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Optimizing tubal ligation service delivery: a prospective cohort study to measure the task-sharing experience of Marie Stopes International Ethiopia

Olivia Nuccio,[1],* Birhanu Sendek,[2] Min Hae Park,[3] Tesfaye Mesele,[1] Francis Ogojo Okello,[4] and Cristin Gordon-Maclean[5]

[1]Marie Stopes International, [2]John Snow Inc, Ethiopia, [3]London School of Hygiene and Tropical Medicine, [4]Abt Associates and [5]Global Oncology at Fred Hutch
*Corresponding author. 1 Conway Street Fitzroy Square London, UK W1T 6LP. E-mail: olivia.nuccio@mariestopes.org

Abstract

The Ethiopian government implements a progressive task-sharing policy for health services as a strategy to address shortages of highly skilled providers and increase access to critical services, such as family planning. Since 2009, Marie Stopes International Ethiopia has trained health officers to provide tubal ligations, a permanent method of family planning, as part of its task-sharing strategy. The objectives of this research were to evaluate task-sharing tubal ligations to health officers at Marie Stopes International Ethiopia, specifically: 1.) to investigate safety, as measured by the proportion of major adverse events; 2.) to evaluate the feasibility, as measured by adherence to the standard tubal ligation procedure protocol; and 3.) to investigate acceptability to clients of the tubal ligation procedure provided by health officers. We established a prospective cohort of women aged ≥18 years presenting for tubal ligation at Marie Stopes International Ethiopia sites in three regions in Ethiopia (March-May 2014). Data on adverse events (incomplete procedure, pain, bleeding, infection, perforation) were collected intra-operatively; peri-operatively (1 hour post-procedure); and post-operatively (7 days post-procedure). To measure feasibility, 65% of procedures were selected for 'audit', where a nurse observed and scored health officers adherence to standard protocol using an 18-item checklist. To assess acceptability, women were asked about their satisfaction with the procedure. In total, 276 women were enrolled in the study. 97.5% of procedures took place in rural settings. All participants were followed up 7 days post-procedure (100% response rate). The overall proportion of major adverse events was 3% (95% CI 1% to 6%). The most frequent adverse event was 'failure to complete the TL' (2.2%, n=6). The average score on protocol adherence was 96.9%. Overall, 98.2% (n=271) of clients would recommend the procedure to a friend. Findings from this study, indicating safety, feasibility and acceptability, are consistent with the existing literature, which indicate safety and acceptability for task-sharing tubal ligations, and other methods of contraception with non-physician health providers. This study adds to scant literature on task-sharing tubal ligations in rural and low-resource settings.

Introduction

Unintended pregnancy contributes significantly to maternal mortality and morbidity in developing nations [1, 2]. Despite this, an estimated 225 million women have an unmet need for modern contraception [3, 4]. In the least developed countries, 6 out of 10 women who do not want to become pregnant, or who want to delay their next pregnancy, are not using any method of contraception [5].

A critical barrier to accessible, equitable and high quality family planning (FP) in developing nations is a shortage of trained providers, particularly in rural areas [6]. Long acting and permanent methods (LAPMs) of contraception (implants, intrauterine devices, tubal ligations (TLs) and vasectomies) are particularly inaccessible due to their need for highly skilled providers and specialised equipment [7]. Task-sharing is formally defined as a division of tasks in which different cadres of providers do similar work [8]. Essentially, task-sharing enables non-physician health professionals, such as health officers, nurses, and midwives, to safely provide clinical services and procedures that would have otherwise been restricted to higher-level cadres. The World Health Organisation (WHO) recognises task-sharing as a promising strategy for addressing the critical lack of health care workers to provide maternal and newborn care, including FP services, in low-income countries [6]. The WHO has developed guidelines that recommend specific cadres of staff take on some delivery of specific FP method provision. The guidelines recommend task-sharing TL procedures to associate clinicians, such as health officers and clinical officers, and several programs have begun task-sharing TL to non-physician cadres of clinicians including health officers, paramedics, and nurse midwives, to expand FP method choice for women [9, 10, 11].

In Ethiopia, over 80% of the population live in rural areas [12]. LAPMs constitute <5% of contraceptive methods used [13], and unmet need for FP remains high at 25% [14], thus, the Federal Ministry of Health (FMoH) has devised progressive policies to expand access to reproductive health services [15]. In the National Reproductive Health Strategy for 2006-2015, the FMoH called for the delegation of FP service provision to the lowest service delivery level possible, for the provision of all FP methods, especially LAPMs. An example of the success of the progressive policy is evidenced by the expanded access to contraceptive implants, such as Implanon®, which has been successfully task-shared to health extension workers (who are trained, salaried community providers stationed in villages, and represent the lowest-level of the health system) since 2009 [16]. Further, since the strategy was published, the FMoH has adopted the policy of task-sharing the provision of TL to non-physician providers such as health officers (who are health workers, or 'associate clinicians' by WHO classification, with four years of clinical training including surgery, obstetrics and gynaecology, medicine and paediatrics, who receive this training prior to any on-the-job FP method specific training), BSc nurses and BSc Midwives. By increasing the number of skilled providers who are able to provide TL services, the human resource barriers to accessing these services will reduce, and access to TLs will be expanded.

Marie Stopes International Ethiopia (MSIE), an organization that provides sexual and reproductive health and FP services in Ethiopia, has provided TL services using a task-sharing strategy since 2009 [17]. However, such programs for TL in Ethiopia have not been rigorously evaluated for safety, feasibility, efficacy or acceptability. A recent systematic review of the literature on mid-level provision of TL services identified nine studies that reported on safety or satisfaction measures [10], but findings were limited in that no study took place in Ethiopia (and further, only two studies took place in Africa),

and that all of the studies were dated (ranging from 1975 to 1983). Further, few studies captured data on task-sharing in rural settings, such as outreach sites. Outreach sites are rural health service posts that receive visiting teams of MSIE health care providers delivering certain short-term and LAPM methods of FP.

The aim of this study was contribute to this gap in the existing literature by evaluating the safety, feasibility and acceptability of TLs provided by health officers in MSIE outreach sites and clinics in Ethiopia.

Methods

Study design

We conducted a single-arm prospective cohort study of women presenting for TLs at two MSIE-owned static clinics, located in urban areas, and six public health centres where MSIE offers outreach services, located in rural areas. The study sites were located in three regions of Ethiopia (Amhara, Oromia and the Southern Nations, Nationalities and People's regions). Data were collected over three months, from March to May 2014. Sites were selected into the study purposively, based on their high volume of TL clients in the past, in order to meet practical requirements of the study.

All women who presented at the study sites expressing an interest in contraception during the data collection period were counselled on all contraceptive methods. Those women who chose a TL and who met the following criteria, were eligible for inclusion in the study: age ≥18 years; able to provide informed consent; not pregnant and had not given birth in the last 42 days; in good health. Women with the following health issues were excluded from the study: pelvic inflammatory disease, sexually transmitted infection, unexplained vaginal bleeding, systemic infection, severe anaemia with clinical symptoms, coagulation disorder/taking anti-coagulants, deep vein thrombosis, poorly controlled diabetes or epilepsy, previous complicated abdominal or pelvic surgery, severe hypertension (systolic blood pressure >160mm Hg or diastolic blood pressure > 100 mm Hg), severe obesity (BMI > 30 kg/m2) with abdominal fatty tissue which precludes a simple procedure, any clinical or physical condition that renders the women unable to recline comfortably in a flat position for 30 minutes. Eligibility screening was first conducted by MSIE nurses, and then confirmed by trained data collectors. Prior to being enrolled in the study, women were given information about the study, and provided informed consent to participate, which was separate to and in addition to their informed consent for the procedure itself. The health officers carrying out TL procedures were also given information about the study, and provided informed consent to participate prior to being observed.

The study protocol received ethical approval from Marie Stopes International's independent Ethics Review Committee and Ethiopia's National Research Ethics Review Committee.

Study size determination

We designed our study with the aim to determine the prevalence of a major adverse event in women who received a TL procedure across all eight purposively selected MSIE sites, estimating prevalence to be approximately 2% (in-line with results from previous Marie Stopes studies). We calculated that a sample size of 330 women would allow us to detect a 2% prevalence of an adverse event at the 95% confidence level with a precision of +/- 1.5%. However, due to lower than expected client flow and ineligibility of some clients, a sample size of 276 eligible women was achieved. The

achieved sample allows us to detect a 2% rate of an adverse event at a 95% confidence level with a ±1.64% precision.

TL procedure and training

The TL procedure is a method of sterilization whereby a woman's fallopian tubes are blocked, which prevents fertilized eggs from reaching the uterus for implantation. TLs are performed under local anaesthesia. Using sterile technique, a 2 – 3 cm skin incision (mini-laparotomy) is made. The Fallopian tubes are visually identified, grasped with an atraumatic clamp, and walked to the fimbriated end to ensure correct anatomy. A 3 cm section of the tube is then ligated with plain suture and transected. The same procedure is repeated on the contralateral side.

Health Officers were trained to perform TLs by MSIE using a competency-based approach, which included both theoretical and practical courses. After the first group of health officers were trained in 2009, subsequent groups were trained in 2010, 2011 and 2012. Theoretical training focused on key preparatory steps for TL, such as: informed consent for the TL procedure, assessment of a woman's eligibility and potential risk factors, identifying contraindications for surgery, local anaesthesia use, preventing and managing complications, and provisions of postoperative instructions. In the practical session, new trainees performed at least 10 TLs under the supervision of an experienced trainer. Trainers were experienced medical doctors employed by Marie Stopes International who had been providing TL for at least five years. Health officers were required to demonstrate excellent knowledge of the TL procedure, female pelvic anatomy, infection control and prevention and management of surgical complications, and were required to competently perform 10 TLs under the supervision of an experienced provider before they were deemed competent to perform the procedure independently. Training was provided to health officers prior and independent of this study.

Data collection

Trained data collectors with medical backgrounds collected data on safety and acceptability. Data collection took place on the day of the procedure and at seven days post-procedure. After providing informed consent for the procedure, women underwent a physical examination from an MSIE provider to assess temperature, blood pressure, pulse rate, weight and height. After providing informed consent for the research, but before the procedure, data collectors administered a questionnaire, where women provided information on socio-demographics, reproductive characteristics, and FP history. Following the baseline questionnaire, women underwent the TL procedure. The start and finish time of each procedure was recorded.

Data collectors recorded any adverse events that occurred during each procedure (intra-operatively, from time of local anesthetic injection to closure of incision) and peri-operatively (within one hour of incision closure and prior to discharge), as well as the response (i.e., treated by the health officer, transferred to a different facility because health officer unable to treat, or transferred because higher-level facilities required). The following types of adverse events were recorded: unable to complete TL procedure (intra-operative only), pain, bleeding, infections, perforations (to bladder, bowel or uterus), and poor wound healing (post-procedure only). Adverse events were classified as minor, moderate, major or critical according to severity, using the MSI Medical Development Team's matrix for classifying adverse events. Minor adverse events cause minor injury/illness that requires a minimal level of intervention and symptoms are managed at home. Moderate adverse events

require clinical intervention from medical personnel. Major adverse events cause long-term incapacity or disability and require hospitalization; this category also includes failed procedures.. All of the women attended a follow-up visit seven days after the TL procedure, at which they completed an interviewer-administered questionnaire to assess post-operative adverse events, treatment-seeking behaviors and post-procedure satisfaction.

To assess providers' adherence to protocol, a convenience sample of 65% of procedures were selected for audit, with a nurse observing the procedure and scoring the procedure according to an 18-item checklist [Figure 1] that assessed compliance with standard procedure protocol during pre-operative evaluation, the surgical procedure, and after care.

Data analysis

Safety was assessed using the proportion of women experiencing major adverse events. Major adverse events are those which require significant follow-up care or hospitalisation, or result in failure to complete the procedure. Adverse events were assessed at three stages-- intra-, peri- and post-operative).

Adherence to clinical protocol (i.e., feasibility) was defined as the average proportion of checklist items (out of 18) that were adhered to during audited procedures. We also assessed the proportion of procedures that did not adhere to protocol (failed to meet one or more criteria on checklist). This is essentially a measure of equivalence with the standard protocol of care, which is critical to evaluating the long-term feasibility of task-sharing.

Acceptability of health officer-administered TL was assessed using the proportion of women that would recommend the procedure to a friend, the proportion that would recommend the facility to a friend and the proportion that reported that the service met or exceeded their expectations.

Data were entered into an SQL database, and analysed using Stata version 13 (StataCorp, 2013). The unit of analysis was the women receiving the TL (n=276). To analyse outcome variables, descriptive analysis was conducted, with means and proportions, along with 95% confidence intervals.

Results

In total, 311 women were screened, of whom 276 (88.7%) were eligible and agreed to participate in the study. All 276 women (100%) were followed up at seven days. [Figure 2]

The majority of procedures (97.5%, n=269) took place at outreach sites [Table 1]. Most participants were between 30 and 34 years old (41.3%, n=114); their ages ranged from 25 to 42 years old. Most participants had 6-7 living children (43.8%, n=121); this ranged from 1 to 10, with an average of 6. Parity was higher, ranging from 1-14, with an average of 7. The majority of participants were married (96%, n=265) and illiterate (76.8%, n=212).

A large proportion of participants (69.6%, n=192) were using some FP method in the three months prior to their TL procedure and 29.4% (n= 81) were not using any FP method [Table 2]. The most commonly reported methods were injectables (48.2%, n=133) and implants (12.3%, n=34). More than a third of participants (34.4%, n=66) using a FP method in the past three months reported experiencing side effects from the method.

In total, N=8 providers participated in the study. Providers on average had 42.4 months of experience providing TLs, ranging between 16 and 61 months. During the study period, the average number of TL procedures administered by each provider was 35, and ranged from 2 to 81. The duration of TL procedures also varied; the average procedure time was 25 minutes. The majority of procedures (76%, n=202) took less than 30 minutes, while 24% (n=74) took 30 minutes or longer. The procedure duration was dependent on the complexity of the cases, and if a major adverse event had occurred (data not shown). Further, duration of procedure was associated with the experience of the providers; among providers with 1-2 years' experience, 59% of procedures took 30 minutes or longer, compared to 29% of procedures for providers with more than 2 years' experience ($p<0.001$).

Safety

The overall proportion of women who experienced a major adverse event was 3.0% [95% confidence interval (CI) 1.0% to 6.0%] (n=8) [Table 3]. The major adverse events were failure to complete the procedure (n=6, 2.2% of procedures), followed by pain classified as 'major' (n=3, 1.1% of procedures). Eight participants (3%, 95% CI 1.0% to 6.0%) experienced a major adverse event intra-operatively. One participant (0.4%; 95% CI 0.1% to 2%) experienced a major adverse event peri-operatively (severe pain). On day 7 post-procedure, two women (1%; 95% CI 0.2% to 3%) reported major adverse events (pain).

Just over a quarter (28%) of the participants had no adverse events. The remaining 72% (n=199, 95% CI 66% to 77%) of women experienced some adverse event at either the intra-, peri- or post-operative stage, the vast majority being 'minor' in nature (most commonly minor pain or minor bleeding, and poor post-operative wound healing). The overall proportion of moderate adverse events was 22% (n=62, 95% CI 18 to 28%), and minor adverse events was 70% (n=194, 95% CI 65% to 75%).

All women with intra-operative or per-operative adverse events on the day of the procedure were treated by the TL provider on site, and none required transfer to another facility or hospitalisation.

Feasibility

In total, 65% (N=176) of procedures were observed and scored for adherence to a standard clinical protocol. The average score across the procedures sampled for the protocol adherence audit was 96.9% (which indicates an average score of 17.5 out of the 18 item checklist). Notably, 100% of observed procedures used clean gown and gloves, and there was generally good adherence to other checklist items [Table 4]. The protocol items most frequently not adhered to included checking the effects of the anaesthesia (88.6%, n=156) and checking that the client is resting comfortably post-procedure (90.9%, n=160). 80.1% (n= 141) of procedures had full (100%) protocol adherence.

Acceptability

Study results show a very high level of acceptability of the TL procedure among participants. Virtually all (98.2%) of the participants would recommend the procedure to a friend. Similarly, 98.6% of the participants would recommend the facility where they received the procedure to a friend; and 97.5% of the participants reported that the experience of receiving a TL from an MSIE health officer met or exceeded their expectations. Participants were also asked to rate their satisfaction with their overall experience, and 94.5% (n= 261) rated their experience good or very good.

There were some notable exceptions to high levels of acceptability. Five participants (1.8%) reported that they would not recommend the procedure to a friend. Of these 5 women, 4 had an unsuccessful procedure (unable to ligate one or more tubes). Reasons for not recommending the procedure included, 'because it failed,' 'I am sick for a few days,' and 'the pain was so hard.' Four participants reported that they would not recommend the facility to a friend. Of these 4 women, 3 had an unsuccessful procedure. Seven women reported that the service did not meet their expectations. Of these, 6 women had unsuccessful procedures.

Discussion

This study demonstrates that TL can be conducted safely by health officers after completion of a competency-based training model, and can be provided at scale, as opposed to just as part of a pilot project. These findings are supported by the high rate of adherence to the TL provision protocols and the low rate of adverse events observed in this study. The findings provide momentum for building the capacity of non-physician health professionals to deliver TL procedures to eligible consenting women. Our findings show that in settings where the health workforce is limited, such as rural outreach settings (where almost all of the procedures in this study took place), task-sharing TL provision with health officers can contribute to increasing access to permanent contraception methods and to expanding contraceptive choice and method mix.

Results also confirm that TL procedures by MSIE health officers are acceptable, with study participants recommending both the procedure and the health facilities from which they received the TL to their friends. Notably, all major adverse events that occurred during and immediately after procedure could be treated by the health officers themselves. In our study population, then, health officers performing TL did not create an additional burden on supervisory providers to assist the health officers when an adverse event occurred. Health officers were able to perform the 276 procedures with no bowel or uterine perforations, which were the main major adverse events reported in previous research [18]. These are also the type of adverse events that would require higher-level treatment or hospitalisation.

The 3% proportion of major adverse events we observed was slightly higher than the 1.5% rate previously observed in a similar study by Marie Stopes in Uganda [18]. While no confidence intervals were reported for that study, the frequency of adverse events appears to have been fairly similar between the two studies (and the 1.5% rate from MSI Uganda falls within the 95% confidence interval of 1% to 6% in our study). However, adverse events were recorded at different points in time, and study designs differed, making it difficult to draw conclusive comparisons between the two studies.

We also look beyond other task-sharing studies to compare the 3% proportion of adverse events observed. A prospective, multi-centre cohort study in the United States found an overall complication rate of 0.9 per 100 procedures [19]. However, there were several key differences between the two studies, most notably that the U.S.-based study took place in a hospital setting, measured different types of complications at different points in time, and did not count 'failure to complete the procedure' as a complication (which is the main adverse event observed in our study). Therefore, it is difficult to drawn comparisons between the two.

This study also captured aspects of the TL service delivery by health officers that could be improved, as evidenced by the scores on the protocol adherence checklist. These include always checking the effects of anaesthesia, and ensuring that clients are resting comfortably after the procedure is over. Actions from these results have been incorporated into trainings at MSIE. This finding also highlights the importance of conducting routine clinical monitoring activities for services that have been task-shared, to ensure compliance to training.

A major strength of this study is its prospective design. As data were collected twice on the day of the procedure, and seven days after the procedure, the risk of recall bias was minimised. All participants were successfully followed-up on day 7, thus we have a complete data set that is not affected by loss to follow-up. Another strength of this study is that, while other studies have introduced training as an intervention with non-physician health professionals, and then observed major adverse events [18], this study observed health officers that had been trained in previous years, and captures their TL performance in a 'real-world' setting. Thus, this study design gives a picture of what happens on the ground, once time has elapsed between training and service delivery, rather than in a research setting.

This study had limitations. As the study design was a single-arm prospective cohort design, there was no physician comparison arm to compare the health officers to. High-volume TL sites were chosen purposively, which may have biased the safety findings as health officers in these sites have more experience providing TLs. This may in turn limit generalizability to other settings, along with the fact that MSIE emphasizes and trains continuously on clinical quality standards, which may be a key requirement for transferability.

Ethiopia's FP guidelines place emphasis on increasing contraceptive prevalence and expanding the method mix, with more emphasis placed on LAPMs [20]. Recent Demographic and Health Survey results show a growing demand for LAPMs in Ethiopia [13]. However, this demand is limited by the shortage of qualified providers, particularly in the provision of permanent methods. This study shows that training existing non-physician providers in TL in-line with the policy guidelines for FP is a viable strategy. These findings are consistent with studies elsewhere that show task-sharing may be a safe and effective approach to delivering LAPMs, although more rigorous research and evaluations are needed [21].

Conclusion

Our study indicated safety, feasibility and acceptability of task-sharing TL procedures to Health Officers at MSIE, as indicated by a low rate of major adverse events, high adherence to surgical procedure among health officers, and high rates of satisfaction. There were few instances of adverse events and non-adherence to protocol, but these few instances did highlight the importance of investing in routine monitoring systems for task-shared surgical procedures that are done at national scale.

While findings from this study can offer an important case study for other governments considering task-sharing as an initiative to expand access to FP services, they should also be interpreted with caution. MSIE is a non-governmental organisation that emphasises training and quality of care, and invests in staff and systems to support that. This may not be possible for other providers in Ethiopia and the region, therefore findings cannot be generalised to Ethiopia or to other countries in East

Africa, where health systems are complex and health care delivery is done in settings that vary widely. Further research should be done to investigate whether health officers providing TLs is feasible, safe and acceptable in more complex settings.

References

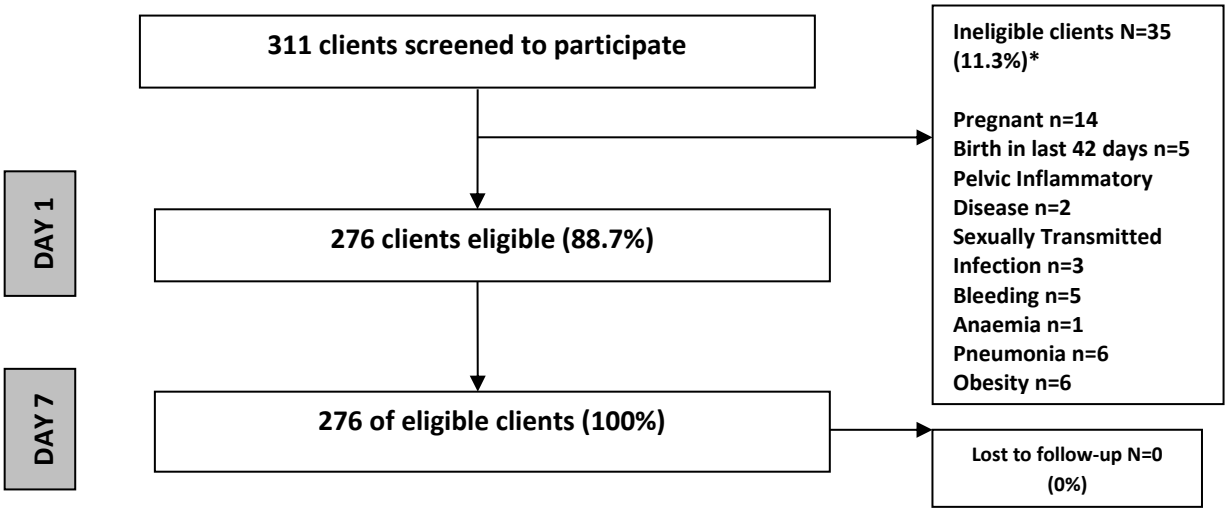
1. Trends in maternal mortality: 1990 to 2008. Geneva, Switzerland: World Health Organizaiton; 2008 2010.
2. Facts on abortion and unintended pregnancy in Africa. New York City: The Guttmacher Institute; 2009.
3. Darroch JE, Singh S, Nadeau J. Contraception: an investment in lives, health and development. Issues Brief (Alan Guttmacher Inst) 2008; Dec(5):1-4.
4. Singh SD, Darroch JE, Ahsford LS. Adding it up: the costs and benefits of investing in sexual and reproductive health 2014. Estimates for 2014. New York City: Guttmacher Institute; 2014.
5. Singh SD and Darroch JE. Adding it up: the costs and benefits of investing in family planning and newborn and maternal health. Estimates for 2012. New York City: Guttmacher Institute; 2012.
6. Optimizing health worker roles to improve access to key maternal and newborn health interventions through task shifting. Geneva: World Health Organization; 2012.
7. Improving access to tubal ligation in Ethiopia by task-sharing services to midlevel providers. London: Marie Stopes International; 2012.
8. Janowitz B, Stanback J, Boyer B. Task sharing in family planning. Studies in Family Planning 2015; 43(1):57-62.
9. Andrews H and Corby N. Improving access to tubal ligation in Ethiopia by task-sharing services to midlevel providers. London: Marie Stopes International; 2012.
10. Rodriguez MI and Gordon-Maclean C. The safety, efficacy and acceptability of task sharing tubal sterilization to midlevel providers: a systematic review. Contraception 2014; (89) 504–511.
11. Dusitsin N, Chalapati S, Varakamin S, Boonsiri B, Ningsanon P, Gray RH. Postpartum tubal ligation by nurse-midwives and doctors in Thailand. Lancet. 1980; 1:638–9.
12. The World Bank Data Table. Rural Population by Country (2010 – 2014). http://data.worldbank.org/indicator/SP.RUR.TOTL (accessed 21 May 2015).
13. Ethiopia Demographic Health Survey 2011; 2011.
14. Singh S. Hospital admissions resulting from unsafe abortion: estimates from 13 developing countries. Lancet 2006;368(9550):1887-92.
15. Ministry of Health. Human resource for health. In: Plan PaFD, editor. Addis Ababa, Ethiopia; 2010.
16. Asnake M and Tilahun Y. Scaling-up Community-Based Service Delivery of Implanon: The Integrated Family Health Porgramme's Experience Training Health Extension Workers. Pathfinder International; 2010.
17. Task sharing in Ethiopia: Improving access to family planning service in Ethiopia by task-sharing services to midlevel providers. London: Marie Stopes International; 2013.
18. Gordon-Maclean C, Nantayi LK, Quinn H, and Ngo TD. Safety and acceptability of tubal ligation procedures performed by trained clinical officers in rural Uganda. International Journal of Gynaecology and Obstetrics 2014; 124(1) 34—37.

19. Jamieson D, Hillis S, Duerr A, Marchbanks P, Costello C, Peterson H. Complications of Interval Laparoscopic Tubal Sterilization: Findings From the United States Collaborative Review of Sterilization. Obstetrics & Gynaecology. 2000; 96(6):997-1002.
20. Federal Democratic Republic of Ethiopia Ministry of Health 2011. National Guideline for Family Planning Services in Ethiopia. Addis Ababa, Ethiopia; 2011.
21. Polus S, Lewin S, Glenton C, Lerberg P, Rehfuess E, and Gülmezoglu AM. Optimizing the delivery of contraceptives in low- and middle-income countries through task-shifting: a systematic review of effectiveness and safety. Reproductive Health 2015; 12 (27) 1-13.

Figure 1: Protocol Adherence Checklist:

Before the procedure:
Check it is the right client
Check client's record
Check consent
Check client is making informed decision
Surgical technique:
Check bladder is empty
Clean gown and gloves
Appropriate position
Correct incision site
Lidocaine
Check anaesthesia effect
Correct incision
Identify tubes
Identify Fimbriae tubes
Correct TL excision
Haemostasis
Correct closure
Post-operatively:
Check client status
Post TL information

Figure 2: Cohort Flow Chart:



*Note: reasons for exclusion add up to more than 35 because some clients met multiple exclusion criteria; clients meeting one exclusion criterion=28, clients meeting two exclusion criteria=7.

Table 1: Cohort Profile

Participant Characteristics	%	n	mean (SD)	range
Sites (no. procedures)				
Outreach – 6 sites	97.5	269		
Static Clinics – 2 sites	2.5	7		
Age (years)			33.4 (3.8)	25 to 42
<25	0	0		
25 -29	11.96	33		
30 -34	41.3	114		
35 -39	38.8	107		
40+	8.0	22		
Parity (n)			6.6 (2.2)	1 to 14
1-3	3.6	10		
4-5	28.6	79		
6-7	40.6	112		
8-9	14.1	39		
10+	13.0	36		
Living children (n)			5.9 (1.7)	1 to 10
1-3	5.4	15		
4-5	37.7	104		
6-7	43.8	121		
8+	13.0	36		
Marital status				
Married	96.0	265		
Divorced/separated/widowed	4.0	11		
Educational level				
Illiterate	76.8	212		
Literate	8.7	24		
Primary education	13.0	36		
Secondary or higher	1.5	4		

Table 2: Family Planning History

Participant Family Planning History	%	n
Main FP method used in the past 3 months (n=276)		
Injectable	48.2	133
Implant	12.3	34
Oral contraceptive pill	4.4	12
Inter-uterine device	4.0	11
Lactational amenorrhea method	0.7	2
No method	29.4	81
No answer/Don't know	1.1	3
Side effects from main FP method (among women using a method, n=192)		
Yes	34.4	66
No	62.0	119
Don't know	3.7	7

Table 3: Minor, moderate and major adverse events:

	Overall		Minor		Moderate		Major	
Stage:	**Proportion (%) (95% CI)**	**n**	**Proportion (%) (95% CI)**	**n**	**Proportion (%) (95% CI)**	**n**	**Proportion (%) (95% CI)**	**n**
Intra-operative	53 (47 to 59)	146	49 (42 to 54)	134	12 (86 to 16)	33	3 (1 to 6)	8
Peri-operative	47 (41 to 53)	129	44 (38 to 50)	121	6 (3 to 10)	17	0.4 (.1 to 2)	1
7 day post-operative	49 (43 to 55)	135	46 (40 to 52)	126	14 (10 to 18)	38	1 (.2 to 3)	2
Overall	72 (66 to 77) [a]	199	70 (65 to 75)	194	22 (18 to 28)	62	3 (1 to 6)	8

[a] Includes any adverse event (intra-, peri- or post-operative) and unsuccessful completion of TL

Table 4: Protocol Adherence

Protocol item	%	n
Check it is the right client	98.9	174
Check client's record	96.6	170
Check consent	99.4	175
Check client is making informed decision	96.6	170
Check bladder is empty	97.7	172
Clean gown and gloves	100.0	176
Appropriate position	99.4	175
Correct incision site	98.3	173
Lidocaine	98.9	174
Check anaesthesia effect	88.6	156
Correct incision	97.7	172
Identify tubes	97.2	171
Identify Fimbriae tubes	97.2	171
Correct TL excision	97.2	171
Haemostasis	97.7	172
Correct closure	99.4	175
Check client status	90.9	160
Post TL information	93.8	165