Safety of Tubal Occlusion by Minilaparotomy Provided by Trained Clinical Officers versus Assistant Medical Officers: A Noninferiority Randomized Controlled Trial in Tanzania
Acknowledgments

Authors:
Mark Barone, Zuhura Mbuguni, Japhet Ominde Achola, Annette Almeida, Carmela Cordero, Joseph Kanama, Adriana Marquina, Projestine S. Muganyizi, Jamilla Mwanga, Daniel Ouma, Caitlin Shannon, and Leopold Tibyehabwa

Project Name:
Responding to the Need for Family Planning through Expanded Contraceptive Choices and Program Services (RESPOND) Tanzania Project (RTP)

Supporting Organizations:
Presentation Outline

- Significance/Background
- Program Intervention/Activity Tested
- Methodology
- Results/Key Findings
- Program Implications/Lessons Learned
Significance/Background

Can Task Shifting Expand Access to Tubal Occlusion?

While Tanzania has notably increased family planning (FP) uptake over the past 25 years, unmet need remains high. Tubal occlusion via minilaparotomy (minilap) is the simplest approach to female sterilization. It can be performed in resource-limited settings with few complications, potentially through task shifting.
Task shifting tubal occlusion—using minilap—to mid-level providers could substantially expand access to this highly effective FP method.

EngenderHealth collaborated with the Ministry of Health to demonstrate the safety, efficacy, and acceptability of task-shifting minilap to these providers.

Is tubal occlusion by minilap, when provided by trained clinical officers, as safe as when provided by trained assistant medical officers?
Methodology

- Enrolled 1,970 participants across 7 health facilities
- Randomly allocated consenting, eligible participants for minilap to a trained clinical officer (CO) or trained assistant medical officer (AMO)
- Participants asked to return at specific intervals postsurgery to determine the occurrence of major adverse events
- Assessed the primary outcome using the 95% confidence interval
- Protocol approved by US and Tanzanian institutional review boards
Results/Key Findings

1,970 women randomized

984 allocated to minilap by CO
(6 excluded)

986 allocated to minilap by AMO
(2 excluded)

978 included in analysis

2 lost to follow-up
1 withdrew consent
1 discontinued

984 included in analysis

10 lost to follow-up
Results/Key Findings

**Major Adverse Events**

<table>
<thead>
<tr>
<th>Group</th>
<th>Events</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>CO Group</td>
<td>0/978</td>
<td>0.0%</td>
</tr>
<tr>
<td>AMO Group</td>
<td>1/984</td>
<td>0.1%</td>
</tr>
</tbody>
</table>

Non-Inferiority Margin

-0.3% 0.1%

Risk difference (CO minus AMO) for percentage of women experiencing a major adverse event

CO better

CO worse
Results/Key Findings

Performance of Minilaparotomy Procedures

<table>
<thead>
<tr>
<th>Outcome</th>
<th>CO</th>
<th>AMO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean procedure time</td>
<td>26 minutes</td>
<td>26 minutes</td>
</tr>
<tr>
<td>Requested verbal instruction from supervisor during the procedure</td>
<td>15/978 (1.5%)</td>
<td>20/984 (2.0%)</td>
</tr>
<tr>
<td>Requested supervisor assist with the procedure</td>
<td>14/978 (1.4%)</td>
<td>13/984 (1.3%)</td>
</tr>
<tr>
<td>Participant very satisfied with provider</td>
<td>834/969 (86.1%)</td>
<td>831/976 (85.1%)</td>
</tr>
<tr>
<td>Participant would recommend to others</td>
<td>970/974 (99.6%)</td>
<td>968/974 (99.4%)</td>
</tr>
</tbody>
</table>
Task shifting of tubal occlusion by minilap to mid-level providers can be safe, effective, and acceptable to women.

Task shifting of minilap to lower-level cadres can increase access, especially in rural and underserved areas.

Minilap can be provided safely in both health facilities and outreach settings.
For more information:

Contact me: Japheth Ominde Achola at jominde@engenderhealth.org

Come find us at **Booth #33**

Visit our microsite: [www.engenderhealth.org/icfp2018](http://www.engenderhealth.org/icfp2018)
Thank you!