Expanding global access to the LNG-IUS

Sally Stephens, Senior Vice President, Corporate Development, Medicines360

Kate Rademacher, Technical Advisor, Contraceptive Technology Innovation, FHI 360

John Townsend, Vice President and Director, Reproductive Health Program, Population Council

Kate Rademacher, Technical Advisor, Contraceptive Technology Innovation, FHI 360
New public-private partnership in Kenya
under Innovation Fund grant

Product developer & supplier

Technical assistance & evaluation

Service delivery & training in Kenya
Innovation Fund Project

Early activities to support introduction in Kenya:

- Preliminary market assessment
- Development of a comprehensive product introduction strategy
- Modification of MSI training materials
- Negotiation of distribution/public sector price ceiling agreement between MSI and Medicines360

*With co-funding from the Bill & Melinda Gates Foundation through FHI 360’s Contraceptive Technology Innovation Initiative*
Market Assessment in Kenya

Overview of the current reproductive health landscape in Kenya (desk review)

Analysis of the current market for Mirena® in Kenya

Interviews with Key Opinion Leaders (KOLs)
Potential for LNG-IUS in Kenya

While prevalence of IUDs is still low, use is increasing. According to recent PMA, IUDs represent 6% of method mix among married women, representing a 116% increase in prevalence since 2008-2009 DHS

- USAID-funded study in Kenya led by FHI 360 among postpartum women showed high uptake and acceptability of the LNG-IUS:
  - Among 671 clients, 16% chose the LNG-IUS
  - Approximately one third of LNG-IUS users indicated that if the product had not been available, they would have chosen a shorter-acting method

Source: Contraceptive method mix among married or in-union contraceptive users ages 15 to 49, PMA report, 2015
# Prices of Mirena™ (2014)

<table>
<thead>
<tr>
<th>Region</th>
<th>Up-market</th>
<th>Central Business District (CBD)</th>
<th>Informal settlement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nairobi</td>
<td>US$111-$167</td>
<td>$56-$111</td>
<td>$56 and below</td>
</tr>
<tr>
<td>Nakuru</td>
<td>$133-$194</td>
<td>$78-$111</td>
<td>Not offered</td>
</tr>
<tr>
<td>Kisumu</td>
<td>$111-$167</td>
<td>$67-$111</td>
<td>Not offered</td>
</tr>
<tr>
<td>Mombasa</td>
<td>$111-$167</td>
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<td>Not offered</td>
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</tbody>
</table>

*Discounts often negotiated by clients ranging from $6-$22/unit

“Up-market” is a region with primarily middle- and higher-income consumers. “CBD” is the central business district. “Informal settlement” is generally comprised of low-income consumers. Discounts are negotiated by clients who cannot afford to pay the full price.
Key Opinion Leader Interviews

Thirteen interviews with individuals from a variety of organizations, ranging from the Ministry of Health (N=2), NGOs (N=4), international donors and normative bodies (N=4), a social franchise network (N=1), a pharmaceutical distributor (N=1), and national RH society (N=1)

Key Feedback from KOLs

- Consensus among respondents that price is barrier and introduction of a more affordable LNG-IUS would increase uptake of the method
- Factors that have historically contributed to low uptake of IUDs in Kenya could impact scale-up of a new LNG-IUS
- Priority target user groups include women seeking clinical benefits (e.g. relief from menorrhagia and severe dysmenorrhea), spacers, limiters, adolescents, postpartum women, and both high- and low-income women seeking the product’s non-contraceptive benefits for lifestyle reasons
- Differing perspectives on whether greatest potential lies in public or private sectors; agreement that Total Market Approach is needed
“Yes, [there will] definitely be fast demand for a more affordable hormonal IUD.”

“100% it’s long overdue…. More demand for it? I would say yes, but in the public sector you definitely would definitely need to give awareness.”

“Let’s go for the total market. We want this hormonal IUCD to get available to the public and the private and the mission sectors. Yes, let it be available.”

--Interviews with Key Opinion Leader
I’m looking at a woman in the village. You already have nutritional setbacks, you have the monthly menstruation that is an excessive amount. So [amenorrhea] is a plus, plus, plus! You’re reducing the anemia risk and the quality of life with pain… [lt] benefits business women and school girls…when you look at the cost benefit there is a lot more to gain and with some degree of independence and freedom.

-- Key Opinion Leader
Key take-aways from Market Assessment

• Early evidence suggests that introduction of a new, more affordable LNG-IUS would drive increased awareness, demand and uptake for this product

• Factors that have contributed to low uptake of IUDs in Kenya must be addressed for LNG-IUS to be successful at scale

• As a newer product with a more favourable side effect profile, the LNG-IUS has the potential to ‘revitalize’ the IUD market in Kenya
Innovation Fund Project

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Gates Foundation’s “Uptake Planning Guide” used as framework for introduction strategy

- **Producers**
  *The companies which manufacture and ship the product to the port of entry*

- **Shapers**
  *The funders, regulators, and normative guidance providers who influence the market’s underlying architecture*

- **Purchasers, consumers, and programs**
  *The patients, consumers, and providers who use the product, and the systems which deliver it to them*

“Successful uptake planning and execution requires addressing all the actors in the marketplace.”
Among the Ministry, the method is usually dismissed as too expensive."

-Informal Advisory Group member
Comparison of Direct Costs of FP methods per Couple Years of Protection (CYP)

Assumptions: Adapted from analysis that was published by Tumlinson et al., 2011. Direct service delivery costs for this analysis include commodity costs, consumable supplies, and direct labor for insertion, removal, and resupply if required. The Couple Years of Protection (CYP) conversion factor for a 5-year IUD (including the LNG-IUS) is 3.3 years (source http://www.usaid.gov/what-we-do/global-health/family-planning/couple-years-protection-cyp). This analysis also assumes that all IUDs would be provided by nurse-midwives in low-resource settings; if a higher cadre of provider was required for insertion, the cost per CYP would increase.
Question to address: Will the product be delivered through public or private channels?

Recommendation from stakeholders: Introduce product in both the private and public sectors through a phased approach with focus on successful launch in the private sector first. Positive experience and demonstrated demand in the private sector can help generate buy-in for public sector introduction.

**Phase I: Private sector introduction**
Led by MSI/MSK with focus on delivery through MSK clinics & social franchises & private clinics

**Phase II: Public sector introduction**
With strong coordination between national and county governments

For purposes of this introduction strategy, “Private Sector” is defined as facilities run by national and international non-governmental organizations (NGOs), faith-based organizations, social marketing groups including social franchises, and privately owned, for-profit clinics.
Provider Training—Private Sector

Questions to address: What training will be required in the private sectors? What is an effective training roll-out strategy? How effective is on-the-job training?

Key Considerations

• **General:** Training on the LNG-IUS can build on providers’ existing knowledge about the provision of IUCDs. Many providers already have basic skills in IUD provision.

Private Sector: The training strategy will be embedded within MSK’s overall FP training approach, specifically tailored for the LNG-IUS.

• **Provider Training:**
  - A clinical and product training will prepare the clinician to be able to understand, counsel on and provide the LNG-IUS as a contraceptive method to users within a rights-based framework. MSK will provide training materials including clinical guidelines, a trainer guide, training/job aids and insertion kits.
  - MSK will identify, plan and undertake an initial training of providers who will become LNG-IUS expert trainers (some are already clinical trainers in FP). These trainers will cascade further training sessions of providers.
  - MSK’s team of medical detailers and community-based agents will be instrumental in creating product awareness supported by educational IEC materials.

Action Items:
- Pre-test training materials and provider messaging
- Evaluate opportunities to train more providers e.g. via distance learning
- Focus initial efforts on training providers already familiar with IUDs
- Generate awareness through information sources that providers currently report using (e.g. K4Health, NHIS, online forums, government sources, and FP2020 publications)
- Address barriers that contribute to providers’ resistance to offering IUDs
- Develop IEC materials to aid medical detailers in creating product awareness among health care providers

Excerpt from Product Introduction Strategy
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Public sector: Public sector training strategy must reflect new ‘devolved’ county system. Providers, in-charges, supervisors, and county-level RH coordinator will all require training on the LNG-IUS. Criteria for selection of clinics for initial roll-out will be adequate FP client load and demonstrated demand for LARCs.

• **Provider training**
  • Human resource constraints create challenges. On-the job training is recommended to avoid exacerbating HR shortages by pulling staff away for off-site training.
  • An eligibility criteria checklist is needed. Eligibility checklists are commonly used in Kenya for other methods.
  • Will be critical for providers to practice skills to gain competency.

• **Supervision mechanism will be two-fold:**
  1. National government officials will monitor on bi-annual basis
  2. County-team led by the RH coordinator will conduct regularly (e.g. monthly or quarterly) visits to clinics as part of broader monitoring of RH service provision

Action Items:
- MOH to coordinate training-of-trainers (TOT) sessions at the national level with support from NGOs (MSI and/or Jhpiego) and/or from bilateral (APHIA+). RMHSU will then support initial TOTs at the country level, i.e. county RH coordinator will be trained. Then cascade training will be offered among providers/in-charges at clinic level.
- Develop and disseminate eligibility criteria checklist health care provider tool as part of package of training materials.
- Focus of supportive supervision should be on identifying and addressing early challenges with both service delivery and logistics.
- Follow-up with the trainees must be completed to evaluate competency.
Additional reflections—Impact of Innovation Fund

- Project raised awareness early on among donors and implementing partners
- Small working group being launched with other organizations planning for product introduction to share lessons learned
- Project addresses all four of strategic pillars of Coalition
Thank you!

**Project team:**
Tracey Brett
Drinda Benjamin
Benard Chiriswa
Jesee Njunguru
Claire Pascual
Kate Rademacher
Marsden Solomon
Andree Sosler
Markus Steiner
Sally Stephens