denne undersøkelsen og er prøvd ut hos en lpilot gruppe av 3 kvinner uten helsefaglig bakgrunn. Kohorten består av kvinner som oppsøker gynekologisk avdeling i primær - og generell poliklinikk i tertiær helse institusjon.

Alle kvinnelige pasienter på venterommene med en gynekologisk problemstilling vil bli informert verbalt og skriftlig om prosjektet og spurt om tillatelse for deltagelse i denne spørreundersøkelsen. Samtykke gis enten med underskrift, eller med fingeravtrykk, i såfall med en tredje, uavhengig vitne (resepsjonist, nurse, kompanjong til kvinnen) som underskriver. Hos inkluderte kvinner samles for del 1 av demografisk informasjon alder, partner status, og utdanningsnivå. Så tas en kort medisinsk anamnese og etterlyses om kvinnen er gravid eller ikke. Informasjon i del 1 brukes for å estimere andel kvinner som oppsøker primær - eller tertiær helsetjenesten med denne problemstilling. Kvinner som ikke har plagsom vaginal utflod blir ekskludert fra videre spørsmålene. Kvinner som har plagsom utflod inkluderes videre i del 2 av studien. Telefonnummer til disse kvinner registreres, det samles informasjon om type utflod, varighet og relaterte symptomer. Etter

REK nord

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konsultasjonen samles informasjon om type undersøkelse, om det har blitt tatt prøver, og hvilken yrkesgruppe pasienten har hatt konsultasjonen med. Hoved endepunkt er type behandlingen gitt (tablett/type, lokalbehandling/ type). I eksplorative del måles tilfredshet med undersøkelsen samt subjektive årsaker for det med hjelp av en numeric rating scale (NRS). Kvinnene blir ringt opp etter fire uker, og man etterlyser om opprinnelige symptomene er bedre, uforandret eller verre, eller om pasienten har vært hos helsepersonell med samme problemstilling i mellomtiden, samt en explorativ del som måler kvinnenes fornøydhets med behandlingen, samt subjektive årsaker for det, med en NRS.

I følge vår styrkeberegning bør vi for prevalens estimering inkludere 200 kvinner for å ha en konfidensintervall med 0.14 bredde, hvis vi antar at prevalensen av plagsom vaginal utflod er omkring 50% .

For del to trenger vi 100 kvinner for å få et konfidensintervall fra 70.8-87.3%, hvis vi antar at 80% av kvinner får antibiotikabehandling.

Hvis master studenten ikke kan gjennomføre alle intervju på grunn av tids problemer, kan intervjuene og telefonisk oppfølging gjennomføres av en kvinnelig, lokal forskningsassistent. Master studenten holder på å søke nepalesisk etisk komite, men det er først behov for svar fra det norske etiske komiteen.

Søknaden ble mottatt 26.10.21 og behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK) i møte 25.11.21. Vurderingen er gjort med hjemmel i helseforskningsloven § 10.

REKs vurdering

Om prosjektet

De prosjektene som skal framlegges for REK er prosjekt som dreier seg om «*medisinsk og helsefaglig forskning på mennesker, humant biologisk materiale eller helseopplysninger*», jf. helseforskningsloven § 2. «*Medisinsk og helsefaglig forskning*» er i § 4 a), definert som «*virksomhet som utføres med vitenskapelig metodikk for å skaffe til veie ny kunnskap om helse og sykdom*». Det er altså formålet med studien som avgjør om et prosjekt skal anses som framleggelsespliktig for REK eller ikke.

I dette prosjektet er det overordnede formålet beskrevet slik “*To describe management of bothersome vaginal discharge and satisfaction with this management, self-reported by women attending primary and tertiary health care facilities in Nepal.*”

Selv om dette er en helsefaglig studie og funnene i studien indirekte vil kunne gi en helsemessig gevinst faller ikke prosjektet inn under definisjonen av de prosjekt som skal vurderes etter helseforskningsloven.

Prosjekter som faller utenfor helseforskningslovens virkeområde kan gjennomføres uten godkjenning av REK. Det er institusjonens ansvar å sørge for at prosjektet gjennomføres på en forsvarlig måte med hensyn til for eksempel regler om taushetsplikt og personvern

Vedtak

Etter søknaden fremstår prosjektet ikke som et medisinsk og helsefaglig forskningsprosjekt som faller innenfor helseforskningsloven. Prosjektet er ikke framleggingspliktig, jf. helseforskningsloven § 2.

Vi gjør oppmerksom på at det må foreligge et behandlingsgrunnlag etter personvernforordningen. Dette må forankres i egen institusjon

Klageadgang

Du kan klage på REKs vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes på eget skjema via REK portalen. Klagefristen er tre uker fra du mottar dette brevet. Dersom REK opprettholder vedtaket, sender REK klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag (NEM) for endelig vurdering, jf. forskningsetikkloven § 10 og helseforskningsloven § 10.

Med vennlig hilsen

May Britt Rossvoll

sekretariatsleder

Kopi til:

Norges teknisk-naturvitenskapelige universitet



Government of Nepal
Nepal Health Research Council (NHRC)



Ref. No.: 3031

19 April 2022

Ms. Kusum Poudel
Principal Investigator
NTNU
Norway

Ref: Approval of thesis proposal

Dear Ms. Poudel,

This is to certify that the following protocol and related documents have been reviewed and granted approval through the expedite review process by the Expedited Review Sub-Committee meeting for its implementation.

Protocol Registration No/ Submitted Date	608/2021 MT 21 October 2021	Sponsor Protocol No	NA
Principal Investigator/s	Ms. Kusum Poudel	Sponsor Institution	NA
Title	Current vaginal discharge management at a tertiary referral hospital in Nepal, patient reported outcomes		
Protocol Version No	NA	Version Date	NA
Other Documents	1. Data collection tools 2. Informed consent form 3. University approval 4. Supervisor recommendation letter 5. Support letter	Risk Category	Minimal risk
Co-Investigator/s	1. Dr. Risa Anna Margaretha Lonn�e-Hoffmann 2. Dr. Sunila Shakya		
Study Site	Dhulikhel Hospital		
Type of Review	<input checked="" type="checkbox"/> Expedited <input type="checkbox"/> Full Board Meeting Date: 18 April 2022	Timeline of Study 19 April 2022 to September 2022 Duration of Approval 19 April 2022 to	Frequency of continuing review NA



Government of Nepal
Nepal Health Research Council (NHRC)



Ref. No.: 3031

		19 April 2023 This approval will be valid one year	
Total budget of research	NRs 1,58,000.00		
Ethical review processing fee	NRs 10,000.00		
<u>Investigator Responsibilities</u>			
<ul style="list-style-type: none">• Any amendments shall be approved from the ERB before implementing them• Submit progress report every 3 months• Submit final report after completion of protocol procedures at the study site• Report protocol deviation / violation within 7 days• Comply with all relevant international and NHRC guidelines• Abide by the principles of Good Clinical Practice and ethical conduct of the research			

If you have any questions, please contact the Ethical Review M & E Section at NHRC.

Thanking you,

Dr. Pradip Gyanwali
Member Secretary

KATHMANDU UNIVERSITY
SCHOOL OF MEDICAL SCIENCES



May 22, 2022

To,

Dr. Risa Anna Margaretha Lonnee-Hoffmann
Norwegian University of Science & Technology (NTNU)
Norway

Subject: Approval of Research Proposal

Dear Dr. Risa Anna Margaretha Lonnee-Hoffmann

This is to certify that the following protocol and related documents have been reviewed and granted approval by Institutional Review Committee, Kathmandu University School of Medical Sciences (IRC, KUSMS) for implementation on 20 May, 2022.

IRC-KUSMS Approval No.	37/22	Duration of Approval	21 May, 2023
Principal Investigator	Dr. Risa Anna Margaretha Lonnee-Hoffmann	Sponsor Institute	N/A
Co-Principal Investigator	Dr. Sunila Shakya Ms. Kusum Poudel		
Title	Current vaginal discharge management at a tertiary referral hospital in Nepal, Patient reported outcomes.		
Other Member of Research Team (Co- Investigator)	N/A		
IRC-KUSMS, Administrative fee	US \$. 200.00		
Chairperson of IRC-KUSMS	Name	Date	
	Prof. Dr. Dipak Shrestha	22 May 2022	
Investigator Responsibilities:			
<ul style="list-style-type: none">➤ Any amendments shall be approved from IRC-KUSMS before implementing them.➤ Comply with all relevant International and NHRC guidelines.➤ Submit final report after completion of protocol at IRC-KUSMS.			

If you have any questions, please contact the IRC-KUSMS section at Kathmandu University School of Medical Sciences/ Kathmandu University Hospital.

With best regards,

Prof. Dr. Rajeev Shrestha
Member Secretary, IRC-KUSMS



ABSTRACT

Background: Abnormal vaginal discharge is a common medical problem among women of childbearing age, with an estimated 5–10 million clinic visits each year worldwide. (1,2,12) Due to hesitation to undergo vaginal examination and unavailability of equipment to do vaginal examination in health facilities, diagnosis of STI is solely done on the basis of symptoms and same approach is used for bothersome vaginal discharge as well. (8) In order to start addressing this problem of overtreatment with antibiotics we should know the numbers of women presenting with vaginal discharge in any health care setting in Nepal. No such reports concerning this issue have been found. Further, we don't know what proportion of women presenting with abnormal vaginal discharge do receive antibiotics. If this diagnostic and treatment approach is planned to be changed in the future, it will be important to know more about the patient's satisfaction with the consultation as well as the treatment to describe the subjective symptom development after standard treatment and if it is related further it can help in improvement. No such study has been done on this subject yet. Therefore, this study aims to determine current vaginal discharge management at tertiary level hospital.

Methods: We conducted cross-sectional study with follow up on women visiting OBGYN department of Dhulikhel hospital. Dhulikhel Hospital is located at Kavrepalanchwok district of Nepal. Data collection was done in OPD of OBGYN department of hospital. For collecting data random selection of OBGYN OPD was done. Randomization was done by throwing a dice where 1 represented OPD 1, 2 was OPD 2 and 3 was OPD 3 respectively. Each consecutive patient of the OPD which came by throwing dice was included in that day. If they gave written consent, they were included in part 1 to find out the proportion and women with bothersome vaginal discharge who gave consent to attend the follow up phone call were included in part II of the study. On the given time frame, we expected that it will be realistic to sample the information of 100 women presenting with vaginal discharge. This would produce the following estimates a sample size of 200 women with and without vaginal discharge. But due to limited time frame we could collect data of 56 women with vaginal discharge and 144 women without vaginal discharge. As the questionnaire was non-validated, a pilot test was conducted and questions were modified accordingly. We determined the factors associated with bothersome vaginal discharge by performing Chi-Square and Fisher Exact test.

Results: Overall prevalence of self-reported bothersome vaginal discharge among the participants was 28%, which was second most reported cause for the hospital visits after low abdominal pain. Among women with self-reported bothersome vaginal discharge majority (89.3%) complaint of having whitish discharge. Among 56 women self-reporting vaginal discharge 80.4% received antibiotics. On a scale of 1 to 10 (0 being least satisfied, 10 being most satisfied and 6 being moderately satisfied) an average 85.71% of women were very satisfied with the consultation with the mean score 8.32 ± 1.674 and 64.29% were very satisfied with the treatment with the mean score 7.2 ± 3.289 . There was significant association between bothersome vaginal discharge and women's educational status ($p=0.029$).

Conclusion: About one third of all women visiting the gynecology out-patient ward at Dhulikhel hospital had complaint of self-reported bothersome vaginal discharge which was second major cause for the women to visit the hospital preceded by lower abdominal pain. Bothersome vaginal discharge was more commonly reported among the women with low education status. One third women with self-reported abnormal vaginal discharge had moderately bothersome vaginal discharge. Almost all women were very satisfied with the examination at the hospital. Targeting women with low educational level may raise awareness regarding reproductive health. Possibly, promoting healthy sexual behavior and hygienic practices may reduce complain of vaginal discharge in women with low educational level

LIST OF ABBREVIATION

STI: Sexually Transmitted Infection

RTI: Reproductive tract infection

HIV: Human Immunodeficiency Virus

STD: Sexually Transmitted Diseases

AIDS: Acquired immunodeficiency syndrome

WHO: World Health Organization

BV: Bacterial Vaginosis

OBGYN: Obstetrics and Gynecology

OPD: Outpatient Department

TABLE OF CONTENTS

ACKNOWLEDGEMENT	i
CLEARANCE CERTIFICATE FROM IRC	ii
ABSTRACT	viii
LIST OF ABBREVIATION	x
LIST OF FIGURES	xiii
LIST OF TABLES	xiv
INTRODUCTION	1
1. BACKGROUND AND RATIONALE	1
2. OBJECTIVE.....	3
General objective.....	3
Specific Objective.....	3
3. HYPOTHESIS	3
METHODOLOGY	4
1. STUDY DESIGN:.....	4
2. STUDY SETTING:.....	4
3. STUDY POPULATION:	4
4. SAMPLE SIZE.....	4
5. PROCEDURE:	5
6. STUDY VARIABLES	6
7. ETHICS:.....	11
FINDINGS	12
PROPORTION OF WOMEN WITH VAGINAL DISCHARGE.....	12
SOCIODEMOGRAPHIC CHARACTERISTICS OF PARTICIPANTS.....	14
REASON FOR HOSPITAL VISIT	15
DURATION OF BOTHERSOME VAGINAL DISCHARGE.....	16
BOTHERSOME VAGINAL DISCHARGE OCCURRENCE.....	16
PREVIOUS COURSE OF VAGINAL DISCHARGE	17
COLOR OF VAGINAL DISCHARGE	17
REASON FOR HOSPITAL VISIT	18
DEGREE OF BOTHERSOME OF VAGINAL DISCHARGE.....	19

METHOD USED FOR EXAMINATION	19
TREATMENT RECEIVED BY PARTICIPANTS	20
RECEIVED TREATMENT FOR HUSBAND.....	20
EXAMINATION PERFORMER.....	21
SATISFACTION WITH CONSUTATION.....	21
SATISFACTION WITH GENDER OF HEALTH PRACTITIONER.....	22
SATISFACTION WITH VAGINAL EXAMINATION	23
SATISFACTION WITH EXPLANATION GIVEN BY HEALTH PRACTITIONER.....	24
SATISFACTION WITH TREATMENT	25
BOTHERSOME OF VAGINAL DISCHARGE AFTER ONE MONTH	25
MEDICINE	26
SATISFACTION OF COST WITH TREATMENT	27
ASSOCIATION OF SOCIODEMOGRAPHIC CHARACTERISTICS WITH PARTICIPANTS WITH VAGINAL DISCHARGE	28
ASSOCIATION BETWEEN BOTHERING VAGINAL DISCHARGE AFTER TREATMENT WITH ASSOCIATED VARIABLES.....	29
DISCUSSION	31
CONCLUSION	33
ANNEXES	34
QUESTIONNAIRE.....	34
INFORMED CONSENT	42
PROGRESS PLAN	48
BUDGET.....	49
REFERENCES	51

LIST OF FIGURES

Figure 1: Flowchart of selection of study population	12
Figure 2: Duration of bothersome vaginal discharge.....	16
Figure 3:Pie chart showing bothersome vaginal discharge occurrence	16
Figure 4: Histogram showing scale of bothersome of vaginal discharge	19
Figure 5: Histogram showing scale of satisfaction from consultation.....	21
Figure 6: Histogram showing scale of satisfaction with gender of health practitioner	22
Figure 7:Histogram showing scale of satisfaction with vaginal examination	23
Figure 8: Histogram showing scale of satisfaction with explanation given by health practitioner	24
Figure 9: Histogram showing scale of satisfaction with treatment.....	25
Figure 10:Histogram showing scale satisfaction of cost with Treatment.....	27

LIST OF TABLES

Table 1: Sociodemographic characteristics of participants	14
Table 2: Reason for hospital visit	15
Table 3: Course of vaginal discharge before	17
Table 4: Color of vaginal discharge.....	17
Table 5: Reason for hospital visit	18
Table 6: Method used for examination	19
Table 7: Treatment received by participants.....	20
Table 8: Received treatment from husband	20
Table 9: Bothered of vaginal discharge after one month	25
Table 10: Medicine	26
Table 11: Association of self-reported vaginal discharge and educational status	28

INTRODUCTION

1. BACKGROUND AND RATIONALE

Abnormal vaginal discharge is a common medical problem among women of childbearing age, with an estimated 5–10 million clinic visits each year worldwide. It is a neglected medical condition commonly caused by bacterial vaginosis, trichomoniasis, vulvovaginal candidiasis, *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. (1,2,12) During the course of a year, one out of every ten women will experience abnormal vaginal discharge. Approximately one-fourth of all women in South Asia have common complaint about experiencing abnormal vaginal discharge and it is common reason for women to seek health care in low-income countries. (4) One of the most common symptoms of gynecological morbidity is vaginal discharge, and the most common cause of abnormal vaginal discharge is vaginitis, followed by cervicitis. (3) Many women who experience vaginal discomfort wrongly self-treat themselves with over-the-counter medications. (1,13) If the right laboratory test is not performed to validate the diagnosis, healthcare professionals themselves may miss correct diagnosis. (14)

Abnormal vaginal discharge has been linked to a number of adverse reproductive tract outcome, including pelvic inflammatory disease, ectopic pregnancy, chronic pelvic pain, infertility and a more than 2–3 fold increased risk of acquiring Human Immunodeficiency Virus. (2) Abnormal vaginal discharge is often present in cases of Sexually Transmitted Disease (STDs) and Reproductive Tract Infection (RTIs) (5). Rate of infection of STD is similar in both male and female but females suffer from more complications than males. STD facilitates transmission of HIV. Thus, control of other STDs may be required to stop individuals from acquiring HIV and AIDS. (3, 4)

STDs is one of the most common diseases after Malaria and Pulmonary tuberculosis in Nepal and the incidence of STDs is increasing in Nepal. (3) The most frequently mentioned symptoms by patients are vaginal discharge in gynecological, antenatal and STD clinics in Nepal and it is difficult to differentiate between pathological and physical discharge in the patients only by asking history and performing clinical examination. (3) Data on STI

prevalence in Nepal are limited, and prevention and control programs have focused primarily on HIV infection. (11) A population based study in a rural community in Nepal showed the prevalence of Trichomoniasis to be 7.2%, *Chlamydia trachomatis* infection 1.2%, Human papillomavirus 11.4% and Hepatitis B virus infection 1.7%, and syphilis 1.5% in married women who were more than 15 years of age. This shows that the prevalence of STIs is low in rural areas. (11) Symptomatic patient present with abnormal vaginal discharge's prevalence is expected to be higher, but there are no current figures for this available in context of Nepal.

According to the national guidelines of Nepal on "Case Management of Sexually Transmitted Infections" the recommendation is to follow the syndromic approach for diagnosis and management of RTIs and STDs, which can be done with or without use of laboratory test, depending on the availability of locally available resources, as suggested by WHO. (6, 7) This recommendation will be applied to women presenting with abnormal vaginal discharge as well. In both rural and urban areas of Nepal, the syndromic approach is used due to lack of laboratory facilities and unavailability of tests. (8) It is often difficult for health care providers and patients to differentiate abnormal vaginal discharge from physiological. (9) Due to hesitation to undergo vaginal examination and unavailability of equipment to do vaginal examination in health facilities, diagnosis of STI is solely done on the basis of symptoms which is by examining abnormal vaginal discharge. (8) As the prevalence of STIs is low in rural areas of Nepal, a syndrome-based therapy will result in overtreatment of patients. (11) In order to start addressing this problem of overtreatment with antibiotics we should know the numbers of women presenting with vaginal discharge in any health care setting in Nepal. No such reports concerning this issue have been found. Further, we don't know what proportion of women presenting with abnormal vaginal discharge do receive antibiotics. If this diagnostic and treatment approach is planned to be changed in the future, it will be important to know more about the patient's satisfaction with the consultation as well as the treatment to describe the subjective symptom development after standard treatment and if it is related further it can help in improvement. No such study has been done on this subject yet.

2. OBJECTIVE

General objective

- a) To describe management of vaginal discharge and satisfaction with its management, self-reported by women attending tertiary health care facilities in Nepal.

Specific Objective

Part I:

- a) To assess the proportion of women presenting with a problem of vaginal discharge at gynecological outpatient clinics in a tertiary health care center

Part II

- a) To describe the proportion of women treated with antibiotics, when presenting with vaginal discharge as a problem
- b) To follow up symptom resolution among women presenting with abnormal vaginal discharge
- c) To explore women's satisfaction with the initial consultation
- d) To explore women's satisfaction with treatment

3. HYPOTHESIS:

We hypothesize that at least 80% of women presenting with vaginal discharge at outpatients, will receive antibiotic treatment, other than anti-fungals.

METHODOLOGY

1. STUDY DESIGN:

Cross sectional study design with follow up on women regarding vaginal discharge.

2. STUDY SETTING:

The study was conducted in Dhulikhel Hospital. Dhulikhel hospital is situated in Dhulikhel municipality of Nepal. Dhulikhel municipality covers a total of 54.62 sq.km located in Kavrepalanchowk district with a population of 33,981. The study was conducted in gynecological outpatient department of Dhulikhel hospital.

3. STUDY POPULATION:

Inclusion criteria: Random selection of OBGYN OPD was done by throwing a dice where 1 was OPD 1, 2 was OPD 2 and 3 was OPD 3. Each consecutive patient of that OPD was included in that day. If they gave written consent, they were included in part I to find out the proportion and women with bothersome vaginal discharge who gave consent to attend the follow up phone call were included in part II of the study.

Exclusion criteria: Women who were not willing to participate in study, women going to OPD which did not come while throwing dice, women who could not be contacted by telephone and women below 18 years of age.

Recruitment: Women visiting randomly selected OPD were asked if they had a gynecological problem. If yes, they were informed about the survey first. Women who meet inclusion criteria and women who were willing to participate with written consent either by signing paper or giving thumb prints were recruited. In the case of thumbprints, it was witnessed with signature by the companion of the patient.

4. SAMPLE SIZE

In the time frame available, and a setting for the study, we expect that it will be realistic to sample the information of 100 women presenting with vaginal discharge. This would produce the following estimates:

Part I: To answer research question a): A sample size of 200 women produces a two-sided 95 % confidence interval with width equal to 0.143 when the proportion of women presenting with vaginal discharge as one of their complaints is 50 % (i.e., a confidence interval of 42.9 to 57.1 %).

Part II: To answer research question b): Again, assuming the proportion of women presenting with vaginal discharge is 50%, an estimated 100 women will contribute to the investigation of the second two research questions. A sample size of 100 will produce a two-sided 95% confidence interval with width equal to 0.165 when the proportion of these women treated with antibiotics is 80 % (i.e., a confidence interval from 70.8 to 87.3 %).

Due to limited time, we were able to take data of only 56 women.

Statistical analysis: The results will be presented using frequency graphs and/or tables and central tendency measures will be calculated for demographic data. To assess associations, we will use Chi-square or Fisher exact tests.

5. PROCEDURE:

The interview questions were both in Nepali and English so that patients could understand, and interview was done by Kusum Poudel the author of the thesis herself.

Eligible women were given the information on the consent form by the interviewer. The women who were literate were able to read themselves. For those, not able to read, the researcher read out the information. This was done in a private setting, in such a way that other patients were not able to hear what was said. Patients who were interested were given a consent form to sign.

Then the interview started. All the information they provided was documented in a paper questionnaire. Their phone number was written as a separate register to maintain confidentiality. Filled questionnaire were kept safely by researchers to maintain confidentiality after data entry and follow-up.

All women attending gynecological outpatients with reproductive health problems in the study period who were above 18 years were eligible for study but there were 5 different OPD in OBGYN department with high patient flow, therefore it was not possible to collect data of every woman as collection of data was done by one person. Therefore, random selection of OPD was done. Only one OPD was selected for one day and that OPD was selected by throwing a dice where 1 represented OPD 1, 2 represented OPD 2 and 3 represented OPD 3. And each consecutive patient of that OPD was included in that day. If they gave written consent, they were included in part 1 to find proportion of women present with vaginal discharge. Women complaining about bothersome vaginal discharge were included in part II of the study.

For part 2 of the study 56 women with complain of bothersome vaginal discharge were contacted and there was no loss to follow up as all women picked up the call for the interview.

6. STUDY VARIABLES

Questions for this project were specifically designed for the study because no validated questionnaire is available in this context. As a small pilot, it has been applied to three local women at different decades of age without a health professional background. This has resulted in slight modifications, the questionnaire was made simpler and more understandable.

Part 1

1. Socio-demographic variables

1.1 Age:

The participants were asked about their age. Age was categorized in 5 groups were 18-30, 31-40, 41-50, 51-60 and 60+ years for the purpose of analysis.

1.2 Marital status:

The participants were asked about their marital status. It was classified into four groups: married, unmarried, divorced/separated/widowed and being engaged/ having a boyfriend.

1.3 Pregnancy status:

Participants were asked if they were pregnant or not. It was a yes or no question.

2. Reason for visit

The participants were asked about the reasons to visit the hospital. The patient could indicate one or more of nine options abnormal vaginal discharge, problems with bleeding, pain in the lower abdomen, pregnancy related, swelling in the lower abdomen, follow up, infertility, urinary leakage and other. In case of others, they were asked to specify reason.

If vaginal discharge was one of the reasons, they were included in the second part of study.

Part 2

Before Consultation

3. History of bothersome vaginal discharge

Three questions were given regarding history of bothersome vaginal discharge.

3.1 Duration of bothersome vaginal discharge:

Four options were given for the participants to answer the duration of bothersome: a week or less, followed by between one week and one month ago, between one month and six months ago and more than six months ago.

3.2 Recurrence of bothersome vaginal discharge:

Participants were asked if they had a previous occurrence of bothersome vaginal discharge. Three options were given first 'yes, one time, followed by 'yes, more than one time' and 'no'.

3.3 Course of bothersome vaginal discharge in past:

Participants were asked regarding the course of bothersome vaginal discharge in the past. Five options were given first was it got relief by itself, followed by I used treatment of my own choice, I received treatment by a health professional, It did not go away and last was I did not have bothersome vaginal discharge before.

4. Characteristics of vaginal discharge

4.1 Color of vaginal discharge

Participants were asked multiple choice question regarding the color of vaginal discharge. Seven options were provided regarding the color of Vaginal Discharge, first option was clear discharge, followed by whitish, yellowish, brownish, reddish, greenish, and other.

4.2 Additional problems present with Vaginal Discharge

Participants were asked multiple choice questions regarding if additional problems were present with vaginal discharge. Seven options were provided, first was offensive smell of the discharge, followed by itchy around private parts, burning or pain around private parts, burning urination, painful intercourse, skin changes and sores on private parts.

4.3 Scale of bother

Participants were asked how bothersome the vaginal discharge was, on the scale of 0 to 10, with 0 corresponding to vaginal discharge is not bothersome at all, 5 to

moderately bothersome, and 10 being vaginal discharge is bothersome in the worst possible way.

After Consultation

5. Type of examination performed

After consultation participants were interviewed, whether a vaginal swab was taken or not, if a speculum was used or not, if the vagina was only examined without doing a swab test or just a verbal interview was performed.

6. Treatment received

6.1 Treatment received by participant

Participants were asked questions regarding the treatment, or treatment recommendation they received from the hospital. They could choose one or seven of given options. The options were antibiotic tablets, tablets to swallow unknown type, injection, local cream, vaginal suppository, painkiller, or no treatment was done. The main outcome is if she received or was prescribed antibiotics or not.

6.2 Treatment of husband of participant

Participants were asked yes or no questions regarding if they received medication for their husband or not.

7. Examiner

Participants were asked who performed the examination. They were provided with three options: the first was doctor, a nurse and other intern doctors and nurses.

8. Satisfaction level

Satisfaction level regarding overall satisfaction with consultation of participants was measured on a scale of 1 to 10. 1 indicating maximum dissatisfaction, 5 neither dissatisfaction nor satisfaction, and 10 maximum satisfactions. In addition, satisfaction

of patients was measured on the scale for gender of healthcare practitioner, vaginal examination performed, and explanation given by health care personnel.

After one month of the first interview patients were followed up by telephone and were asked following questions

9. Degree of bother of vaginal discharge

Participants were asked how much they were bothered by the vaginal discharge Three options were provided: less bothering-it has improved, more bothering-it has deteriorated and unchanged.

10. Medication

10.1 Consumption of given medication

Participants were asked yes or no questions regarding if they took medication given by a health care practitioner.

10.2 Took additional medical treatment for vaginal discharge

Participants were asked if they took any other medical treatment for vaginal discharge. They were provided with three options: yes- bought it myself, yes- went to another health practitioner and no.

11. Admitted to hospital

Participants were asked a yes or no question about admission to hospital. If the answer was yes, the reason for the admission was asked for.

12. Satisfaction with treatment

Participants were asked about overall satisfaction with the treatment on a scale of 1 indicating maximum dissatisfaction, 5 neither dissatisfaction nor satisfaction, and 10 maximum satisfactions.

13. Reason for satisfaction or dissatisfaction with treatment

Participants were asked about reasons for satisfaction or dissatisfaction with the treatment on a scale of 1 to 10, 1 to 5 being not true at all and 10 being very true.

First question was regarding whether discharge was normal after treatment.

Followed by a second question regarding experience of side effects.

And lastly, a question regarding the cost of the treatment. Participants were asked on the scale of 1 to 10, 1 indicating the cost of treatment far too high and 10 being absolutely perfect.

7. ETHICS:

Written informed consent was obtained from participants who meet inclusion criteria and who were willing to participate in the study. This study was conducted after ethical approval from the Regional Committee for Medical and Health Research Ethics (REC) in Norway, Nepal Health Research Council (NHRC) in Nepal and Ethics and Research Committee in Dhulikhel hospital, Nepal. As reproductive health is a sensitive issue there were some ethical challenges regarding patient confidentiality which was assured before taking the interview. Written and verbal consent was taken by signature or fingerprint for each patient coming to the hospitals and clinics.

After the data analysis completion all the collected, personally identifiable information, such as name, address or area participant live and telephone number were deleted. And other original data was kept safely by researcher herself.

We failed to notify Norwegian Centre for Research Data before the start of the project. That we would have been supposed to do so, we only became aware at the end of the project, when data was already anonymous.

FINDINGS

PROPORTION OF WOMEN WITH VAGINAL DICHARGE

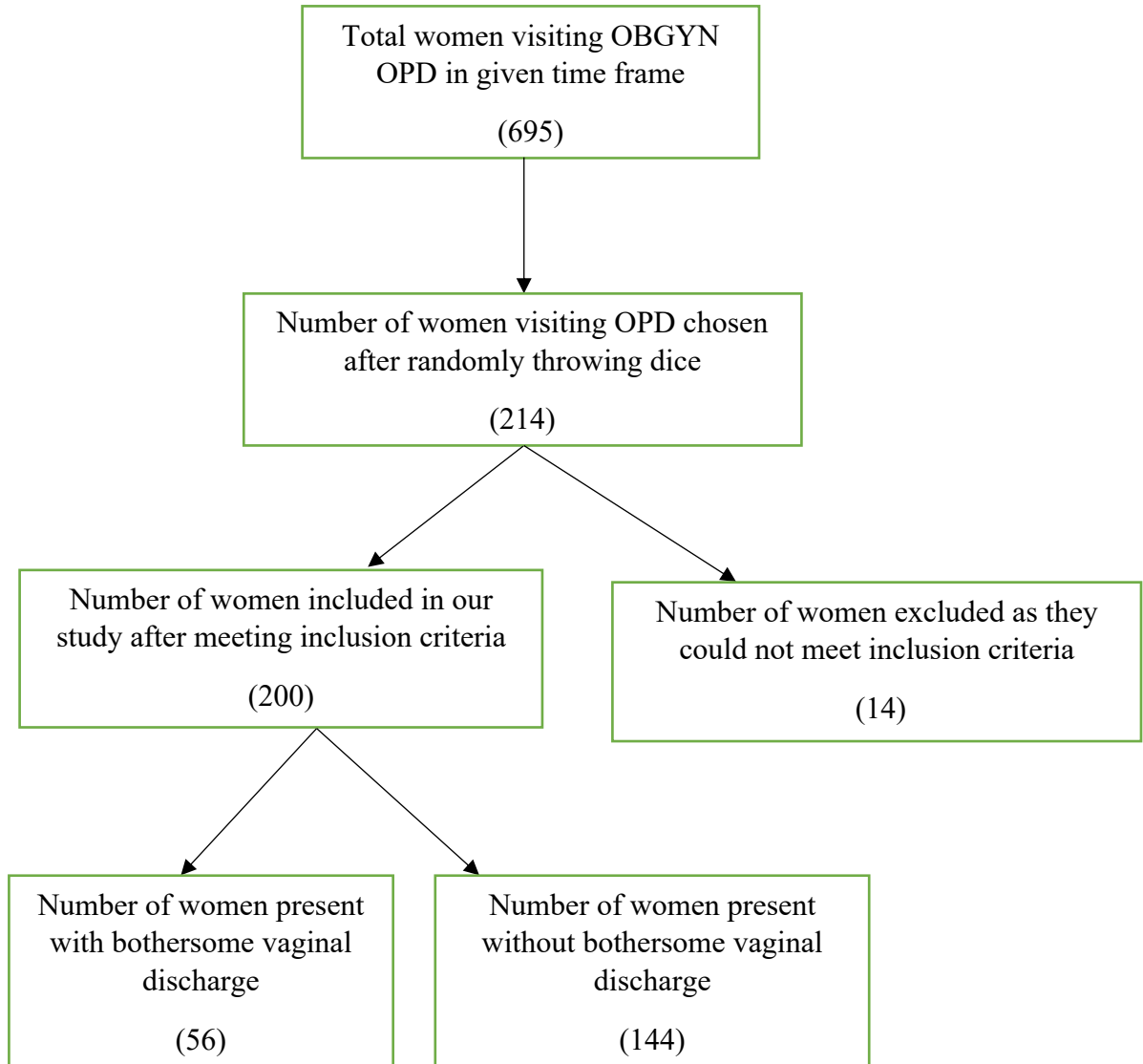


Figure 1: Flowchart of selection of study population

In total 695 women visited OBGYN department during our study period 31st May to 12th June. All women attending gynecological outpatients with reproductive health problems in the study period who were above 18 years were eligible but it was not possible to collect data of every woman due to limited time frame. Therefore, random selection of OPD was done by throwing

a dice where 1 was OPD 1, 2 was OPD 2 and 3 was OPD 3. And each day randomly OPD were selected by throwing dice and consecutive patient of that OPD was included in that day. If they gave written consent, they were included in part 1 to find out proportion. 214 women were approached for the initial interview among them 14 women didn't meet the age criteria for the study and were excluded and remaining all 200 women agreed to participate in study and gave written consent. Therefore, 200 women visiting OBGYN department of Dhulikhel Hospitals were interviewed. Among them 56 women visited hospital with complaint of bothersome vaginal discharge.

Proportion of women with vaginal discharge was calculated by dividing total number of women with vaginal discharge (56) divided by total number of women visiting OBGYN department after random sampling who meet inclusion criteria (200). The proportion of women present with vaginal discharge was 0.28.

SOCIODEMOGRAPHIC CHARACTERISTICS OF PARTICIPANTS

Table 1: Sociodemographic characteristics of participants

Sociodemographic Characteristics		Frequency	Percentage
		N=200	
Age	18-30	82	41
	31-40	61	30.5
	41-50	43	21.5
	51-60	12	6
	60+	2	1
Marital Status	Married	188	94
	Unmarried	11	5.5
	Divorced/Separated/Widowed	1	0.5
Level of Education	Illiterate	18	9
	Primary School	76	38
	Secondary School	73	36.5
	Diploma	6	3
	Bachelors	21	10.5
	Masters	6	3

Table 1 summarizes the socio demographic characteristics of the participants. Mean age of the respondents was 35.21 ± 9.89 years. And the majority of participants, that is 38% of females, had primary level education. Among the participants included in our study nearly all were married (94%).

REASON FOR HOSPITAL VISIT

Table 2: Reason for hospital visit

Reason for Hospital visit	Yes (%)	No (%)
Pain in lower abdomen	76 (38)	124 (62)
Vaginal discharge	56 (28)	144(72)
Follow up	30 (15)	170 (85)
Pregnancy Related	25 (12.5)	175 (87.5)
Abnormal bleeding	17 (8.5)	183(91.5)
Other Irregular Menstruation	10 (5)	190 (95)
Swelling in the lower abdomen	6 (3)	194 (97)
Other- back pain	6 (3)	194 (97)
Other- Itchiness around vagina	5 (2.5)	195 (97.5)
Infertility	3 (1.5)	197 (98.5)
Urinary Leakage	2 (1)	198(99)
Other-Family planning	2 (1)	198 (99)
Other-tumor	1 (0.5)	199 (99.5)

From the table above we can see that the majority of women visited the OBGYN department of Dhulikhel hospital due to pain in the lower abdomen 38% followed by vaginal discharge 28%.

DURATION OF BOTHERSOME VAGINAL DISCHARGE

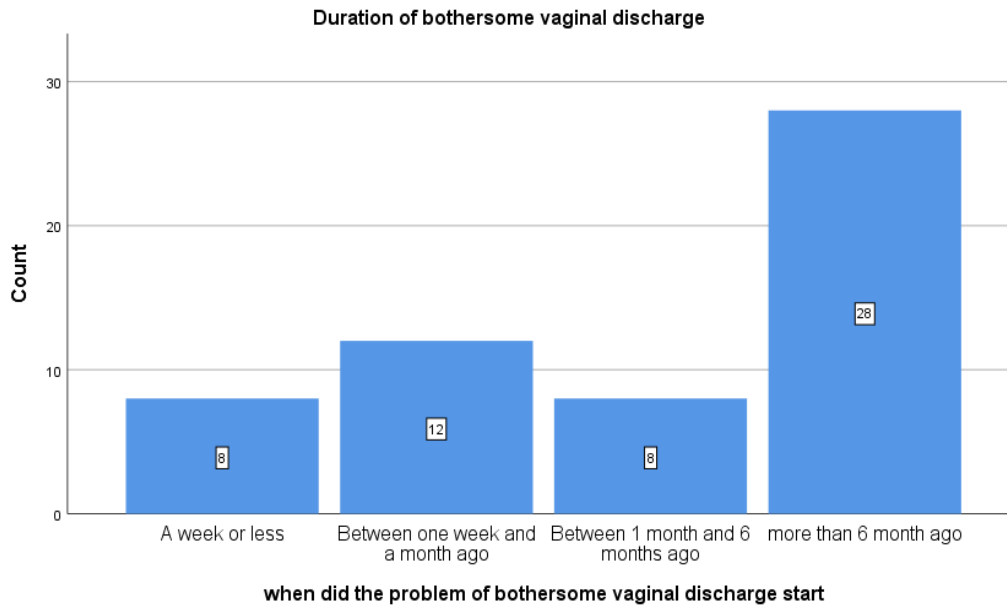


Figure 2: Duration of bothersome vaginal discharge

From the figure above we can see half i.e., 28(50%) of women's bothersome vaginal discharge started more than 6 months ago.

BOTHERSOME VAGINAL DISCHARGE OCCURRENCE

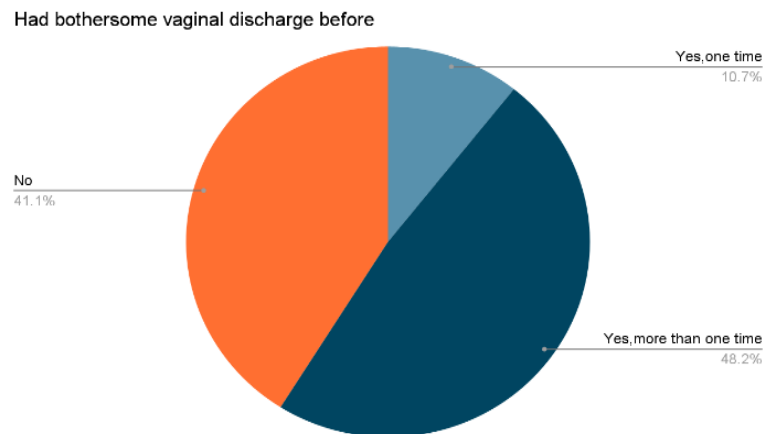


Figure 3: Pie chart showing bothersome vaginal discharge occurrence

The pie chart above shows that 48.2% women had bothersome vaginal discharge more than one time and 41.1% did not had bothersome vaginal discharge before.

PREVIOUS COURSE OF VAGINAL DISCHARGE

Table 3: Course of vaginal discharge before

Course of vaginal discharge before	Frequency	Percentage
	N=56	
I received treatment by a health professional	29	51.8
I did not have bothersome vaginal discharge before	23	41.1
It went away by itself	2	3.6
I used treatment of my own choice	1	1.8
It did not go away	1	1.8

The table above shows that the majority of women received treatment from health professionals when they had a problem of bothersome vaginal discharge before.

COLOR OF VAGINAL DISCHARGE

Table 4: Color of vaginal discharge

Color of vaginal discharge	Frequency	Percentage
	N=56	
Whitish	50	89.3
Yellowish	4	7.1
Clear	1	1.8
Reddish	1	1.8

The table above shows the majority of women, 89.3% had whitish color vaginal discharge.

REASON FOR HOSPITAL VISIT

Table 5: Reason for hospital visit

Reason for Hospital visit among women with abnormal vaginal discharge		
	Yes (%)	No (%)
Offensive smell of the discharge	49(87.5)	7(12.5)
Itchy around your private parts	42(75)	14(25)
Burning or pain around your private parts	38(67.9)	18(32.1)
Burning urination	29(51.8)	27(48.2)
Painful intercourse	17(30.4)	39(69.6)
Sores on your private parts	16(28.6)	40(71.4)

From table above majority of women visited hospital due to these reasons offensive smell of discharge followed by itchy around private part, burning or pain around private parts and burning urination. As the reasons for hospital visit had multiple choice options where the participants were allowed to choose from more than one option thus having the total response to more than 56.

DEGREE OF BOTHERSOME OF VAGINAL DISCHARGE

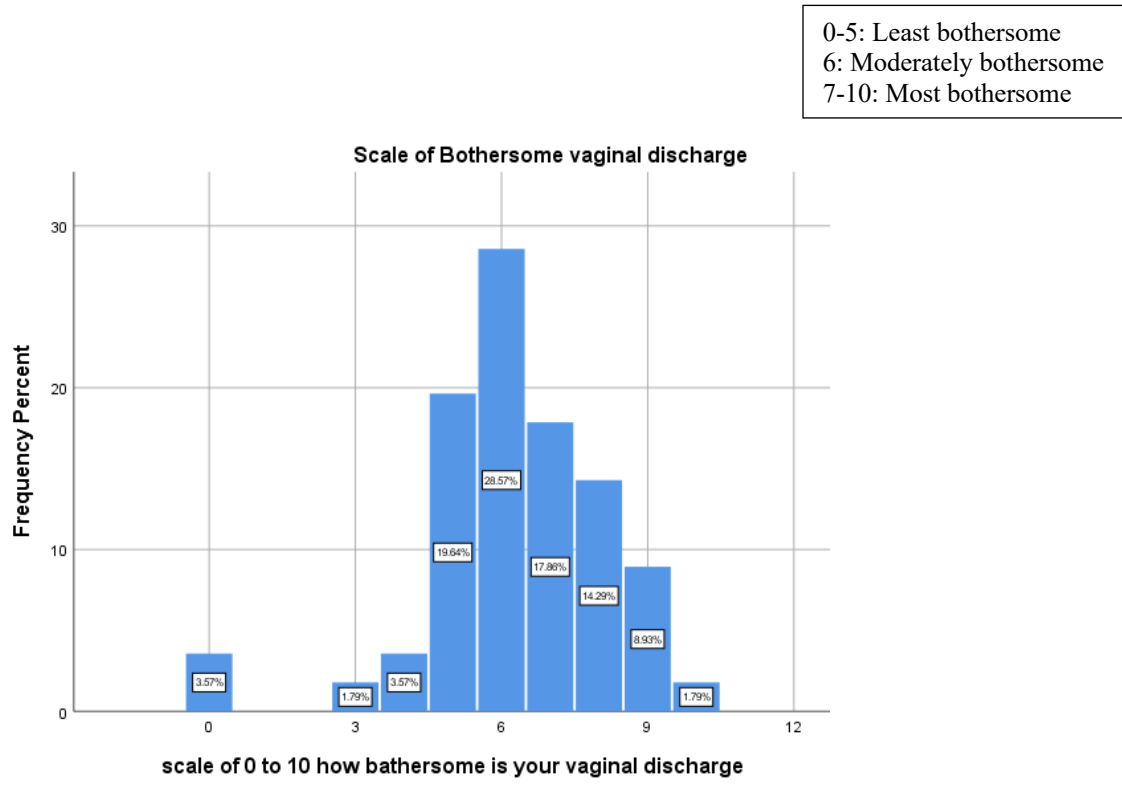


Figure 4: Histogram showing scale of bothersome of vaginal discharge

28.57% of respondents had moderately bothersome vaginal discharge with mean of 6.27 ± 1.90 SD.

METHOD USED FOR EXAMINATION

Table 6: Method used for examination

Method used for examination	Yes (%)	No (%)
Speculum examination	52(92.9)	4(7.1)
Vaginal examination without speculum	3(5.4)	53(94.6)
Vaginal swab	2(3.6)	54(96.4)
Not Sure	2(3.6)	54(96.4)

The table above shows; nearly all participants were examined by using a speculum.

TREATMENT RECEIVED BY PARTICIPANTS

Table 7: Treatment received by participants

Treatment received by participant	Yes (%)	No (%)
Antibiotic tablets to swallow	45(80.4)	11(19.6)
Tablets to swallow, don't know what type	31(55.4)	25(44.6)
Vaginal suppository	29(41.8)	27(48.2)
Cream	6(10.7)	50(89.3)
Painkiller	6(10.7)	50(89.3)
Injection	5(8.9)	51(91.1)
Nothing	1(1.8)	55(98.2)

Both self-report by patient and checking of prescription by data collector for this answer. More than one answer was possible for this question. The above table shows the majority of participants received the following treatments: antibiotic tablets to swallow 80.4%, tablets to swallow (don't know what type) 55.4% and vaginal suppository 41.8%.

RECEIVED TREATMENT FOR HUSBAND

Table 8: Received treatment from husband

Received treatment for husband	Frequency	Percentage
Yes	12	21.4
No	44	78.6

The above table shows the majority that is 78.6% of participants' husbands, did not receive treatment.

EXAMINATION PERFORMER

We asked the question, not being aware that only doctors were involved in performing an examination. We excluded it because apparently patients were confused about this as approximately 40% thought it was a nurse who performed examination.

SATISFACTION WITH CONSULTATION

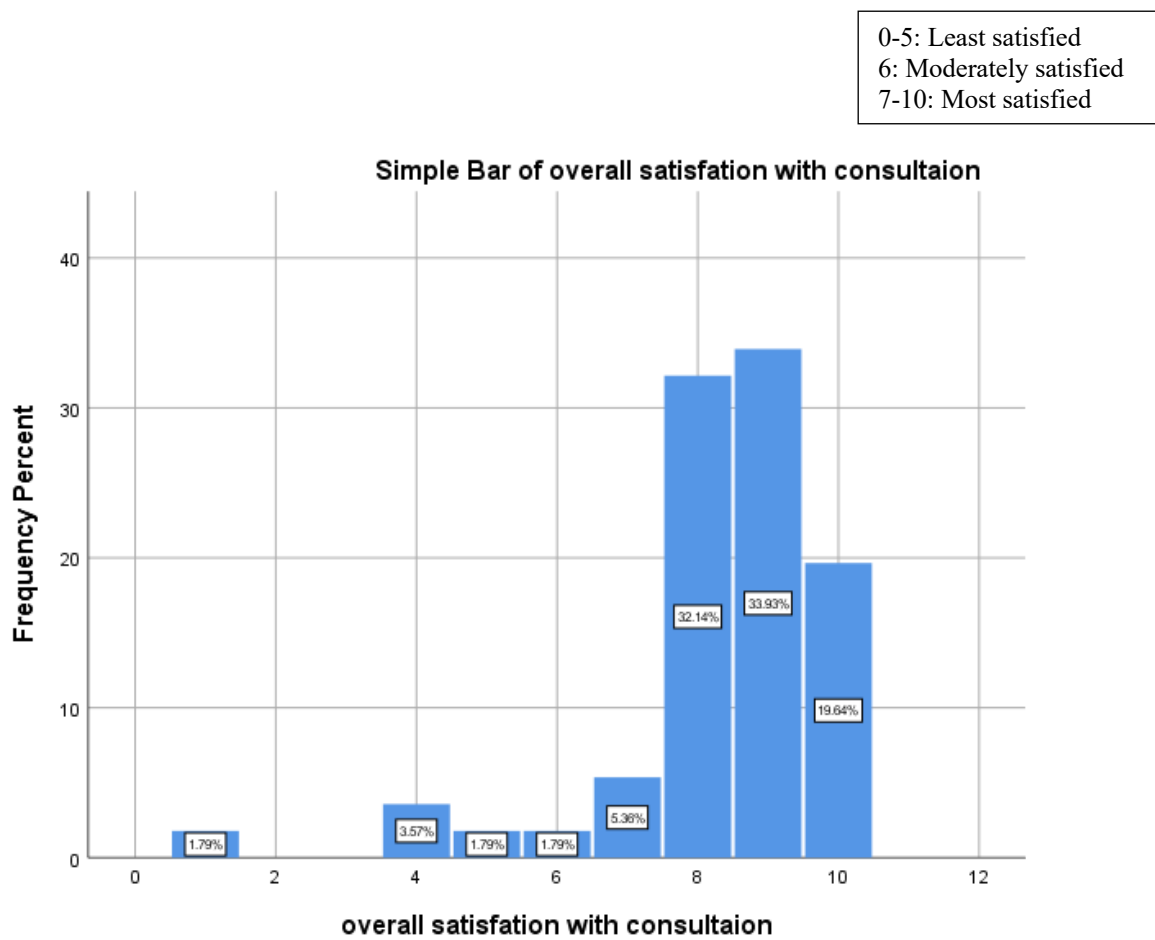


Figure 5: Histogram showing scale of satisfaction from consultation

More than half of the respondents were very satisfied with consultation. The mean score was 8.32 ± 1.674 SD.

SATISFACTION WITH GENDER OF HEALTH PRACTITIONER

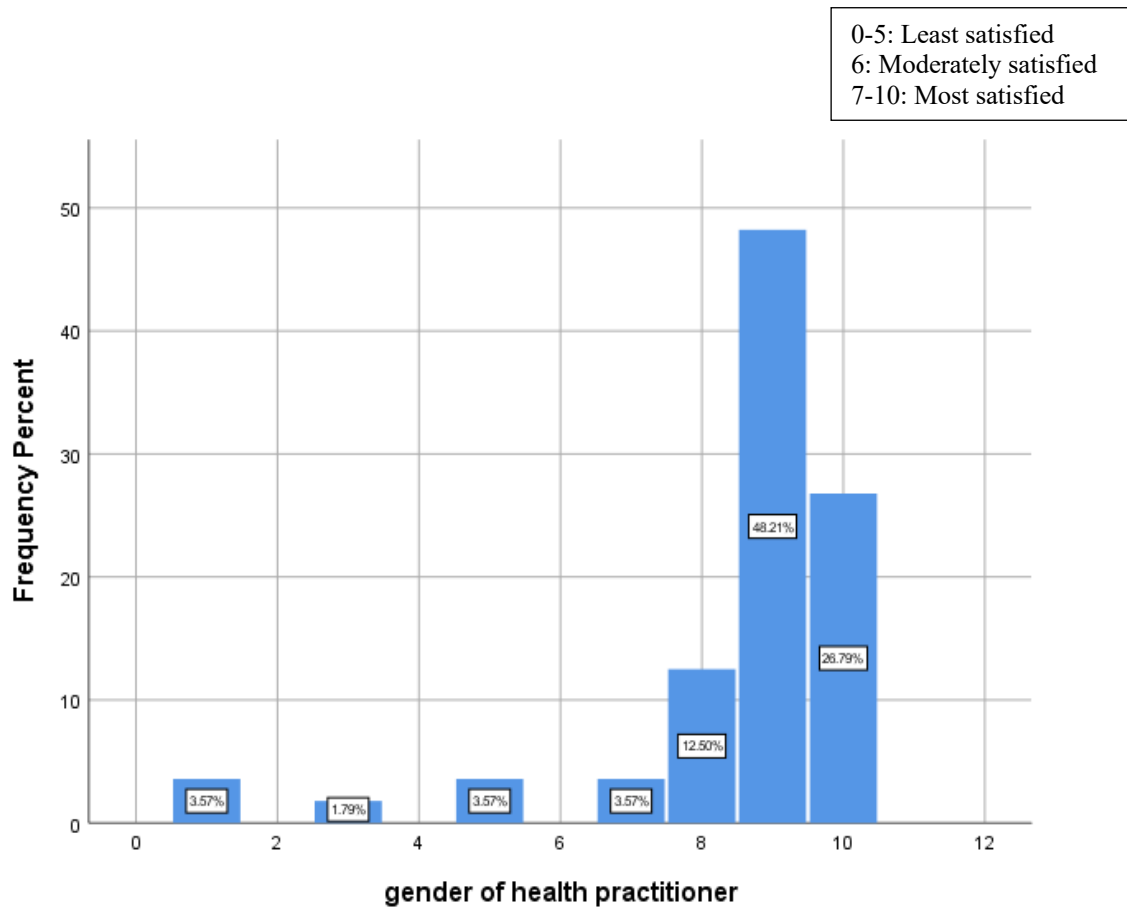


Figure 6: Histogram showing scale of satisfaction with gender of health practitioner

Majority of respondents were very satisfied with the gender of health practitioner. 48.2%, gave a score of 9 to satisfaction with the gender of the health practitioner. The mean score was 8.54 ± 1.972 SD.

SATISFACTION WITH VAGINAL EXAMINATION

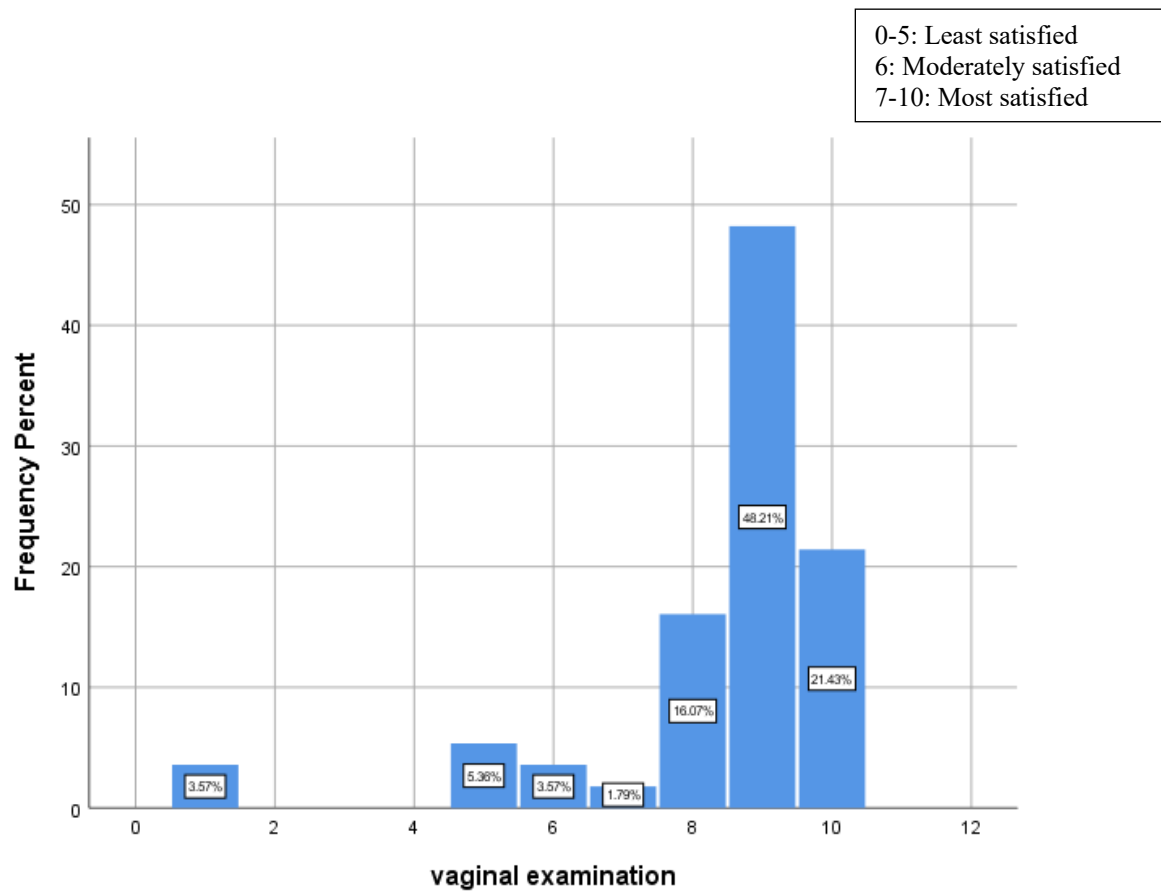


Figure 7: Histogram showing scale of satisfaction with vaginal examination

Majority of respondents 87.5% were most satisfied with the vaginal examination, 48.2% participants gave score 9 to satisfaction with the vaginal examination. The mean score was 8.41 ± 1.905 SD.

SATISFACTION WITH EXPLANATION GIVEN BY HEALTH PRACTITIONER

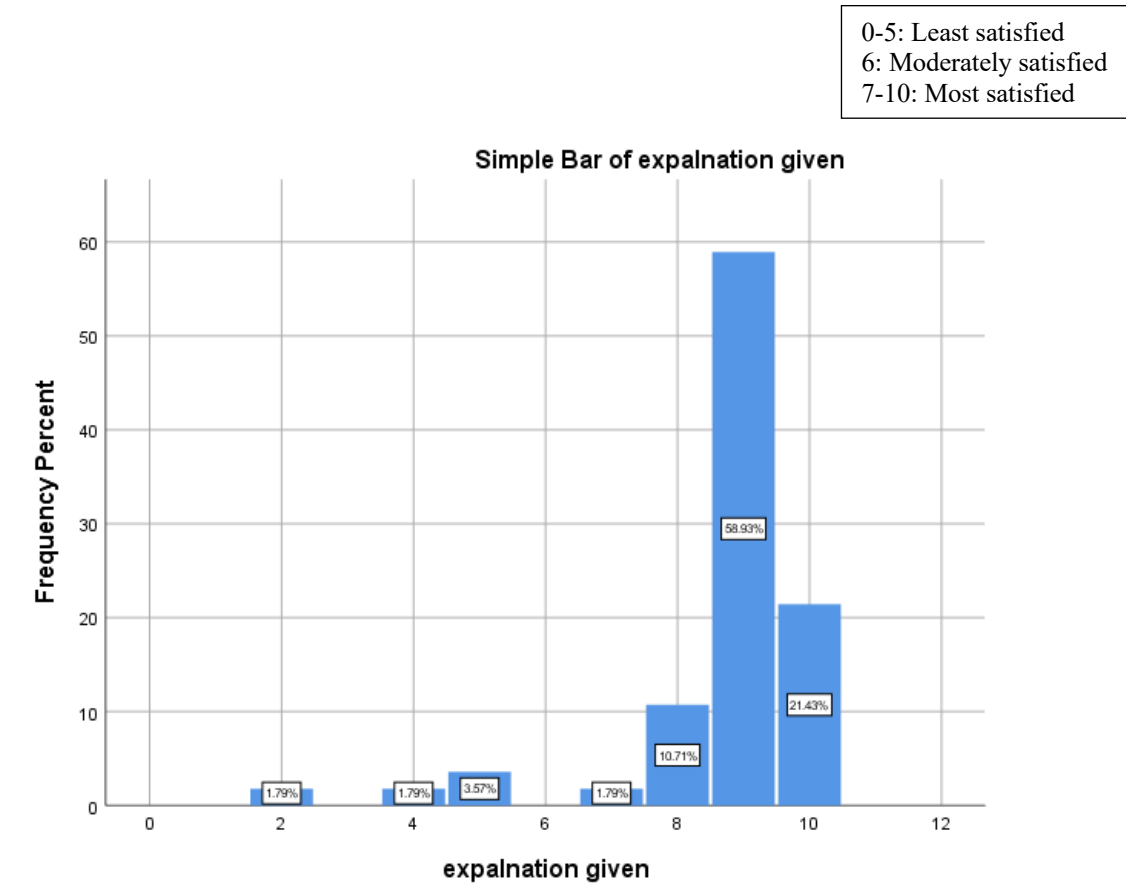


Figure 8: Histogram showing scale of satisfaction with explanation given by health practitioner

Majority of respondents that is 58.92%, gave a score of 9 to satisfaction with the explanation given by the health practitioner. The mean score was 8.71 ± 1.498 SD. The majority of participants were very satisfied with the explanation given by a health practitioner.

SATISFACTION WITH TREATMENT

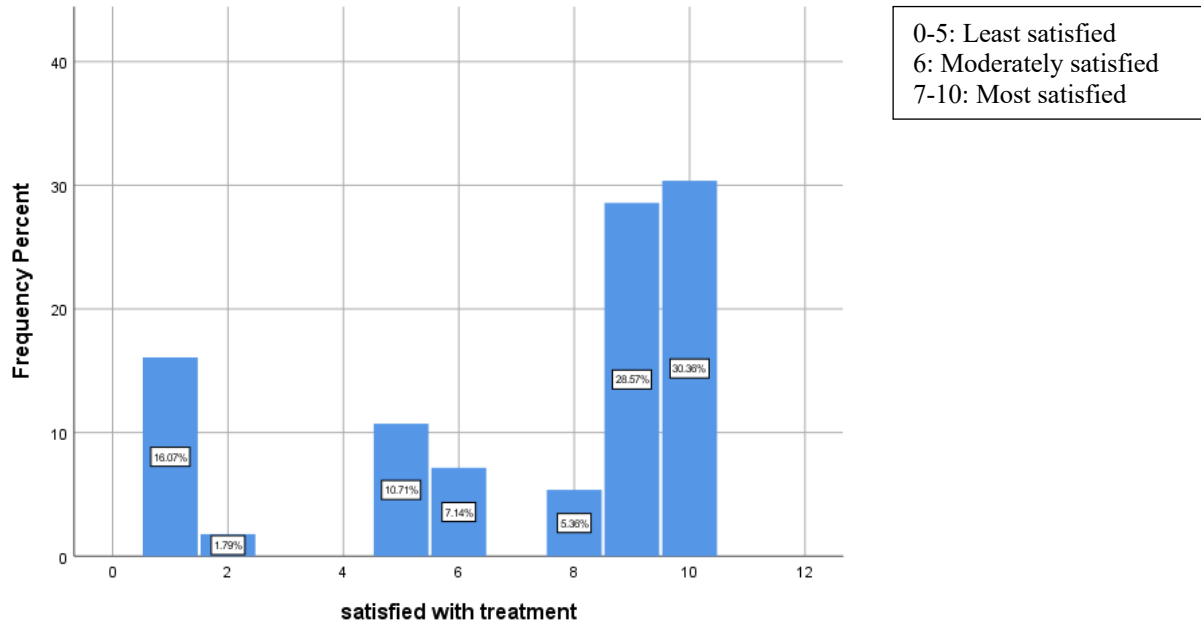


Figure 9: Histogram showing scale of satisfaction with treatment

The table above shows, one third women were very satisfied, and one fifth women were not satisfied at all with treatment. Similarly, the average women were moderately satisfied. The mean score was 7.2 ± 3.289 .

BOTHERSOME OF VAGINAL DISCHARGE AFTER ONE MONTH

Table 9: Bother some of vaginal discharge after one month

Bothersome of vaginal discharge after one-month		
	Frequency	Percentage
	N=56	
Less bothering- it has improved	39	69.6
More bothering- it has deteriorated	6	10.7
Unchanged	11	19.6

The table above shows that the majority of participants vaginal discharge was less bothersome, that is it had improved after one month.

MEDICINE

Table 10: Medicine

Medicine		Frequency	Percentage
		N=56	
Consumed medicine given	Yes	53	94.6
	No	3	5.4
Took additional treatment for vagina discharge	Yes-went to another health practitioner	3	5.4
	No	53	94.6
Admitted to Hospital	Yes	5	8.9
	No	51	91.1

The table above shows that the majority of participants i.e., 94.6% consumed the medicine that was prescribed by the healthcare practitioner. Majority of participants i.e., 94.6% of participants did not take additional treatment for vaginal discharge and only 8.9% of participants were admitted to hospital within one month and the reason for their admission was bothersome vaginal discharge.

SATISFACTION OF COST WITH TREATMENT

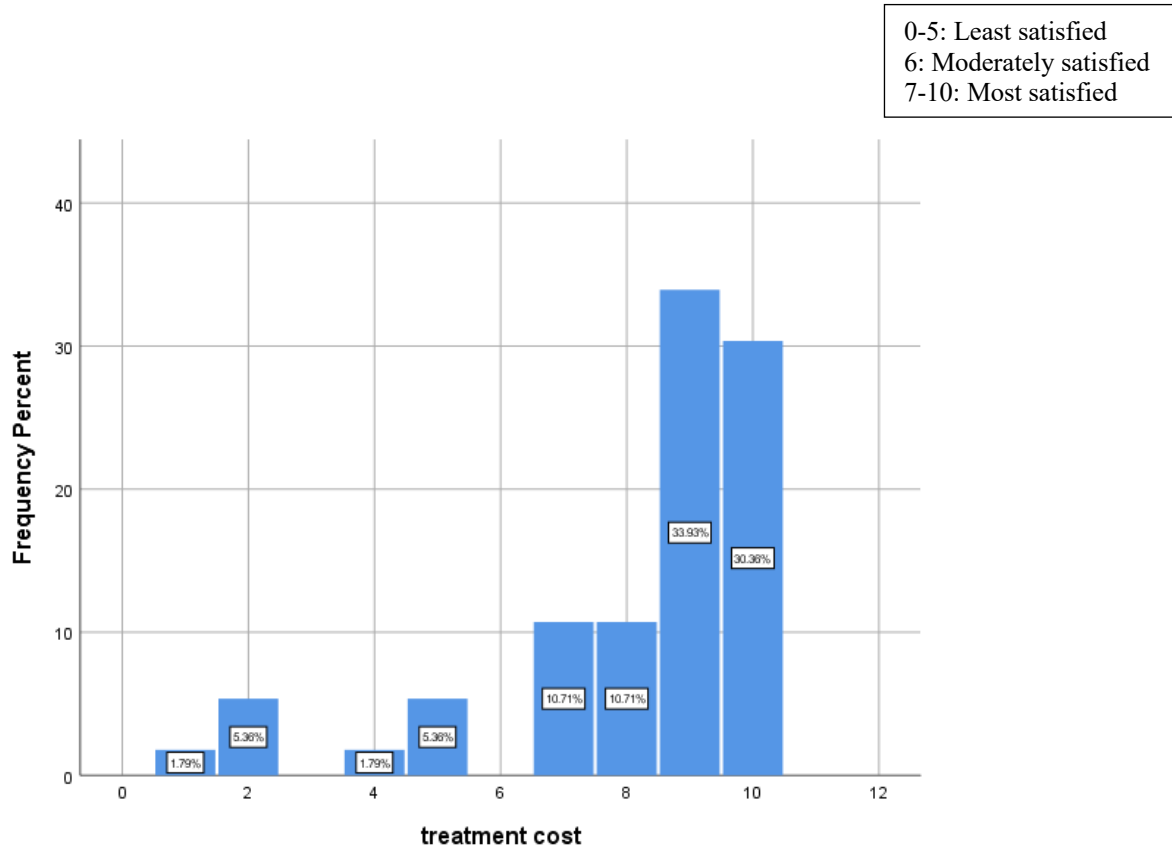


Figure 10: Histogram showing scale satisfaction of cost with Treatment

Majority of participants i.e., 85.71% women were satisfied with the cost of treatment. The mean score of satisfaction was 8.16 ± 2.302 SD. However, 14.3% of the participants found the treatment very expensive.

ASSOCIATION OF SOCIODEMOGRAPHIC CHARACTERISTICS WITH PARTICIPANTS WITH VAGINAL DISCHARGE

Table 11: Association of self-reported vaginal discharge and educational status

Education Status	Self-reported abnormal vaginal discharge		P-value
	Yes (%) (N=56)	No (%) (N=144)	
Illiterate	4(7.14)	14(7)	*0.029
Primary School	28(50)	48(24)	
Secondary school	17(30.35)	56(28)	
Diploma	4(7.14)	2(1)	
Bachelors	2(3.57)	19(9.5)	
Masters	1(1.78)	5(2.5)	

There was no association between the complaint of vaginal discharge and age or marital status. However educational status was significantly associated with complaint of vaginal discharge. 50% of women with primary level education complained of abnormal vaginal discharge followed by 30.35% in secondary level, 7.14% in diploma, 7.14% in illiterate, 3.57% in bachelor's level and 1.78% in Masters level. Chi-square test was used to assess the association between the bothering vaginal discharge and education status.

ASSOCIATION BETWEEN BOTHERING VAGINAL DISCHARGE AFTER TREATMENT WITH ASSOCIATED VARIABLES

Characteristics	Still bothering abnormal vaginal discharge in follow-up			p-value
	Less bothering (%)	More Bothering (%)	Unchanged (%)	
Received Antibiotics				
Yes	33(58.92)	4(7.14)	8(14.28)	0.368
No	6(10.7)	2(3.57)	3(5.35)	
Any other treatment for vaginal discharge				
Yes	1(1.78)	2(3.57)	0	*0.04
No	38(67.85)	4(7.14)	11(19.64)	
Unknown tablet received				
Yes	23(53.57)	3(5.35)	5(8.92)	0.76
No	16(28.57)	3(5.35)	6(10.7)	
Received medication from husband				
Yes	7(12.5)	1(1.78)	4(7.14)	0.34
No	32(57.14)	5(8.92)	7(12.5)	
Examination performer				
Doctor	28(50)	3(5.35)	4(7.14)	0.07
Nurse	11(19.64)	3(5.35)	7(12.5)	
Currently taking medication				
Yes	38(67.85)	5(8.92)	10(17.85)	0.21
No	1(1.78)	1(1.78)	1(1.78)	

Bothersome vaginal discharge after treatment was not significantly associated with antibiotics received, unknown tablet received, received medication from husband, examination performer and if currently taking medication. However, there was an association between still bothering vaginal discharge and any other treatment received but as the association is marginal and also the sample

size is small we could not draw the conclusion that the association is significant. ($p=0.04$) The Fisher exact test was used to assess the association between currently bothering vaginal discharge and other associated variables.

DISCUSSION

In this hospital-based cross-sectional study among semi-urban residence women of reproductive age visiting the gynecology ward of Dhulikhel hospital, we found the proportion of self-reported abnormal vaginal discharge to be 0.28. Among the women complaining about bothersome vaginal discharge, the majority of women reported of having whitish discharge along with offensive smell. This could be because of the physiology or because of the yeast growth. The major reasons for women visiting OPD of OBGYN department were lower abdominal pain followed by abnormal vaginal discharge. Among the women with complain about abnormal vaginal discharge majority reported that they were treated with antibiotics. We found a significant association between abnormal vaginal discharge with lower education status. Lack of knowledge regarding hygiene, healthy sexual practice and variation in cultural belief may have led to bothersome vaginal discharge in women with low education status. Almost all women with complain of bothersome vaginal discharge were examined using speculum. Majority of women with bothersome vaginal discharge were treated with antibiotics tablets. 85.71% of women were very satisfied with the consultation they received during their checkup however approximately 20% of women were very dissatisfied with the treatment and majority moderately satisfied.

A systematic review and meta-analysis published in 2016 reviewed the studies from 2000s to 2015 showed that in India among women seeking care in the primary and secondary health care settings, about 11 to 38.4% of women seeked care for abnormal vaginal discharge. (9) Our study showed among the women seeking care at tertiary level hospital 28% was for self-reported abnormal vaginal discharge. One of the main reasons for the similarity could be because of the similar status of both countries along with similar health care foundation and service delivery.

In our study we found significant association between education status and self-reported abnormal vaginal discharge. About twice as many women with the complaint of vaginal discharge had only primary education, compared to women with no complaint of vaginal discharge; in contrast to a study conducted in Ludhiana. (4) This could be because of the different study setting. In Ludhiana the study was conducted in urban setting whereas in Nepal the study was conducted in semi-urban setting. Lower education is an indicator for low socio-economic status, and it is associated with low health education, access to information and appropriate decision making. It is reasonable that

low education level may contribute to low information regarding proper vaginal and sexual health hygiene leading to increase complaint of bothersome vaginal discharge.

Identification of specific cause of bothersome vaginal discharge is a big challenge in Nepal because of the hesitation and stigma regarding sexual health and due to scarce human resources at health facilities.

This is the first study describing current management of bothersome vagina discharge in a tertiary level hospital in Nepal. Most of the studies conducted in Nepal focus on STIs/RTIs, so this study with its major focus on vaginal discharge as a specific symptom will help to determine the proportion of bothersome vaginal discharge and its management at tertiary level hospital. Another strength of our study is that we did a pilot study before conducting an actual study to adapt to the tool.

Our study also has several limitations. First as the study is cross-sectional study, we could not establish the temporality in the relationship between the associated factors and abnormal vaginal discharge. Second, as the sampling in the study is purposive there might be chances of selection bias which limits the generalizability. Furthermore, another major limitation of the study is that the tool used for the study is not formally validated. Also, half of the planned number of the women were not included in the study. As the study was conducted in the hospital periphery the participant could not have been more open to talking about their dissatisfaction which might result in biased answer.

CONCLUSION

About one third of all women visiting the gynecology out-patient ward at Dhulikhel hospital (Tertiary level hospital) located in a semi-urban region of Nepal had complaint of self-reported bothersome vaginal discharge which was second major cause for the women to visit the hospital preceded by lower abdominal pain. Bothersome vaginal discharge was more commonly reported among the women with low education status. One third women with self-reported abnormal vaginal discharge had moderately bothersome vaginal discharge. Almost all women were very satisfied with the examination at the hospital.

The findings underline that vaginal discharge is a very common and moderately bothersome problem. The treatment is in most cases with antibiotics and that in about one third the symptoms are unchanged or worse after a month.

Targeting women with low educational level may raise awareness regarding reproductive health. Possibly, promoting healthy sexual behavior and hygienic practices may reduce complain of vaginal discharge in women with low educational level. And focus on research is needed to explore women's perceptions and variations in cultural beliefs.

ANNEXES

QUESTIONNAIRE

Time at Beginning:

1. Week (मिति) :
2. How old are you? (तपाईंको उमेर कति भयो?)
3. What is your marital status? (तपाईंको वैवाहिक स्थिति के हो?)
 1. Married (विवाहित)
 2. Unmarried (अविवाहित)
 3. Divorced/separated/widowed (सम्बन्धविच्छेद भएको/विछोडिएको/विधवा भएको)
 4. Engaged/boyfriend (इन्गेज्ड/प्रेमी)
4. What is your level of education? (तपाईंको शिक्षा को स्तर के हो)
 1. Illiterate (निरक्षर)
 2. Primary school (प्राथमिक विद्यालय)
 3. Secondary school (माध्यमिक विद्यालय)
 4. Diploma (डिप्लोमा)
 5. Bachelors (स्नातक)
 6. Masters (मास्टर्स)
5. Are you currently pregnant?
 1. Yes (हो)
 2. No (होइन)

6. What is the reason for your visit to the outpatient clinic today? More than one answer possible.
(तपाईं आउट पेशेंट क्लिनिकमा जानुको कारण के हो? एक भन्दा बढी उत्तर सम्भव छ।)

1. Vaginal discharge (योनि स्राव)
2. Problems with bleeding from the vagina? (योनिबाट रगत बग्ने समस्या छ?)
3. Pain in the lower abdomen (तल्लो पेटमा दुखाइ)
4. Pregnancy related (गर्भावस्था सम्बन्धित)
5. Swelling in the lower abdomen (तल्लो पेटमा सुन्निने)
6. Follow up (पुनः कुराकानी अगाडि बढाउनु)
7. Infertility (बाँझोपन)
8. Urinary leakage (मूत्र रिसाव)
9. Other (अन्य).....

End Time/Continue

If vaginal discharge is not included in question 6 , you are finished with the questionnaire (यदि योनि डिस्चार्ज प्रश्न 6 मा समावेश गरिएको छैन भने, तपाईंले प्रश्नावलीको साथ समाप्त गर्नुभयो)

If vaginal discharge is included please continue (यदि योनि डिस्चार्ज समावेश छ भने कृपया जारी राख्नुहोस्)

OPD number:

7. When did the problem with bothersome vaginal discharge start (कष्टप्रद योनि स्रावको समस्या कहिले सुरु भयो)

1. A week or less (एक हप्ता वा कम)
2. Between one week and one month ago (एक हप्ता र एक महिना अघि)
3. Between 1 month and 6 months ago (१ महिना र ६ महिना अगाडि)

4. more than 6 months ago (६ महिनाभन्दा अघि)

8. Did you have a bothersome vaginal discharge before? (के तपाईंलाई पहिले योनीबाट कष्टप्रद स्राव भएको थियो?)

1. Yes, one time (हो, एक पटक)
2. Yes, more than one time (हो एक पटक भन्दा बढी)
3. No (छैन)

9. If you had bothersome vaginal discharge before, how was the course of it that time? (यदि तपाईंलाई पहिले योनीबाट कष्टप्रद स्राव भएको थियो भने, त्यो समयको पाठ्यक्रम कस्तो थियो?)

1. It went away by itself (त्यो आफैँ गयो)
2. I used treatment of my own choice (मैले आफ्नै रोजाइको उपचार प्रयोग गरें)
3. I received treatment by a health professional (मैले स्वास्थ्यकर्मीबाट उपचार पाएको छु)
4. It did not go away (त्यो हटेको छैन) थिएन

10. What is the color of vaginal discharge? (योनि स्राव को रंग के हो?)

1. Clear (सादा तरल पदार्थ)
2. Whitish (सेतो तरल पदार्थ)
3. Yellowish (पहेँलो)
4. Brownish (खैरो तरल पदार्थ)
5. Reddish (रातो तरल पदार्थ)
6. Greenish (हरियो)

7. Other (अन्य).....

11. Are there any of these problems also present? More than one answer is possible. (के यी समस्याहरू पनि छन्? यदि हो भने के?)

1. Offensive smell of the discharge (डिस्चार्जको अपमानजनक गन्ध)
2. Itchy around your private parts (आफ्नो निजी अंग वरिपरि चिलाउने)
3. Burning or pain around your private parts (तपाईंको गोप्य भाग वरिपरि जलन वा दुखाइ)
4. Burning urination (पिसाब जल्ने)
5. Painful intercourse (पीडादायी संभोग)
6. Skin changes on your private parts (तपाईंको गोप्य भागहरूमा छाला परिवर्तन)
7. Sores on your private parts (तिम्रो निजी भागमा घाउ)

12. On the scale of 0 to 10 how bothersome is your vaginal discharge (० देखि १० को मापन मा तपाईंको लक्षण कती दर्दनाक छ?)

Not at all 0 1 2 3 4 5 6 7 8 9 10 worst possible

हुदै हैन 0 1 2 3 4 5 6 7 8 9 10 सबैभन्दा खराब सम्भव

छ

Time before consultation:

-----AFTER CONSULTATION-----

-----परामर्श पछि-----

13. What examination was performed? More than one choice possible (कस्तो परीक्षा भयो?)

1. Vaginal swab (योनि स्वाब)
2. Vaginal examination without speculum (स्वाब नगरी योनि जाँच गरियो)
3. Speculum examination (स्पेक्युलम) (show picture of speculum to patient)



4. Not sure (निश्चय छैन)

14. What treatment did you receive for the vaginal discharge? (More than one answer possible) के उपचार पाउनुभयो? (बहु विकल्प प्रश्न). The patient may show the prescription or the medication.

1. Antibiotic tablets to swallow (एन्टिबायोटिक ट्याब्लेटहरू निल्न)
2. Tablets to swallow, don't know what type (ट्याब्लेटहरू निल्न, थाहा छैन कस्तो प्रकारको)
3. Injection (इंजेक्शन)
4. Cream (क्रीम)
5. Vaginal suppository (योनि सपोजिटरी)
6. Painkiller (दुखाई निवारक)
7. Nothing (केहि छैन)

15. Did you receive medication for your husband as well? (के तपाईंले आफ्नो श्रीमानको लागिपनि औषधि प्राप्त गर्नुभयो)

1. Yes (हो)
2. No (होइन)

16. Who performed the examination? (कसले परीक्षा दियो?)

1. Doctor (डाक्टर)
2. Nurse (नर्स)
3. Other assistant (अन्य सहायक)

17. How satisfied with the consultation were you overall? (तपाईं समग्र परामर्शबाट कतिको सन्तुष्ट हुनुहुन्छ?)

Very dissatisfied 1 2 3 4 5 6 7 8 9 10 very satisfied
धेरै असन्तुष्ट 1 2 3 4 5 6 7 8 9 10 धेरै सन्तुष्ट

18. How satisfied were you with the following points: (तपाईं यी बिन्दुहरूसँग कतिको सन्तुष्ट हुनुहुन्छः)

1. Gender of Health Care Practitioner (स्वास्थ्य सेवा व्यवसायी को लिंग)

Very dissatisfied 1 2 3 4 5 6 7 8 9 10 very satisfied
धेरै असन्तुष्ट 1 2 3 4 5 6 7 8 9 10 धेरै सन्तुष्ट

2. Vaginal examination (योनि परीक्षा संग सम्बन्धित)

Very dissatisfied 1 2 3 4 5 6 7 8 9 10 very satisfied
धेरै असन्तुष्ट 1 2 3 4 5 6 7 8 9 10 धेरै सन्तुष्ट

3. Explanation given (स्पष्टीकरण दिइएको)

Very dissatisfied 1 2 3 4 5 6 7 8 9 10 very satisfied
धेरै असन्तुष्ट 1 2 3 4 5 6 7 8 9 10 धेरै सन्तुष्ट

Time of goodbye:

-----AFTER ONE MONTH (एक महिना पछि)-----

19. Is your vaginal discharge still bothering you? (के तपाईंको योनि डिस्चार्जले तपाईंलाई अझै परेशान गरिरहेको छ?)

1. Less bothering- it has improved (कम परेशानी - यो सुधार भएको छ)
2. More bothering- it has deteriorated (थप चिन्तित- बिग्रियो)
3. Unchanged (अपरिवर्तित)

20. Did you take the medication? (के तपाईंले औषधि लिनुभयो?)

1. Yes (हो)
2. No (होइन)

21. Did you take any other medical treatment for the vaginal discharge afterwards? (के तपाईंले योनि डिस्चार्जको लागि पछि कुनै अन्य चिकित्सा उपचार लिनुभयो?)

1. Yes - bought myself (हो - आफैले किनेको)
2. Yes- went to another health practitioner (हो- अर्को स्वास्थ्य चिकित्सककहाँ गएँ)
3. No (होइन)

22. Were you admitted to hospital within the last month (के तपाईं पछिल्लो महिनामा अस्पतालमा भर्ना हुनुहुन्थ्यो?)

1. Yes (हो)
2. No (होइन)

23. If yes. Why? (यदि हो भने। किन?)

.....
24. Were you satisfied with the treatment? (के तपाईं प्रारम्भिक परामर्श र उपचार बाट सन्तुष्ट हुनुहुन्थ्यो?)

Very dissatisfied 1 2 3 4 5 6 7 8 9 10 very satisfied
धेरै असन्तुष्ट 1 2 3 4 5 6 7 8 9 10 धेरै सन्तुष्ट

25. Why were you satisfied or not- satisfied with the treatment? Please chose the number corresponding most to your opinion (तपाईं उपचारबाट किन सन्तुष्ट वा असन्तुष्ट हुनुहुन्थ्यो? कृपया तपाईंको रायसँग मिल्दो नम्बर छान्नुहोस्)

1. My discharge was normal after the treatment (उपचार पछि मेरो डिस्चार्ज सामान्य थियो)

Not true at all 1.....2.....3.....4.....5.....6.....7.....8.....9.....10 very true
बिल्कुलै सत्य होइन 1.....23.....4.....5.....6.....7.....8.....9.....10 धेरै साँचो

2. I experienced side effects (मैले साइड इफेक्ट अनुभव गरें)

Yes, very true 1.....2.....3.....4.....5.....6.....7.....8.....9...10 not true at all
हो, धेरै सत्य 1...2.....3.....4.....5.....6.....7.....8.....9...10 बिल्कुल सत्य होइन

3. The cost of the treatment (उपचार खर्च)

Was too high 1.....2.....3.....4.....5.....6.....7.....8.....9.....10 was low
धेरै उच्च थियो 1.....2.....3.....4.....5.....6.....7.....8.....9.....10 कम थियो

INFORMED CONSENT

CONSENT FORM FOR RESEARCH PROJECT “CURRENT VAGINAL DISCHARGE MANAGEMENT AT A TERTIARY REFERRAL HOSPITAL IN NEPAL, PATIENT REPORTED OUTCOME”

“नेपालमा तेस्रो रेफरल अस्पतालमा हालको योनि डिस्चार्जको व्यवस्थापन, बिरामीले रिपोर्ट गरिएको परिणाम”

Do you want to take part in this research project to describe how many women currently visit health care facilities with bothersome vaginal discharge, how it is investigated and treated and the women's satisfaction with the examination and the treatment?

के तपाईं यस अनुसन्धान परियोजनामा भाग लिन चाहानुहुन्छ कि हाल कति जना महिलाहरू कष्टप्रद योनि स्राव भएका स्वास्थ्य सेवा केन्द्रहरूमा आउँछन्, कसरी यसको अनुसन्धान र उपचार गरिन्छ र परीक्षा र उपचारबाट महिलाहरू सन्तुष्ट छन्?

PURPOSE OF THE PROJECT AND WHY YOU ARE BEING INVITED TO PARTICIPATE

परियोजनाको उद्देश्य र तपाईंलाई किन सहभागी हुन आमन्त्रित गरिएको छ

This research is part of a master's thesis for a Nepalese master student studying in Norway. We plan to publish results in an international journal, present results to the local health care community and a local radio station.

This hospital was chosen, because they are connected to a research facility in Norway, responsible for this project. You are invited to participate because you are a woman and are visiting this hospital during the study period. We are also gathering information from women without bothersome vaginal discharge to compare to women with the problem.

यो अनुसन्धान नर्वेमा अध्ययनरत नेपाली मास्टर विद्यार्थीको मास्टर्स थिसिसको अंश हो। हामीले परिणामहरू अन्तर्राष्ट्रिय जर्नलमा प्रकाशित गर्ने, स्थानीय स्वास्थ्य सेवा समुदाय र स्थानीय रेडियो स्टेशनमा परिणामहरू प्रस्तुत गर्ने योजना बनाएका छौं।

यो अस्पताल छनोट गरिएको थियो किनभने तिनीहरू नर्वेमा अनुसन्धान सुविधासँग जोडिएका छन्, यो परियोजनाको लागि जिम्मेवार। तपाईंलाई सहभागी हुन आमन्त्रित गरिएको छ किनभने तपाईं एक महिला हुनुहुन्छ र अध्ययन अवधिको समयमा यो अस्पताल भ्रमण गर्दै हुनुहुन्छ। हामीले समस्यामा परेका महिलाहरूसँग तुलना गर्न कष्टप्रद योनि स्राव नहुने महिलाहरूबाट पनि जानकारी सङ्कलन गरिरहेका छौं।

How will the project be carried out?

परियोजना कसरी अघि बढ्छ ?

Questions will be asked about your age, your marital status, prior serious medical problems and the reason why you are here today. If you have no problem with vaginal discharge, there will be no further questions. If you do have a problem with vaginal discharge, we will ask detailed questions about the discharge and other problems sometimes experienced with a vaginal discharge. After the consultation with the health professional, we will ask about the type of examination, if tests were taken, what type of medication you received and how satisfied you were with the examination and why. We will ask about your telephone number because we will contact you after one month to find out if your problem with vaginal discharge changed, and how satisfied you were with the treatment and why.

We will record all information gathered directly into a computer. Your telephone number will be deleted after we contacted you telephonically for a maximum of two times after one month.

The interview will take about 10 minutes before the consultation, 10 minutes after the consultation, and again 10 minutes at follow up after one month. There will be no costs for you in connection with this project. Charges for the consultation or medication will be unchanged.

तपाईंको उमेर, तपाईंको वैवाहिक स्थिति, पहिलेको गम्भीर चिकित्सा समस्या र तपाईं आज यहाँ हुनुको कारण बारे प्रश्न सोधिनेछ। यदि तपाईंलाई योनि स्रावको साथ कुनै समस्या छैन भने, त्यहाँ कुनै थप प्रश्नहरू हुनेछैनन्। यदि तपाईंलाई योनि डिस्चार्जमा समस्या छ भने, हामी योनि स्रावको साथमा कहिलेकाहीं अनुभव हुने डिस्चार्ज र अन्य समस्याहरूको बारेमा विस्तृत प्रश्नहरू सोधिनेछौं। स्वास्थ्य व्यवसायीसँग परामर्श गरेपछि, हामी परीक्षणको प्रकार, परीक्षणहरू लिइयो भने, तपाईंले कस्तो प्रकारको औषधि पाउनुभयो र परीक्षाबाट तपाईं कतिको सन्तुष्ट हुनुहुन्छ र किन। हामी तपाईंको टेलिफोन नम्बरको बारेमा सोधिनेछौं किनभने योनि स्रावको साथ तपाईंको समस्या परिवर्तन भएको छ कि छैन, र तपाईं उपचारबाट कतिको सन्तुष्ट हुनुहुन्छ र किन थाहा पाउनको लागि हामी एक महिना पछि तपाईंलाई सम्पर्क गर्नेछौं।

हामी सिधै कम्प्युटरमा जम्मा गरिएका सबै जानकारी रेकर्ड गर्नेछौं। तपाईंको टेलिफोन नम्बर मेटिनेछ जब हामीले तपाईंलाई एक महिना पछि अधिकतम दुई पटक टेलिफोन सम्पर्क गरौं।

अन्तर्वार्ताले परामर्श गर्नु अघि लगभग 10 मिनेट, परामर्श पछि 10 मिनेट र एक महिना पछि फलोअपमा फेरि 10 मिनेट लिनेछ। यस परियोजनाको सम्बन्धमा तपाईंको लागि कुनै लागत लाग्ने छैन। परामर्श वा औषधिको लागि शुल्क अपरिवर्तित हुनेछ।

POSSIBLE ADVANTAGES AND DISADVANTAGES

सम्भावित लाभ र बेफाइदाहरू

There is probably no personal advantage for you to participate in the study, apart from that it gives you an opportunity to share your opinion. It will not influence the investigations by the health care professional, or the treatment given to you. If you still have the same problem or a deterioration,

at the follow up telephonic interview, we will advise you to be referred to a tertiary health care facility or to come back for another appointment. The project may help to improve the current management of bothersome vaginal discharge in Nepal in the long term. Further it will help to put more focus on this bothersome problem and on how a patient experiences a consultation and the treatment given in general.

तपाईंले अध्ययनमा भाग लिनुको लागि सायद कुनै व्यक्तिगत फाइदा छैन, यस बाहेक यसले तपाईंलाई आफ्नो विचार साझा गर्ने मौका दिन्छ। यसले स्वास्थ्य हेरचाह व्यवसायी वा तपाईंलाई दिइएको उपचार द्वारा अनुसन्धान प्रभावित गर्दैन। यदि तपाईंलाई अझै पनि उही समस्या वा बिग्रिएको छ भने, टेलिफोनिक अन्तर्वार्तामा, हामी तपाईंलाई तृतीयक स्वास्थ्य सेवा सुविधामा पठाउन वा अर्को अपोइन्टमेन्टको लागि फिर्ता आउन सल्लाह दिनेछौं। यस परियोजनाले दीर्घकालीन रूपमा नेपालमा कष्टप्रद योनि स्रावको वर्तमान व्यवस्थापनमा सुधार गर्न मद्दत गर्न सक्छ। थप यो कष्टप्रद समस्यामा र बिरामीले कसरी परामर्श र सामान्य रूपमा दिइने उपचारको अनुभव गर्छ भन्ने कुरामा थप ध्यान केन्द्रित गर्न मद्दत गर्नेछ।

VOLUNTARY PARTICIPATION AND RIGHT TO WITHDRAW CONSENT

स्वैच्छिक सहभागिता र सहमति फिर्ता लिने अधिकार

Participation in the project is voluntary. If you would like to participate, please sign the consent form at the end of this document. You can withdraw your consent without giving a reason. There will be no negative consequences for you or your treatment if you do not want to participate or if you choose to withdraw at a later stage. You can request access to the information gathered from you, and this will be provided within 30 days. You can also request for your data in the project to be changed or deleted. If it is deleted, it will not be used in any research. The right to have your data changed or deleted does not apply anymore, once your telephone number has been deleted after the follow up after one month.

If you want to withdraw or have questions about the project, you can contact the project manager, see the contact details at the end of this document.

परियोजनामा सहभागिता स्वैच्छिक छ। यदि तपाईं सहभागी हुन चाहनुहुन्छ भने, कृपया यस कागजातको अन्त्यमा सहमति फारममा हस्ताक्षर गर्नुहोस्। तपाईं कुनै कारण नदिई आफ्नो सहमति फिर्ता लिन सक्नुहुन्छ। यदि तपाईं भाग लिन चाहनुहुन्छ वा तपाईं पछिको चरणमा फिर्ता लिने छनोट गर्नुहुन्छ भने तपाईं वा तपाईंको उपचार को लागी कुनै नकारात्मक परिणाम हुनेछैन। तपाईंले तपाईंबाट सङ्कलन गरिएको जानकारीमा पहुँचको लागि अनुरोध गर्न सक्नुहुन्छ, र यो 30 दिन भित्र प्रदान गरिनेछ। तपाईं परियोजनामा तपाईंको डेटा परिवर्तन वा मेटाउनको लागि अनुरोध गर्न सक्नुहुन्छ। यदि यसलाई मेटाइयो

भने, यो कुनै पनि अनुसन्धानमा प्रयोग गरिने छैन। एक महिना पछि फलोअप पछि तपाईंको टेलिफोन नम्बर मेटाइएपछि तपाईंको डाटा परिवर्तन वा मेटाउने अधिकार अब लागू हुँदैन।

यदि तपाईं फिर्ता लिन चाहानुहुन्छ वा परियोजनाको बारेमा प्रश्नहरू छन् भने, तपाईं परियोजना प्रबन्धकलाई सम्पर्क गर्न सक्नुहुन्छ, यस कागजातको अन्त्यमा सम्पर्क विवरणहरू हेर्नुहोस्।

WHAT HAPPENS TO THE INFORMATION HELD ON YOU?

तपाईंलाई राखिएको जानकारीमा के हुन्छ?

The data registered about you will only be used as described under the purpose of the project, and is planned for use in 2021 and 2022. You have the right to access the information that is registered about you and to have any errors in this information corrected. You can lodge a complaint about any process in connection with this research to the [Norwegian Data Protection Authority](#) and the [Norwegian University for Science and Technology, Data Protection Officer](#).

No names or personal identification numbers will be recorded. The only personally identifiable information is your telephone number, which will be deleted after the telephonic follow up.

तपाईंको बारेमा दर्ता गरिएको डाटा परियोजनाको उद्देश्य अन्तर्गत वर्णन गरिए अनुसार मात्र प्रयोग गरिनेछ, र 2021 र 2022 मा प्रयोगको लागि योजना गरिएको छ। तपाईंसँग तपाईंको बारेमा दर्ता गरिएको जानकारी पहुँच गर्ने र यस जानकारीमा कुनै त्रुटिहरू सुधार गर्ने अधिकार छ। तपाईंले यस अनुसन्धानको सम्बन्धमा कुनै पनि प्रक्रियाको बारेमा नर्वेजियन डाटा प्रोटेक्शन अथोरिटी र नर्वेजियन युनिभर्सिटी फर साइंस एण्ड टेक्नोलोजी, डाटा प्रोटेक्शन अफिसरमा उजुरी गर्न सक्नुहुन्छ।

कुनै नाम वा व्यक्तिगत पहिचान नम्बरहरू रेकर्ड गरिने छैन। व्यक्तिगत रूपमा पहिचान योग्य जानकारी मात्र तपाईंको टेलिफोन नम्बर हो, जुन टेलिफोनिक फलोअप पछि मेटिनेछ।

FOLLOW-UP

पुनः कुराकानी अगाडि बढाउनु

You will be contacted again after one month telephonically up to two times, if you are not able to answer the telephone the first time. We will ask, if your bothersome vaginal discharge has changed, if you visited another health practitioner with the same problem, and how satisfied you were with the treatment and why. If necessary, we will help you to be referred from primary to tertiary health care.

यदि तपाईं पहिलो पटक टेलिफोनको जवाफ दिन सक्षम हुनुहुन्न भने, तपाईंलाई एक महिना पछि दुई पटकसम्म टेलिफोनबाट पुनः सम्पर्क गरिनेछ। हामी सोध्नेछौं, यदि तपाईंको कष्टप्रद योनि स्राव परिवर्तन

भएको छ भने, यदि तपाईंले उही समस्या भएको अर्को स्वास्थ्य चिकित्सकलाई भेट्नुभयो भने, र तपाईं उपचारबाट कतिको सन्तुष्ट हुनुहुन्छ र किन। आवश्यक भएमा, हामी तपाईंलाई प्राथमिक देखि तृतीयक स्वास्थ्य सेवामा पठाउन मद्दत गर्नेछौं।

APPROVALS

अनुमोदनहरू

The Regional Committee for Medical and Health Research Ethics in Norway, Nepal Health Research Council and Ethical review community IRC of Dhulikhel have approved the project.

नर्वेको क्षेत्रीय चिकित्सा तथा स्वास्थ्य अनुसन्धान नैतिकता समिति र नेपाल स्वास्थ्य अनुसन्धान परिषद्ले आयोजनालाई स्वीकृत गरेको छ ।

The Norwegian University for Science and Technology and the project manager Kusum Poudel are responsible for privacy and data protection in this project.

नर्वेजियन युनिभर्सिटी फर साइन्स एन्ड टेक्नोलोजी र परियोजना प्रबन्धक कुसुम पौडेल यस परियोजनाको गोपनीयता र डेटा सुरक्षाको लागि जिम्मेवार छन्।

If you have questions about the project or want to withdraw your participation, you can contact

Name: Kusum Poudel

Telephone number: +977 9745390407

Email: Kusum53513@gmail.com

यदि तपाईंसँग परियोजनाको बारेमा प्रश्नहरू छन् वा तपाईंको सहभागिता फिर्ता लिन चाहनुहुन्छ भने, तपाईं सम्पर्क गर्न सक्नुहुन्छ

नाम: कुसुम पौडेल

टेलिफोन नम्बर: +977 9745390407

इमेल: Kusum53513@gmail.com

I AGREE TO PARTICIPATE IN THE PROJECT AND CONSENT TO MY PERSONAL INFORMATION BEING USED AS DESCRIBED

म परियोजनामा भाग लिन सहमत छु र वर्णन गरिए अनुसार मेरो व्यक्तिगत जानकारी प्रयोग गर्न सहमत छु

Place and date स्थान र मिति	Participant's signature or Thumb print सहभागीको हस्ताक्षर वा औंठा छाप						
	<table border="1"><tr><td></td><td></td><td></td></tr><tr><td>Signature</td><td>Right Thumb</td><td>Left Thumb</td></tr></table>				Signature	Right Thumb	Left Thumb
Signature	Right Thumb	Left Thumb					
	Participant's name in block capital letters ब्लक क्यापिटल अक्षरहरूमा सहभागीको नाम						

Name and signature or thumb print of witness साक्षीको नाम र हस्ताक्षर/ औंठा छाप		
Signature	Right Thumb	Left Thumb

PROGRESS PLAN

Activity	Start Date	End Date
Project planning and literature research	February 2021	March 2021
Protocol writing	March 2021	March 2021
Protocol submission and approval	April 2021	May 2021
Sick leave	August 2021	October 2021
Apply to ethical committee	October 2021	November 2021

Sick leave	November 2021	December 2021
Meeting with hospital department	May 2022	May 2022
Data collection and data entry	May 2022	July 15, 2022
Data analysis	July 15 2022	September 2022
Write thesis	September 2022	November 2022
Defend thesis	November 2022	

BUDGET

Items	Cost
Stationeries (Questionnaire print, fingerprint pad, register)	1014.23 NOK
NHRC Approval	775.02 NOK
Dhulikhel Hospital IRC approval	1440.44 NOK
Transport Airways Trondheim to Kathmandu Kathmandu to Trondheim	7908 NOK 7345 NOK = 15,253

Transport to the Site (Dhulikhel hospital)	30 NOK *30 days =900 NOK
Transportation for NHRC, IRC Dhulikhel, Site visit, Introduction with faculty of Dhulikhel Hospital	702.16 NOK
Phone bill for telephonic interview	390.18 NOK
Total	20,475.03 NOK

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