RESEARCH ARTICLE

Could EAISI-trained providers provide better quality of IUD services? Results of a secondary data analysis of complications as a proxy indicator [version 2; peer review: 2 approved]

Previously titled: Could trained providers provide better quality of IUD services? Results of a secondary data analysis of complications as a proxy indicator

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Abstract

Background: For accelerating its progress towards FP2020 goals, the Government of India has focused on improving the quality of intrauterine device (IUD) services. EngenderHealth has supported the Governments of Rajasthan and Gujarat since 2014 through its Expanding Access to IUD Services in India (EAISI) project by building the capacity of service providers, monitoring their compliance with standard practices, and strengthening health systems. This study sought to assess whether EAISI trained providers provide a better quality of IUD services as compared to non-EAISI trained providers, as indicated by a reduction in confirmed IUD complications?

Methods: This study was an analytical cross-sectional study of secondary data collected from the follow-up registers of 176 intervention facilities (138 in Rajasthan and 38 in Gujarat) during Phase I of EAISI project. The analysis included clients who returned between April 2018 and March 2019 to the same facility for a follow-up visit. Multivariate logistic regression was performed to determine factors associated with IUD complications.

Results: A total of 56,733 IUD insertions were conducted, and 10,747 (18.9%) client follow-ups were documented. Of these, 49.4% (N=5,305) clients received IUDs from EAISI-trained providers, while 50.6% (N=5,442) received IUDs from non-EAISI trained providers. A total of 4.0% (N=432) of clients experienced complications (Expulsion: 1.3%, Missing Strings: 1.7%, Infection: 1.1%). Clients who received IUDs from non-EAISI-trained
providers were 55.5% more likely [95% CI (26.2%, 91.5%), p<0.0005] to have complications compared to clients who received insertions from EAISI-trained providers. Other significant factors include the type of IUD, timing of the follow-up visit and timing of the insertion.

**Conclusion:** The findings demonstrate that intensive, hands-on training of providers to improve clinical skills for IUD insertions can have a positive impact on the reduction of post-insertion complications.

**Keywords**
Quality of IUD services, complications of IUD insertions, secondary data analysis, client follow-ups

This article is included in the International Conference on Family Planning gateway.
Introduction

India is the second most populous country in the world, contributing to 18% of the global population. In 1952, it became the first country in the developing world to introduce a national family planning program to lower fertility and stabilize population growth. India’s FP2020 goals aim to drive access, choice, and quality of family planning services. Since first making an FP2020 commitment in 2012, India has continued its efforts to expand the range and reach of contraceptive options through rolling out new contraceptives and delivering a full range of family planning services at all levels. For example, India has integrated family planning into the Reproductive, Maternal, Newborn, Child, and Adolescent Health (RMNCH+A) Strategy. Increasing awareness and generating demand for family planning services through comprehensive media campaigns have also been prioritized. Reflecting this, data from India’s Demographic and Health Survey revealed that 72% of women reported hearing or seeing a family planning message in the past few months.

Within the broader commitment to increase access and use of family planning services, a focus of the Government of India has also been to improve access to quality IUD services. It is recognized that ensuring the availability and quality of IUD services can improve family planning uptake, increase modern contraceptive methods use, and reduce unmet need for family planning services. While current use of IUDs among married women is low in India (1.5%), evidence suggests that contraceptive discontinuation rates are lowest for IUD methods (26%), as compared to other methods such as injectables (51%), condoms (47%), and pills (42%).

Evidence has shown that ensuring the quality of IUD services can lead to improved client satisfaction, a reduction in complications, continuation of IUD use, and increasing demand for this family planning method and reducing negative beliefs about IUDs within the community.

Since 2014, the international NGO, EngenderHealth has been providing technical assistance to the Government of India to improve access to quality IUD services. The project, “Expanding Access to IUD Services in India” (EAISI) has been implemented in Gujarat and Rajasthan districts. The interventions under the EAISI project include capacity building of service providers to provide quality IUD services, monitoring their compliance with standard practices, and strengthening the public health system by training administrators. The EAISI project trains public sector service providers in client assessment, counselling skills, IUD insertion and infection prevention practices, as well as ensuring services protect clients’ sexual and reproductive health rights. Providers practice their skills on anatomic models and clients.

Estimation of complications of clinical procedures is an important outcome measure, as it has been an established outcome measure of quality of care. To the best of our knowledge, studies that have investigated the quality of IUD services, have not explored the importance of provider training and the extent to which this may influence the incidence of IUD complications. Given that follow-up information is routinely collected from IUD clients in India, the availability of facility data provided an opportunity to investigate factors associated with IUD complications. The primary aim of the study was to estimate factors associated with IUD complications, including the extent to which provider training influenced the rate of IUD complications. The rate of complications was deemed to serve as a proxy measure of the effectiveness of the EAISI project in reducing complications in the clients who have availed IUD insertion. A secondary aim of the study was also to estimate the magnitude of complications.

Methods

Study design

This study was an analytical retrospective cross-sectional study based on secondary data of follow-ups captured in the intervention facilities of EAISI project between April 2018 and March 2019. This manuscript is written on the basis of the Standardized Reporting of Secondary Data Analysis (STROSA) guidelines.

Data source

Data for insertions and follow-ups are recorded in case records and registers at the facilities. The source of data for this study was the IUD follow-up registers, which were being used for many years for documenting the follow-ups of the reference population consisting of clients who had returned to EAISI intervention facilities for follow-up after IUD insertion. The format of IUD registers mirrored the Government of India guidelines. The data captured in the registers included the identification details of the client, details of IUD insertion, timing of the follow-up visit, as well as findings of the follow-up visits.
including complications and reason of removal if applicable. The data were owned by the health department of Rajasthan and Gujarat State of India.

Approvals, confidentiality, and data availability
Permission to publish data was obtained from Ministry of Health and Family Welfare, India. In accordance with Declaration of Helsinki, since the study was based on secondary data, institutional ethics approval was not needed. Client privacy was maintained throughout the analysis. No client identifiable data were disclosed. The data has been anonymized without distorting scientific meaning using safe harbor method. The dataset has been deposited in the Harvard Dataverse repository under a CC0 1.0 Universal License.13

Data flow
The data were collected from health facilities every month by EngenderHealth staff. Data were entered into the EAISI project database by data entry operators, as mandated by the Family Planning Department of Ministry of Health and Family Welfare, India. For this analysis, an Excel file was exported from EAISI software for the required period, for the data of the follow-up entries in the software. The data was imported and analyzed using SPSS version 24 by the investigators of the study.

Inclusion and exclusion criteria
The facilities included in the analysis were 138 facilities in Rajasthan (1 sub-distinct hospital, 130 Community Health Centers, and 7 Primary Health Centers) and 38 facilities in Gujarat (14 district hospitals, 5 sub-district hospitals, 19 community health centers) in which 1306 providers were trained by the EAISI project during the first phase of the project implemented from June 2014 to November 2016. Only clients that returned to the facility for facility-based clinical follow-up were included in the data analysis. Client data was excluded from the analysis if any of the following criteria were met: the client was contacted by phone for a telephonic follow-up, the client was visited at their home by a health provider for home-based follow-up, or the client went to a facility for follow-up other than where she had availed IUD insertion. A full survey of the available data in the targeted facilities for the study period was done by universal sampling.

Analysis unit and variables analysed
The unit of analysis was a client case that was confirmed through clinical follow-up to have experienced complication after IUD insertion. The presence of complication was described as presence of any one or more out of expulsion, infection, and missing strings. This variable served as a proxy indicator for the quality of IUD services.14,15 For the analysis, the data were disaggregated according to whether clients had received IUD insertions from providers trained by EngenderHealth versus clients that received IUUD insertions from providers that were not trained by EngenderHealth. The latter group included providers that were not formally trained in IUD insertions or had been trained by other institutions.

Other variables that were investigated included the timing of the IUD insertion (post-placental, immediate postpartum, intra-caesarean, interval), timing of follow up after insertion, age, state of residence, and the type of IUD inserted (IUD 380A or IUD 375).

Study size
The study size was determined by the number of entries documented in EAISI software for the study period.

Statistical analysis
A multivariate logistic regression analysis was performed to determine the probability of complications (reference category: no complication) by training status, after controlling for other variables of timing of insertion, timing of follow up after insertion, age, state, and type of IUD inserted. Odds ratio and p value were estimated. Chi square and Nagelkerke R² values were also estimated. SPSS 24 was used for performing the entire statistical analysis.

Results
Selection of study population
Selection of study population was based on inclusion and exclusion criteria (Figure 1). Of 16,672 clients in the database, Figure 14. Clients in Gujarat of the IUD insertion (post-placental, immediate postpartum, Other variables that were investigated included the timing of the IUD insertion (post-placental, immediate postpartum, intra-caesarean, interval), timing of follow up after insertion, age, state of residence, and the type of IUD inserted (IUD 380A or IUD 375).

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Results
Selection of study population
Selection of study population was based on inclusion and exclusion criteria (Figure 1). Of 16,672 clients in the database, 10,747 client records (6,013 in Rajasthan and 4,734 in Gujarat) met the inclusion criteria and were included in the secondary analysis.

Descriptive results
Six facilities in Rajasthan and four facilities in Gujarat did not document any follow-up after IUD insertions during the study period due to a lack of follow-up registers and poor documentation practices. The remaining 166 facilities (132 in Rajasthan and 34 in Gujarat) reported that of the 56,733 clients (Rajasthan: 42,231, Gujarat: 14,502) who had availed IUD insertions in these facilities, 10,747 (18.9%) came to the facility for clinical follow-up during the study period. Among these 10,747 clients, 432 (4%) experienced IUD complications: 144 clients experienced expulsions (1.3%), 179 clients had missing strings (1.7%), and 113 clients had infections (1.1%). The sample distribution, according to the different variables, is provided in Table 1. Raw data are available from Harvard Dataverse.13

Bivariate analyses
Cross-tabulation of various variables with complications reported post insertion is shown in Table 1. Clients in Gujarat reported a higher complication rate (4.7%) compared with those in Rajasthan (3.5%). While 159 complications (3%) were reported among insertions done by EAISI-trained providers, 273 complications (5%) were reported among insertions done by other providers who were either not formally trained or trained by other sources. Missing strings was the most common complication in both the groups and was reported in 1.3% insertions by EAISI-trained providers, and 2.0% insertions by other providers. Incidence of complications varies considerably with timing of insertion – it is highest among intra-caesarian clients (8.8%) followed by immediate post-partum (4.7%), post-placental (3.6%) and lowest among interval IUD clients (2.7%). IUD 380A clients reported higher rate of complications (4.4 %) compared with IUD 375 (3.3%). There is also decline in the frequency of complications according to the time of
follow-up, complications are higher among those that were followed-up within 6 weeks of their IUD insertion (4.7%) as compared to clients who were followed-up after six months of insertion (1.5%).

Multivariate analyses
A total of 10,422 cases were included in analysis ($\chi^2 = 82.996$, p <0.0005, Nagelkerke $R^2$ 0.028) (Table 2). Insertions done by other providers who were either not formally trained or trained by other sources were 55.5% more likely to result in a complication than were insertions done by EAISI-trained providers. Clients receiving IUD 380A were 43.5% more likely than IUD 375 to have a complication. Intra-cesarean clients were 135.7% more likely to report a complication compared with clients having insertions done in the post-placental period. The other two categories of timing of insertion, immediate post-partum and interval, did not have a statistically significant association with incidence of complication. Clients who came for follow-up within 6 weeks of insertion or from 6 weeks to 6 months after insertion were 175% and 178% more likely to report complication than who came more than 6 months post insertion.

Discussion
This study explored the frequency of complications among IUD clients across two states in India. Our findings highlight the frequency of complications among these women, and also present factors associated with this, including the training of the provider, the type of IUD, timing of the follow-up and timing of the insertion.

Globally, it is estimated that between 2% to 8% of IUD clients will experience missing strings; 1.6 per 1,000 women/years will have infections; and between 2 and 10% of IUD clients will experience expulsions in their first year. Missing strings was the most common complication in insertions by EAISI-trained providers as well as in insertions by non-EASI trained providers. Our evidence data suggest that the occurrence of missing strings, infection and expulsion among our sample were lower than other studies. This is perhaps reflective of the effort the Government of India and EngenderHealth have made to ensure the quality of IUD services.

Our results also illustrate that several factors are associated with the frequency of IUD complications. Of note, complications
were significantly more common among clients who obtained their IUD from non-EAISI trained providers, a promising outcome from the EAISI project. These positive findings may reflect several efforts by the project to ensure that the providers are maintaining quality of IUD insertions and counseling of patients. The findings also demonstrate the importance of intensive, hands-on training of providers to build up their clinical skills to provide quality services and reduce post-insertion complications.

The findings that complications were significantly more common among women who returned for follow-up within 6 weeks, possibly reflects that clients noted some type of discomfort, or pain, or noted the expulsion and returned immediately to seek consultation. The finding that complications were significantly more frequent among clients with the IUD 380A has also been observed in other studies. For example, while a clinical trial evaluating the effectiveness of the copper T 380A and multiload copper 375 (MLCU 375) IUD concluded that both types demonstrated comparable performances in the first year of use, several issues with the 380A were noted. Clients who received the 380A had higher discontinuation rates after a year, reported greater abdominal pain during menstruation and bleeding, and higher expulsion and termination rates than the 375 IUD. The results of this study, and that of others, suggest that additional clinical research may be merited to explore the effectiveness of the copper T 380A in the context of India.

Timing was also significantly associated with complications, with women who received their IUD during the intra-caesarean

<table>
<thead>
<tr>
<th>Variable</th>
<th>Number of clients (% of total)</th>
<th>Number of complications/n (% of complications)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>State</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rajasthan</td>
<td>6013 (56.0%)</td>
<td>210/6013 (3.5%)</td>
</tr>
<tr>
<td>Gujarat</td>
<td>4734 (44.0%)</td>
<td>222/4734 (4.7%)</td>
</tr>
<tr>
<td><strong>Training status of providers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EAISI-trained providers</td>
<td>5305 (49.4%)</td>
<td>159/5305 (3%)</td>
</tr>
<tr>
<td>Other providers</td>
<td>5442 (50.6%)</td>
<td>273/5442 (5%)</td>
</tr>
<tr>
<td><strong>Timing of insertion</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-placental</td>
<td>7112 (66.2%)</td>
<td>254/7112 (3.6%)</td>
</tr>
<tr>
<td>Immediate postpartum</td>
<td>2395 (22.3%)</td>
<td>112/2395 (4.7%)</td>
</tr>
<tr>
<td>Intra-caesarean</td>
<td>498 (4.6%)</td>
<td>44/498 (8.8%)</td>
</tr>
<tr>
<td>Interval</td>
<td>693 (6.4%)</td>
<td>19/693 (2.7%)</td>
</tr>
<tr>
<td>Unspecified</td>
<td>49 (0.5%)</td>
<td>3/49 (6.1%)</td>
</tr>
<tr>
<td><strong>Type of IUD</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IUD 375</td>
<td>3454 (32.2%)</td>
<td>113/3454 (3.3%)</td>
</tr>
<tr>
<td>IUD 380A</td>
<td>7074 (65.8%)</td>
<td>310/7074 (4.4%)</td>
</tr>
<tr>
<td>Unspecified</td>
<td>219 (2.0%)</td>
<td>9/219 (4.1%)</td>
</tr>
<tr>
<td><strong>Time of follow up after insertion</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Within 6 weeks</td>
<td>3142 (29.2%)</td>
<td>147/3142 (4.7%)</td>
</tr>
<tr>
<td>6 weeks to 6 months</td>
<td>6440 (59.9%)</td>
<td>267/6440 (4.1%)</td>
</tr>
<tr>
<td>More than 6 months</td>
<td>1114 (10.4%)</td>
<td>17/1114 (1.5%)</td>
</tr>
<tr>
<td>Unspecified</td>
<td>51 (0.5%)</td>
<td>1/51 (2%)</td>
</tr>
<tr>
<td><strong>Type of complication experienced</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any one complication</td>
<td>432 (4%)</td>
<td></td>
</tr>
<tr>
<td>Expulsions</td>
<td>144 (1.3%)</td>
<td></td>
</tr>
<tr>
<td>Missing strings</td>
<td>179 (1.7%)</td>
<td></td>
</tr>
<tr>
<td>Infections</td>
<td>113 (1.1%)</td>
<td></td>
</tr>
<tr>
<td><strong>Age in years</strong></td>
<td>Mean</td>
<td>Range</td>
</tr>
<tr>
<td></td>
<td>24.58</td>
<td>16–45</td>
</tr>
</tbody>
</table>

IUD, intrauterine device.

*3 cases had both expulsion and infection, while 1 case had both infection and missing strings
This finding is consistent with other research, which reports unacceptably high expulsion and displacement rates among clients who receive IUDs during the intra-caesarean period. For example, one study observed a 20% expulsion rate among copper IUDs inserted during the intra-caesarean period, within the 12-week follow-up period\textsuperscript{20}. Another study found an IUD expulsion rate at 1 year of 17.6% in post-caesarean section women using the 380A IUD\textsuperscript{21}. The method was viewed by the authors as unacceptable for general use. These findings are of concern, given that the expulsion rates after caesarean delivery could prevent proper healing of the laparotomy wound by leading to a shortened interpregnancy interval, which can lead to significant problems during a subsequent pregnancy\textsuperscript{22}.

The age of the client was not significantly associated with incidence of complications, which contradicts other research that observed significantly higher rates of expulsion among younger women, under the age of 18\textsuperscript{23}. Given that few of our sample comprised of women under the age of 18, and ranged from 16–45 years, with an average age of 25, may explain why no significant differences in age were observed among our sample.

This study had several limitations. Out of the sampled 176 facilities of Phase 1, 10 facilities had no records of follow-up clients. In addition, 81% of clients who had availed insertions from the remaining 166 facilities could not be documented. This was due to a number of reasons, including the low return rate of clients to facilities, poor documentation practices, and/or incomplete documentation. Although providers stress the importance of the need to returning to the facility for a follow-up after 1.5 months, it is apparent from our data that many do not. This lack of follow-up to the facility by the client may be attributable to a number of factors, including economic, geographical and logistical issues\textsuperscript{24,25}. As such, the estimation of complications may be biased towards women who were able to return for follow-up visits. Furthermore, the long-term expulsion rates could not be determined, as the vast majority of clients followed-up within 4 to 6 weeks. Due to resource constraints and incompleteness of secondary data, matched sample could not be assured and a case control study could not be conducted. It is also recognized that complications could also have occurred due to other factors. Infections could also have occurred due to sexually transmitted illnesses. Missing strings could also have happened due to failure of IUD, although no such case was reported in the study. These confounders may have been unevenly distributed among the clients who availed insertions from the EAISI-trained providers or from the other providers. Further, the category of non-EAISI trained providers in this study could have been trained on IUD insertion and related aspects during their pre-service and other post service training which could have masked the effect of IUD training on incidence of complications in our analyses. The limited fields in the hospital registers restricted our ability to control for these confounding variables. Finally, the caveats of the analysis framework were that

Table 2. Multivariate logistic regression of complications post intrauterine device (IUD) insertion by other variables.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Odds ratio</th>
<th>95% CI</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>State</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rajasthan*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gujarat</td>
<td>0.996</td>
<td>0.772, 1.284</td>
<td>0.975</td>
</tr>
<tr>
<td>Training status of providers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EAISI-trained providers*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other providers</td>
<td>1.555</td>
<td>1.262, 1.915</td>
<td>&lt;0.0005</td>
</tr>
<tr>
<td>Timing of insertion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-placental*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immediate postpartum</td>
<td>1.189</td>
<td>0.909, 1.554</td>
<td>0.206</td>
</tr>
<tr>
<td>Intra-caesarean</td>
<td>2.357</td>
<td>1.607, 3.459</td>
<td>&lt;0.0005</td>
</tr>
<tr>
<td>Interval</td>
<td>0.893</td>
<td>0.548, 1.458</td>
<td>0.652</td>
</tr>
<tr>
<td>Type of IUD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IUD 375*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IUD 380A</td>
<td>1.435</td>
<td>1.143, 1.801</td>
<td>0.002</td>
</tr>
<tr>
<td>Time of follow up after insertion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>More than 6 months*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 weeks to 6 months</td>
<td>2.778</td>
<td>1.664, 4.639</td>
<td>&lt;0.0005</td>
</tr>
<tr>
<td>Within 6 weeks</td>
<td>2.752</td>
<td>1.623, 4.665</td>
<td>&lt;0.0005</td>
</tr>
<tr>
<td>Age (continuous variable)</td>
<td>0.974</td>
<td>0.948, 1.002</td>
<td>0.068</td>
</tr>
</tbody>
</table>

*Reference category.
the data was secondary, and the completeness of data could not be ensured.

Despite these limitations, the study demonstrates a cost-effective method of monitoring the quality of IUD services in healthcare facilities. While the other studies on quality of IUD services have derived data by interviewing providers, interaction with clients, or hospital operations indicators, the data in follow-up registers considered in this study, is filled after clinical evaluation, and carries expert assessment and diagnosis of complication or client’s condition. Since complications at the time of follow-up reflect the overall quality of IUD services including enabling environment, skills and practices of providers, and client satisfaction, this model denotes the effectiveness of IUD services in the real world. This analytical framework can be adopted to evaluate the outcomes of any skill-based training.

**Conclusion**

Training, follow-up practice and monitoring schemes used by the EAISI project could enhance the skills of the providers and improve the quality of IUD services. Based on this, the EAISI model can be used to scale up trainings to other geographic areas, by government or other partners. Besides this, the use of secondary data is cost-effective method of monitoring quality of IUD services. These findings create grounds for further research and presents feasible model for periodic assessment of the quality of IUD services in FP programs.

To facilitate such secondary analyses, follow-up registers should be made available at all the facilities, documentation practices should be improved, and reporting at facilities should be periodically reviewed. The data generated should be used for decision making and informing the implementers and policy makers, which will go a long way in enhancing quality of services.

**Data availability**

Harvard Dataverse: Could Trained Providers Provide Better Quality of IUD Services—Results of A Secondary Data Analysis of Complications as a Proxy Indicator, https://doi.org/10.7910/DVN/JYZP7N.

Data are available under the terms of the Creative Commons Zero “No rights reserved” data waiver (CCO 1.0 Public domain dedication).

**Acknowledgments**

We are thankful to MoHFW, India and the Governments of Rajasthan and Gujarat for their kind support regarding this study. We acknowledge the support provided by the facility in-charges by providing the data for secondary analysis. The efforts of the EAISI staff are also appreciated in collecting data every month for line listing and follow-ups of the clients and entering into soft copies as a part of the project activities.

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4. International Institute for Population Sciences (IIPS) and ICF: Quality of IUD Services-Results of A Secondary Data Analysis of Complications as a Proxy Indicator. DRAFT VERSION. Harvard Dataverse.


21. Bugold E, Gauthier RJ: Risk of uterine rupture associated with an interdelivery...


Open Peer Review

Current Peer Review Status: 

Version 2

Reviewer Report 04 October 2019

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✔ Nuriye Ortayli Freelance Consultant, Instabul, Turkey

Authors have addressed the issues they could. Changing the study design is a huge task and I understand that they cannot embark on it at the time being, but I hope they will try it in the future given the availability of huge dataset. I think it can be indexed.

Competing Interests: No competing interests were disclosed.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 01 October 2019

https://doi.org/10.21956/gatesopenres.14203.r27869

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✔ Avita Rose Johnson Department of Community Health, St. John’s Medical College, Bangalore, Karnataka, India

Making changes as suggested, has resulted in a new and improved version of the original paper.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Maternal and Child health, Reproductive health

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.
I think this is a study addressing an important issue. For decades substantial resources have been committed to training of providers in method provision and specifically in provision of IUDs with little evidence regarding its impact. Working with a large database to measure the effect of provider training is going to be a meaningful contribution to the literature. However I have a few questions. First one is the most important and it is related to study design:

Based on the research question (what is the effect of provider training on complications of IUD) and the database available, in my view study design should have been case control. Thus instead of assessing the contribution of several factors on IUD complications (such as provider training, age of user, time of insertion etc), researchers could have compared cases (those with complications) with controls (a matched sample of those without complications). As authors say that percentage of IUDs provided by trained and non-trained providers are almost equal and therefore, given that a higher percentage of complicated cases received services from non-trained providers we can assume that training of a provider is an important factor. However, I think a case control design could have given us a result without making that assumption. Therefore, I believe this paper can benefit a lot from a review by a statistician/epidemiologist regarding study design.

Other points I want to raise are:

1. Why pregnancy with IUD in situ is not considered among the complications. If there were no such cases it should be stated so.

2. Being an IUD provider for thousands of women, and a trainer of many years, I find it hard to believe that IUD strings can disappear due to manipulation by the woman, or infection can be the result of menstrual hygiene and/or sexual practices (if the authors want to say STIs, then they should state it clearly)

Beyond these points I think this is an important issue, and researchers have pulled together a database of impressive size. With advise from peer epidemiologists, I think results can be more convincing for the audiences.

Is the work clearly and accurately presented and does it cite the current literature?
Yes
Is the study design appropriate and is the work technically sound?
No

Are sufficient details of methods and analysis provided to allow replication by others?
Yes

If applicable, is the statistical analysis and its interpretation appropriate?
I cannot comment. A qualified statistician is required.

Are all the source data underlying the results available to ensure full reproducibility?
Yes

Are the conclusions drawn adequately supported by the results?
Partly

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Reproductive Health

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 30 Aug 2019

**Manish Gehani,** EngenderHealth Inc., Ahmedabad, India

Dear Nuriye

Thank you for the comments. The authors fully appreciate that a case-control study would have strengthened the conclusions that could be made, and this limitation will be added to the paper. Given several resource constraints, we were unable to implement a study using a case-control methodology. Rather, we took a cost-effective and opportunistic approach to utilize valuable, secondary data. Several steps were taken during our analysis to address any potential confounding factors, such as age, timing of insertion, type of IUCD. We believe that the application of this analysis helps to alleviate the potential confounded effects related to the incidence of complications as a result of provider training. The current study design is robust as per epidemiology and research methodology.

IUD failure was not the complication taken into consideration in the study as a proxy indicator and there was no such case reported in the study.

We will correct the text regarding the other potential causes of infection and missing strings, besides as a complication of IUD insertion, as this was a mandatory reporting item as per STROSA guidelines.

Regards

On behalf of all authors-

Dr Manish Gehani

**Competing Interests:** No competing interests
Summary:
This study looks at whether women who had IUD inserted by EAISI trained health care providers, had lower complications than women whose IUD was inserted by a non-EAISI trained provider. The rates of complication being a surrogate indicator for the quality of IUD services provided. An analysis of secondary data from follow-up registers of 176 health facilities, revealed 10,747 client follow-ups, half of the IUD insertions were conducted by EAISI trained providers and half by non-EAISI trained providers. Complications among the latter were significantly higher. This study indicates the need for hands-on training for health providers to improve the quality of IUD services.

Suggestions:
1. Need to state specifically if HMSC (Health Ministry Scientific Committee) permission was obtained, as the data has been shared and stored overseas.
2. Table 1 and 2 can be combined by adding a total N(%) column in table 2.

Is the work clearly and accurately presented and does it cite the current literature?
Yes

Is the study design appropriate and is the work technically sound?
Yes

Are sufficient details of methods and analysis provided to allow replication by others?
Yes

If applicable, is the statistical analysis and its interpretation appropriate?
Yes

Are all the source data underlying the results available to ensure full reproducibility?
No source data required

Are the conclusions drawn adequately supported by the results?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Maternal and Child health, Reproductive health

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.
Author Response 30 May 2019

**Manish Gehani**, EngenderHealth Inc., Ahmedabad, India

Dear Dr Avita

We informed Health Ministry prior to using the data for research and sought the due approvals. This has been mentioned in the section on Approvals, confidentiality, and data availability as per STROSA guidelines.

We will try to club both the tables as suggested.

Many thanks and best regards

**Competing Interests:** No competing interests.

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**Comments on this article**

**Version 1**

Reader Comment 26 Jun 2019

**John Stover**, Avenir Health, Glastonbury, CT, USA

This is a useful article that provides evidence that provider training for IUCD staff can reduce the frequency of complications. The results show significant lower post-insertion complications for clients of EAISI-trained providers.

However, there are some limitations to the study that are not directly addressed by the authors. The main one is a concern about selectivity bias. If I understand correctly, less than 20% of patients who had an IUD inserted came to a facility for a follow-up visit during the study period. What about the other 80%? If we assume that none of them had any complications then the difference between EAISI-trained and other providers would much smaller. If they did not come back because of poor counseling about what to do in the case of complications then the complication rate could be much higher. I would be good to know what proportion of patients who received an IUD from an EAISI-trained provider returned for a follow-up visit and how that compares to other IUCD clients.

In the discussion the authors claim that EAISI is a cost-effective method, but they do not provide any information about the costs of the training compared to other types of training. How do we know it is cost-effective?

**Competing Interests:** I declare that I have no competing interests.