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Implementation fidelity of trichiasis surgery program in Northern and Eastern Uganda

Innocent Ssemanda*, Jerry Banda, Choolwe Jacobs
Department of Epidemiology and Biostatistics, School of Public Health, University of Zambia, Uganda

Okwadi Tukei
Mbarara University of Science and Technology

***Corresponding Author**

Abstract

Implementation fidelity is the degree to which an intervention is delivered as intended. Reduced level of fidelity of trichiasis surgery program may be why there is increased unfavorable postoperative trichiasis surgery outcomes. Trachomatous trichiasis (TT) is a sign of trachoma which comes as a result of multiple rounds of Chlamydial trachomatis infection which causes recurrent chronic inflammation in the tarsal conjunctiva, which later progress to conjunctival scarring, entropion, and corneal opacification to blindness if left untreated. Trichiasis surgery is done to correct trachomatous trichiasis and prevent blindness. However, unfavorable outcomes after surgery are frequent. This study measured the level of implementation fidelity of trichiasis surgery and the factors associated with trichiasis surgery outcomes in Northern and Eastern Uganda. We conducted a cross-sectional survey on health workers implementing trichiasis surgery programs in Eastern and Northern Uganda; from December 2019 to March 2020. Self-administered questionnaires were distributed to 408 study participants who attend the study site, and to those who failed to attend in person, the survey was emailed and others were visited and interviewed face-to-face in their offices. The direct observation study was a participatory observation approach. The collected data was entered into Epi-info7 software and the scores from the survey were entered into computer Microsoft Excel

spreadsheets 2016. STATA version 14.2 (Stata-Corp, College Station, TX) was used for analysis. Fisher's exact test, t-test, and multi logistic regression were used to report proportions and effective measures of association. Akaike information criterion (AIC) or Bayesian information criterion (BIC) models (nested model) were used to select the best predictors. A total of 408 participants which include; trichiasis nurse, ophthalmology clinical officers, consultant ophthalmologist, and trichiasis case finders were surveyed, and 155 direct trichiasis surgery observations were evaluated. The level of fidelity to program content was; 46.08%, coverage 51.72%, duration 31.86%, methods of delivery 82.80%, exposure was 42.16% and participants' responsiveness 17.16%. Factors associated with implementation fidelity for trichiasis surgery program outcomes were; quality of delivery (OR=0.439, 95% CI [0.267 .723], P<0.001), characteristics of the community (OR=70.389 95% CI [14.016 353.490], p<0.001), facilitation and sustainability strategies (OR=0.095, 95% CI [0.042 .216], p=<0.001), characteristics of patients0.105, 95% CI [0.013 .169], p<0.001), program content (OR=8.122. 95% CI [1.709 38.582], p<0.008), Participants' responsiveness (OR= 0.048, 95% CI [0.013 .169], p<0.001), and structural/ organizational (OR=0.535, 95% CI [0.338 .846], p=<0.008). Implementation fidelity of the trichiasis surgery program was found low. To reduce unfavorable postoperative Trichiasis surgery outcomes, program implementers should adhere to the protocol, and deliver as it was prescribed by the program designer. This can be achieved if the potential associated moderating factors such; facilitation and sustainability strategies, quality of delivery, patient characteristics, and program content are improved.

Keywords: *The measure of Implementation fidelity, Trachomatous Trichiasis surgery, moderating factors*

Introduction

Implementation fidelity is the degree to which an intervention is delivered as intended. Reduced level of implementation fidelity of trichiasis surgery program may be why trichiasis surgery produces unfavorable postoperative trichiasis surgery outcomes(1). Trachomatous trichiasis (TT) is a sign of trachoma which comes as a result of multiple rounds of *Chlamydial trachomatis infection* which causes recurrent chronic inflammation in the tarsal conjunctiva. Long stay without treatment, the condition progress to fatal complications like; conjunctival scarring, entropion, trichiasis, and corneal opacification to blindness. The World Health Organization through public health agencies and implementing partners have made numerous efforts to eliminate *Chlamydial trachomatis infection* and prevention of trachoma-related blindness globally. This effort has taken many forms which include; mass drug administration of antibiotics, facial cleanness, environmental control, and surgery for trichiasis (2). However, unfavorable postoperative trichiasis surgery outcomes are unexpectedly high and undermining the global trachoma elimination effort (3). According to Geopogui et al, the rate of unfavorable outcomes of trichiasis surgery program has increased from 28% to 41.6%, (4), and this increase was associated with implementation-related issues like fidelity to the implementation of trichiasis surgery programs (5-8). For example, a current study indicated that when patients undergo trichiasis surgery majority suffer from bad postoperative trichiasis surgery outcomes, for example; recurrence, development of granuloma, entropion, trichiasis, and corneal opacification(9, 10). If these issues are not addressed, trichiasis patients will refuse surgery. Gupta, 2018. Indicated that people refuse trichiasis surgery because of recurrence and severe pain after surgery(10). Secondly, to achieve the global effort of trachoma elimination and to prevent its related blindness shall be unachievable.

WHO recommends Trichiasis surgery to improve visual acuity as a routine clinical practice in trachoma endemic countries(11). Unfortunately, the coherence and relevance of the trichiasis surgery program are still substantially deprived. For example, literature shows that TT-related blindness is still a public health problem(12). Globally it is estimated that about 158 million people live in trachoma endemic areas and are at risk of trachoma blindness

(13). Literature shows that *Chlamydia trachomatis infection* is responsible for the blindness and visual impairment of about 1.9 million people, and it has caused about 1.4% of all blindness worldwide(13). Overall, Africa remains the most affected region with a high prevalence of trachoma, and it is estimated that; 137 million people are infected with *Chlamydial trachomatis infection*(13, 14)., and it is estimated that in Africa, over 1.6 million people are irreversibly blind and more than 83.5 million people are already infected with the infection that causes trachoma (13).

In Uganda particularly Northeastern Region, over 22,465 children aged 1-9 years have trachomatous trichiasis and 24,652 cases are in the age group above 9 years (15). Studies show that Uganda is one of the African countries that have a high prevalence of trachomatous trichiasis (15). There are five trichiasis surgery approaches recommended to reduce the risk of visual impairment from trachomatous trichiasis. For example; (I) Bilamellar tarsal rotation (BLTR), (ii) posterior lamellar tarsal rotation (PLTR), (iii) trichiasis Clamp (TC), (iv) Anterior tarsal flap rotation (ATFR) (v) Anterior lamellar reposition (ALTR), (vi) Anterior lamellar resection and lid margin split of the upper eyelid (16, 17). The surgery involves an incision through the eyelid parallel to and a few millimeters above the lid margin (16). In trachoma endemic countries like Uganda, trichiasis surgery is usually performed by trained trichiasis nurse/paramedics health workers (5), to support the global effort to scale up surgical services to clear the current trichiasis backlog by 2020(3). Currently, the World Health Organization epidemiology report 2019, shows that over 146 112 people receive surgical treatment for trachomatous trichiasis each year worldwide. In Uganda, according to Sightsavers (2019), more than 6400 Trichiasis surgery cases were conducted to save sight(18). However, unfavorable outcomes after trichiasis surgery are considerably high compared with the 5% rate recommended by WHO (6, 19-24). Furthermore, evidence from existing literature reports that; trachomatis infection and trachoma blindness are surprisingly high duet to recurrence of the disease (25-28). Current existing evidence from the literature also shows that trichiasis surgery yields unexpected unfavorable outcomes when translated into practices in the communities (6, 16, 29-32), and the rate is unacceptably high (33). Further, it is reported that poor outcomes of TT surgery were associated with; surgical related, deficient knowledge, skills and experience of TT surgeons, capacity of Health facility related factors and availability of facilitation and sustainability strategies (7, 31, 34-36). Many studies done around trichiasis surgery outcomes and an excellent work is done to demonstrate the quality of trichiasis surgery outcomes and documenting the associated factors, but the studies measured the degree to which Trichiasis surgery is delivered as intended in Uganda and measured the associated factors to its outcomes are scanty. Therefore, the study measured the level of implementation fidelity of the trichiasis surgery program and the associated factors to the outcomes. We hope that; findings from this study will inform policymakers, program implementers, and other concerned bodies on the need for improvement and restructuring the available strategies to successfully eliminate trachoma and prevent future trachoma blindness in Uganda.

Methods

Study area and period

The study was conducted in Eastern and Northern Uganda between December 2019 and March 2020. The individual study regions had an estimated total population of 8606300 from northern Uganda, 10836500 million people from the Eastern region. Geographically, these regions were divided into 28 wards (administrative districts). In many districts, rains do not often exceed 800 millimeters per year, sometimes hovering around a mere 500 millimeters. The socioeconomic status of these regions is agro-pastoralist, their main economy is based on cattle herding. Northeastern Uganda is considered by many as “hard to reach” and “hard to live in”, because of cattle rustling, insecurity from armed nomadic tribes, and a semi-arid climate. The selected wards within regions had 99 health facilities with ‘trichiasis surgery centers” where the study was conducted.

Study design and population

We conducted a cross-sectional survey to measure the level of implementation fidelity of the trichiasis surgery program and the associated factors in Uganda. Data was collected from program managers and health workers providing trichiasis surgery program components (i.e. trachomatis trichiasis nurses (TT nurses), trained trichiasis case finders, Ophthalmologist clinical officers (OCOs), Trained Trichiasis surgeons (TT surgeons)) who were working in hospital ophthalmology clinics, eye care clinics, and in trachoma-community outreach posts. For a systematic evaluation of the trichiasis surgery program, a conceptual framework for Implementation Fidelity was used. See Fig 1. The fidelity framework. Allows to evaluate both adherence to the intervention and to assess moderating factors for adherence to the intervention from the eight key intervention component.

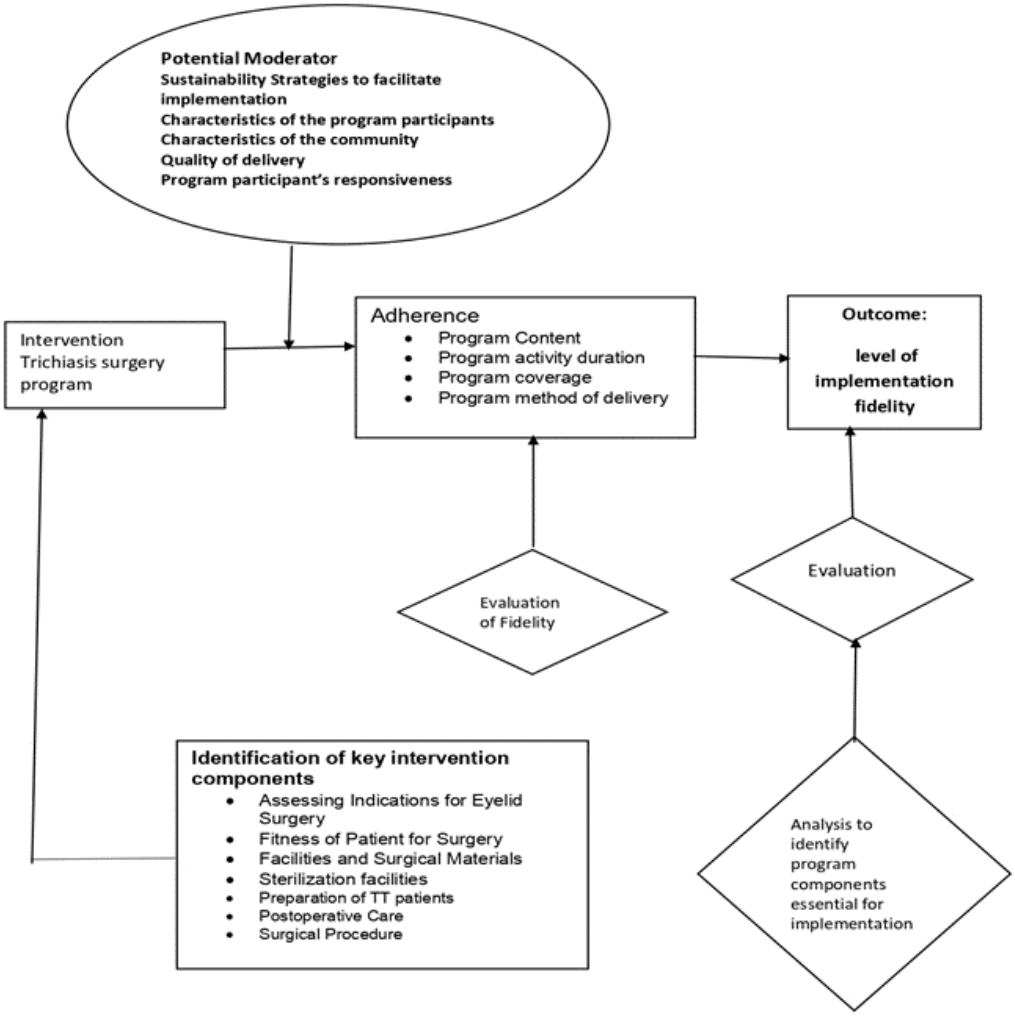

Fig 1: Implementation fidelity conceptual framework (37)

The Implementation fidelity framework developed by Carroll et al(38) was used for this study. In this framework, we included the potential determinants of implementation fidelity (moderating factors) that influence the level of implementation fidelity of trichiasis surgery program and considering the complex relationships between these factors to outcomes. The strength of the framework lies in its ability to draw pragmatic solutions to improve outcomes from the intervention by consideration of the moderating factors and essential components needed to improve the program implementation process. In adapting the framework to study fidelity of the Trichiasis

surgery program and its outcomes, three moderating factors were studied: (I) Facilitation strategies to Implementation (ii) characteristics of program participants, and (iii) the characteristics of the community where the intervention is implemented, also (vi) Quality of delivery and (v) participant's responsiveness to comprehensively explore both the internal and external contextual factors influence trichiasis surgery program outcomes, as it's detailed in Fig 1.

Sampling and sample size determination

The study estimated that a sample size of 385 study participants would provide the study power of 80% to detect the difference between the anticipated rate of 50% level of implementation fidelity of trichiasis surgery, and precision of 10%, at a 95% confidence interval and a design effect of ±5 was assumed. The design effect of 1.0 was also estimated given that there were 99 health facilities from both urban and rural areas being studied. By putting into account the non-respondent, the study assumed to have 10% non-respondent study subjects, therefore giving a total sample size estimation of 424 study participants. However, during the study, 408 individuals turned up, all were considered and participated in the study. The sample size was determined as illustrated below.

$$\mathbf{n} = \frac{\boldsymbol{Z^2 P(1-P)}}{\boldsymbol{e^2}} \approx \mathbf{n} = \frac{\mathbf{(1.96)^2 \times 0.5(1-0.5)}}{\mathbf{0.05^2}} \quad \text{n} = \frac{3.8416 \times 0.5 \times 0.5}{0.0025}$$

$$\mathbf{n} = \frac{\mathbf{3.8416 \times 0.25}}{\mathbf{0.0025}} \quad \mathbf{n = 384.16} \quad \mathbf{= 385} \text{ study participants.}$$

Sampling techniques and procedure

A multiple-stage (cluster) sampling technique was used to select the sample population in each study site. A cluster was defined as the population within a single district or health facility. In the first place; regions were defined as; Southern, Eastern, Northern, Western and Central regions. Northern and Eastern regions were purposively selected because these are regions where Sightsavers- Uganda predominantly implement Trichiasis surgery programs. In cluster Stage-One, 28 districts were selected randomly from the 70 districts listed in the sampling frame obtained from the Uganda Bureau of statistics 2019 report. In the Second stage (Stage-Two), 49 health facilities were randomly selected from the sampling frame generated from the 99 district health facilities registered. A complete enumeration of participants found in the selected health facilities was conducted, and the entire 96.2% (408) respondents were considered for the study, ignore the 3.8% nonresponse. The population found in the selected health facilities (clusters) were all considered to participate in the study. In direct observation; this was a participant observation – nonrandom intervention study included 20-30 lids of patients with upper eyelid cicatricial entropion selected from the ophthalmology outpatient clinic from the 49 health facilities studied. The researchers observed participants in their natural surgical practices.

Inter-rater reliability (IRR) for assessing the levels of implementation fidelity of trichiasis surgery program

Examining the level of implementation fidelity of trichiasis surgery, four dimensions of fidelity was considered (38). The study used an Inter-rater agreement-scale to measure fidelity of the trichiasis surgery program which was used in a similar study "community-based health intervention" to rate adherence (39, 40). In this study, it was adopted to evaluate each variable against the fidelity of the trichiasis surgery program. In this evaluation the level of fidelity of trichiasis surgery, the team set the acceptable level of adherence to trichiasis surgery protocol to be between 80% to 100% score. This means out 5(Five) dimensions of fidelity ((i) content, (ii)coverage, (iii) duration, (iv) exposure/ dose, (v)quality of delivery) evaluated. The intervention must achieve 4 to 5 $\left(> {}^{4}/_{5}\right)$ individual dimension of fidelity scored between 75%–100%) grades (41, 42). Table 3. Shows how each dimension of fidelity was graded.

Trichiasis surgery checklist (TTSCs) was used to assess rating reliability by comparing the variability of different ratings of the same participant (group) to the total variation across all ratings. In this particular participation observation – nonrandom intervention we included 20-30 lids of patients with upper eyelid cicatricial entropion selected for surgery. A step by step observation was done to evaluate quality of delivery of trichiasis surgery, and the following ratings were done; 'yes/done/ present' equating to a score of 6 to 10points, 'no/absent' (zero points), or 'attempted' 5(Five)points. Table 1. Trichiasis surgery checklist shows the Ten (10) assessment areas ((1) Assembly of necessary materials before surgery, (2) Knowledge on surgical materials (3) Sterilization techniques of equipment before use, (4) Examination of the patient (5) Preoperative preparation of TT patients (6) Injecting anesthetic drug (7) Operation (8) Suturing (9) Pulling and knotting sutures, and (10) Postoperative care principles). The operation was graded 75% to 100% if the procedure was performed satisfactory (means the operation done well in more than six areas of assessment $\left(\geq \frac{6}{10}\right) points$ or graded <74%, if the procedure was performed unsatisfactory (means the operation done well below six areas of assessment($\leq \frac{6}{10}$)$points$(16). Our grading scale system was structured according to the WHO-Trichiasis surgery for trachoma guideline.

The validity and reliability of implementation fidelity rating 'percentage grading scale"

Implementation fidelity of trichiasis surgery program data was the ordinal type of data, expressed as the percentage of ratings that are in agreement within a 2-5 interval scale and was ranked as; either the highest or the lowest importance. Fidelity dimensions each had survey questions ranging between 4-14 individual questions (Indices). By using inter-rater agreement scale (IRAs) (43), each construct was graded either 'high score" above average score" or below-average score", if the measuring index was marked as; disagree/agree, strongly agree, good, very good, satisfying, or extremely satisfying 'which was considered as high importance "and that was marked either 'disagree/strongly disagree, poor/fair, unsatisfying/somewhat, was considered as low importance respectively.

Data collection tools and procedures

A self-administered questionnaire survey was distributed to 408 study participants who attend the study site, and to those who failed to attend in person, it was emailed and others were visited and interviewed face-to-face in their offices. The survey consisted of socio-demographic variables, dimensions of implementation fidelity variables; and trichiasis surgery program indicators. The participants were clearly informed the purpose of the survey was to measure the level of implementation fidelity trichiasis surgery, and it was clearly defined for them to understand the meaning, and they were informed about the anonymous of the information provided. Formal informed consent was sought. Each participant was requested to complete the questionnaire or to defy it. Further, they we asked to return the completed questionnaire into envelop and hand in back to the researcher within after 45 to 60 minutes. Further, registries of the health facilities and organizations studied were visited to do document reviews. Documents reviewed were; in-patient and out-patient record books, theatre registers, trichiasis surgery outreach record books, and annual program report. This was done to collect information on the number of TT surgeries, postoperative trichiasis surgery patients who developed bad outcomes, recurrences after surgery, the type of surgery and quality of the procedure, number of community outreaches done, and the set target et cetera. Trichiasis surgery checklist (Appendix 2) was also used to score direct trichiasis surgery participatory observations on the variables listed in (Appendix 1). The table of variables. Trichiasis surgery participatory direct observation was evaluated and scored across Ten (10) Trichiasis surgery-procedural steps. For example; (1) Assembly of necessary materials before surgery, (2) Knowledge on surgical materials (3) Sterilization techniques of equipment before use, (4) Examination of the patient (5) Preoperative preparation of TT patients (6) Injecting anesthetic drug (7) Operation (8) Suturing (9) Pulling and knotting sutures, and (10) Postoperative care principles. The team of research assistants included; supervising ophthalmologists, trained TT surgeon-medical officers, ophthalmology clinical officers, TT nurses; and

interviewers who were all trained in questionnaire administration and document review by the District ophthalmologist in the form of lecture and role play. The data collected from 408 self-administered questionnaire surveys, and document review were extracted and entered into computer Microsoft excel sheet, whiles others were entered directly into Epi info data US version 7.2.2.6, info7 software, after clearing and coding, data were imported into STATA version 14.2 (Stata-Corp, College Station, TX) for analysis.

Data processing and analysis

A histogram and Shapiro–Wilk test were used to test for the normality of the data. To report descriptive statistics, a t-test for continuous variable distance to health facility and age of health workers was used to report the median and the inter-quartile range (iqr). Fisher's exact test was used to modeling the level of fidelity group as the dependent variable and explanatory variables (Appendix 1). To compare and report frequencies, percentages and to establish the associations between the dependent and explanatory variables, the chi-squared test was used. Logistics regression was used to report the unadjusted and adjusted odds ratio. and the P-value, at a 95% confidence interval. Using Akaike information criterion (AIC) or Bayesian information criterion (BIC) models (nested model) which predicted nine variables to be strongly statistically significant with $p< 0.0001$. Since this was implementation research we settled with the investigators' lead.

Table 1; The study Variable

Response variable: High / Low Implementation fidelity (Categorical Variable)

Explanatory variables: The explanatory variables are presented in Table1 below.

Table 1: Study Variables

Explanatory Variables	Type	Coding
Background Characteristic		
Age	Continuous –variable	
Distance	Continuous – variable	
Gender	Categorical	
Working Experience	categorical	
Professional Background	Categorical	
Highest level of training	categorical	
Trained as a trichiasis surgery Implementer	categorical	
Location of the health facility	categorical	
Measures of Implementation fidelity (Categorical ordinal / Nominal data scale)		
Programme content		
Programme coverage		
Program activity duration		
Program methods of delivery		
Program Exposure/ dose		
Moderators the levels of Implementation fidelity (Categorical ordinal/ nominal data scale)		
Participant responsiveness		

Program Quality of delivery		
Characteristics of the program participants		
Program sustainability Strategies		
Characteristics of the community		
Characteristics of the service providers		

Results

The study had 408 Trichiasis surgery program Implementers who were surveyed, from 99 trichiasis surgery centre points in 28 wards. Table 2 represents the distribution of the study health facilities, districts, regions, and the number of trichiasis surgery directly observed.

Table 2; Illustrate the study districts, health facilities both hospital-based and community outreach trichiasis surgery centre posts, direct observations of TT surgeries, and study participants

Study regions	Number of districts	Number of TT surgery Centre	Number of TT surgeries observed	Number of TT surgery program implementers surveyed in their respective districts
North-eastern region	10	19	19	61
Northern region	8	17	31	95
Eastern region	10	63	105	252
Total	28	99	155	408
TT= Trachomatis Trichiasis				

The characteristics of trichiasis surgery program implementers

Table 2 indicates that; Four hundred eight (408), trichiasis surgery program implementers surveyed from the 99 trichiasis surgery centre points; 48(11.76%) were medical officers, 195(47.79%) clinical offices, 126(30.88%) trichiasis nurses, and 39(9.56%) were supporting staff, with the median age of 35years. Trichiasis surgeons' experience; 81(19.85%) had an experience of ≥ 10 years; 270(66.18%) had ≥ 5 years and 57(13.97%) had ≤ 3years. The location of trichiasis surgery centre points; 253(62.16%) located in rural, and 154(37.84%) in urban. The distance from the nearest health facility to another had a median distance of 17 kilometers apart.

Table 3: The baseline characteristics of the study participants

Frequencies and percentages of participants' characteristics

Individual characteristics (variables)	**Frequency (n)**	**Percentage (%)**	**median**	**Variance**	**P-Value**
Age (N=408)			35	83.997	0.046
Distance to the facility (N =408)			17	173.724	0.002
Gender (N=408)					0.249
Male	117	28.68%			
female	291	71.32%			
Professional background (N=408)					0.059
Medical background	48	11.76%			
Clinical officer	195	47.79%			
Nurse	126	30.88%			
Social scientist	39	9.56%			
Experience of TT surgeon(N=408)					0.002
≤ 3 years of experience	281	68.87%			
≥5years of experience	106	25.98%			
≥ 10year of experience	21	5.15%			
Type of Training (N=408)					0.047
Yes, ophthalmologist	136	33.33%			
Ophthalmology clinical officer	233	57.11%			
TT nurse	33	8.09%			
Non	6	1.47%			
Location (N=408)					0.641
Rural	253	62.16%			
urban	154	37.84%			
P-value obtained from Fisher's exact test					

Normality test for the implementation fidelity Data

The normality assumptions for implementation fidelity data were tested to assign the statistical model that fits the assumptions. We tested whether the variable age and distance, are normally distributed, findings are detailed in **Fig2.**

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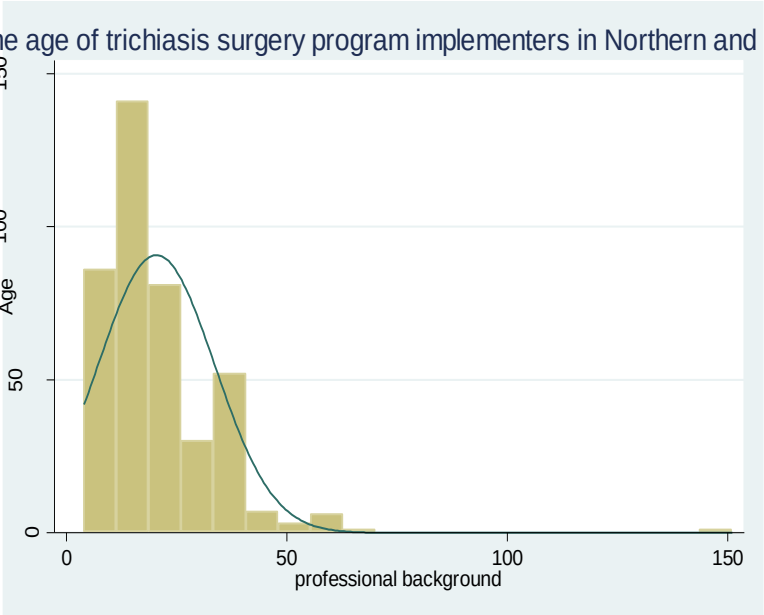

Fig 2: A histogram showing the right-skewed implementation fidelity data

Histogram showed the clustering of all participants' age against implementation fidelity. However, the age of the program service provider suggested implementation fidelity data not normally distributed, in otherwise, it was skewed to the right.

The level of implementation fidelity of the Trichiasis surgery program

To assess the level of fidelity to trichiasis surgery; a percentage agreement scale exact was considered a more realistic measure to use (44).

Percent Agreement Scale calculation

The percentage of absolute agreement was simply calculated by the number of times raters(respondent) agree on a rating, then divides by the total number of ratings. Thus, this measure varied between 0 and 100%. In this study, the measure has been called the percentage of exact and adjacent agreement, as the measured fidelity constructs had 5 (five) rating levels scale. For this study, the percentage agreement scale was an exact, and more realistic measure to use (44).

The calculation of the percentage agreement scale (IRA) described in the formula below, and Table 3. The rating of the individual fidelity constructs.

$$\text{percentage Agreement} = \frac{\text{Number of concordant responses}}{\text{Total number of responses}} \times 100$$

Table 4: Implementation fidelity of trichiasis program at baseline

Variable (fidelity constructs)	Number of Questions per construct (items)	Lower Ratings (Interval scale)	Higher Ratings (Interval scale)	Below average score (%)	Average Score (%)	High score (%)	Outcome Fidelity Low/high
Content	14	8	6	42.86%			Low
Coverage	6	3	3	50%			Low
Duration	4	3	1	25%			Low

Exposure	4	2	2	50%		Lo
Participant's responsiveness	6	4	2	33.3%		Low
Quality of delivery	10	6	4	40%		Low
Methods of delivery	4	0	4		100%	High

This is in agreement with the inter-rater reliability scale (IRRs) as described in the previous section above. The study graded the level of implementation fidelity as; (adherence Scale = 94%, quality of delivery Scale= 80%). Participant's responsiveness was measured at a Scale of >75% (75%–100%, (41, 42).

Table 4; The level of implementation fidelity of the trichiasis surgery program; indicates that. fidelity to program content was (46.08%) significantly lower among the rural health facilities implementing trichiasis surgery program (OR=0.023, 95% CI [0.01 .145], p>0.001). These findings suggest that program content had a reduced odd of 0.02 less likely the health facilities to implement surgery with a high level of fidelity. Fidelity to program coverage of trichiasis surgery program was 51.72% coverage significantly lower in rural areas (OR= 0.8, 95% CI [0.424 1.485], p>0.001). The level of participant's responsiveness to the trichiasis surgery program component was 17.16% relatively lower in communities where program information was low (OR =0.2, 95% CI [0.028 1.053], p>0.004). Program exposure was 42.16% relatively lower than the set standard fidelity scale (OR= 0.23, 95%CI [0.092 0.537], p>0.01), program duration was 68.14%, (OR=101.2, 95% CI [29.4 521.9], p> 0.001). The methods of delivery were 82.80% relatively higher compared to all other dimensions of fidelity.

Table 4: The overall measure of Implementation fidelity of trichiasis surgery

Level of Implementation fidelity findings			**Adjusted Odds ratio**	
Measures of fidelity (variables)	**Frequency and Percentage (%)**	**Outcome**	**Odds ratio (95% CI)**	**P value**
Program content (N=408)				
Not at all satisfactory	220(53.92%)		0.02(0.003 .081)	
Very satisfactory	188(46.08%)	Low fidelity	0.023(0.005 .145)	<0.001***
Program coverage (N= 408)				
Low	197(48.28%)		0.011(0.001 .0459)	
high	211(51.72%)	Low fidelity	0.8(0.424 1.485)	<0.001***
Program duration (N=408)				
Low	278(68.14%)		101.2(29.4 521.9)	<0.001***
high	130(31.86%)	Low fidelity	_(0 .333)	
Program exposure/dose (N=408)				
Low	236(57.84%)		n/a	

high	172(42.16%)	Low fidelity	0.231(0.092 .537)	<0.001***
Quality of delivery (N= 408)				
Not at all satisfactory	67(16.42%)		n/a	
Slightly satisfactory	92(22.55%)		4.636(1.629 13.352)	
Neutral	65(15.93%)		47.357(7.825 464.862)	
Very satisfactory	98(24.92%)		27.9(3.898 1184.53)	<0.001***
Extremely satisfactory	86(21.08%)	Low fidelity	n/a	
Methods of delivery (N= 155)				
disagree	70(17.20%)		199.8(20.88 8381.8)	
agree	337(82.80%)	High fidelity	1.12(0.473 2.786)	< 0.000***
Participant's responsiveness (N=408)				
Not at all satisfactory	64(15.69%)		n/a	n/a
Slightly satisfactory	274(67.16%)		0.463(0.269 .791)	
Very satisfactory	70(17.16%)	low	0.2(0.028 1.053)	< 0.004***
***odds ratio and p value obtained from Fishers' exact test,**				

According to Hallgren et al.,2012, the level of implementation fidelity can be calculated in percentage agreement scale (IRA), as illustrated in the formula below. Therefore, from the results displayed in Table 4. The level of implementation fidelity of trichiasis surgery achieved in Northern and Eastern Uganda was calculated as; percentage Agreement $= \frac{\text{Number of concordant responses}}{\text{Total number of responses}} \times 100$ Level of fidelity $= \frac{1}{7}$ x100 = 0.143x100 = 14.3% level of implementation fidelity of trichiasis surgery . Therefore, studying aspects of implementation fidelity such as; adherence, quality of delivery, and participants' responsiveness to trichiasis surgery program; the study finds a low-level implementation fidelity of trichiasis surgery program achieved in Northern and Eastern Uganda. Assessment and description of factors associated with implementation fidelity and Trichiasis surgery program outcome.

Description of Implementation fidelity and associated factors to trichiasis surgery program outcomes

The results indicate how the dimensions of fidelity interact with the determinants of implementation fidelity of the trichiasis surgery program. Table 4, Findings suggest; the level of experience of trichiasis surgeons, and level of training were significantly more likely to influence the level of fidelity. Table 5; The predictors associated with trichiasis surgery outcomes. The level of patients' interest in the trichiasis surgery program had increased odds of (OR=91.8 95% CI [1.126 3.123], p>0.389), however, findings were insignificant. The availability of medicine and supplies and surgical technologies were significantly more likely to increase the level of implementation fidelity (OR= 8.31,95% CI [4.86 14.19], p>0.001).

Table 5: The best predictors model 2

Predictors	Adjusted odds ratio model 2.	
	Odds ration	**95% confidence interval**
		P- Value

Used prescribed program content			
No	ref	n/a	n/a
Yes	0.182	0.001**	(0.097 .341)
Appropriate methods of delivery			
No	ref	n/a	n/a
Yes	0.014	0.001**	(0.001 .041)
Level of participants' engagement			
Low	ref	n/a	n/a
High	0.014	0.001**	(0.001 .041)
Use of TT surgery checklist			
No	ref	n/a	n/a
Yes	0.362	0.020**	(0.153 .854)
Providers' preparedness			
Unsatisfying	ref	n/a	n/a
Satisfying	0.520	0.047	(0.273 .992)
Very satisfying	0.083	0.001**	(0.033 .205)
Quality of operating room			
Very poor	ref	ref	n/a
Below average	0.139	0.001**	(0.052 .372)
Average	0.478	0.138	(0.181 1.268)
Above average	0.393	0.067	(0.144 1.068)
Excellent	0.0487	0.001**	(0.015 .154)
Level of patient interaction into program			
Low	ref	n/a	n/a
moderate	0.528	0.095	(0.250 1.117)
High	0.233	0.001**	(0.122 .447)
very high	3.77	0.987	n/a

** P-value obtained from logistic regression, TT= Trachomatis Trichiasis

Fidelity to the Quality of delivery

Fidelity to quality of delivery was measured to determine whether trichiasis surgery program was delivered in appropriate way to achieving intended trichiasis surgery outcomes. The study indicates that; training of health workers, program materials, provider's preparedness and program support supervisions to those delivering an intervention. Results presented in Table 4 indicated low level of fidelity to quality of delivery (46.85%) level of fidelity). Table 6 shows the predicators to the level of fidelity to quality of delivery. The use of program content as it was prescribed had adjusted odds ratio of; 0.182 95% CI [0.097 .341], p<0.001, appropriate methods of delivery had; 0.014 95% CI [0.001 .041], p<0.001, level of patients' engagement into trichiasis surgery program activities had 0.014 95% CI [0.001 .041], p<0.002, the use of TT surgery checklist during trichiasis surgery implementation had 0.362 95% CI [0.153 .854], p<0.020, providers' preparedness had 0.52 95% CI [0.273 .992], p<, 0.047, and operating room had 0.14 95% CI [0.052 .372], p<0.001, and the level of patients' interaction into program had adjusted odds ratio of; 0.23, 95% CI [0.122 .447], p<0.001. Findings were significantly less likely to increase the level of implementation fidelity and the quality of trichiasis surgery program outcomes respectively. However, level of patient interaction into program and level of confidence had increased odds to influence the level of implementation fidelity and trichiasis surgery program outcomes (OR=2.243, 95% CI [1.279 3.926], p<0.005), and 9.3, 95% CI [(1.441 60.01)], p<0.019, respectively.

Table 6: Fidelity to quality of delivery findings: A practical and direct observation of Trichiasis surgery implementation provided an objective assessment

Unadjusted and adjusted estimates Model 1

Variables	Unadjusted odds ratio			Adjusted Odds ratio		
	Odds ratio	P value	95% CI	Odds ratios	p. value	95% CI
provider preparedness (N=408) Unsatisfied	ref	n/a	n/a	ref	n/a	n/a
Satisfied	0.825	0.393	(0.531 1.281)	0.653	0.241	(0.320 1.332)
Very satisfied	1.196	0.432	(0.765 1.869)	0.081	0.001**	(0.029 .227)
Delivered prescribed content (N=408) No	ref	n/a	n/a	ref	n/a	n/a
Yes	0.123	0.001	(0.077 .196)	0.173	0.001**	(0.092 .327)
Used appropriate delivery method (N=408) No	ref	n/a	n/a	ref	n/a	n/a
Yes	0.181	0.001	(0.118 .279)	0.198	0.988	n/a
Engaged participant into the session (N=408) Low	ref	n/a	n/a	ref	n/a	n/a
High	0.014	0.001	(0.001 .039)	0.013	0.001**	(0.004 0.139)
Used a checklist (N=155) No	ref	n/a	n/a	ref	n/a	n/a
Yes	1.696	0.010	(1.132 2.541)	0.312	0.010**	(0.128 .759)
operating room (N=408) Very poor	ref	n/a	n/a	ref	n/a	n/a
Below average	0.377	0.003	(0.196 .725)	0.126	0.001**	(0.041 .391)
Average	1.471	0.277	(0.733 2.950)	0.590	0.325	(0.207 1.685)
Above average	0.861	0.638	(0.462 1.605)	0.617	0.399	(0.201 1.894)
Excellent	0.101	0.001	(0.043 .233)	0.048	0.001**	(0.014 .167)
Level of respectfulness to program participants (N=408) Low	ref	n/a	n/a	ref	n/a	n/a
Moderate	2.932	0.001	(1.882 4.569)	3.281	0.001**	(1.794 6.001)
High	0.801	0.494	(0.425 1.509)	0.467	0.083	(0.197 1.103)
Level of confidence (N=408) High	ref	n/a	n/a	ref	n/a	n/a
Moderate	0.839	0.607	(0.430 1.635)	0.534	0.196	(0.206 1.382)
Low	0.359	0.005	(0.175 .738)	0.235	0.006**	(0.083 .662)
Non	4.839	0.007	(1.541 15.199)	9.300	0.019**	(1.441 60.01)
Ability to respond TT question (N=155) No	ref	n/a	n/a	ref	n/a	n/a
Yes	0.178	0.001	(0.115 .274)	7.19	0.986	(6.622 37.352)
The level of Interaction style of program participants into program activities (N=408) low	ref	n/a	n/a	ref	n/a	n/a
Moderate	0.429	0.005	(0.237 .778)	0.444	0.079	(0.179 1.101)

High	0.187	0.001	(0.112 .312)	0.384	0.015**	(0.177 .832)
very high	5.47	0.976	n/a	2.17	0.982	n/a

** P-value obtained from logistic regression, TT= Trachomatis Trichiasis

The factors associated with implementation fidelity of trichiasis surgery program

Table 7, the findings from the predictors model 2 indicate, quality of delivery had adjusted odds ratio of; 73 95% CI [0.563 .907], P<0.006, participant's responsiveness had 0.34 95% CI [0.143 .0815], P<0.001, characteristics of patients had 0.22 95% CI [0.143 .329], p<0.001, structural organization had 0.4 95% CI [0.258 .474], P<0.001, and facilitation and sustainability strategies had 0.383 95% CI [0.249 .587], p<0.001. Results found a strong statistically significant association between the moderating factors and the level of implementation fidelity and trichiasis surgery program outcomes. Also, the characteristics of the community where trichiasis surgery is implemented, and program content were found significantly more likely to reduce the level of implementation fidelity and trichiasis surgery program outcomes; at an adjusted odds ratio of; 7.2 95% CI [3.117 16.727], p<0.001, and 7.0 95% CI [3.117 18.259], p<0.001 respectively.

Table 7: Factors associated with implementation fidelity and trichiasis surgery program outcomes

Model 1: Unadjusted and adjusted estimates.

Variables	**Unadjusted odds ratio**			Adjusted odds ratio		
	Odds ratio	**P value**	**95% CI**	**Odds ratio**	**P value**	95% CI
Program Quality of delivery (N=408) **Slightly satisfactory**	0(ref)	n/a	n/a	0.235	0.040**	**(0.059 .935)**
Neutral	1.471	0.277	(0.733 2.950)	0.414	0.186	**(0.112 1.529)**
Very satisfactory	0.861	0.638	(0.462 1.605)	0.075	0.001**	**(0.017 .329)**
Extremely satisfactory	0.101	0.001	(0.043 .233)	0.186	0.050	**(0.036 1.001)**
Characteristics of the community (N=408) **Slightly favor**	(ref)	n/a	n/a	ref	n/a	**n/a**
Extremely favor	3.505	0.001	(2.906 4.103)	19.827	0.001**	**(8.602 45.701)**
Characteristics of service providers (N=408) **Somewhat favor**	(ref)	n/a	n/a	ref	n/a	**n/a**
Extremely favor	0.265	0.001	(0.168 .418)	0.271	0.001**	**(0.161 .459)**
Facilitation and sustainability strategies (N=408) **Not at all satisfactory**	ref	n/a	n/a	ref	n/a	**n/a**
Slightly satisfactory	0.232	0.001	(0.142 .379)	0.091	0.001**	**(0.025 .331)**
Very satisfactory	0.253	0.001	(0.149 .429)	0.070	0.001**	**(0.021 .241)**
Characteristics of the patients (N=408) **Strongly oppose**	ref	n/a	n/a	ref	n/a	**n/a**
Somewhat oppose	0.186	0.001	(0.111 .311)	0.180	0.003**	**(0.058 .557)**
Somewhat favor	0.429	0.005	(0.236 .778)	0.007	0.001**	**(0.0009 0.005)**
Strongly favor	5..47	0.976	n/a	7.76	0.979	**n/a**

Structural- organizational challenges (N=408) **Strongly oppose**	ref	n/a	n/a	ref		
Somewhat oppose	1.053	0.869	(0.571 1.943)	2.282	0.152	**(0.738 7.047)**
Somewhat favor	0.389	0.001	(0.226 .669)	0.573	0.288	**(0.205 1.601)**
Strongly favor	0.112	0.001	(0.054 .230)	0.036	0.001**	**(0.012 .111)**
Program contents (N=408) **Not at all satisfactory**	ref	n/a	n/a	ref	n/a	**n/a**
Very satisfactory	11.231	0.001	(7.010 17.99)	11.096	0.001**	**6.789 18.135)**
Participant's responsiveness (N=408) **Not at all satisfactory**	ref	n/a	n/a	ref	n/a	**n/a**
Slightly satisfactory	0.154	0.001	(0.079 .295)	0.002	0.001**	**(0.002 0.132)**
Very satisfactory	0.037	0.001	(0.015 .095)	00.001	0.001**	**(0.0013 .011)**

**** means P-value was obtained from logit-logistic regression, TT= Trachomatis Trichiasis, n/a – not available , ref= reference**

Discussion

The data shows that the level of implementation fidelity of the trichiasis surgery program was generally low. Fidelity was measured across its five dimensions; that is; content. Coverage, duration, dose, quality of delivery, and methods of delivery only scored above the average. The data also show that participant's responsiveness, characteristics of patients, surgical skills and experience, structural organization, facilitation and sustainability strategies, characteristics of the community, and program content were the factors associated with implementation fidelity of the trichiasis surgery program and its postoperative unfavorable outcomes in Eastern and Northern Uganda. These findings suggest that unfavorable postoperative trichiasis surgery outcomes are correlated with a low level of fidelity(45). To successfully trichiasis surgery improving visual acuity, eliminate trachoma, save sight loss, and improve postoperative trichiasis surgery outcomes, the program must be delivered as intended. Secondly, at the initial stage of project planning and implementation; the program implementer should determine the link between internal and external factors that influence the quality of postoperative trichiasis surgery outcomes(46).

Furthermore, previous studies have established that moderating factors like surgical skills-related factors, patient characteristics, and the capacity of the implementing organization had strongly influenced implementation fidelity, and the quality of the interventions' outcomes(9), which are similarly the same found in this study. Further, a similar study indicated that for the intervention to achieve a high level of fidelity, several factors may influence or moderate the degree of fidelity with which an intervention is implemented. Therefore, each of the potential moderators of this relationship should be considered during the entire program implementation process(38). These findings were not a surprise. Van et al,2015 and Willeboordse et al, 2018. Their findings were in agreement with this study's findings(47, 48). Furthermore, Breitenstein et al, 2010 and Carroll, 2007, reported the same(49, 50). The findings from this study are novel. Because this is the first study that assessed the level of implementation fidelity of the trichiasis surgery program in Uganda and described the moderating factors associated with unfavorable postoperative trichiasis surgery outcomes. The results indicate a high potential to improve the level of implementation fidelity and quality of trichiasis surgery program outcomes by improving the potential moderators 'determinants". The moderators; like program quality of delivery, characteristics of the community, characteristics of service providers, facilitation and sustainability strategies, characteristics of the patients, structural- organizational, program contents and participant's responsiveness, that this study identifies are in agreement with Hasson and others*(39, 49, 51)* who applied Carroll's framework to study the complexity of health interventions and suggested 'potential participant responsiveness, facilitation strategies, quality of delivery as moderators to the level of fidelity. Given that implementation fidelity is dependent on interrelationships between moderators, overall, findings call for consideration of the contextual factors

'moderating factors" associated with implementation fidelity of trichiasis surgery program, and by taking into account the barriers and facilitators influence implementation fidelity and trichiasis surgery program outcomes during program design. Based on quantitative data analysis of implementation fidelity and trichiasis surgery program data, it can be concluded that; implementation fidelity of the trichiasis surgery program was low in all dimensions of fidelity evaluated, (table 4, and table 10) has the detail.

Limitations

First, although we reported lower levels of fidelity correlated with unfavorable trichiasis surgery program outcomes and the associated moderating factors, we were unable to conclude from the levels of fidelity to methods of delivery, as it was very true that a big number of health facilities where trichiasis surgery was performed had no the necessary required surgical and theatre technologies in place to enable us to determine the realistic level of fidelity scored. This compromised the ability of the research team to draw a comprehensive conclusion that, trichiasis surgery unfavorable outcomes follows surgical failure was as a result of lower levels of fidelity to methods of delivery. The study populations were nomadism and hostile, the study site was hard to reach communities. These characteristics enabled us to reach out to the key identified study subjects who were enriched with the information required to develop a comprehensive report. Second, our study was restricted to the Northern, northeastern, and eastern regions in Uganda, but qualitative participants snowballed to study participants in the Central region. Therefore, our findings may not be generalizable to the central region of Uganda.

Conclusion

The inclusion of fidelity to the trichiasis surgery program, and the moderators, a cross-section design served to a better model to understand the complexity of the factors that may contribute to variation in the quality of trichiasis surgery program outcomes. The study suggests that, in health intervention or program evaluations or when trying to predict the quality of program outcomes, the entire intervention components involved; both the internal and external contexts surrounding the implementation process should be viewed exclusively. This study offers an example of some of the complexity that interacts to impact one aspect of implementation, fidelity. These relationships can be further explored within the broader scope of implementation science. By understanding the nature and interplay of these multiple factors, conditions, and the implementation process itself, there is great promise for more effective interventions, quality trichiasis surgery program outcomes, and an easier transition of evidence-based practices into health programs. This understanding will form the basis for all planning, organization, and implementation of trachoma elimination strategies, where trichiasis surgery for trachoma is included, if we are to reach the elimination of Neglected Tropical Diseases National Masterplan 2019-2023. We, therefore, recommend that a further study on assessment and description of the levels of implementation fidelity on other trachoma elimination interventions know by the acronym "SAFE" which is not evaluated in this study to be considered, but more focus on the main implementation issues as identified by this study.

Recommendations

The study projected the predictors to low and high-level implementation fidelity and trichiasis surgery program outcomes. To achieve a successful implementation of trichiasis surgery program and other related public health interventions, and to ensure that community-based intervention that was shown to be efficacious; yields population benefits once translated to the community. Therefore, the study suggests; Implementers of trachoma elimination strategies (SAFE), public health practitioners and those involved in programming and designing, and an implementation process of health interventions; (1) To put the notion of implementation fidelity at the center as a key component and, (2) To examine the core implementation program components which include: Practitioner selection, Pre-service, and in-service training, Ongoing coaching and supervision, Practitioner performance evaluation

(assessment of implementation fidelity), decision support data systems, facilitative administrative supports, and strengthening health system intervention. For the program to achieve the intended objectives.

The study reported low spread of program information, low trichiasis surgery program coverage, inadequate facilitation, and sustainability strategies, limited programs' active ingredients, deprived structural and organization support systems; as the determinates to a low level of implementation fidelity and unfavorable trichiasis surgery program outcomes. Therefore, finding suggests the need for (1) regular community health education through specified channels, (2) comprehensive integration of trachoma/ trichiasis elimination program components into primary health care (PHC), (3) prioritization in allocation of health resources, (4) partnership with Non- Governmental organization and other authorized implementing partner (IPs) in the districts that implement healthcare services.

The study found a limited number of trichiasis surgeons, trichiasis nurses, and a lack of knowledge, experience, and surgical skill among trichiasis surgery program implementers in the study districts. This finding suggests the need for enhancing refresher courses and training more experts. The ministry of health (MoH) through the district local government should consider retraining and training more trichiasis surgeons to increase the capacity of health human resources available in the endemic areas.

There was a self-re-infection of trachomatous trichiasis infection amongst the community members. To emphasize hard immunity in the endemic communities. By resisting the spread of a contagious disease like trachoma within a population. Secondly, by emphasizing complete program activity coverage in the endemic areas.

Strength of the study

The previous studies have made contributions by demonstrating the predictors of Trachomatous trichiasis surgery outcomes, without describing and documenting the implementation issues surrounding the whole process to outcomes(52). So this study has outlined the direct relations between trichiasis surgery program outcomes and the implementation of contextual factors surrounding the whole implementation process. These findings are likely to be useful to implementation science(53, 54), a science in its infancy. Secondly, this study contributes to its use of mixed methods, by demonstrating that relations between fidelity and trichiasis surgery program outcomes which seem to vary in a complex way. Without the inclusion of qualitative and quantitative analyses, the additional layers of the complex relations between fidelity, moderating factors, and trichiasis surgery program outcomes would not have come to light. These results are consistent with the rationale for and benefits of conducting mixed methods research. The design of the study, with qualitative and quantitative measures, along with the small sample size and focus of the research questions, suggested that a mixed-methods approach was most appropriate and allowed for the most in-depth exploration of the data(55). Altogether, the study is significant because it includes fidelity observations as a potential mediator for trichiasis surgery program outcomes in a health intervention study, its exploration of trichiasis patients and trichiasis program experts' perception, experience, the insights, and individual moderators as a way to further understand the potential relations between the barriers and facilitators both implementation fidelity and trichiasis surgery program outcomes.

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Appendix 1: Study Variables

Response variable: High / Low Implementation fidelity (Categorical Variable)
Explanatory variables: The explanatory variables are presented in Table1 bellow.

Study Variables

Explanatory Variables	Type	Coding
Background Characteristic		
Age	Continuous –variable	
Distance	Continuous – variable	
Gender	Categorical	
Working Experience	categorical	
Professional Background	Categorical	
Highest level of training	categorical	
Trained as a trichiasis surgery Implementer	categorical	
Location of the health facility	categorical	
Measures of Implementation fidelity (Categorical ordinal / Nominal data scale)		
Programme content		
Programme coverage		
Program activity duration		
Program methods of delivery		
Program Exposure/ dose		
Moderators the levels of Implementation fidelity (Categorical ordinal/ nominal data scale)		
Participant responsiveness		
Program Quality of delivery		
Characteristics of the program participants		
Program sustainability Strategies		
Characteristics of the community		
Characteristics of the service providers		

Appendix 2: Trichiasis surgery checklist

Surgical procedure protocols	MEASUREMENT SCALE (0 to 100%)										TTOTAL SCORE
1. Quality of delivery	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	9	10	
Assembly the necessary materials before surgery?											
Knowledge of surgical materials											
Used a bright torch to examine the lid											

Looked up at the lid from below to see trichiasis											
Correctly identified trichiasis											
Determined whether there was defective lid closure											
Obtained a relevant medical history from the patient											
Sterilization of equipment before use											
Knowledge of sterile techniques											
Appropriate sterilization by autoclave or pressure cooker of all non-disposable instruments											
Handling of sterilized instruments and items											
Using sterile gloves, forceps, towels											
Participant's responsiveness: Participant's responsiveness good as was estimated											
Did you Identify eye for surgery											
Greeted the patient appropriately											
How many patients with Trichiasis did you target? And did you achieve the target?											
The level of engagement was:											
(a) High											
(b) Medium											
(c) Low											
2. **Adherence: Program contents covered as was prescribed in the project work plan**											
Identification of eye for surgery											
Assessing Fitness of patients for surgery											
Facilities and surgical materials											
Sterilization facilities											
Surgical Procedure											
Qualification and certification of Trichiasis surgeon											
Pre-operatives' preparation											
Postoperative care											
Practitioner selection											
Methods of delivery: Program delivered as was prescribed by the program designer											
BLTR											
PLTR											
Trichiasis Clamp											
Epilation											
Others											

Not Applicable											
Activities conducted : Number of activities covered as prescribed in the project work plan											
Numbers of activities was set											
We covered all the set activities											
Program exposure (Dose):) the amount of program delivered in relation to the amount prescribed by the program model											
Number contacts to patients (All)											
Attendance of patients											
(a) High											
(b) Medium											
(c) Low											
Preoperative preparation											
Explained to the patient what was wrong and what was going to happen during the procedure											
Administered topical anaesthetic											
Washed hands appropriately											
Put on sterile gloves so as to maintain sterility											
Prepared patient's face and eyelids using skin preparation solution (e.g. povidone iodine)											
Anaesthesia observational											
Check the bottle label											
Anaesthetic kept sterile											
Correct amount of anaesthetic drawn up (e.g. not more than 5 ml of lidocaine)											
Re-checked that correct eye was receiving anaesthetic											