INTERVENTIONAL STUDY ON THE EFFECTS OF RAPID ETHICAL ASSESSMENT ON INFORMED CONSENT COMPREHENSION AND QUALITY OF INFORMED CONSENT PROCESS, AND ASSOCIATED FACTORS IN BIOMEDICAL RESEARCH IN WUKIRO KILTE-AWULAELO AND HINTALO-WAJIRAT, TIGRAY, ETHIOPIA

BY SEREBE ABAY GEBRIE (BSc)

A THESIS SUBMITTED TO THE SCHOOL OF GRADUATE STUDIES OF ADDIS ABABA UNIVERSITY IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR DEGREE OF MASTER IN PUBLIC HEALTH

Addis Ababa, Ethiopia

April 2014

Addis Ababa University

School of Graduate studies

Interventional study on the effect of rapid ethical assessment on informed consent comprehension and quality of informed consent process, and associated factors in biomedical research in Wukiro kilte-awulaelo and Hintalo-wajirat districts, Tigray, Ethiopia

By: Serebe Abay (BSc.)

School of Public Health

College of Health Science, Addis Ababa University

Approved by examining board

_____ _____

Chairman, Department Graduate committee

Dr. Adamu Addissie _____

Advisor

Dr. Fitsum Girma _____

Examiner

Abiy Seifu _____

Examiner

STATEMENT OF THE AUTHOR

I declare that this thesis is my work and all sources of materials used for this thesis have been duly acknowledged. I solemnly declare that this thesis is not submitted to any other institution anywhere for the award of any academic degree, diploma or certificate.

Name: Serebe Abay Signature:_____

Place: Addis Ababa University, school of public Health

Date of Submission: _____

Name of advisor: Adamu Addissie Signature:_____

ACKNOWLEDGEMENT

I would like to express my special thanks to my advisor Dr. Adamu Addissie for his invaluable support, comment and guidance from proposal development to the writing of this thesis.

I am grateful to thank School of Public Health, College of Health Science, Addis Ababa University and the librarian for their kindest cooperation by providing necessary materials.

I would like to express my special thanks to my friends Thomas Addissie, Mehari Yihdego, and Haftay G/medihin for their kindest support provided me to accomplish this work.

Finally my special thanks go to Prof Gail Davey, Brighton and Sussex Medical School (BSMS) UK and the International Orthodox Christian Charities (IOCC) podoconiosis research group, for their financial support for the study.

ABBREVIATIONS

AAU – Addis Ababa University

ANC –Antenatal Care

AOR –Adjusted Odds Ratio

BICEP–Brief Informed Consent Evaluation Protocol

BIQ–Brief Investigator Questionnaire

DICCT–Deaconess Informed Consent Comprehension Test

ESTC–Ethiopian Science and Technology Commission

FGD–Focused Group Discussion

HPV–Human Papilloma Virus

HRRC–Health Research Review Committee

HST–Health Science and Technology

IDI– In-depth Interview

IERCs– Institutional Ethics Review Committees

MICCA– Modular Informed Consent Comprehension Assessment

NERC–National Ethics Review Committee

NHSTC–National Health Science and Technology Council

QuIC– Quality of Informed Consent

REA–Rapid Ethical Assessment

RERCs–Regional Ethics Review Committees

RHB –Regional Health Bureau

TABLE OF CONTENT

LIST OF TABLES

LIST OF FIGURES

LIST OF ANNEXES

ABSTRACT

Back ground: Informed consent is a corner stone in researches involving human participants. The process of obtaining informed consent is a challenge for low-literacy and resource-limited settings. Potential research participant should be assisted with interventions to improve their comprehension. Rapid Ethical Assessment (REA) is an intervention developed to contextualize consent processes in low-income setting. An interventional study was done to evaluate the effects REA on recruitment rate, compliance rate, comprehension level and quality of the informed consent process among participants of biomedical research.

Methods: A community based qualitative study followed by institutional based interventional study was employed among pregnant women of age 18-45 years in Wukiro kilte-awulaelo and Hintalo-wajirat districts, Tigray regional state, Ethiopia from July 8 to August 20, 2013. The intervention was modifications in the informed consent content and process based on community based qualitative REA findings. This qualitative REA study was done among key informants in the intervention site concerning biomedical research, cancer in general and cervical cancer particularly, communication channel, socio-cultural dynamics, sample collection and how to find informed volunteer participants with fully understanding for the parent study. We did a total of 11 formal recorded In-depth Interviews (IDIs), and 5 Focused Group Discussions (FGDs) with key informants. A total of 300 healthy pregnant women who were eligible for the Parent Study were included in this study. One hundred fifty were allocated in to intervention group with modified and 150 in to control group with the standard informed consent forms and procedures. In both group comprehension levels and quality of consent process were measured using Modular Informed Consent Comprehension Assessment (MICCA) and Quality of Informed Consent (QuIC) process assessment tools, respectively.

Result: The initial recruitment rate to participate in the parent study for the intervention and control groups were 88.7% and 80.7%, respectively. The compliance rate to show follow-up 12 days after initial consent were 85.7% for the intervention group and 70.3% for control group. Overall mean score of informed consent comprehension for the intervention and control groups were 73.1% and 45.2%, respectively. Mean difference in comprehension score was 27.9% (P<0.000, 95% CI= 24.0%-33.4%).

Educational level of secondary and above (AOR= 6.68, 95% CI=1.01- 44.03), Previous participation in any biomedical research (AOR=2.77, 95% CI=1.01-7.58), being Merchants by occupation (AOR=5.43, 95% CI=1.78-16.60) and having monthly income less than 1000.00 Ethiopian birr (AOR= 0.38, 95%

CI=0.15-0.96) were found significantly associated with comprehension score status. Concerning the quality of informed consent process the mean scores for the intervention group was 89.1% and for control group was 78.5%. The mean difference in quality of informed consent process was 10.5% (P<0.000, 95% CI =6.8-14.2). No significant association was found between socio-demographic variables and quality of informed consent process taking a mean score of 75% as a cut point.

Conclusion and recommendation: The level informed consent comprehension, recruitment rate, compliance rate and quality of consent process among the control group were low as compared to the intervention group. These were improved through modifying the consent form and information sheet locally and contextually tailored to the study area based on REA findings. This implies that potential study participant in a research can be assisted to comprehend consent components, and subsequently comply with further tasks to be performed. Therefore, it is recommended that REA to be further used to address gaps on comprehension and quality of informed consent process.

Key words: modified and standard consent forms, recruitment rate, compliance rate, Informed consent comprehension level, Quality of informed consent process, Rapid Ethical Assessment (REA), Ethiopia

1. INTRODUCTION AND BACK GROUND

Guidance and regulation of the ethics of medical research have primarily evolved in the developed world, using principles that stem from Western values and social traditions [1]. International research collaborations now commonly include investigators and participants from developing countries, while international ethical guidelines may govern these collaborations. In reality, these take very little account of the different social structures, cultural norms, legal frameworks and communication channels of the countries involved [2].

Prospective participants in research may have experienced different traditions of healthcare, hold varying beliefs about illness and Views about the causation of illness may differ from the western medical model. Participants will often be unfamiliar with the concept of research and may be sensitive to some practices, such as taking blood samples. Currently there is increasing recognition of the need for research in developing countries where disease burden is high. It is critically important that the local, social, cultural and economic context should be considered when research is designed [3, 4].

Research in the developing world is prone to a confusing array of guidance and international declarations. In Ethiopia, research is governed mainly by principles and regulations established by regulatory authorities such as the Ethiopian Science and Technology Commission (ESTC).The problem is not lack of regulation, rather international guidance and regulations are necessarily generic inform and content. This has given rise to criticism of the western approach to identifying and addressing ethical issues related to research in developing country settings [5]. The inflexible use of international ethical guidelines in health research has at times led to situations which have prompted investigators to seek an approach to adapting these guidelines to local situations [6-8]. Various studies conducted in developing countries have emphasized the importance of addressing local context beyond the universal context, especially in the developing world where there is a difference between what is assumed by researchers and the practical reality on the ground.

Farsides and Bull, in their study in Gambia, developed an approach of REA which is carried out among key stakeholders, and the results used to inform the design of the consent process for the studies in question. Valuable information from researchers, fieldworkers and potential participants helped to guide development of a consent process that took into account key issues surrounding how the research was explained, how decisions to participate were reached and how true respect for participants could be fostered [9].

Subsequently, Tekola F. et al applied REA tool before a genetic study in southern Ethiopia. Information gathered from patients and the community has helped to shape the research agenda as well as the consent process for subsequent studies [4].

Rapid Ethical Appraisal

Rapid Ethical Appraisal is a kind of rapid ethnographic assessment conducted at the beginning of research to guide the consent process. The consent process includes all the activities ranging from the conception and development of the consent form to the way how consent is obtained, monitoring, and making sure participants are recruited and included in the study in affair manner. The assessment is conducted among key stake holders to inform the design of the particular study [7].

Rapid ethical assessment is a brief qualitative intervention designed to map the ethical terrain of the research setting prior to participant recruitment. It attempts to discover, describe and respond to the ethical issues specific to a particular research setting, and help researchers to address the issues that genuinely matter to proposed participants [7, 9].

Research Question: Is REA use full tool to improve comprehension and quality of informed consent process among biomedical research participants in a low income setting, like Ethiopia?

Statement of the Problem

The challenge to international research ethics is to apply universal ethical principles to biomedical research in a multicultural world with a multiplicity of health-care systems and considerable variation in standards of health care. The Guidelines take the position that research involving human subjects must not violate any universally applicable ethical standards, but acknowledge that the superficial aspects, in the application of the ethical principles, e.g., in relation to individual autonomy and informed consent, needs to take account of cultural values, while respecting absolutely the ethical standards [10].

In Ethiopia research ethics is a relatively recent phenomenon. The mandate to ensure ethics in health research falls in the hands of the Ethiopian Science and Technology Ministry and is governed by the internationally held principles and guiding documents. It is not much known how often the principles are tailored to the local contexts of the research participants. Having a country of diverse ethnic groups and culture makes rapid ethical assessment really important issue.

Justification of the Study

Until now REA has been employed mainly in very limited settings with a clear interest in the intellectual as well as practical issues raised by this approach. In this study we would like to evaluate the effect of REA on informed consent comprehension, recruitment rate, compliance rate and the overall quality of informed consent process in biomedical research.

This study will have relevance to increase insight into the limitations of current practices of research and ethical review. The study will have a significant contribution to increase public engagement and to build capacity within the local research community to enhance informed consent and quality of consent process through the use of REA. It also uses to provide evidence base for future research ethics policy development.

2. LITERATURE REVIEW

Today, more than ever, human ethical responsibility must form an integral part of intervention in the mechanisms of life if respect for human rights and human dignity is to be secured. Donation and transplantation of organs, palliative care, equitable access to health services, the artificial reproductive technologies, participation of human beings in experimental research and treatments are the major domains of bioethics [5].

Several international organizations have issued ethical guidance on clinical trials. The Numberg code (1947), the Helsinki declaration, the Belmont report (1979), the World Health Organization, *Guidelines for Good Clinical Practice for Trialson Pharmaceutical Products* (1995); and the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (1996) are the most internationally known ethical regulations and guide lines designed to ensure human rights and dignity [5, 10].

2.1. Ethics of Research in Developing World

Many people in developing world suffer from poor health and reduced life expectancy. The role of research that contributes to the development of appropriate treatments and disease prevention measures is vital. However, lack of resources and weak infrastructure mean that many researchers in developing countries have very limited capacity to conduct their own clinical research. They therefore often undertake research in partnership with groups from developed countries. A sound ethical framework is a crucial safeguard to avoid possible exploitation of research participants in these circumstances [3].

Comprehension of study information varies among participants in both developed and developing countries. Participants in developing countries appear to be less likely than those in developed countries to refuse participation in or withdraw from a trial, and are more likely to worry about the consequences of refusal or withdrawal [11].

The array of research works by different researchers has emphasized the need for special attention to the way in which western ethical principles are applied to a research project in the developing world. They have emphasized that the challenges associated with research ethics in developing countries are complex and cannot be addressed by regulatory processes alone. There is a need to move beyond guidelines and

mere ethical review to a broader system perspective cognizant of the spectrum of additional determinants in developing countries [12, 13].

Some researchers have proposed a participatory model that would enhance informed consent based on experience. Such models illustrate the significance of working with community members in the creation of a consent form that is comprehensible to potential participants and an informed consent process that remains active throughout the study, by addressing issues like undue inducement, psychological risks, and lack of awareness of basic principles. This was shown to strengthen research efforts through recruitment and retention of participants who better understand their roles and responsibilities in the study [14].

Any medical treatment, healthcare activity or research requires the consent of the patient or person directly affected by such activity. This requirement is based on the fundamental moral duty that we do not act against a person‟s wishes, and that we respect a person‟s human dignity. Informed consent thus entails a shared decision by both the investigator and the participant. The duty of obtaining informed consent is a requirement in research ethics, which is widely recognized in national and international guidelines as well as legislation [15].

In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the researcher should then obtain the subject‟s freely given informed consent, preferably in written [16].

With regard to information for the proposed research participants, the following need to be noted; the amount of information needed, how to determine the information needed, and how to convey the technical or scientific information in a way that the research participant can understand [11,17].

Recruiting research volunteer participants, obtaining informed consent and building the research endeavor would encounter difficulties unless a bond of trust develops between scientists or researcher and the community as complementary partners in the research enterprise. Effective interaction between

scientists and the community, between researcher and volunteer participant requires additional competence, and resources at institutional level besides compliance with ethical requirements and competence in research. Among these are communication skills and information facilities. So a significant consideration should be given to effective information contacts with the public to enhance awareness of the relevance of research [17].

A major challenge for researchers is to deliver complex information at the right time in appropriate language and style. To this effect, informed consent documents should be adapted to the local culture and the educational level of the population. Even though developing such a comprehensive document may take several reviews and assessments, when the subjects clearly understand this information, they make better decisions, comply with research procedures, experience less surprise later on, and stay longer in the trials [18].

Accepting and imposing the mostly western model of autonomy as an international regulatory norm in a developing country context could be questionable. Even modifying the methods of obtaining informed consent or the composition and content of consent form may not be adequate to overcome this problem. It is necessary to reflect on culturally sensitive and effective safeguards for protecting human research subjects [19].

Consent is an ongoing process that should be revisited often throughout the study. The process is a continuous interaction between investigator and research subjects that begins at the time of subject recruitment and ends only after the study has been completed. Prior to an invitation to participate research study; the potential subject needs to know about researches, the differences between research participation and standard care, and their rights as a research subject [20].

The investigator must ensure that the prospective subject has adequately understood the information, should give each one full opportunity to ask questions, and should answer them honestly, promptly and completely. In some instances the investigator may administer an oral or a written test or otherwise determine whether the information has been adequately understood [10].

2.2. Research Ethics in Ethiopia

In Ethiopia the agenda of health research ethics is a recent phenomenon. Despite the serious global attention given to the issue, the knowledge and practice of standardized regulations and guide lines remains still shallow and yet there is a growing interest from researchers.

Based on the responsibility vested on it, the health department of the Ethiopian Science and Technology Commission (ESTC) in collaboration with the national health science and technology council (NHSTC) embarked to address health research ethics issues in the country. In 1994, the commission officially launched a national health science and technology policy and established NHSTC which is a broad based body with a function to advise the federal government on health science and technology issues in general and research in particular. The council has different standing committees of which the national health research ethics review committee is one, empowered by the NHSTC to review health research ethics issues, fundamental principles of health research ethics and their applications in the Ethiopian context. The first health research ethics guideline was developed in 1995 and has been revised twice, in 1997 and 2004, respectively. This guideline is expected to confirm universal ethical values [5].

The last century witnessed about 10,000 health research and development publications about Ethiopia which have been financially and/or technically driven by foreign researchers and donors. During the time when there was no policy, national responsible body or standardized national guidelines for appraisal of research projects [17].

With the expansion of post graduate programs in AAU and other new universities, and with the availability of funding related to HIV/AIDS and other diseases of public health importance, the number of research projects with human subjects on yearly basis is progressively increasing. This clearly puts demand on the current system to be more effective and efficient without a compromise on the study subjects [17].

Health research ethics review committees have been established at three levels in order to review proposals for their ethical merits. These levels include national, regional and institutional ethics review committees [17]. NERC is one of the standing committees of the NHSTC which is responsible for the final approval of all clinical trials, research on very sensitive issues, multi-centered collaborative research including graduate student projects, research financed and/or carried out by external donors, research to be carried out by national agency with bilateral or multilateral collaboration, research to be

conducted in more than one region of the country and projects that requires sample transfer. Secretariat for regional ethics review committee (RERCs) is the regional health research council and RERCs are responsible for the ethical review of projects involving more than one institution in the region. RERCs review projects other than those mentioned under the mandate in NERC, in the absence of institutional review committees. Institutional ethics review committees (IERCs) review all health research proposals of the institute and are responsible for reviewing and deciding upon all proposals of the institute which do not come under the mandates of either the NERC or RERC. All applications need to be submitted to the respective institutional or regional committees which will give the final decision for projects under their mandates or give recommendations and send the applications to the national committee according to the guideline [17].

2.3. Informed Consent Comprehension Test

Different Informed consent comprehension tests had been developed to provide much-needed evidence to make judgments about whether adequate comprehension of informed consent occurs among potential participants. Among these; the Deaconess Informed Consent Comprehension Test (DICCT), the Quality of Informed Consent (QuIC) and the Brief Informed Consent Evaluation Protocol (BIECP) were developed to measure clinical trial informed consent comprehension in non-cognitively impaired adults. Adequate reliability had been established for all the three. But validity was only conducted for the DICCT and result showed that DICCT is moderately effective in measuring comprehension. The DICCT contains specific questions related to the use of medication. Therefore; this instrument may not be appropriate for other type of trials such as preventive, diagnostic, screening trials or quality of life trials [21].

QuIC measures both subjective and objective quality of consent process but the questionnaire was developed specifically for cancer clinical trials (phase I-III) and includes cancer specific languages. The author suggests that the QuIC should not be used in non-cancer settings without further study. Many elements of informed consent, such as the details of risks and procedures, are trial specific, and no generic instrument could do justice to their complexity [22].

Latter on two instruments were developed; the Modular Informed Consent Comprehension Assessment (MICCA) and the Brief Investigator Questionnaire (BIQ). Both instruments were developed as web-based applications providing flexibility to construct comprehension test that is specific to a particular

trial and so far can be utilized across a variety of trial that focus on different diseases/conditions. BIQ consists of 10 questions corresponding to one or more of the trial specific test item on the MICCA. This questions guide the researcher how to develop the trial specific test items based on response to BIQ [21].

MICCA measures comprehension by incorporating both generic and trial specified approaches. Readability, validity, generalizability and reliability of the test have been checked, and sufficient result was found. Results of psychometric study provide preliminary evidence that the MICCA can be utilized in various clinical trial setting and can produce reliable and valid score [21]. Therefore; we prefer MICCA to measure informed consent comprehension of participants and QuIC with some modifications to assess the quality of consent process on participant perspective (subjective only) in this study.

2.4. Findings about Informed Consent Comprehension Studies

Kiguba et al. did a cross-sectional study to assess the quality of informed consent in a resource-limited setting conducted at the Mulago National Referral Hospital, Kampala, Uganda. Semi structured interviewer-administered questionnaires on clinic days after initial or repeat informed consent procedures for the respective clinical studies had been administered to each study participant. The study found that 33.7%, (201/596) of the participants were not aware that they could, at any time, voluntarily withdraw participation from these studies [23].

Another interventional study conducted in Lilongwe and Blantyre, Malawi, sites of a multi-country microbicide trial to improve understanding of clinical trial procedures among low literacy populations. The intervention was tested using a sample of 36 women who had been identified as low scorers during the empirical study. The 36 low scorers were randomly assigned to control (n=18) and intervention arms (n=18). Participant in the intervention group were provided with a narratives in ChiChewa, the local language, and power point presentation of concepts under study. Findings of the intervention positively impacted on understanding of trial procedures under study, as 13 of the 18 women in the intervention arm, obtained high scores (above 75%) during the post intervention assessment and none of the 18 in the control arm obtained a high score. The study suggested that potential trial participants can be assisted to understand key clinical trial procedures, their justification and personal implications by using innovative tailored local narratives [24].

Institutional based cross-sectional study was done in Worcester, a rural setting in the Western Cape province of South Africa, to evaluate the quality of informed consent of mothers whose children involved in immunologic study. Nursing staff conducted the interview within one hour of mothers' consent to their infant's participation in the immunology study about Tuberculosis vaccine field trial. These parents were asked to complete a questionnaire that contained questions about the key elements of informed consent (voluntary participation, confidentiality, the main risks and benefits, etc.). The recall and understanding were measured. Result of the study showed that majority of the 192 subjects interviewed obtained scores greater than 75% for both the recall and understanding sections. The median score for recall was 66%; inter quartile range (IQR) = 55%–77% and for understanding 75% (IQR = 50%–87%). Most (79%) were aware of the risks and 64% knew that they participated voluntarily. Participants who had completed Grade 7 at school and higher were more likely (OR = 4.94; 95% CI = 1.57 – 15.55) to obtain scores greater than 75% for recall than those who did not [25].

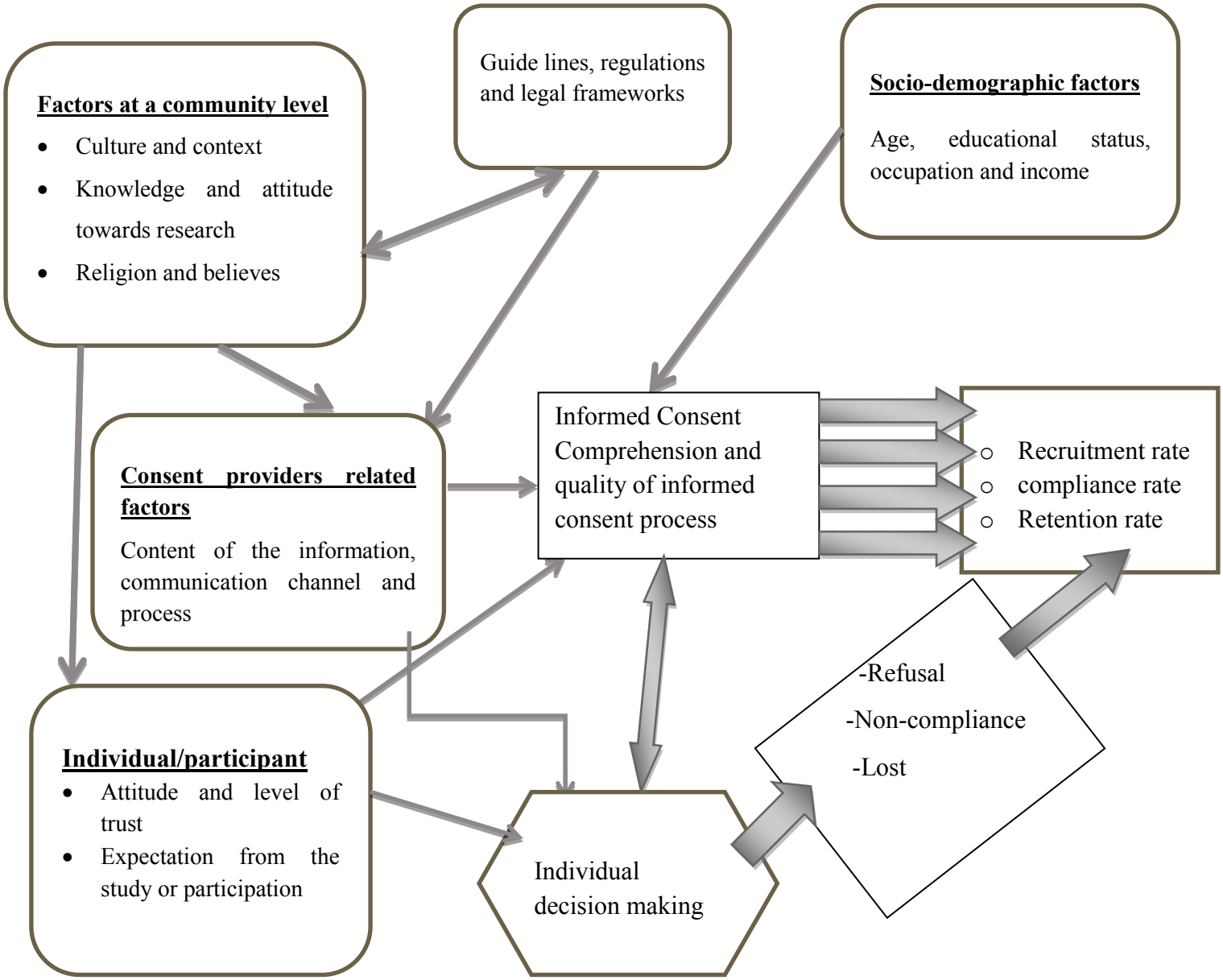
A qualitative study using in-depth interviews, focus group discussions and observations of consent processes was done in Ghana to examine the issues arising when enrolling participants into a genetic and genomic research in a rural Ghanaian setting. The study used a rapid assessment tool within the social sciences designed to inform the adaptation of interventions to local cultures and conditions. Result of the study showed that MalariaGEN participants and field staff seeking consent were generally satisfied with their understanding of the project and were familiar with aspects of the study relating to malaria [26].

Bull and Farsides recognized that problems often arose when ethics committees in low-income countries made decisions based on international guidance that either missed issues of importance locally or over-emphasized issues that had little ethical importance outside a western perspective. In their research in Gambia, Bull and Farsides developed a REA technique based on rapid ethnographic assessment to ensure that relevant ethical issues were addressed in a culturally appropriate manner prior to the start of research. The approach was believed to solve the problem of reconciling the 'volume of sophisticated international guidance and regulation' which is derived from 'specific research contexts', as we move from theory to practice in applying the ethical principles in seeking consent to research [9].

More recently, Fasil Tekola used this approach prior to commencement of a genetic study in Southern Ethiopia to inform the process of consent form development and the processes of seeking consent from the community and individual participants. The study applied in depth interviews (IDI) and focus group

discussions (FGD) to gather data from research participants, non-participant community members, field workers, researchers, and other relevant stake holders. It was found that the extent of use of everyday language, the degree to which expectations of potential participants were addressed, and the techniques of presentation of information had considerable impact on comprehension of information provided about research. Approaching study subjects via locally trusted individuals and preceding individual consent with community sensitization were considered the optimal means of communication. The findings of the rapid assessment were subsequently used to inform the consent process for the genetic research [4].

Figure 1: Conceptual frame work of factors affecting informed consent comprehension and quality of consent process in biomedical research in developing countries



3. OBJECTIVES

3.1. General Objective:

To assess the effect of Rapid Ethical Assessment on informed consent comprehension, recruitment and compliance rate and quality of informed consent process among participant in biomedical research: in Wukro kilte-awulaelo and Hintalo-wajirat districst, Tigray, Ethiopia.

3.2. Specific Objectives:

- ✓ To determine study recruitment and compliance (retention) rates and compare among participants enrolled with modified (intervention) and standard consent form (control group).
- ✓ To determine and compare informed consent comprehension level of study participants among the intervention and control groups
- ✓ To determine and compare quality of consent process during recruitment of study participants among intervention and control groups.
- ✓ To determine socio-demographic factors associated with consent comprehension level and quality of informed consent process.

4. METHODS AND MATERIALS

4.1. Study Area

This study was conducted in two Districts; Wukro Kelete-awlelo and Hintalo-Wajirat from July 8-August 20, 2013. These districts are adjacent to Mekelle, capital city of Tigray, and were most research center for Mekelle University and other colleges within the city. District Wukro Kelete-awlelo is located in the eastern zone of Tigray region. Wukro town is 47 km north of Mekelle with total area of988 square kilometers [40]. As projected by CSA the total population of this district as of June 2005G.C was, 107,862 with 60,330 females and 57,532 males. In 2005, there were 27,322 people living in Wukro Town and 90,540 were living in Kelete-awlelo [41]. The health service coverage in 2003/04 for the study area was 59 % and the antenatal coverage 68.4 %. A total of 1650 pregnant women visited antenatal care clinics in the same year.

Hintalo-Wajirat district is located in south eastern part of Tigray. Adigudom town is the capital of this district with 37 km far from Mekelle. The total area of the district is approximately 1393 square kilometers [41]. The district comprises of 22 *Tabias* (the smallest administrative region in Ethiopia) and 7 health centers. According to the CSA 2007/8 G.C, the total population is estimated to be 152,219. Out of this, males constitute about 75,262 (49.4%) and that of females about 76,957 (50.6%). Out of the total population, 11,928 (7.8%) of them live in town and the remaining 140,291(92.2%) live in the rural areas of the district [41].

Based on the 2007 G.C Census conducted by the Central Statistical Agency of Ethiopia (CSA), the largest ethnic groups of Mekelle were reported the Tigre (96.2%), and Amhara (2.26%); all other ethnic groups made up 1.54% of the population. Tigrigna is spoken as a first language by 95.55%, and Amharic by 3.18%; the remaining 1.27% spoke all other languages. 92.68% of the populations were Orthodox Christians, and 6.03% were Muslim [41].

4.2. Study Design

A qualitative community based REA was done to modify information sheet and consent process. Then interventional study was conducted to assess the Effect of REA on comprehension level and quality of consent process among prospected study participants in health research. The study intervention was introduction of modified information sheet and consent form based on REA findings for the intervention

group. The control group had the standard information sheet and consent form of the proposal for the "Parent study".

4.3. Population

4.3.1. Source population

For the qualitative study all key informants who were residents of the intervention site (district Hintalo-Wajirat), whereas for the quantitative study the source population were all pregnant women attending ANC follow up in the selected health centers.

4.3.2. Study population:

For the qualitative study selected community members, religious and community leaders, field workers and health professionals in district Hintalo-Wajirat.For the quantitative one the study population was all healthy pregnant women age 18-45 years who attend their regular ANC follow up in the four selected health facilities during the study period.

4.3.3. Inclusion and exclusion criteria

Inclusion Criteria

All pregnant women age 18-45 years attending ANC follow up.

Exclusion Criteria

Participants were excluded if they had, sever illness, dementia, or were deaf, delirious

Late 3rd trimester (gestational age greater than 34 weeks) for the convenience of coming back in their follow up

Not volunteer to come back after two weeks for the comprehension assessment interview

4.4. Sample Size Determination

Statistically adequate sample size was determined based on double-population proportion formula with the inputs of 95% confidence level, 80% power of test and since there is no a comprehension and quality of consent process study in Ethiopia we used the comprehension assessment study done in Worcester, a rural setting in the Western Cape Province of South Africa, which showed that high score of 75% and 66% for understanding and recall respectively [25].

$$\text{Participant per group} = \frac{P_1 (1- P_{1)} + p_2 (1-P_2) \text{ X } f(\alpha, \beta)}{(P_2- P_1)^2}$$

Assumptions:

P_1 = 0.75[75% obtain high scores for understanding and 66% for recall studied in South Africa]

P_2 = 0.88[88% expected to obtained high scores for understanding in intervention group]

Power of 80% and significance level of 5% [f (α, β) = 7.85]

$$n = \frac{0.75(1-0.75) + 0.88(1-0.88)}{(0.88-0.75)^2} \times 7.85 = 136$$

Using ratio of 1:1 the total (N) will be 2(136) + 10% non-respondent rate= 300 participants of which 150 participant allocated for each group.

4.5. Sampling Procedure

First two districts which are near to Mekelle and most research center for Mekelle University and other colleges within the city were selected. The districts randomly assigned to intervention and standard sites. Then four health centers (2 health center in each district) which provide ANC service were selected randomly. A total of 300 healthy pregnant women attending their regular ANC during the study period were approached to participate in the study. Sample size to each of the selected health center was allocated proportional to their ANC client flow by taking a one year report.

4.6. Study Variables

Independent variables	Dependent variable
• Age • Marital status • Religion • Educational level • Income • Occupation • Previous exposure to health research	• Recruitment rate • Compliance rate • Informed consent comprehension level

4.7. Data Collection and Instruments

4.7.1. Qualitative data

Rapid Ethical Assessment was done at the beginning of the research to modify the consent form and consent taking procedure. This was done by multi-disciplinary team by using open ended questions in relation to the parent study (HPV-serotype prevalence study). The multi-disciplinary team was composed of one MSC graduate in social anthropology, two MPH graduates, and the principal investigator. Three of the team members were Tigrigna speakers and two of them were residents of the study area. Community workers also involved when needed. After we introduced the study for all the responsible bodies at different level, we started the IDI and FGDs with key informants in two randomly selected Tabiyas where the selected health centers found. Majority of the group discussions were relaxed and participatory of the entire members. Semi-structured open ended questions about biomedical research in relation to the parent study were used. These includes: cancer in general and cervical cancer particularly, communication channel, socio-cultural dynamics, and concerning how to find informed volunteer participants with fully understanding, how and who should collect blood and vaginal secretion samples [Annex VI].

Tape recorder was used for recording the responses of the in depth interviews and focused group discussions. Each day debriefed the findings, took correction measure if any and planned for the next day. After the necessary data had been collected the team analyzed the findings. Then modified the consent form and translated in to Tigrigna for the intervention group. The team also planned the design, training of data collectors and the procedures how the consent should be taken to recruit participants in a fair manner with full understanding. With this direction the principal investigator continue to the comprehensive and quality of consent process assessment study.

4.7.2. Quantitative data

Participants‟ socio-demographic data, comprehension and quality of consent process were collected using structured questionnaire based interview. The questionnaire was initially prepared in English and then translated to Tigrigna. The Tigrigna version was again translated back to English to check for consistency of meaning. Participants in the intervention group were provided with modified information sheet and consent form which was developed by the rapid ethical assessment team. Whereas, in the control site participants were provided with the information sheet and consent form developed by the

principal investigator of the "*HPV-Subtype Prevalence Study"*approved by IRB which was used as a standard in this study. This epidemiologic survey is carried out within the collaboration of Addis-Ababa-University (AAU), Ethiopia and Martin-Luther-University Halle (Saale), Germany from September 2010 to December 2014. This study includes a total of 200 breast specimens collected from Addis Ababa and from Wollega hospital via AAU, and 600 Cervical and serum specimens collected from asymptomatic women attending antenatal clinics age 18-45 years in different parts of the country in which Mekelle was one site. For this study cervical cancer sub-project which is aimed to investigate HPV infection rate in Ethiopian womenwere selected as a parent study. Criteria for this parent study selection includes, a project with interventional or with invasive procedures, with gender sensitive issues, with expected ethnographic, language and cultural barriers and where the principal investigator of the clinical research is volunteer. Therefore, this study used vaginal swab and blood sample collection with possible gender sensitivity and cultural barriers which mean rapid ethnographic assessment could be essential before the actual study.

About 12 days after initial consent taken to participate in the parent study; retention rate, comprehension and quality of consent process of prospective participants in both group were assessed. MICCA and QuIC tools were used to assess informed consent comprehension and quality of consent process, respectively.

4.7.3. **Data quality assurance**

First round (consent seeking for the parent study) data collectors were ANC provider nurses with work experience of 2-6 years. A half day training was given how to provide information sheet and ask consent to participate in the parent study. They were blinded regarding the group of the individuals that they were taking consent and the purpose of the REA study; instead they knew the purpose of the parent study to minimize interviewer bias. Second round data collectors were new BSC graduate nurses and all were equally trained on the informed consent comprehension and quality of consent process assessment tool. Different data collectors were used for consent taking and for informed consent assessment so as to avoid interviewer bias and participant discomfort to speak out freely about the consent process during recruitment for the parent study. The translated Tigrigna version questionnaires were pre tested prior to the actual data collection on 15 respondents that were not included in the study. The result of the pre-test was discussed, and some correction and changes were made on the questionnaires. During data

collection, the supervisors visited study sites at least once a day. The Principal Investigator and the supervisors rechecked all filled questionnaires daily to see whether the interviewers have done correctly or not. Anything that was unclear or ambiguous and incomplete was corrected on the next day. The questionnaire was used to collect information on variables such as socio-demographic characteristics, score of informed consent comprehension and quality of consent process.

4.8. Operational Definition

Comprehension Level Assessment: It is the measurement of the level of participant understanding and recall by memorizing from the information they were given from the consent document to the study they signed or involved. Assessment done based on the Comprehension Test provided after about two weeks of recruitment in to the study. Based on the overall scores comprehension levels were categorized in to three [high >=75%, medium 50%-75%, low =< 50%]. This was adopted from earlier similar studies some modification with adjustment [25].

Understanding–is correctness of interpretations of statements presented

Recall - is the success in selecting or remembering the correct statement

Recruitment Rate: The rate measures the efficiency of the process in the selection of participants in a research and persuading them to join the study. Recruitment rate is a proportion (percentage) of participants voluntarily decides and consented to participate in the study out of those who were approached to take part and consent.

Compliance Rate: It measures compliance to follow-up and appointments as directed in the visit before. Compliance rate refers to the proportion (percentage) of participant that attends their appointment in the specified time divided by the number of participants who were given appointment and agreed to come.

Quality of Informed Consent Process Assessment- is measure of the quality of consent process concerning information adequacy, participant perception and satisfaction of the process, and the situation of decision making during the recruitment process. In this study only participant perspective quality of consent process was assessed**.** Scoring and leveling was the same as for comprehension.

Modified Consent Form- is a consent form modified by REA team based on the rapid ethical assessment findings tailoring to the context assuming that culturally and locally appropriate.

Parent Study: - is *"*Human Papilloma Virus-Subtype Prevalence Study*"*conducted in urban and rural parts of Ethiopia.

Standard Consent Form – is the consent form developed by the principal investigator of the parent study approved by the institutional review board (IRB).

4.9. Data Processing and Analysis

4.9.1. Qualitative data

The tape recorded data was transcribed in Tigrigna and translated to English. Open code software was used to summarize, condense and analyze the data. The data was coded, categorized and thematically analyzed.

4.9.2. Quantitative data

Data were entered into EPI info version 3.5.1 and analyzed using SPSS version 20 computer software packages. Data cleaning and editing were carried out. Dummy tables that consider the main research questions were drafted. Analysis of frequencies of different variables, independent sample T-test, cross tabulation and chi squared test for some selected variables were done to test significant differences. Bivariate logistic regression analysis with the help of Odds ratios (ORs), 95% confidence interval (CI) and P-value were used to assess the presence and degree of association between independent and outcome variables. Odds ratios were calculated to determine the strength of association of selected variables. Multivariate logistic regression model using adjusted odd ratio (AOR) was also used to identify the important determinants for consent comprehension and quality of consent process.

4.9.3. Measurement

Participant comprehension level was determined by measuring the understanding and recall of participants concerning study participant right, purpose of the study, risks and benefits of the study, confidentiality and the basic facts of the *HPV-Subtype Prevalence Study.*A total of 25 questions were used to assess informed consent comprehension of participants of which the 13 questions were to assess understanding and the rest were for recall. Participants were expected to select the appropriate interpretations for a total of 13 questions offered for understanding. This was taken as an indication of the extent to which participants' decisions were based on understanding. In the recall section, participants were expected to remember the correct possible answer from the given choice for each question. One of the answers was an exact reflection of the information in the consent document and selecting the correct answer was taken as an indicator of correct recall. The comprehension assessment tool includes 13 true or false, 7 multiple choices with single correct answer and 5 check boxes with multiple possible answers each score 1 value.

The test items consisted both generic and trial specific questions. Of the 25 test items the14 were generic test items that appear on each version of MICCA, 6 were trial specific test items which did not appear on every version of the MICCA and were generated based on response to BIQ and the rest 5 were trial specific test items appear on each version of the MICCA in which the response option for each of these test items are generated based on response to BIQ. The type of the question and the correct answer for each question is written in superscript numbers and brackets, respectively [Annex VIII].

To assess the quality of consent process on participant perspective a questionnaire specifically designed for this study was used. Thirteen questions derived from QuIC tool were used concerning information adequacy and the process of decision making during the recruitment process. Participant were asked to selected "Agree, disagree or I don‟t know" for each question about the situation of recruitment. Participants were requested to select the correct option or explain their convenience accordingly while the data collectors read the questions.

4.9.4. **Consent forms**

Consent form and information sheet were modified by the REA team based on the rapid ethnographic assessment findings. The team further planned and designed the consent process and data collection procedures.

Two consent forms were used to enrolled participants in the "*HPV-Subtype Prevalence Study"* which was a parent study for the comprehension assessment study. One was the standard information sheet which was developed by the principal investigator of the parent study. This consent form was approved by IRBs of AAU and used as a standard for the prospective participants in the control group. The second information sheet and consent form was developed after REA has done by multi-disciplinary team and used to enrolled participants in the intervention group. Both consent forms and information sheets were font 12(except headings) and translated to Tigrigna language by the REA team for the intervention group and used the Tigrigna version already prepared by the principal investigator of the parent study for the control group.

The information sheet for the intervention group was written using local terminologies, concrete explanations with examples, and contextual clues based on the REA findings [Annex III]. Information and consent was provided by trained ANC provider nurses by reading for both group but additional

narratives used in the intervention group [Annex IV]. The average time for reading and providing information was 9.63 and 10.00 minutes in the control and intervention group respectively. The length of sentences and paragraphs for the modified form was relatively shorter and inclusive of the most pertinent information with local and easy words [Table 1].

Table 1 : Comparison of modified and standard consent forms used to enroll participants in the intervention and control groups, respectively July 2013

Consent Form and Information Sheet	Modified Form	Standard Form
Font, style	12, power geez uni-code 1	12, power geez uni-code 1
Language	Tigrigna, with local terminology	Tigrigna
Average words per sentence	12.4	16.3
Average word per paragraph	67.1	97.8
Average sentences per paragraph	5.6	7.6
Total words	604	587
Total No of paragraphs	9	6
No of pages	Two and half	Two and half
Average times taken	Mean=10.00 min Median=10 min	Mean=9.63 min Median=10 min
Include information		
Who collect sample	Female health professionals	Health professional
Political or religious agenda	Well explain that has no Political or religious agenda	As usual (Explain the purpose of the study)
Consent provision	Interviewer reading	Interviewer reading
Used narrative explanations, give examples and tell history	Yes *	No
Let to ask for unclear ideas or concepts	Yes/included in the information sheet.	Yes/orally at the end
Type of consent seeking	Verbal consent	Signed/ written
No of days b/n consent taking and Comprehension assessment	Mean =12 days Median =12 days	Mean=11.9 days Median=12 days

***see Annex III**

4.10. Ethical Consideration

Informed Consent: Informed written consent was obtained from each selected prospective study participant in the control group but verbal consent was obtained from the intervention group. The reason to obtained verbal consent in the intervention group was based on the participant preference in the REA. Key informants were also verbally consented to confirm informed voluntary participation and tape recording in the IDIs and FGDs. Each participant was informed about the purpose of the study, confidentially, the benefit and possible risk of participation in the parent study. Each participant was also affirmed that they have the right not to participate in the study and they are free to withdraw participation at any time without any form of prejudice.

Ethical Clearance: Ethical clearance was first obtained from Research Ethics Committee (REC) of Addis Ababa University School of Public Health. Following the endorsement by the REC, Tigray RHBs was informed about the objectives of the study through a support letter from AAU, School of Public Health. After reviewing the proposal Tigray RHB had written a permission and support letter to district wukiro kilte-awulaelo and Hintalo-wajirat. Then written consent with signature was obtained from each participant in the in control site, whereas in the intervention site each participant was verbally asked to participant in the study.

4.11. Dissemination of Result

This result will be presented to School of Public Health, College of Health Science, AAU for partial fulfillment for the requirement of degree of master in public Health. The results will be disseminated to school of Public Health and Mekelle Regional Health Bureau and ERCs. The finding of this study will be presented at different workshops and it will be sent for possible publication on relevant scientific journal.

5. RESULT

5.1. Qualitative

A qualitative REA was conducted in the intervention site; Hintal-wajirat district, before recruitment of the prospective study participants for the parent study (HPV-Subtype Prevalence Study) to provide a rapid and comprehensive information for the study in question. The findings were used for consent form and information sheet contextual modification, and to guide the best consent procedure to provide information for participant to take part in the parent study. We did a total of 11 formal recorded IDIs, 2 informal non-recorded conversations and 5 FGDs with key informants. A total of 45 people were participated formally with recordings in the FGDS and IDI. Composition of participants: 31 were female of which 2 were pregnant. Occupationally; 3 were administrative leaders, 3 were religious leaders (2 Orthodox and 1 Muslim), 2 were health workers with in health facilities, 6 were urban health extension professionals and supervisors, and the rest were community leaders and residents of district Hintalo-wajirat. The team members were also involved in different social activities, in markets and attend meetings to collect some socio-cultural data by observation.

5.1.1. Knowledge about health related research and treatment

The interview started after introducing the team members; the purpose of the interview in relation to the proposed parent study and confidentiality of the information that they were going to give us. Then we verbally asked their voluntarily participation and recording of the interview. The interview started with explanation of the meaning of research in general and health related researches. Most of the participants understand research as laboratory investigation and some as community surveillance. When asked to differentiate a health related research and treatment, most didn‟t know the difference between health related research and treatment. Some interviewees explain research associating with land and agricultural farming. A 45 years old female respondent said that:

> *"A study done from one place couldn't get important thing without researching. For example; to identify the type of water and soil; for what purpose the soil is important, for what purpose the land is important, what type of fertilizer would be appropriate, what type of medicine is needed? Like this researching or studying is needed. In this way I see what a study mean."*

5.1.2. Awareness and language or terminologies of cancer

Almost all had heard the name cancer and consider that it is a disease discovered recently. They mentioned that they had got the information about cancer from health professionals and rural heath

extension workers. They had also a smallest community team called "Gujile Limat" (health developmental team). They discussed on their health aspects, especially on maternal and child health. They had also received information about cancer. Fifty years old, resident in the area for 10 years said that.

> "*It (cancer) existed previously. It is "**Menkersa**" but for example one time in a market day, Saturday, here in Adigudom, Dr. XXX educated us about cancer and TB going around by a car, and said cancer is a worst disease even than HIV. That has no treatment. I heard this and understood its seriousness. So the communities understand that cancer is a dangerous disease and there is no more cure for it. Previously was known by **Menkersa** but when you see now cancer is a worst disease than HIV. Even the Fana Health Education and health promotion program educate us on this. As I said you before the whole community of the district on a market day were awared that cancer is a disease with no curing treatment."*

Different local names were given to cancer by the community. **Menkersa** and **Menshiro** are most frequently mentioned. Cancer was also well known by the community in its medical term "cancer". Rarely some people also call it: **kintarot, kamezene** and **menzia** in the past. When we ask the different types of cancer they know more about breast cancer. They have low awareness particularly about cervical cancer and some believe that a wound is changed to cancer unless timely treated. One male member of the FGD explains like this:

> "*Cancer is known as cancer now. Before, for example, when mothers develop breast swelling they call it something else. They used to treat it with herbal medicine. Then the diseases become disseminated and worsen. The disease cause harm so now it causes many harms. For example if a mother has breast cancer, it cannot be cured. So why treatment is not found until now? The disease is known but its treatment is not found still. Now when about the cervical cancer most do not know but called the name cancer. So the slogan said ‚mother shouldn"t lose her life to give birth" is something comes in the present, not in the previous time. Before for example was said **boils**, **swelling** (malignant) and also called **kintarot.** Those names were not well known before. **Kintarot** is also a name comes recently but now the knowledge become near and near to us that we know its name and we also know that people are searching for its treatment.* Another participant in this group said:

"*Now in the issue of cancer, we watch cancer on TV, listen in radio, we see cancer, we see that they got cancer in the breast, we see it inflaming the breast, it is seen when it is disseminating. Now in our community in the issue of cervical cancer, we heard it now. But mainly about cancer the Ethiopian community knows more about it specially breast cancer. Now in the previous week one woman in our village has breast something. She was afraid and said that „Ithink this is the cancer"But later cheeked and it was boils. Do you know boils? What we call it … (yes, we know) so the community knew it. More over when somebody has thought that has got cancer, they report immediately to health facility. So our community due to the present time development, education, different media and watching on TV, they have the information about cancer. But the awareness is on breast cancer*."

5.1.3. Consent seeking procedure

About the way to seek participant consent, we asked participants if they know which was better - written document with signature or verbally ask their voluntarily participation. Majority explain that the signature is not good because the participants related the signature with legal accountability for their respond. The signing also hinders participants to explain their feeling. Make participant to respond carefully and calculating the risk.

"*We don"tneed signature. It seems for other thing. Means people do not know. Now like you ask me that „Are you volunteer?"ask them like what you say to me. Other wise to say come and sign, I may know but the other community didn"t believe the signature"* (40 yrs., Female, women"s association leader).

"*Difficult, as the view of the community they worry what happen to them after signing? He/she may say that what will happen to me? They doubt of things. If somebody agrees, since it is for health even for another thing they can participate. If we ask them verbally that we are going to investigate for cancer no one afraid and refuse. So verbal consent is better than written"*(Female, 28 years old).

5.1.4. Sample collection

Regarding giving blood and vaginal secretion sample for the parent study; Participant said that they prefer female health professionals than male. Particularly for the vaginal secretion and reproductive health interviews, since the participants are healthy and not in labor they may feel embarrassed. For

blood sample collection has no effect being female or male sample collector. But few may associate giving blood with HIV test or fear that their test result may show cancer.

> "*I…yes, to participate confidentially, I think female sample collectors prefer than males. If she is a lady, she is a lady like herself, no shy; it is for her health but if male she may feel ashamed. If she is a lady, it decreases the embarrassment*" (Male, age of 62 years, farmer).

Another participant said:

> "*Yes, now professional eh…, when you see the main things they have a close contact with female when we see health package workers (female) and when compare with me in order to tell and discus freely, it is conducive with females. If in a difficult situation or they are sick and last option no matter who ever but in a healthy condition they can tell all for females.*"

5.1.5. Information dissemination and communication channel

The most accepted information communication was through religious leader. Health professionals and community leaders (bayto, Tena-fana) were also a good channel for dissemination of information to community level. Political administration should be involved only for its legal issues. Otherwise going directly to the target individuals decrease the acceptance and participant may relate with political and religious agendas. Concerning the preferable communication channel a female participant age of 40 years said:

> "*Community leaders (bayto) are preferable but for health aspects, health professionals are better to do that. Others like community leaders also have the chance to meet the community.*"

Another respondent replied that

> "*Religious leader is the most accepted more than the famous people in the community and administrative members of the Tabiya because they have the chance to say „you are my son/daughter but unless you do this I will leave you" can say the priest. So in this time religious leaders are the most accepted one.""*

5.1.6. Gender dynamics on decision making

The decision that the woman to participated in this study was up to her- she could decide alone in any aspect of her life. But there are also some circumstances that the woman should discus with or bring her

husband like for HIV test and choosing of family planning method. Some participant recommended husband involvement in decision making for participation of the woman. This helps for sharing of the idea and to involve partner support in any future tasks to be performed by the woman.

A 28 years old community worker said that

> *"The decision for participation is made mainly by the woman herself but her husband also has role in decision making for example when they come for HIV test. In this study also it is better to discuss with their partner even though they could decide alone."*

Another male participant in the group discussion replied as follow

> *"The decision maker is the woman herself. For example to day to participate in this discussion I didn"task my wife"spermission. Likewise the woman can decide whether or not to participate in any study. But being as a supportive, for sharing of idea and to know my opinion my involvement might be needed, otherwise me as individual the decision maker is herself. The community in this area also has the same attitude. I don"tthink that many are out of this when I simply see it. I think those who have better awareness, believe that the decision makers are them self. But some those with less awareness may still need to ask their husbands" permission to participate in the study."*

Box 1: summary of the rapid ethnographic assessment in the intervention site, Hintalo-wajirat district, Tigray, July 2013:

- Low community perception about biomedical research. Most didn‟t differentiate health related research from treatment. Few participants consider that participating in a research was individual‟s obligation and has legally accountability for the information they gave.
- Some narrative explanations for research were given relating to farming.
- Terminologies used for cancer includes **Menshiro, Menkersa, Kintarot**, and as a **swelling**. Breast cancer was the well-known type of cancer in women, and cervical cancer is the less known.
- During consent seeking asking participants to sign for their agreement could result high non-respondent rate and hinder to get genuine information from participant.
- Female sample collectors were preferable than male so that the pregnant women voluntarily participate and freely discus on reproductive health issues.
- Giving vaginal secretion sample for test could highly associate with embarrassment, whereas giving blood sample might associate with fear to test for other than the purpose and/or the result confidentiality.
- Gender dynamics on decision making; women had full right to participate actively in different social activities, and to decide on their life except some circumstances that the husband should involve like choice of family planning and partner HIV testing.
- The community had past experience that some investigators come with some aids (eye glass) and then reflect their hidden religious agendas. So information communication channel was preferable through religious leaders and health professionals who are well-known by the community.
- Regarding participant expectation- in health related research participant do not expect any immediate benefit like incentives or money. Instead they worry about their test results and need treatment according to the result.
- About sample selection both the selected and non-selected participant could have negative feeling. The selected one might thought that they were selected based on their health condition and suspecting that they had the disease to be studied. The unselected community parts might also feel as if they were mal-treated for some benefits of the incentives given for their participation in the study or other safety net programs (like, WFP). So need to create awareness about the research, its purpose and participant selecting method through health extension workers, religious and community leaders.

5.2. Quantitative

5.2.1. Socio- demographic and economic characteristics of the study participants

A total of 300 healthy pregnant women aged between 18 and 45 years were approach to participate in this study. The response rate for both groups was 84.7% (254).The mean age of the study participants was 27.3±6.3 years. Eighty three percent of the participants were married. About 99.5% of the participants were Tigre by ethnicity with Tigrigna mother tongue language and 86.4% of the participants were orthodox Christian followed by Muslim (11.6%) [Table **2**]. Among the participants 29.1% were not able to read and write [Figure 2]. Occupationally 35.7% were house wives. The monthly family income of 61.8% of the participants was greater than ETB 1000 and 30.2% was ETB 500-1000. About 72.9% of the participants respond that it was the first time to participate in any medical research [Table 2].

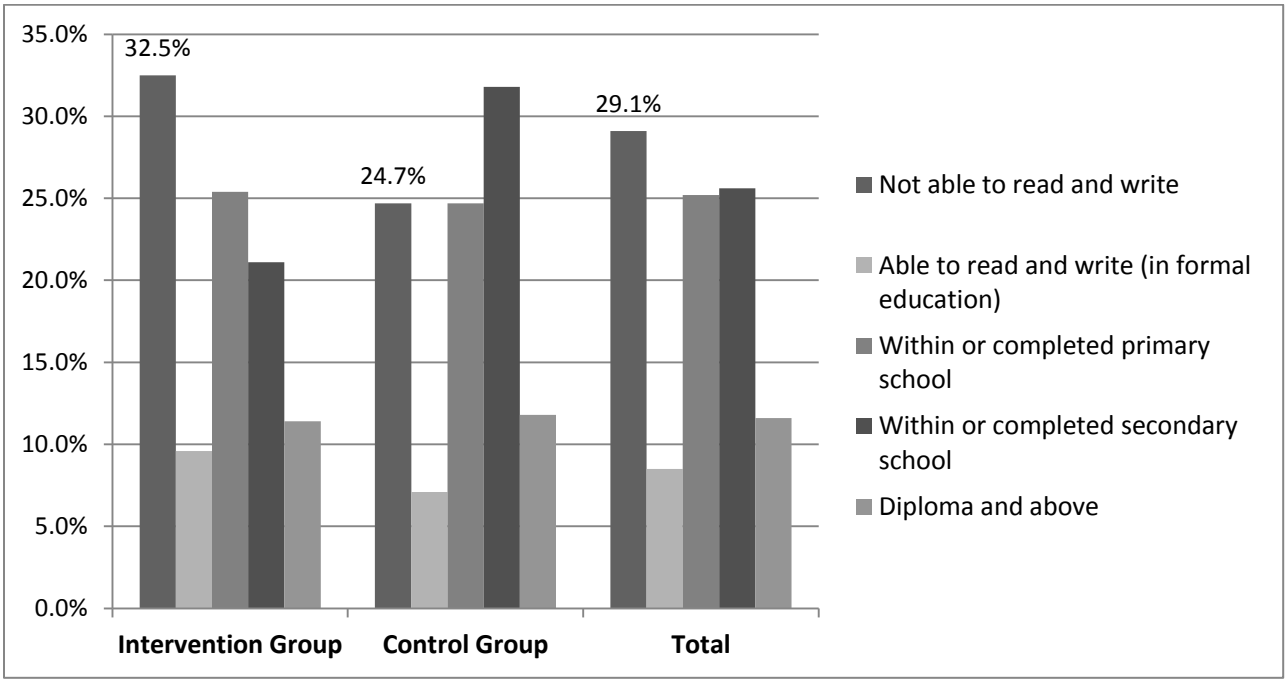


Figure 2 : Educational level of participants of the two groups in wukiro kilte-awulaelo and Hintal-wajirat districts, Tiray region, July 2013

Table 2: Socio-demographic and economic characteristics of respondents in wukiro kilte-awulaelo and Hintal-wajirat districts, Tiray region, July 2013

Variables	Intervention (n=114)	Control (n=85)	Total (N=199)
Age in years			
18-24 yrs.	34(29.8%)	38(44.7%)	72(36.2%)
25-31 yrs.	45(39.5%)	30(35.3%)	75(37.7%)
32-38 yrs.	30(26.3%)	14(16.5%)	44(22.1%)
39-45 yrs.	5(4.4%)	3(3.5%)	8(4%)
Mean + SD	27.99+ 6.17 yrs.	26.4+ 6.3 yrs.	27.3+6.3yrs.
Marital status			
Married	99(86.8%)	67(78.8%)	166(83.4%)
Single	5(4.4%)	8(9.4%)	13(6.5%)
Divorced	7(6.1%)	6(7.1%)	13(6.5%)
Widowed	3(2.6%)	4(4.7%)	7(3.5%)
Religion			
Ortho. Christian	100(87.7%)	72(84.7%)	172(86.4%)
Muslim	13(9.6%)	10(11.8%)	23(11.6%)
Others(catholic, protestant)	1(0.9%)	3(3.5%)	4(2.0%)
Occupation			
House wife	24(21.1%)	47(55.3%)	71(35.7%)
Private employee	4(3.5%)	10(11.8%)	14(7.0%)
Government employee	15(13.2%)	13(15.3%)	28(14.1%)
Daily laborer	2(1.8%)	0	2(1.0%)
Merchant	28(24.6%)	6(7.1%)	34(17.1%0
Farmer	38(33.3%)	4(4.7%)	42(21.1%)
Others (student,)	3(2.6%)	5(5.9%)	8(4.0%)
Family monthly income			
=< 500 ETB*	6(5.3%)	10(11.8%)	16(8.0%)
>500 &<1000 ETB	26(22.8%)	34(40.0%)	60(30.2%)
>=1000 ETB	82(71.9%)	41(48.2%)	123(61.8%)
Past participation in any medical research			
Yes	21(18.4%)	15(17.6%)	36(18.1%)
No	85(74.6%)	60(70.6%)	145(72.9%)
I don't know/ I am not sure	8(7.0%)	10(11.8%)	18(9.0%)

* 1 USD (US Dollar) ~ 20 ETB (Ethiopian Birr)

5.2.2. Recruitment rate, compliance rate and lost rate among participants enrolled with modified and standard consent form.

The recruitment rate to participate in the parent study for the intervention and control groups were 88.7% (133/150) and 80.7% (121/150), respectively. Of those voluntarily agreed and consented to participate in the parent study, the compliance rate to show their follow appointment on average 12 days after consent taking were 85.7% (114/133)in the intervention and 70.3% (85/121)in the control group. Lost rate to follow up appointment in the intervention and control groups were 14.3% (19/133) and 29.7% (36/121), respectively [Figure 3].

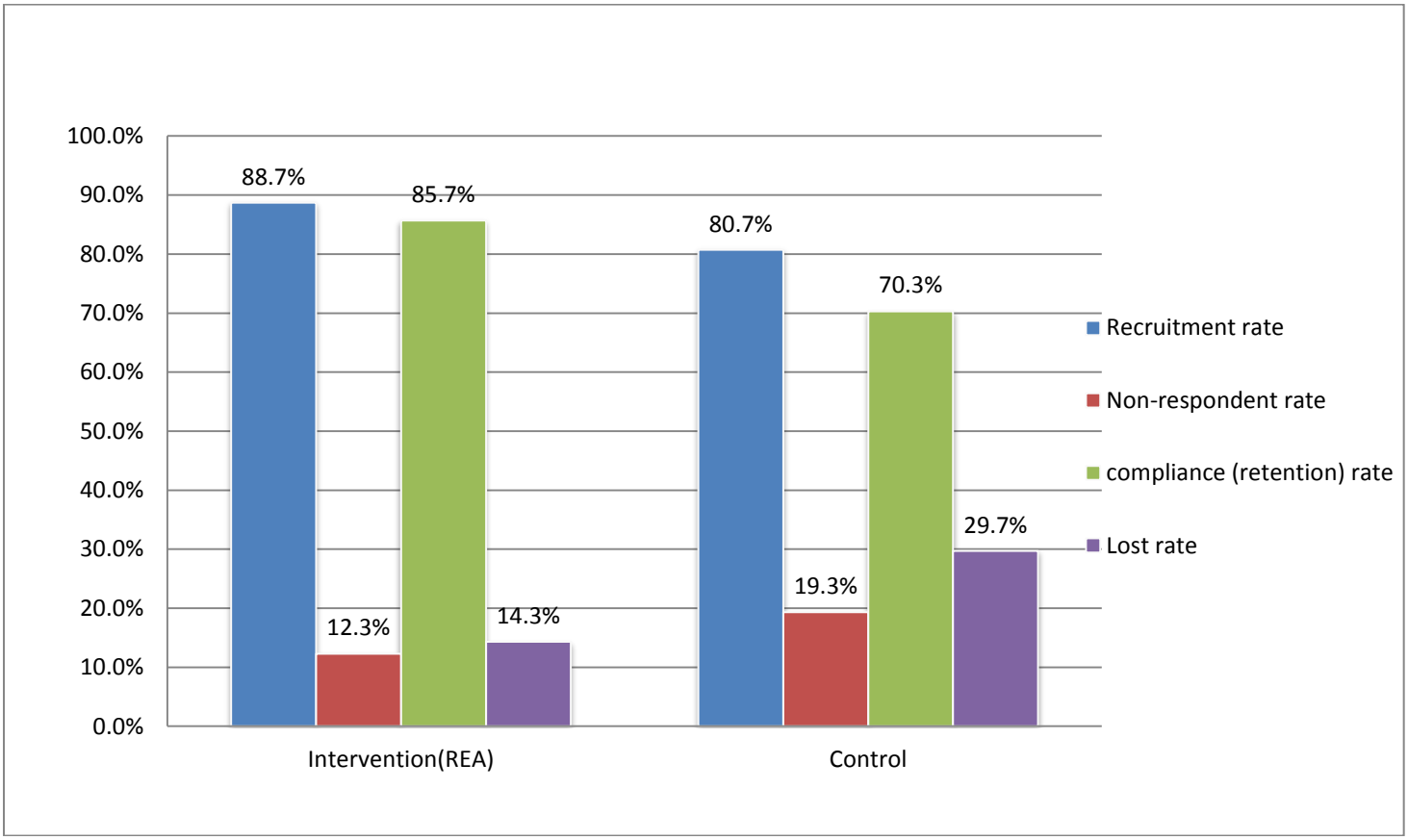


Figure 3: The recruitment rate, retention rate and lost rate among participants in wukiro kilte-awulaelo and Hintal-wajirat district, Tigray region, July 2013

5.2.3. Informed consent comprehension assessment

Comprehension assessment for 199 participants in both groups was done on average 12 days after consents were taken. Participants obtained an average score for understanding 73.0% and 45.6% in the intervention and control groups, respectively. In the recall sections the mean score of participants were 73.2% and 44.8% in the intervention and control groups, respectively. Independent-Sample T-test showed that a significant difference in mean score of 27.4 % (P<0.000, 95% CI =22.6-32.2) for understanding and 28.3 % (P<0.000, 95% CI= 23.3-33.4) for recall [Table 3].

The overall mean score of informed consent comprehension of this study showed that 73.1% for the intervention (REA) and 45.2% for control group. The comprehension score of control group vary more widely around their average score than the intervention group. A statistical test showed that a mean different in comprehension scores of 27.9% (P<0.000, 95% CI= 24.0%-33.4%) in the intervention compared to control [Table 3].

Table 3 : Comparing comprehension mean score among the intervention and control group in wukiro kilte-awulaelo and Hintal-wajirat district, Tigray region, July 2013

Summary comprehension score(% of correct answer)	**Mean %CS**		**Mean difference (95% CI)**	**P-value**
	Intervention (N=114)	**Control (N=85)**		
*Understanding	73.0	45.6	27.4 (22.6, 32.2)	0.000
**Recall	73.2	44.8	28.4 (23.3, 33.4)	0.000
Over all C- score	73.1	45.2	27.9 (24.0, 31.9)	0.000

*Understanding -score of Q201, 202, 205, 209, 210, 211, 212, 213, 301, 304, 305, 306, 307
**Recall- score of Q 203, 204, 206, 207, 208, 302, 303, 308A, 308B, 309C, 310A, 310C, 311A, 312A, 312B

Comprehension level of participants was classified as low (=<50%), medium (>50% &<75%) and high (>=75%) based on previous comprehension assessment studies.In the intervention group 55.3% of participants got high comprehension scores (75% or greater), only 7.9 % obtained a low comprehension score (50% or less) and the remaining 36.8 % had a medium score of between 50% and 75%. In the control group about 64.2% had low comprehension score; only 4.7% had high comprehension and the remaining 17.6 % had medium comprehension score [Table 4]. Compared to those who had low comprehension, the participants in the intervention group had 4.6 times probability to have medium

score than those in the control group. In addition, compared to those who had low scored the participants in the intervention group had 14.5 times higher probability to have high comprehension score than participants in the control group [Table 4].

Table 4 : Level of informed consent comprehension in the intervention and control group district wukiro kilte-awulaelo and Hintal-wajirat, Tigray region, July 2013

Comprehension Score	**Intervention Group f (%) (n=114)**	**Control Group f(%) (n=85)**	**RR (95% CI)**	**P**
Low* [<=50%]	9(7.9)	55 (62.4)	1 * (ref group)	
Medium* [>50% &<75%]	42 (36.8)	28(32.9)	4.6 (2.9, 7.3)	<0.0000
High* [>=75%]	63 (55.3)	4 (4.7)	14.5 (5.6, 37.9)	<0.0000

*Low: [=<50%], *Medium: [>50% &<75%] and *High: [=>75%]

Regarding comprehension of the main consent components there was a significant difference in mean score comprehension in most of the components in the intervention group compared to the control. These includes: information about the study, procedures of sample collection, risks and benefits of the study, confidentiality and participants right. The highest mean difference was observed in the understanding of participants‟ right which was a mean difference of 42.7% (p<0.000, 95% CI=36.4-49.0) to score a correct answer in the intervention group compared to the control but there was no a significant mean difference in score about disease information which was 15.8% (P= 2.4, 95% CI=2.1-29.5[Table 5].

About 15% of participant in the intervention and 6% in the standard group correctly knew the information about the study. Concerning the right of participants in a research 16.7% in the intervention correctly answered all the four questions, whereas none of the participants in the control group answered all the questions correctly. About 80% and 88.2% participants in the intervention and control group respectively replied that participation in a medical research was their obligation. Eighty two percent of participant in the intervention group knew that they could stop/ leave the study at any time, whereas majority of participants (66%) in the standard group replied that they couldn‟t leave the study once they enrolled. Only 20% of participant in this group knew that they could withdraw from the study at any time. The rest 3.5% in the intervention and 14% in the standard didn‟t know concerning when to stop participation in the medical research they consented to participate. Nearly half of the participant (44.7%)

in the intervention group knew that there was no immediate benefit from participation in the study. But majority (74%) in the control group thought that they would be treated for the infection tested in the research they involved.

Table 5 : Mean score of consent components among participants of the two groups in district wukiro kilte-awulaelo and Hintal-wajirat, Tigray region, July 2013

Consent component	Mean %CS		Mean difference (95% CI)	P-value
	Intervention (N=114)	Control (N=85)		
Disease information [Q 302]	67.5	51.8	15.8 (2.1, 29.5)	2.4
Information about the study [Q 201, 203, 204, 208]	55.3	37.6	17.6(9.5, 25.8)	0.000
Aim /purpose of the study [Q308A, 308B]	79.4	51.8	27.6 (19.5, 35.7)	0.000
Selection criteria [Q301]	99.1	78.8	20.3 (12.5, 28.1)	0.000
Procedure of sample collection [Q310A, 310C]	93.9	61.2	32.7 (25.2, 40.9)	0.000
Tasks to be performed by participants [Q311A]	98.3	83.5	14.7 (7.3, 22.2)	0.000
Risk of the study/ side effect of sample collection [Q312A, 312B]	52.2	37.7	14.6 (4.1, 25.0)	0.007
Benefit of the study [Q206, 207,209, 309C]	68.2	29.7	38.5 (29.4, 47.6)	0.000
Confidentiality [Q205, 213]	76.8	65.3	11.5(2.2, 20.7)	0.015
Participant right [Q202, 210, 212, 304, 305, 306]	70.3	27.6	42.7 (36.4, 49.0)	0.000

Participants with higher educational level (secondary and above) were found about 6.7 times more likely (AOR= 6.68, 95% CI=1.01- 44.03) to obtain high score (>=75%) in the comprehension assessment than those with no formal education. Participants who had ever participated in any medical research were 2.8 times more likely to scored high (AOR=2.77, 95% CI=1.01-7.58) than those who had never. Occupation and income was also found significantly associated with high score of comprehension [Table 6].

Table 6 : variables associated with comprehension status among study participants in wukiro kilte-awulaelo and Hintalo-wajirat district,Tigray, July2013

Variables	Comprehension score status (N=199)		AOR (95% CI)	P-value
	High (>= 75%) f(%)	Low (<75%) f(%)		
Age in years				
18-24 yrs.	23(34.3%)	49(37.1%)	1.09(0.38, 3.10)	0.876
25-31 yrs.	26(38.8%)	49(37.1%)	1*Reference gp	
32-38 yrs.	16(23.9%)	28(21.1%)	1.7(0.64, 4.55)	0.285
Marital status				
Married	58(86.6%)	108(81.8%)	1*Reference gp	
Single	3(4.5%)	10(7.6%)	1.05(0.17, 6.58)	0.955
Divorced	4(6.0%)	9(6.8%)	0.59(0.14, 2.53)	0.479
Religion				
Ortho. Christian	54(80.6%)	118(89.4%)	1*Reference gp	
Muslim	13(19.4%)	10(7.6%)	2.4(0.80, 7.15)	0.089
Educational status				
Not able to read and write	13(19.4%)	45(34.1%)	1* Reference gp	
Able to read and write	6(9.0%)	11(8.3%)	2.20(0.48, 10.15)	0.314
Within or completed primary school	15(22.4%)	35(26.5%)	2.23(0.57, 8.72)	0.251
Within or completed secondary school	20(29.9%)	31(23.5%)	2.37(0.52, 10.86)	0.266
Diploma and above	13(19.4%)	10(7.6%)	6.68(1.01, 44.03)	0.048
Occupation				
House wife	8(11.9%)	63(47.7%)	1*Reference gp	
Private employee	4(6.0%)	10(7.6%)	3.39(0.64, 17.92	0.151
Government employee	15(22.4%)	13(9.8%)	2.91(0.62, 13.67)	0.177
Merchant	18(26.9%)	16(12.1%)	5.43(1.78, 16.60)	0.003
Farmer	18(26.9%)	24(8.2%)	9.05(2.79, 29.23)	0.000
Monthly family income				
=< 500 ETB	3(4.5%)	13(9.8%)	0.67(0.13, 3.35)	0.623
>500 &<1000 ETB	9(13.5%)	51(38.6%)	0.38(0.15, 0.96)	0.041
>= 1000 ETB	55(82.1%)	68(51.5%)	1*Reference gp	
Previous participation				
Yes	21(18.4%)	15(17.6%)	2.77(1.01, 7.58)	0.047
No	85(74.6%)	60(70.6%)	1*Reference gp	

5.2.4. Quality of informed consent process on participant perspective

About 99.1% and 81.2% of participant agreed that they were satisfied with the informed consent process in the intervention and control groups, respectively. The mean score of some other components in the quality of consent process didn‟t showed significant difference. The overall mean score for assessment of quality of informed consent process for the intervention group was 89.06% and 78.53% for the control group. This study showed a mean score difference of 10.53% (P= 0.000, CI =6.83-14.23) concerning the quality of informed consent process [Table 7]. Multiple logistic regression model done and no significant association found between socio-demographic variables and quality of informed consent process on participant perspective taking a mean score of 75% as a cut point.

Table 7 : Comparison of mean score of quality of informed consent process on participant perspective among the two groups, July 2013

Informed consent process components	**Mean % QuIC**		**Mean difference (95% CI)**	**P-value**
	intervention (n=114)	**Control (n=85)**		
There was sufficient time for consent discussion.[**Agree**]	93.9	82.4	11.5 (2.7, 20.3)	0.010
Agreed to participate in this study voluntary and with full understanding.[**Agree**]	100	87.1	12.9 (6.7, 19.2)	0.000
Enrolment decision made mainly by me the respondent.[**Agree**]	99.1	92.9	6.2 (1.0, 11.3)	0.019
Discussed about the research with other patients or participants.[**Agree**]	91.2	17.6	-8.9 (-18.2 , 0.5)	0.062
Consent form read or explained carefully.[Agree]	82.5	81.2	1.3 (-9.7 , 12.2)	0.818
Consent form was important source of information.[**Agree**]	92.1	88.2	3.9 (-4.5 , 12.2)	0.361
Consent form was easy to understand.[**Agree]**	97.4	90.6	6.8 (0.4, 13.2)	0.039
Consent form was important to the decision.[**Agree**]	95.6	95.3	0.3 (-5.6, 6.2)	0.915
Pressure from provider to sign/agree/ consent form.[**Disagree**]	95.6	76.5	19.1 (10.1, 28.2)	0.000
Sufficient opportunity to ask questions.[**Agree]**	95.6	67.1	28.6 (18.8, 38.3)	0.000
Questions answered thoroughly by the consent provider.[**Agree**]	99.1	74.1	25.0 (16.6, 33.4)	0.000
Satisfied with informed consent process.[**Agree]**	99.1	81.2	17.9 (10.4, 25.5)	0.000
Decision to participate was easy.[**Agree**]	99.1	87.1	12.1 (5.5, 18.6)	0.000
Quality of informed consent	**89.1**	**78.5**	**10.5 (6.8, 14.2)**	**0.000**

5.2.5. Sources to gather health information

Based on the response of the participants the main sources of health information were health care providers (Drs, nurse, and health extension Professionals etc.). About 95.6% of the total participants in this study respond that either always or sometimes they used health professionals including health extension workers as their source for health related information. About 85% of the participant had ever used radio as a source of health information. Discussing with friends/families (60.3%) and watching Television (57.3%) health programs were also used as a source of health information next to health professionals and radio. Internet, popular magazines, books and journals were found the less frequently used source of health information in this study [Table 8]. No significant association was found between source of information with comprehension level and quality of informed consent comprehension.

Table 8 : Source of health information for the study participant in district wukiro kilte-awulaelo and Hintal-wajirat, Tigray region, July 2013

Source of health information	**Always f(%)**	**Sometimes f(%)**	**Neverf(%)**
Books/Journals	3(1.5)	40(20.1)	156(78.4)
Friends/Families	3(1.5)	117(58.8)	79(39.7)
Health care provider	89(44.7)	103(51.8)	7(3.5)
Internet	1(0.5)	8(4.0)	190(95.5)
Popular magazines	1(0.5)	32(16.1)	166(83.4)
Radio	19(9.5)	152(76.4)	28(14.1)
Television	40(20.1)	74(37.2)	85(42.7)

6. DISCUSSION

The comprehension assessment study revealed important findings related to levels of comprehension and quality of informed consent process. The parent study ("HPV Subtype Prevalence Study") for this study was selected primarily based on the criteria to implement REA; has a well-defined population group as its study population with some degree of homogeneity in language, ethno-cultural, geographic parameters; and the anticipated ethical issues such as sensitivity of the subject, ambiguity of terms, decision dynamics etc.

The two study sites were purposively identified and randomly allocated to be either an intervention or control site. The sites had similarities in the basic major societal parameters. The sites are adjacent to Mekele, capital city of Tigray, and belong to the same ethno-cultural cosmos including health system profiles. The other option would have been to conduct the assessment in the same district (cluster) and randomise individuals in to intervention and control. In the other hand conducting the study in the same cluster by randomizing individuals would have been difficult to control for possible communication between members of the two groups - contamination and spill-over of information.

The rapid ethical assessment in this study revealed that a number of issues concerning the parent study. These findings were help full to modify the information sheet, consent form and consent procedure adapting to the local culture and the educational level of the population**.**Other researchers have employed the same approach to inform consent information for researches in low income countries [4, 26, 27]. A bond of trust should develop between researchers and the community as complementary partners in the research enterprise to improve informed comprehension of research participant which leads to increase recruitment and retention rate [17]. The over outputs of these qualitative rapid ethical assessment were important for consent form contextual modification, and to guide the best consent procedure to provide information for participant to take part in the parent study. Other qualitative study done by Farsides and Bull, in TB case-contact study, and a vaccine trial in Gambia, developed an approach in which a form of rapid ethnographic assessment was carried out among key stakeholders, and the results used to inform the design of the consent process for the studies in question [9]. Similarly Tekola et al. applied the REA tools before a genetic study in southern Ethiopia and findings were help full to know the formats and routes by which they preferred to receive information about research,

enabling an appropriate model to be developed, to shape the research agenda as well as the consent process for subsequent studies [4].

In this study, we tried to document the overall effects of REA on recruitment and retentions rates as well as informed consent comprehension of potential study participants and the quality of consent process. Informed consent comprehension, recruitment rate and retention rate are considered important in monitoring the quality of conduct of research. It is assumed that by providing improved understanding of the ethno-cultural context of the research setting, REA provides inputs for improving consent process in terms of its content and decision making processes. Improving consent contents and processes to the setting presumably improves understanding by participants.

Various researchers have recommended and utilized different interventions to improve consent process and understanding, such as use of local narratives [24]; extended one-to-one discussion [28, 19, 30] enhanced consent [30, 31]; and modified consent process [32]; a booklet in participants rights [33]. Cultural and linguistic modifications to the informed consent were considered to significantly enhance understanding by study participant in low income settings [34]. The results and evidence generated by the current study have shown that REA could then be considered as one of the approaches for improving informed consent comprehension and quality informed consent processes.

In this study the recruitment and compliance rate was found relatively higher in the intervening group than the control group. The likely hood to attend their appointment was 2.5 times higher in the intervention group compared to the control group, whereas the difference in recruitment rate between the two groups was not significant. This might be due to high non-respondent rate more than expected which smaller sample size may mask significant of the difference. Though the difference was not significant, it was found 8% increase in requirement rate in the intervention group compared to control group. Further analysis was not done for factors associated with the recruitment and compliance rate because of no socio-demographic data was collected for non-respondent and lost participants.

This study showed that a significant improvement of understanding and recall in the intervention group with a mean score difference of 27.4% and 28.4% for understanding and recall, respectively compared to the control. The following sub-components of comprehension were documented to improve significantly; study information and objective; selection criteria; sample collection procedures; participant tasks and responsibilities; risks and benefits of the study; participants rights and

confidentiality. The REA based adjustments in the content and delivery of consent information in the intervention group have potentially contributed to improved understanding and recall documented. These findings concur with studies which have reported improved consent information comprehension with appropriate interventions such as provisions of more explanations and socio-culturally tailored approaches [34]. Provision of tailored terminologies and additional narrative explanations on the pre-identified ethical issues and the allowing of more time for discussions and question from the participants in the intervention group might have been potential determinants.

There was no any significant difference in comprehension levels related to disease information between the intervention and control group. Though it was not statistically significant documented in the levels of comprehension on disease information, it was found increased in the intervention group by 15.7% over the control group. The reasons for non-significance could be the sensitivity and novelty of the issues of cervical cancer in the area. The sample size also might have potentially masked the difference.

The mean score of understanding (45.6%) and recall (44.8%)of the control group in this study was found to be lower compared to non-intervention cross-section study done in South Africa which was 75% and 66% for understanding and recall, respectively[25]. This might be due to the time gap between consent taken and comprehension assessment which was 1 hour in South Africa and on average 12 days for this study. Other reasons such as economic, educational level and socio-demographic differences should be also considered.

In this study 16.5% of participants in the intervention group and none in the control group had correctly answered all the four questions concerning participants‟ right in a research. Eighty two percent of participants in the intervention group knew that they could stop/ leave the study at any time and about 44.7% of participants in this group knew that there is no immediate benefit from participation in the study and the purpose of the study was to know more about cancer disease in Ethiopia and to introduce vaccine for the future generation (girls). Whereas 66% of participants in the control group replied that they couldn‟t stop/leave the study once they enrolled. About 74% in this group thought that they would be treated for the infection tested in the research they involved. Other studies also showed that considerably a high percentage of participants have miss conception about the right of voluntarily withdrawal and refusal [23, 24, 25]. A study done in Mulago National Referral Hospital, Uganda, to assess the quality of informed consent in a resource-limited setting showed that 33.7% (201/596) of the

participants were not aware that they could, at any time, voluntarily withdraw participation from the study [23].

The overall comprehension score of this study showed that a significant improvement in the intervention group. About 55.3% of participants in the intervention group had obtained a high score (75% and above) of comprehension but only 4.7% of participant in the control group obtained a high score. This showed that potential participants of a proposed research can be assisted to understand key consent components of a research that they are going to be enrolled by using innovative locally and contextually tailored consent form and local narratives maintaining the standard rules and regulations of research ethics. These findings are similar with an interventional study done in Malawi in which the intervention positively impacted on understanding of trial procedures under study, as 13 of the 18 women in the intervention arm, obtained high scores (above 75%) during the post intervention assessment but none of the 18 in the control arm obtained a high score [24].

Although there is a significant difference in understanding on the rights of participant between the two groups, considerably high percent of participants in both groups perceived that their participation in the parent study were their obligation. This was compatible with the findings of the qualitative assessment as some participants mention that participation was individuals obligation and majority were not differentiate treatment from health researches.

In this study factors such as educational level secondary and above, past participation in any medical research, being merchants by occupational and having family monthly income greater than 1000.00 ETB were found to be positively associated with high informed consent comprehension score. Similarly a study done in South Africa showed that educational level grade 7 & above was found to be associated with high informed consent comprehension score[25]. This study didn‟t show any association between comprehension level and factors such as age, language and ethnicity. This might be due to the reason that almost all participants in this study were same language and ethnicity.

This study also assessed the quality of informed consent based on the respondents‟ perspectives. The quality in informed consent is understood as addressing the following issues from the participants perspective; adequacy of the information provided; understand ability of the purpose, benefits and risks of the research; distinction between research and clinical care; voluntariness of participation; recall of signing a consent document; and satisfaction with the consent process [11, 17, 37, 39].

In this study the overall quality of informed consent was improved among the intervention group compared to the control group. In addition there was statistically significant difference in most of the components of quality assessment (adequacy of time for consent, voluntariness of consent decision, understand ability of consent information; absence of coercion; and overall satisfaction) except for three components (whether consent form was read and explained carefully; whether consent from was important source of information; and whether informed consent form was important for consent decision). Possible reasons for the improved perception about the quality of informed consent process by the intervention group include the improved consent information based on REA; and modified consent procedures based on REA which are geared to the needs and concerns of the potential participants. The possible reasons for lack of statistically significant improvement concerning informed consent in these three areas could be regarding readability which was provided by interviewers reading in both groups. Otherwise though not significant, improvement was observed in the three categories and if more samples were used this could have been significant. We had non-response rate more than expected (we assumed 10% but had 15%).The sample size assumption also relied on assumption from another country and sample size was calculated only for comprehension assessment, we did not calculate a separate sample size for quality of informed consent process. Another reason could be that all the three measures were already high in the control group and the REA might have contributed lesson top. However the subjectivity of responses and absence of objective observations might limit the reliability of findings.

No socio-demographic and economic factors found to be significantly associated with the quality of informed consent process. The reason could be quality of informed consent process is mainly depend on consent providers‟ experience, knowledge and skill of communication and this is best if measured both subjectively (participant perspective) and objectively through observation by trained data collectors[22].

Based on the response of the participant the main source of health information were Health care providers, radio and Television. No significant association was found between these sources of information and comprehension level. This could be due to the reason that health research information didn‟t included in the routine information communication activities. General knowledge and sources of health research information other than the consent form and information sheet also could positively affect the comprehension level of participant if biomedical research information had been given to the general community through these widely used channels of communication.

7. STRENGTH AND LIMITATION OF THE STUDY

7.1. Strength

Comparative study design which increases the grade of evidence compared to descriptive

We used improved and validated informed consent compression assessment techniques which are appropriate to use in settings like ours as well (MICCA and BIQ).

We used both qualitative and quantitative study methods.

We tried to control (adjust) for personal level confounders (socio-demographic characteristics) to informed consent comprehension.

7.2. Limitation

Comparability of the intervention and control group: maximum effort have been put to ensure the uniformity of the two sites however there could have been undocumented differences in the settings which might have confounded the study outcomes.

Subjective quality assessment: Quality of informed consent process is based on participant perceptions on the quality of informed consent process unaccompanied by independent observational methods.

Loss to follow-up with unknown characteristics: Reasons for lost to follow-up of those who did not show up after consenting is not documented and we did not document their basic socio-demographic characteristics.

Sample size assumptions: The sample size determination was done based on assumptions from other countries as there was not local estimate available. In addition we assumed 10 % non-response rate while the non-response rate for the study was about 15%. The relative inadequacy of sample size could have masked some statistical tests.

8. CONCLUSION

Based on the findings and discussions provided above, it is possible to make the following conclusions

In this study the comprehension level, recruitment rate, compliance rate and the overall quality of informed consent process in the control group was found to be lower compared to the intervention group. These findings suggest that researchers can improve participants‟ informed consent comprehension and participant satisfaction on the consent process by conducting qualitative REA and then by improving the informed consent document based on the findings of this qualitative assessment.

Rapid ethical assessment was help full to modifying the consent form and consent procedure contextually. These includes understanding of the community‟s culture, terminologies, knowledge and perception of research, gender dynamics on decision making and information communication channel. With this approach, recruitment rate, compliance or retention rate, participants‟ informed consent comprehension, quality of consent process and the overall participant satisfaction had been improved.

Though there is a significant improvement of consent comprehension in the intervention group compared to the control group, still there is considerably high percentage of misconception on participants‟ rights to refusal and withdrawal at any time.

In this study factors such as educational level secondary and above, past participation in any medical research, being merchants by occupational and having monthly income greater than 1000.00 ETB were found to be positively associated with high informed consent comprehension score. But no socio-demographic factor found to be associated with quality of informed consent process in this study.

9. RECOMMENDATIONS

1. For Policy Makers

Policy makers should develop guide lines and mechanisms that for that researchers, health professionals and media could include health research information to create community awareness.

It should be included rapid ethical assessment in the research proposal to be reviewed by the ERCs for projects with expected gender and socio-cultural sensitivities.

2. Researchers

It is recommended to use rapid ethical assessment as a base line investigation to cut the gaps between researchers and prospective participants.

It is recommended for researchers to develop modified, quality of informed consent process (P-QuIC) assessment tool which is inclusive both generic and trial specific questions that can be used universally.

Community members should be involved in any community based projects through effective communication channel using grass root working health professionals, health developmental community teams, community and religious leaders.

Further studies on recruitment, retention rate and associated factors are needed.

3. For Health Professionals and Field Workers

Health professionals and field workers should include health research information as part of their routine activities to create community awareness and community engagement in biomedical research.

10. REFERENCES

1. International Conference on Harmonization. ICH harmonised tripartite guideline for good clinical practice (E6), in International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.1996
2. Nuffield Council on Bioethics. The ethics of clinical research in developing countries: a discussion paper. London: 1999.
3. Nuffield Council on Bioethics. The ethics of research related to healthcare in developing countries: a follow-up Discussion Paper based on the Workshop held in Cape Town, South Africa 12–14th February 2004. Available on line at: www.nuffieldbioethics.org).
4. Tekola F, Bull SJ, Farsides B, Newport MJ, Adeyemo A, Rotimi CN, et al. Tailoring Consent to Context: Designing an Appropriate Consent Process for a Biomedical Study in a Low Income Setting. PLoS Negl Trop Dis. 2009a;3(7):e482. Epub 2009/07/22.
5. Ethiopian Science & Technology Commission (ESTC), National health science and technology council, and Health research department. *Health Research Ethics Review Guideline.* Addis Ababa, 2005, 4th ed
6. Angell M. The ethics of clinical research in the Third World. N Engl J Med. 1997, 333(12):847-849
7. Beebe J. Rapid Assessment process: An Introduction. Walnut Creek, CA. Altamira Press.
8. Farmer P. Can transnational research be ethical in the developing world? Lancet. 2002, 360(9342): 1266
9. Bull SJ. Consent to research in a Gambian context: legal, social and ethical issues (PhD thesis). London: Kings College; 2007.
10. CIOMS. International Ethical Guidelines for Biomedical Research Involving Human Subjects. In: Sciences CfIOoM, editor. Geneva Council for International Organizations of Medical Sciences; 2002.
11. Mandava A, Pace C, Campbell B, Emanuel E, Grady C. The quality of informed consent: mapping the landscape. A review of empirical data from developing and developed countries. J Med Ethics. 2012;38(6):356-65. Epub 2012/02/09.

12. Bhutta Z. Building Capacity for ethical review in developing countries. Science and Development. Network, 2004. http//www.Scidev.net/en/policy.breifs/building capacity of ethical review in developing. html (Accessed April 2008)

13. Hyder AA. Moving from research ethics review to research ethics systems in low-income and middle-income countries. Lancet. 2009, 373: 862-65

14. Woodsong C. and Abdool Q. A Model Designed to Enhance Informed Consent: Experiences From the HIV Prevention Trials. Network. American Journal of Public Health. 2005, 95(3): 412-419

15. Andanda P.Developing World Bioethics. Blackwell Publishing Ltd. Johannesburg, 2005. 5(1): 1471-8847

16. World Medical Association, Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects. 59th WMA General Assembly, Seoul, October 2008

17. Ethiopian Science and Technology Commission in collaboration with the Ethiopian Public Health Association and Regional State Health Bureaus, training module 4, Addis Ababa, Ethiopia, June 2005

18. Sanchez S, Salazar G, Tijero M, Diaz S. Informed consent procs: responsibilities of reseaedurerchers in developing countries. Bioethics. 2001;15(5-6):398-412. Epub 2002/06/13.

19. Oguz NY. Research ethics Committees in Developing Countries and Informed Consent: with special reference to Turkey. Journal of Laboratory and Clinical Medicine. 2003, 141(5): 292-296

20. Allina Research Subjects Protection Program: The Research Consent Process: A Guide for Researchers. August 2009.

21. Buccini L. Developing an instrument to measure informed consent comprehension in non-cognitively impaired adults [PhD]: University of Wollongong; 2009a;4:17-23

22. Joffe S, Cook E, Cleary P, Clark J, Weeks J. Quality of Informed Consent: a New Measure of Understanding Among Research Subjects. J Natl Cancer Inst. 2001a;93:139 - 47.

23. Kiguba R, Kutyabami P, Kiwuwa S, Katabira E, Sewankambo N. Assessing the quality of informed consent in a resource-limited setting: A cross-sectional study. BMC Med Ethics. 2012;13(21).

24. Ndebele P, Wassenaar D, Munalula E, Masiye F. Improving understanding of clinical trial procedures among low literacy populations: an intervention within a microbicide trial in Malawi. BMC Med Ethics. 2012;13(29):1-14.

25. Minnies D.et al**.** Evaluation of the quality of informed consent in a vaccine field trial in a developing country setting: University of Cape Town, South Africa, *BMC Medical Ethics* 2008, **9**:15 doi:10.1186/1472-6939-9-15

26. Tindana P, Bull S, Amenga-Etego L, de Vries J, Aborigo R, Koram K, et al. Seeking consent to genetic and genomic research in a rural Ghanaian setting: A qualitative study of the MalariaGEN experience. BMC Medical Ethics. 2012; 13(15):1-12.

27. Bull S, Farsides B, Tekola Ayele F. Tailoring information provision and consent processes to research contexts: the value of rapid assessments. J Empir Res Hum Res Ethics. 2012;7(1):37-52. Epub 2012/03/02.

28. Flory J, Emanuel E. Interventions to Improve Research Participants‟ Understanding in Informed Consent for Research. A Systematic Review. JAMA 2004;292:1593-601.

29. Tamariz L, Palacio A, Robert M, Marcus E. Improving the Informed Consent Process for Research Subjects with Low Literacy: A Systematic Review. J Gen Intern Med. 2012;28(1):121-6

30. Nishimura A, Carey J, Erwin PJ, Tilburt JC, Murad MHM, J. B. Improving understanding in the research informed consent process: a systematic review of 54 interventions tested in randomized control trials. BMC Medical Ethics. 2013;14(28):1-15.

31. Dunn L, Lindamer L, Palmer B, Schneiderman L, Jeste D. Enhancing Comprehension of Consent for Research in Older Patients With Psychosis: A Randomized Study of a Novel Consent Procedure. Am J Psychiatry. 2001;158:1911-3.

32. Sudore R, Landefeld C, Williams B, Barnes D, Lindquist K, Schillinger D. Use of a Modified Informed Consent Process among Vulnerable Patients. A Descriptive Study. J Gen Intern Med. 2006;21:867- 73.

33. Benatar J, Mortimer J, Stretton M, Stewart R. A Booklet on Participants‟ Rights to Improve Consent for Clinical Research: A Randomized Trial. PLoS ONE 2012;7(10):e47023.

34. Penn C, Evans M. Assessing the impact of a modified informed consent process in a South African HIV/AIDS research trial. Patient Education and Counselling. 2010; 80:191-9.

35. Miller C, O'Donell D, Searight H, Barbarash R. The Deaconess Informed consent Comprehension Test: An Assessment Tool for clinical research subjects. Pharmacotherapy. 1996;16:872-8.

36. Joffe S, Cook E, Cleary P, Clark J, Weeks J. Quality of Informed Consent in Cancer clinical Trials: a cross-sectional survey Lancet. 2001b;358:1772 - 7.

37. Sugarmann J, Lavori P, Boeger M, al e. Evaluatng the Quality of Informed Consent Clin Trials. 2005;2:34-41.

38. Cohn E, Jia H, Smith W, Erwin K, Larson E. Measuring the Process and Quality of Informed Consent for Clinical Research: Development and Testing. Oncol Nurs Forum. 2011;38(4):417-22.

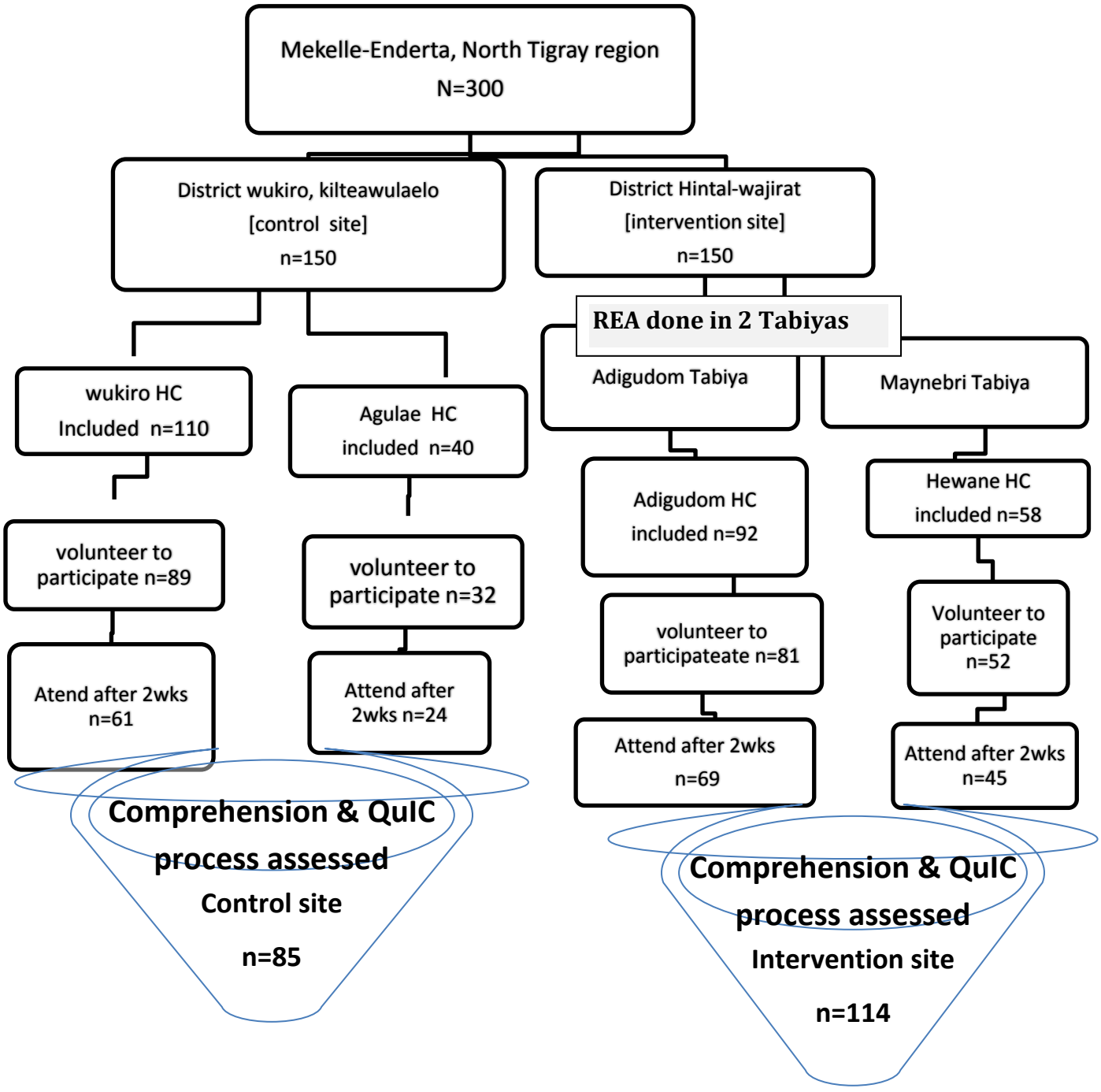
39. Buccini L, Jones C, Iverson D, Caputi P. Toward a construct definition of informed consent comprehension. Journal of Empirical Research on Human Research Ethics. 2009b;4(1):17-23.

40. From Wikipedia, the free encyclopedia.

41. Census 2007 Tables: Tigray Region.

11. ANNEXES

Annex I: Schematic presentation of the sampling.



Annex II: Standard information sheet and Consent form for "HPV-Subtype Prevalence Study"

Information sheet

Introduction: Good morning, my name is _____.I am part of a group from Addis Ababa School of Public Health. We are trying to find out more about cancer diseases in Ethiopian women. Most common is cervical cancer. Sometimes infections like HPV and others can make the cervix weak and then a cervical cancer can grow. There are different options to help women to avoid cervical cancer. Please always see a doctor if there is too much vaginal bleeding. To implement a vaccination in the future, information on HPV infections and co-infections must be collected. We want to collect information in 600 women from different parts of Ethiopia. We ask you if you are willing to give a small drop of blood (when you are in the lab) and if you could take a small amount of fluid from the vagina for us. This does not cause any harm to you or to the baby. Someone will assist you to do that.

There will be no names on the blood and fluid sample – they will be anonymous. Therefore information on the results will not be given back to you. The samples will be analysed and doctors from School of Public Health at Addis Ababa University will discuss the results. Then the government can decide to implement a vaccination against cervical cancer in the country. The future generation of girls will benefit.

Risk and Benefits: There is no perceived harm to the individual participants. To maintain privacy and confidentiality, all the specimen (body fluid and blood) will be linked and stored totally anonymous. The data will be kept in password and all formats will be properly locked in. Since the investigations are for epidemiological research, high-throughput testing is done. The findings of the survey will inform further policy related discussions for cervical cancer in Ethiopia. The infections tested are naturally acquired infections. Detection of prevalence of viruses will help subsequently to implement national programmes for immunisation.

Study Consent and Decision to Participate: Informed consent will be taken from each person in advance to every interview. Participation is purely on voluntary bases. You are free to decide to take part in the study or not. If you do not want to answer any of the questions you have the right not to answer. You can stop the interview any time as well. The names of the interviewees will be kept in a separate code list until all data is clarified and there is no need to

come back to the interviewee. All personnel data will be kept in a separate list with codes. Results of the interviews will be recorded with the code. After the end of the interview-phase, all codes will be destroyed.We would be very happy if you could help us in this study. But you can decide not to take part in the study and this will not in any way interfere with your ANC clinic follow-up. Note that your regular antenatal clinic will be done in any case – if you decide to participate or if you do not participate in the study.

Contact Persons for any question:

Investigator's Address

Dr Adamu Addissie, AAU- SPH, Addis Ababa

Tel – 01155473xx

IRB Contact

Dr Yimtubezinash W/Amanuel, AAU, CHS-IRB, Addis Ababa

Tel – 0118961xx

Consent Form

I _____ after understanding the purpose of the study understanding that I have the right to take part or to withdraw from the study have decided to take part in the study.

I am aware that the study is carried out by medical doctors in order to find out more about women 18-45 years of age in the area and also authorities are aware of the study carried out by physicians from the local, Addis Ababa University and collaborators. I am aware that the researchers would like to ask about reproductive health issues in women and will take blood and vaginal specimens for testing.

I have also understood that all information given will be confidential – no personnel data will be revealed to the public. After completion of the study, all names will be deleted I hereby sign to express my consent to take part in the study out of my voluntary will.

If Agree Sign of participant _____Disagree_____(refusal)

(For data collectors: use explanation in the bottom to appoint after 2 weeks)

Signature of the data collector _____ date _____ code: _____

Appointment after two weeks: *Thank you for participation in this study. Today there will no blood or vaginal secretion taking. We ask you again if you are voluntarily to come back after* ***two*** *weeks for second part interview of this study and we will discuss about giving the sample then*. [**For data collector:** *give an appointment about* ***12-16 days*** *after first consent taking. The date should be at their convenience.*

Annex III: Modified information sheet and consent form for "HPV-Subtype Prevalence Study" developed by the rapid ethical assessment team

Information sheet

Introduction: Hello /Greetings, my name is _____. I am health professional. I am member of a team from Addis Ababa University School of Public Health. We are trying to find out more about cancer (Menkersa or Menshiro) diseases in Ethiopian women. Most common is cervical cancer. Sometimes infections like "Human Papiloma Virus" and other infections can make the cervix weak and then a cervical cancer can grow. There are different options to help women to avoid cervical cancer. **Please** always see a doctor if there is too much vaginal bleeding. Vaccination for human papiloma virus (virus that cause infection of the cervix) is one possible option to prevent cervical cancer.

To implement a vaccination in the future, information on HPV infections and co-infections must be collected. We want to collect information in 600 women from different parts of Ethiopia. From this study area we need 75 volunteer pregnant women. This study conducted by Addis Ababa University in coorporation with Saale University of Germany. The study is approved by respective authority at different levels and the administrative office of this district. This study has no any hidden political or religious agenda.

Procedures: The study process includes a face to face interview, drawing a small amount of blood and small vaginal fluid (secretion) from pregnant mothers. Pregnant mothers selected by chance when they come for their regular ante natal care follow up. The sample will be taken by a female health professional. The collected samples will be analysed and doctors from School of Public Health at Addis Ababa University will discuss on the results. Then the findings help the government to implement vaccine against cervical cancer in the future.

Risk and Benefits: There is no perceived harm to you or your baby. However, you may feel some pain, bruise or minimal bleeding as a result of the injection. You may also feel discomfort following disclosing your private parts.The result of the HPV-test will not be given back to you because there is no treatment for human papilloma virus. This infection is naturally acquired. The benefit will only be for future generations. The findings of the survey will inform further policy related discussions for cervical cancer in Ethiopia. Detection of prevalence of the virus will subsequently help the government to implement national programmes for immunisation against cervical cancer.

Study Consent and Decision to Participate: - Participation is purely on voluntary bases. You can decide not to take part in the study and this will not in any way interfere with your ante natal care follow-up. If you do not want to answer any of the questions you have the right not to answer. You can also stop the interview at any time.

To maintain privacy and confidentiality, there will be no names on the questiannare, blood and vaginal fluid (secretion) sample. We use codes instead. Therefore information on the results will not be given back to you.No personnel data will be revealed to the public. The collected data and samples will not be used other than for the purpose of this study.

Contact Persons for any question aboutb the study:

Investigator's Address

Dr Adamu Addissie, AAU- SPH, Addis Ababa

Tel – 01155473XX

Ithical review board Contact

Dr Yimtubezinash W/Amanuel, AAU, CHS-IRB, Addis Ababa

Tel – 01189613XX

Consent Form

Now I can continue the interview if and only if you are volunteer to participate. As I explain you before, if you agree to participate in this study you are expected to respond to a questionnaire, give asmall amout of blood and vaginal secretion. A female health professional will assist you to do that. If you believe that you have clear and enough information about the study, you are kindly invited to participate in this study. I would like to remind you again that you have the right not to take part or to withdraw from the study at any time. However, your participation has a great contribution for the success of this study.

Note that your regular antenatal clinic will be done in any case – weather you decide or not to participate in this study.

In general do you have any question or concern about the study?

1. Yes (**for data collector**: give enough explanation for questions and concerns, use Annex IV)
2. No (**for data collector**: ask for consent)

Are you willing to participate? (**For data collector**: tick in the box)

1. Yes, I am will to participate ☐
   (**For data collectors:** *Thank for participation and appoint for second part interview of this study. Use explanation in the bottom*)
2. No, I am not willing to participate ☐
   (Thank the participant and end the interview)

I _____ [the data collector] assure that I have explain all necessary information about this study to the respondent and she agree to participate voluntarily.

Signature of the data collector _____ date _____ code: _____

Appointment after two weeks: *Thank you for participation in this study. Today there will no blood or vaginal secretion taking. We ask you again if you are voluntarily to come back after **two** weeks for second part interview of this study and we will discuss about giving the sample then.* [**For data collector:** *give an appointment about **12-16 days** after first consent taking. The date should be at their convenience.]*

Annex IV: Narrative Explanations used in the intervention group

1. **Research** is a work trying to find new facts. For example a farmer wants to use new method of farming like sowing in line or to use fertilizer to make his farm land more productive. So first he tries the new method or the fertilizer in a plot of land. If the product is better enough then he use this method for the Whole of his farm land. This best experience will be expanded to his neighbors.
2. **Medical research:** In a medical research is also the same. If the findings from few study subjects are important for health, then will be used for the majority of the community. As you know before many years there was no vaccine for measles (Nifyo, local language). Many children were blind and died due to this disease. Now after research has done vaccine for measles has found and many children saved from blindness and death by vaccination. Similarly this study is to introduce vaccine against "Human Papilloma Virus" and to prevent cervical cancer. Then future generation girls could be benefited.
3. **Use local words:** for cancer**: - "menkersa" (very** common**), cancer (some**) **"menshiro" (**rarely).

Annex V: English version data collection format: Informed consent comprehension and quality of consent process assessment

General information for the study participants

Hello, my name is _____; I am health professional. Now I am collecting data from the study participants in a research conducted in different parts of Ethiopia to know more about **cancer in Ethiopian women**. Thank you for your coming in your appointment. You had asked to participate in this study about two weeks before. Now I would like to ask you some questions about how you gave informed consent to participate in the study about **"cancer in Ethiopian women"** and what you understand about participating in that study. These questions are just to assess medical research participants understanding and the situation how they signed or agreed to participate. This research is conducted by Mr. Serebe Abay who is Master of public Health student in Addis Ababa University.

The aim of this research is to know the effect of based line Ethnographic Assessment before a medical research to improve participant consent understanding and quality of consent process. The result of the study is important to identifying a better way to improve informed consent understanding of participant in medical research. It is also helpful to design ethical approaches that fit to local social and cultural values. This study will be conducted only by interview which lasts about 20 minutes. So we need your voluntary participation in this study by responding the following questions concerning consent taking and your decision to participate in the study to know more about **cancer in Ethiopian women**.

When you respond to these questions feel free that the questions are just to know the situation of agreement and how do you understand about the study you agreed to participate. **Not** to measure you general knowledge. All the information you are going to give me will be kept in secrete and your name will not be written on this form.

Responding to these questions will be based on your voluntary help and without any enforcement. You can also jump questions that you don"t like to answer or with drown at any time. However, your participation and honest answer to these questions will help me to know how people understand about the study they agreed to participate and their right as a participant.

So shall we continue with the interview? (**Data collector:** circle 1 or 2)

1. **Yes** (start the interview) 2. **No** (Thank participant: end interview)

Data collection questionnaire: comprehension and quality of consent process assessment

Assessment of the Effect of „Rapid Ethical Assessment (REA)" on informed consent comprehension and quality of consent process in biomedical research in Wukro and Adigudom town, Tigray, Northern Ethiopia

Inclusion criteria

- Pregnant women age 18-45 years who have ANC follow up
- Healthy and come for their regular follow up.
- Competent to give consent

Exclusion criteria

- Participants were excluded if they had dementia, or were deaf, delirious
- Late 3rd trimester (Gestational age greater than 34 weeks)

Questionnaire identification number _____

Timing and duration of the interview: starting time |___|___|:|___|___|

Completion time |___|___|:|___|___|

Name of the data collector _____ signature _____ Date _____

Supervisor name _____ signature _____ Date _____

Please, completed the following after participant completes the questionnaire /interview or after ascertain that this is not possible

Was the questionnaire completed? 1. Yes 2. No

If your answer is "**2-NO,** "please indicate why

1. Participant refuse
2. Others (specify)_____

PART-I: SOCIO DEMOGRAPHIC DATA OF PARTICIPANTS

S.No	Question	Response and Coding
101	Age (in complete years)	_____years
102	What is your current marital status?	Single ……..……...…1 Married …….....2 Divorced …….…..…..3 Widowed……..…….…...4
103	What is your highest educational status?	Cannot read and write…..……...…1 Can read and write …….....2 Grade 1-8 completed …….……..3 Grade 9-12 completed ……..…….4 Diploma and above ……..5
104	What is your religion?	Orthodox Christian ……...1 Muslim …….....2 Others (specify) ……..88
105	What is your ethnicity?	Tigre……..…..1 Amhara……...…2 Others (specify)…….88
106	What is your mother tongue or commonly used language?	Tigrigna ……..…..1 Amharic……..…..2 Others (specify) ……88
107	What is your current occupation?	Housewife……..….1 Private employee……..…2 Government employee……3 Daily laborer……4 Merchant…….5 Farmer ……....6 Others (specify) ……..…..88
108	What is your family total monthly income? ETB	=< 500 ETB……...….1 Between 500 & 1000 ETB…..….2 >=1000 ETB……...….3
109	Have you ever participated in any medical research?	Yes …….……1 No …….……..2 I don‟t know …….99

PART II: INFORMED CONSENT COMPREHENSION ASSESSMENT TEST

Instruction 1: please circle the numbers that best answers each statement listed below. (**You may only circle on one number for each question)**.

S.No	Question	True	False	I do not know/ I am not sure
201	This health related study is a form of a research [1].	1	2	99
202	It is my obligation to participate in this medical research [1].	1	2	99
203	I have been told who is funding this research [1].	1	2	99
204	I have been told the total number of people that participate in this research [1].	1	2	99
205	During this research other than the study team no one will be allowed to see my health information [1].	1	2	99
206	I will be told about my test results from this research [2].	1	2	99
207	I will be treated for the infection tested by this research [2].	1	2	99
208	I have been given the name and phone number of the person to contact if I have questions or concerns about the research [1].	1	2	99
209	I will get a special care in my regular ante natal care in response to my participation in this research [2].	1	2	99
210	My participation in the study can be stopped at any time without any form of prejudice [1].	1	2	99
211	I will be asked for costs related to participating in this study [1].	1	2	99
212	I will be paid or got any incentive for participating in this study [1].	1	2	99
213	The sample taken from me can be used other than the purpose of this study [1].	1	2	99

Participant promoted to choose I don't know rather to guess

---

[1]Generic test item- These test items appear on each version of MICCA

[2]Trial specific test item- These test items are not appears on every version of the MICCA. They are generated based on response to BIQ.

Instruction 2: for question **301-307**, please circle the numbers that best answers each statement listed below. (**You may only circle on one number for each question**.)

301. How do you selected to participate in this study? [2]

A. I was asked to participate in this study when I come for regular my Ante Natal Care follow up.

B. I was selected to participate in this study based on my health situation and suspecting that I might have cancer

C. I don‟t know how I was selected

302. When do you have to visit your doctor to avoid cervical cancer? [2]

A. Always

B. When I have too much vaginal bleeding

C. I don‟t know

303. Who analyze and discuss your test results? [2]

A. Doctors from Addis Ababa University

B. My routine Ante natal care providers

C. I don‟t know

304. At what time can you leave the study? [1]

A. I can leave at any time

B. I can only leave if the investigator is volunteer

C. I can only leave after all data has been collected

D. I don‟t know

305. What does it mean when you agreed or signed to participate in this research? [1]

A. I will be legally asked if not participate in this research

B. My participation will be obligatory

C. I agreed voluntarily to participate in this study

D. I don‟t know

306. Can you leave this study if you want to stop after you singed to participate? [1]

A. Yes

B. No

C. I don‟t know

307. Suppose that you had decided not to participate in this study, do you think that would have made any difference to your regular ante natal care? [1]

A. Yes

B. No

C. I don‟t know

Instructions 3:- For questions **308-313** you may circle on **more than one** number for each question.

308. Which describes the main purpose(s) of the study? [3]

A. To know more about cancer disease in Ethiopia

B. To introduce vaccine which benefit future generation girls

C. To improve my own medical/health condition

D. I don‟t know

309. Which describes the main benefit(s) taking part in this research? [3]

A. I will be informed of my test results

B. I will be treated according to my test results

C. Future generation girls but not me will be benefited

D. I don‟t know

310. Which procedure(s) you asked to take part in? [3]

A. Giving a small amount blood for test

B. Having X-ray examination

C. Giving vaginal secretion for test

D. I don‟t know

311. Which task(s) will be asked to complete? [3]

A. Attend on your appointment

B. Coming without eating food

C. I don‟t know

312. Which side effect(s) might occur during blood drawing for test? [3]

A. Pain or bruising on the vein

B. Bleeding at the site of the needle

C. It cause blood deficiency

D. I don‟t know

313. What is your concern or fear taking part in this study?[3]

A. This study may have hidden religious or political agenda

B. I might be diagnosed to have cancer in this study

C. Other people may know my test result

D. I have no any concern or fear

---

[1]Generic test item- These test items appear on each version of MICCA

[2]Trial specific test item- These test items are not appears on every version of the MICCA. They are generated based on response to BIQ.

[3]Trial specific test items appear on each version of the MICCA. The response option for each of these test items are generated based on response to BIQ.

Instruction 4: Please tell us (circle the number) how often you use the following resources to gather health information. **Please circle only one number for each item.**

S.No	**Source**	**Always**	**Sometimes**	**Never**
401	Books/Journals	**1**	**2**	**3**
402	Friends/Families	**1**	**2**	**3**
403	Health care provider (Drs, nurses, health extension professionals etc.)	**1**	**2**	**3**
404	Internet	**1**	**2**	**3**
405	Popular magazines	**1**	**2**	**3**
406	Radio	**1**	**2**	**3**
407	TV/Movies	**1**	**2**	**3**

PART III: Quality of Informed Consent (QuIC) process assessment

Instruction: Please tell us (circle the numbers below) how the information given to you and your decision making was to involve in this study. (**Please circle only one number for each item.)** When you respond to these questions feel free that the questions are just to know the situation of agreement and how do you understand about the study you agreed to participate. **Not** to measure you general knowledge.

S.No	**Questions**	**Agree**	**disagree**	**I don't know /I am not sure/**
501	There was sufficient time for consent discussion	**1**	**2**	**99**
502	Agreed to participate in this study voluntary and with full understanding	**1**	**2**	**99**
503	Enrolment decision made mainly by me the respondent	**1**	**2**	**99**
504	Discussed about the research with other patients or participants	**1**	**2**	**99**

505	Consent form read or explained carefully	**1**	**2**	**99**
506	Consent form was important source of information	**1**	**2**	**99**
507	Consent form was easy to understand	**1**	**2**	**99**
508	Consent form was important to the decision	**1**	**2**	**99**
509	Pressure from provider to sign/agree/ consent form	**1**	**2**	**99**
510	Sufficient opportunity to ask questions	**1**	**2**	**99**
511	Questions answered thoroughly by the consent provider	**1**	**2**	**99**
512	Satisfied with informed consent process	**1**	**2**	**99**
513	Decision to participate was easy or very easy	**1**	**2**	**99**

You have now completed the survey. The sample needed for this study is now collecting for Mekelle hospital. Thank you for taking time and giving us important information for the study!!(**Data collectors: -** explain the purpose of this study and give health education on cervical cancer for participant)

Annex VI: Interview guiding questionnaire for IDI and FGD used for Rapid Ethical Assessment

1. **Introduce yourself and about the study**: - Hello /Greetings! my name is _____. I am health professional. I am member of a team from Addis Ababa University School of Public Health. There is a proposed study to know more about cancer diseases in Ethiopian women. Now we are collecting a base line assessment before conducting the actual study. So we are going to discuss with you about the proposed study in regarding to this society. The information you give us will be recorded to put on words later. All the information you give us and the records will kept confidentially.
2. Would you please tell us your age, job, educational level and duration for how long you live here? No need to mention your name.
3. What do you know about research? How the communities understand it? How you understand medical research? What about medicine or treatment mean?
4. What do you know about cancer? What about cervical cancer?
5. Would you please tell us the local name given to cancer if any!
6. As I explained you earlier there is a proposed study to find out more about cancer disease in Ethiopian women. Cervical cancer is the most prevalent and mostly associated with human papilloma virus and other co-infections of the genital or reproductive organ infection. For this study pregnant women who have ante natal follow up in health facilities will be interviewed, and small drop blood and vaginal fluid will be collected. The findings of the study will help the government to introduced vaccine against cervical cancer in the country. Future generation of girls will benefit. How could we get volunteer pregnant women participant in this study?
7. Which consent take method do you prefer? Oral or signed consent? Why?
8. Who decide in participation of a medical research in the family members? Who decide the pregnant women to participate in this proposed study?
9. In general what is the decision making power of women in this society?
10. What could be the possible barriers for pregnant women to give a small amount blood and vaginal secretion? Cultural or religious effect if any.
11. How can we help pregnant women to understand consent and participate voluntary? Who do you thing better to collect the samples? Male or female health professional?
12. During participants selection what could be the effect of including some participant in the study and others not?
13. What the participant expect in response to participation in a research?

Annex VII: Tigrigna version data collection format: Informed consent comprehension and quality of consent process assessment

እዙይ መፅናዕቲ ብዝምልከት ሓፈሻዊ ሓበሬታ

ሰላም፡- ጥዕና ይሀበለይ! ሽመይ ይብሃል። ኣነ ብዓል ሞያ ጥዕና እንትኸውን ኣብዚ ሕዚ እዋን ኣብ ዝተፈላለዩ ክፍልታት ኢትዮጵያ ኣብ ዝካየድ ናይ ማህፀን ካንሰር መፅናዕቲ ብዝምልከት ካብ ተሳተፍቲ ኣዶታት ሓበሬታ እናኣከብኩ ይርከብ። ብቐዐሮ ብምምፅአን ብጣዕሚ እየ ዘመስግን። ኣብዚ መፅናዕቲ ንክሳተፉ ከባቢ ቅድሚ ክልተ ሰሙን ተሓቲተን ነይረን። ሕዚ ብዛዕባ እቲይ መፅናዕቲ ብዝምልከት ዝተወሰኑ ሕቶታት ክሓተን ይደሊ። ዓላማ እዚ ዝቐርበለን ቓለ-መሕተት ኣብ ሕክምና ተንከፍ መፅናዕቲ ዝሳተፉ ሰባት ብዛዕባ እቲይ መፅናዕቲ ዘለዎም ግንዛበን ኩነታት ስምምዕነትን እንታይ ከምዝመስል ንመፍላጥ እዩ። እዙይ መፅናዕቲ ዝካየድ ኣብ ኣዲስ ኣበባ ዩኒቨርሲቲ ብሓለዋ ጥዕና ሕብረተሰብ ናይ ማስተርስ ተምሃራይ ብዝኾኑ ብኣይተ ሰረበ ኣባይ እዩ።

ውዕኢት እዙይ መፅናዕቲ ሰባት ኣብ ሕክምና ተንከፍ መፅናዕቲ ኣብ ዝሳተፍሉ እዋን ምስ እኹል ግንዛበ ናይ ምስታፍ ክእለትን ከይዲ ዕርየት ስምምዕነትን ንምምሕያሽ ዘኽእሉ፣ ምስ ከባብያዉን ባህላዉን ኩነታት ዝተጠዓሙ ሜላታት ንምድላዉ ይሕግዝ። እዙይ መፅናዕቲ ዝካየድ ብቓለ-መሕተት ጥራሕ እንትኸዉን ብሐፈሽኡ ከባቢ 20 ደቓይቕ ዝወሰደለን ይኸውን።

ስለዝኾነ ኣብዚ ናይ ካንሰር/መንቀርሳ/ መፅናዕቲ ንምስታፍ ኣብዝወሰናሉ እዋን ዝነበረን ግንዛበን ከይዲ ስምምዕነት እንታይ ይመስል ከም ዝነበረን ዝፍትሹ ሕቶታት ብድልተን ብምምላስ ንክተሓባበራና በኣክብሮት ይሓተን ኣለኹ። ንዝቐርቡለን ሕቶታት ነፃ ኾይነን ዝመለሰለን ይመልሳ።

ዝህበኡ መልሲ ሚስጥራዊነቱ ሙሉእ ብሙሉእ ዝተሓለወ እንትኸዉን ሽመን በዚ ሓበሬታ መእከቢ ቅጥዒ ፈፂሙ ኣይፀሐፍን። ንዝቐርቡለን ሕቶታት መልሲ ናይ ምሃብ ኩነታት ኣብ ድልየተን ዝተደረኸ ይኸውን። ዘይደለይኡ ሕቶ መልሲ ዘይምሃብን ኣብዝደለይኡ እዋን እዚ መፅናዕቲ ምቁራፅን ይኽእላ እየን። ይኹን ድኣ'በር ዝህበኡ ሓበሬታ ትኽክለኛ ምኻኑ ሰባት ኣብ ሕክምና ተንከፍ መፅናዕቲ አብ ዝሳተፉሉ እዋን ዘለዎም ግንዛበን ዕርየት ከይዲ ስምምዕነትን ንምፍላጥ ተሳትፎአን ዓብይ ግደ ኣለዎ።

ሰለዚ እዙይ ቓለ- መሕተት ክንቀፅል ዶ ንኽእል? (**ኣከብቲ ሓበሬታ፡ ቁፅሪ 1 ወይካዓ 2 የኽብቡ**)

1 እወ (**ቓለ- መሕተቱ ይቐፅሉ**) 2 የለን (**ተሳታፊ ኣመሰጊኖም ቓለ- መሕተቱ የቁሙ**)

1ይ ክፍሊ፡- ዉልቀዉን ማሕበራዉን ሐበሬታ

ተ.ቑ	ሕቶ	መልስን መለለይ ኮድን
101	ዕድመአን ክንደይ እዩ?	_____ ዓመት
102	ናይ ሕዚ ኩነታት ሓዳረን እንታይ ይመስል?	ባዓልት ሓዳር----------1
		ዘይተመርዐወት----------2
		ዝተፋትሐት----------3
		ባዓል ሓዳራ ዝሞታ----------4
103	ዝለዓለ ናይ ትምርቲ ደረጅአን ክንደይ እዩ?	ምምባብን ምዕሐፍን ዘይኽእል--------1
		ምምባብን ምዕሐፍን ዝኽእል----------2
		ካብ 1ይ-8ይ ክፍሊ ዝወድአ----------3
		ካብ 9ይ-12ይ ክፍሊ ዝወድአ----------4
		ዲፕሎማን ካብኡ ንላዕልን----------5
104	ሃይማኖተን እንታይ እዩ?	ኦርቶዶክስ ክርስቲያን----------1
		እስልምና----------2
		ካልኦት(ይጥቀሱ)----------88
105	ብሄረን እንታይ እዩ	ትግራዋይ----------1
		ኣምሓራይ----------2
		ካልእ (ይጥቀሱ) ----------88
106	ኣፍ መፍተሒ ወይካዓ ብበዝሒ ዝናገርኦ ቋንቋ እንታይ እዩ?	ትግረኛ ----------1
		ኣምሓርኛ ----------2
		ካልእ (ይጥቀሱ)----------88
107	ናይ ሕዚ ስርሐን እንታይ እዩ?	እምቤተይ ገዛ ----------1
		ናይ ውልቂ ተቐጣሪ----------2
		መንግስቲ ሰራሕተኛ ----------3
		ማዓልታዊ ስራሕተኛ----------4
		ነጋዳይ ----------5
		ሓረስታይ----------6
		ካልኦት(ይጥቀሱ)----------88
108	ናይ ስድረአን ሐፈሻዊ ወርሓዊ እቶት ክንደይ እዩ?	ካብ 500ብር ንታሕቲ----------1
		ካብ 500-1000 ብር ----------2
		ካብ 1000 ብር ንላዕሊ ----------3
109	ቅድሚ ሕዚ አብ ሕክምና ተንከፍ መዕናዕቲ ተሳቲፈን ዶ ይፈልጣ?	እወ ----------1
		የለን ----------2
		እረግፀኛ አይኮንኩን ----------99

2ይ ክፋል፡- ምስ እኹል ሐበሬታን ግንዛበን ናይ ምስምዕማዕ ክእለት መዐቀኒ

መምርሒ1. በይዝአን ካብዚ ንታሕቲ ንዝቐረቡ ሕቶታት፣ ትኽክል ንዝመስለን "እወ" ትኽክል ንዝይመሰለን "ኣይፋልን" ንዘይፈልጥኦ ወይከዓ ምዝካር ንዝኸበደን ካዓ "ኣይፈልጥን/ኣይዝክርን" ብምባል ይተሓባበራና (ንሓደ ሕቶ ሓደ መልሲ ጥራሕ)

ተ.ቁ	ሕቶ	እወ /ሓቂ/	ኣይፋልን /ሓሰት/	ኣይፈልጥን /ኣይዝክርን/
201	ሕክምና ተንከፍ መዕናዕቲ ሓደ ዓይነት ምርምር እዩ።[1]	1	2	99
202	ኣነ ኣብዚ መዕናዕቲ ንክሳተፍ ግቡኣይ እዩ።[1]	1	2	99
203	ነዚ መዕናዕቲ ዘድሊ ገንዘብ ዝለገሰ ኣካል ተነጊሩኒ እዩ።[1]	1	2	99
204	ኣብዚ ሕክምና ተንከፍ መዕናዕቲ ዝሳተፉ ጠቅላላ በዝሒ ተሳተፍቲ ተነጊሩኒ እዩ።[1]	1	2	99
205	ኣብ እዋን እዙይ መዕናዕቲ ዉዕኢት ምርመራ ጥዕናይ ካልኦት ሰባት ክርእይዎ ኣይፍቀደሎምን።[1]	1	2	99
206	ድሕሪ እዚ መዕናዕቲ ዉዕኢት ምርመራ ጥዕናይ ዝንገረኒ ይኸዉን።[1]	1	2	99
207	ድሕሪ እዚ መዕናዕቲ ዉዕኢት ምርመራ ጥዕናይ ተራእዩ ሕክመና ክግበረለይ እዩ።[2]	1	2	99
208	ብዛዕባ እዙይ መዕናዕቲ ብዝምልከት ክሓቶ ዝግበኣኒ ኣካል ሙሉእ ሽሙን ኣድራሽኡን ተነጊሩኒ እዩ።[1]	1	2	99
209	ኣብዚ ሕክምና ተንከፍ መዕናዕቲ ብመስታፈይ ምኽንያት ዝተፈለየ ናይ ጥንሲ ክንክን ክግበረለይ እዩ።[2]	1	2	99
210	ኣብዚ መዕናዕቲ ኣብ ዝሳተፈሉ እዋን አብ ዝኾነ ግዜ ብዘይምንም ቅድመ ኩነት ተሳትፎይ ምቁራፅ ይኽእል እዩ።[1]	1	2	99
211	ኣብዚ መዕናዕቲ ብምስታፈይ ምክንያት ንዝመፅእ ወፃኢ ንኽኽፈል ተሓታቲ ይኸውን እዩ።[1]	1	2	99
212	ኣብዚ መዕናዕቲ ብምስታፈይ ገንዘብ ወይካዓ ካልእ ረብሓ ክረክብ እዩ።[1]	1	2	99
213	እቲ ዝተወሰደ ደም ኣብዚ መዕናዕቲ ዓላማ ወፃኢ ንኻሊእ ምርመራ ምጥቃም ይካኣል እዩ።[1]	1	2	99

ተሳተፊቲ ንዘይፈልጥኦ ሕቶ ካብ ምግማት ኣይፈልጥን/ኣይዝክርን/ ዝብል ንክመረፁ የበረታትዑ

<u>መምርሒ 2</u> ካብ ቐ.301-307 ዝተቐመጡ ሓሳባት ንባዕለን ትኽክል ዝመስልን ሐሳብ ዝሐዘ ብምምራፅ ይተሐባበራና! (ንሐደ ሕቶ ሐደ መልሲ ጥራሕ)

301. ኣብዚ መፅናዕቲ ንክሳተፉ ብኽመይ መንገዲ ተመሪፀን?[1]

ሀ. ዝተመረፅኩ ናብ ስሩዕ ናይ ጥንሲ ክትትል ክመፅእ ከለኹ ብኣጋጣሚ ተሓቲተ እዩ።

ለ. ዝተመረፅኩ ኩነታት ጥዕናይ መሰረት ብምግባርን ሕማም ካንሰር ብምጥርጣርን እዩ።

ሐ. ብኽመይ ከምዝተመረፅኩ አይፈልጥን።

302. ናይ ኣፍ ደገ ማህፀን ካንሰር ንምክልኻል ብሓኪም ክርእያ ዘለወን መዓዘ እዩ?[2]

ሀ. ኩሉ ግዘ

ለ. በዝሒ ዘለዎ ናይ ማህፀን ደም ምፍሳስ ክህልወኒ ከሎ።

ሐ. መዓዘ ከምዝኾነ ኣይፈልጥን።

303. ናይዚ መፅናዕቲ ዉፅኢት ዝትርጉሞን ዝመያጠሉን ኣካል መን እዩ።[2]

ሀ. ሓካይም ኣዲስ ኣበባ ዩኒቨርሲቲ

ለ. ስሩዕ ናይ ቅድመ ወሊድ ክትትል ዝገበሩለይ ባዓል መ.ያ

ሐ. መን ከምዝኾነ ኣይዝክርን

304. ካብዚ መፅናዕቲ ተሳትፎኣን ምቁራፅ ዝኽእላ መዓዘ ይመስለን?[1]

ሀ. ኣብ ዝደለኽዎ እዋን ምቁራፅ ይኽእል እየ

ለ. ናይዚ መፅናዕቲ በዓል ዋና ፍቓድ እንተኾይኑ ጥራሕ

ሐ. ድሕሪ እኹል ሓበሬታ እዙይ መፅናዕቲ ምእካቡ ጥራሕ

መ. መዓዘ ከምዝኾነ ኣይፈልጥን

305. ኣብዚ መፅናዕቲ ንምስታፍ ተሰማፅሚዐን ወይካዓ ውዕል ፈሪመን ኣለዋ ክብሃል ከሎ እንታይ ማለት እዩ?[1]

ሀ. ኣብዚ መፅናዕቲ እንተዘይተሳቲፈ ተሓታቲ ይኽውን እየ ማለት እዩ።

ለ. ኣብዚ መፅናዕቲ ንክሳተፍ ናይ ግድን እዩ ማለት እዩ።

ሐ. ኣብዚ መፅናዕቲ ንክሳተፍ ብድልየተይ ወሲነ ኣለኹ ማለት እዩ።

መ. እንታይ ማለት ምኺኑ ኣይፈልጥን

306. ኣብዚ መፅፅቲ ድሕሪ ምፍራም ውዕል ስምምዕነት ንምስታፍ እንተዘይደሊየን ምቁራፅ ዶ ይኽእላ?[1]

ሀ. እወ ምቁራፅ ይኽእል

ለ. የለን ምቁራፅ ኣይኽእልን

ሐ. ኣይፈልጥን

307. ኣበዚ መዕናዕቲ ንዘይምስታፍ ወሲነን ንበል፤ ኣብ ስሩዕ ናይ ጥንሲ ክትትለኒ ዝተፈለየ ነገር ክህልይ ይኽእል እዩ ኢለን ዶ ይሓስባ?[2]

ሀ. እወ ለ. የለን

<u>መመርሒ 3.</u> ካብ ቐዕሪ 308- 313 ንዝተጠቐሱ ሕቶታት ትኽክል ዝመሰለን ብምምራፅ ይተሓባበራና (ንሓደ ሕቶ ካብ ሓደ ንላዕሊ መልሲ ምሃብ ይካኣል እዩ)

308. ናይዙይ መዕናዕቲ ዋና ዓላማ ዝገልፅ(ፁ) ኣየናይ እዩ?[3]

ሀ. ኣብ ኢትዮጵያ ብዛዕባ ሕማም ካንሰር ብዝበለፀ ንምፍላጥ እዩ

ለ. ንመፃኢ ወለዶ ደቂ-ኣንስትዮ ዝጠቅም ክትባት ንምድላው እዩ

ሐ. ናይ ባዕለይ ኩነታት ጥዕና ንምምሕያሽ እዩ

መ. ዓላምኡ እንታይ ከም ዝኾነ ኣይፈልጥን

309. ኣብዚ መዕናዕቲ ብምስታፈን ዝረኽብኡ ረብሓ እንታይ እዩ?[3]

ሀ. ውዕኢት ምርመራ ጥዕናይ ክንገረኒ እዩ

ለ. ብውዕኢት እዚ መዕናዕቲ መሰረት ሕክምና ክግበረለይ እዩ

ሐ. ንመፃኢ ወለዶ ደቂ-ኣንስትዮ እምበር ኣነ ብቀጥታ ዝርብሖ ነገር የለን

መ. ኣይፈልጥን

310. ኣብዚ መዕናዕቲ ክሳተፉ ከለዋ ካብዞም ዝስዕቡ ተግባራት ንኽከናውና ዝሕተትኡም ኣየንኡም እዮም?[3]

ሀ. ዝተወሰነ ንጣብ ደም ንምርመራ ምሃብ

ለ. ናይ ራጅ/ ጨረር/ ምርመራ ምግባር

ሐ. ካብ መሃፀን ዝውሰድ ፈሳሲ ንምርመራ ምሃብ

መ. ኣይፈልጥን

311. ኣብዚ መዕናዕቲ ክሳተፉ ከለዋ ካብኡን ዝሕለይ ነገር እንታይ እዩ?[1]

ሀ. ኣብቀፀሮ ምምላእ

ለ. ምግቢ ከይበልዓኹ ኣብጥራሕ ክበደይ ምምላእ

ሐ. ካባየ እንታይ ከም ዝሕለይ ኣይፈለጥን

312. ዝተወሰነ ንጣብ ደም ንምርመራ ኣብዝውሃበሉ እዋን ክፍጠር ዝኽእል ቀሊል ሳዕበን?[3]

ሀ. ናይ ደምስር መጠናዊ ቃንዛ ወይካዓ ሰምበር

ለ. መርፍእ ኣዝውገኣሉ ቦታ ዝተወሰነ ናይ ምድማይ

ሐ. ዋሓዲ ደም ከብፅሓለይ ይኽእል እዩ

መ. ዘስዕቦ ሳዕቤን ኣይፈልጥን እየ

313. ኣብዚ መፅናዕቲ ብምስታፈን ዘስግዐን ነገር እንታይ እዩ?[3]

ሀ. እዚ መፅናዕቲ ካሊእ ሃይማኖታዊ ወይካዓ መንገስታዊ ኣጀንዳ ክህልዎ እዩ ዝብል ስግኣት ኣለኒ

ለ. በዚ መፅናዕቲ ምርመራ ካንሰር ክርከበኒ እዩ ዝብል ስግኣት ኣለኒ

ሐ. ውፅኢት ምርመራ ጥዕናይ ካልኦት ሰባት ክፈለጥዎ ይኾኑ ዝብል ስግኣት ኣለኒ

መ. ምንም ዓይነት ስግኣት የብለይን

መምርሒ 4፡ ካብዚ ንታሕቲ ዝተዘርዘሩ ምንጭታት ሓበሬታ ጥዕና ክንደይ ዝኣክል ከም ዝጥቀማ ብምምራፅ ይተሓባበራና

ተ.ቁ	ሕቶ	ኩል ግዘ	ሓልሓሊፉ	ፈፂሙ
401	ካብ መፅሓፍ/ሕትመት/	1	2	3
402	ካብ መሓዛ/ ስድራ/	1	2	3
403	ካብ ብዓል መ.ያ ጥዕና/ሓኪም፤ነርስ፣ በዓል ሞያ ኤክስተንሽን ጥዕና ወዘተ/	1	2	3
404	ካብ ዓለም ለኻዊ ሓበሬታ ኮምተር/ኢንተርኔት/	1	2	3
405	ካብ ፍሉጣት መፅሔታት	1	2	3
406	ካብ ሬድዮ	1	2	3
407	ካብ ቴለቭዥን	1	2	3

3ይ ክፋል፡- ፅሬት ከይዲ ምስምዕማዕ ተሳትፎ መፅናዕቲ

መምረሒ- በይዝአን ኣብዚ መፅናዕቲ ንምስታፍ ኣብ ዝተስማዕምዓሉ እዋን ከይዲ ሓበሬታ ስምምዕነትን ኩነታት ምውሳን ተሳትፎን እንታይ ይመስል ከም ዝነበረ ዝፍትሹ ሕቶታት ብናይባዕለን ኣተሓሳስባ ትኽክል ዝመስለን "**ይስማዕማዕ እየ**" ትኽክል ንዘይኮነ "**ኣይስማዕማዕን**" ከምኡውን ንምዝካር ዘፀገመለን "**ኣይዝክርን**" ዝብሉ ሓሳባት ብምምራፅ ይተሓባበራና፡፡ ዝቐረቡ ሕቶታት ፍልጠተን ንምዕቃን ዘይኮነስ ኣብዚ መፅናእቲ ናይምስታፍ ከይዲ እንታይ ይመስል ከምዝነበረ ንምፍላጥ ዝሕግዙ ብምኺኖም ነፃ ኮይነን ዝመስለን ይግለፃ፡፡

ተ.ቐ	ሕቶታት	ይስማዕማዕ'የ	ኣይስማዕማዕን	ኣይዝክርን
501	ኣብዚ መፅናዕቲ ክሳተፍ ንክውስን እኹል መመያየጢ ግዘ ነይሩኒ እዩ፡፡	1	2	99

502	ኣብዚ መፅናዕቲ ዝተስማዕማዓኹ ብድልየተይን ምስ እኹል ግንዛበን እዩ፡	1	2	99
503	እቱይ ስምምዕነት ብዋናነት ዝተወሰነ ብኣየ እዩ፡፡	1	2	99
504	እዙይ መፅናዕቲ ብዝምልከት ምስ ካለኦት ተሳተፍቲ ወይካዓ ተሓከምቲ ተመያይጥናሉ ኢና፡፡	1	2	99
505	ናይ ስምምዕነት ቅጥዒ ብዝግባእ ተነቢቡለይ /ተገሊፁለይ/ እዩ፡፡	1	2	99
506	ናይ ስምምዕነት ቅጥዒ ጠቓሚ ምንጭ ሓበሬታ ነይሩ፡፡	1	2	99
507	ናይ ስምምዕንት ቅጥዒ ንምርዳእ ቀሊል ነይሩ፡፡	1	2	99
508	ናይ ስምምዕነት ቅጥዒ ኣብዚ መፅናዕቲ ክሳተፍ ንክውስን ጠቓሚ ነይሩ፡፡	1	2	99
509	ኣብዚ መፅናዕቲ ንምስታፍ ንክውስን ወይካዓ ናይ ስምምዕነት ቅጥዒ ንክፍርም ናይ ሓታታይ ኣካል ተዕእኖ ነይርዎ፡፡	1	2	99
510	ዘይተረድኣኒ ንምሕታት እኽል ግዘ ነይሩኒ እዩ፡፡	1	2	99
511	ንዝተልዓሉ ሕቶታት መልሲ ብዝግባእ ተዋሂብዎም እዩ፡፡	1	2	99
512	ኣብዚ መፅናዕቲ ንምስታፍ ብዝተገበረለይ ገለዓን ብዝነበረ ክይዲ ምስምዕማዕን ረውየ ኣለኹ፡፡	1	2	99
513	ኣብዚ መፅናዕቲ ንምስታፍ ንምውሳን ቀሊል/ብጣዕሚ/ቀሊል ነይሩ፡፡	1	2	99

እዙይ ናይዚ ቃለ-መሕተት መወዳእታ እዩ፡፡ (**ንኣከብቲ ሓበሬታ፡ዓላማን ጥቕምን መፅናዕቲ “HPV” ስርጭትን ሕማም ካነሰር ብዝምለከትን ብድጋመ መብረሂ ይሃቡ፡፡**) ብምቕባል ነዚ መፅናዕቲ ዝኸውን ደምን ናይ ማህፀን ራሕስን ካብ መቐለ ሆስፒታል እንዳተኣከበ ይርከብ፡፡ ንሰን ብእጃመን እዚ መፅናዕቲ ብዝምልከት ጠቓሚ ሓበሬታ ስለ ዝሃባና የቕንየለይ ብጣዕሚ የመስግን፡፡

Annex VIII: Table showing the type of question (superscripts numbers) and their correct answer (given in brackets) used for comprehension and quality of consent process assessment

A. TRUE or FALSE: correct answer given in brackets

Consent component
This health related study is a form of a research [1]**.[True]**
Obligation to participate in this medical research [1]**.[False]**
Told who is funding this research [1]. **[True]**
Told the total number of people that participate in this research [1].[False]
Other than the study team no one will be allowed to see my health information [1]**.[True]**
I will be told test results from this research [2]. **[False]**
Treated for the infection tested by this research [2].[**False**]
I have been told contact person address [1]. [**True**]
I will get a special care in my regular ANC follow up [2]. [**False**]
My participation in the study can be stopped at any time [1]. [**True**]
I will be asked for costs related to my participation in this study [1].[**False**]
I will be paid or got any incentive for participating in this study [1].[**False**]
The sample taken in this study can be used for other purpose [1].[**False**]

[1]**Generic test item**- These test items appear on each version of MICCA

[2]**Trial specific test item**- These test items are not appears on every version of the MICCA. They are generated based on response to BIQ.

[3]**Trial specific test item-** appear on each version of the MICCA. The response option for each of these test items are generated based on response to BIQ.

B. MULTIPLE CHOICES with single and multiple correct answers given in brackets used for comprehension assessment

Consent component
Participate selection in this study [1].[**A**]
When to visit a doctor to avoid cervical cancer [2].[**B**]
Who analyze and discuss test results **[2].[A]**
At what time can leave the study? **[1][A]**
Agreed or signed to participate in this research mean **[1].[C]**
Can stop participation after you singed to participate? **[1][A]**
Any difference made to regular ante natal care if not participate? **[1][B]**
The main purpose(s) of the study? [3] To know more about cancer disease in Ethiopia **[A]**
To introduce vaccine which benefit future generation girls **[B]**
The main benefit(s) taking part in this research? [3] Future generation girls but not me will be benefited.**[C]**
Procedure(s) asked to take part in? [3] Giving a small amount blood for test **[A]**
Giving vaginal secretion for test **[C]**
Task(s) asked to complete? [3] Attend appointment **[A]**
Side effect that might occur during blood drawing for test? [3] Pain or bruising on the vein **[A]**
Bleeding at the site of the needle**[B]**

[1]**Generic test item**- These test items appear on each version of MICCA

[2]**Trial specific test item**- These test items are not appears on every version of the MICCA. They are generated based on response to BIQ.

[3]**Trial specific test item-**appear on each version of the MICCA. The response option for each of these test items are generated based on response to BIQ.

C. Table showing the questions and their correct answer give in brackets respectively used for quality of informed consent process assessment

Informed consent process components
There was sufficient time for consent discussion.[**Agree**]
Agreed to participate in this study voluntary and with full understanding.[**Agree**]
Enrolment decision made mainly by me the respondent.[**Agree**]
Discussed about the research with other patients or participants.[**Agree**]
Consent form read or explained carefully.[Agree]
Consent form was important source of information.[**Agree**]
Consent form was easy to understand.[**Agree]**
Consent form was important to the decision.[**Agree**]
Pressure from provider to sign/agree/ consent form.[**Disagree**]
Sufficient opportunity to ask questions.[**Agree]**
Questions answered thoroughly by the consent provider.[**Agree**]
Satisfied with informed consent process.[**Agree]**
Decision to participate was easy or very easy.[**Agree**]