Contraceptive Microarray Patch (MAP) Development at FHI 360

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Treatment Action Group Webinar
Community Engagement on Microarray Patches
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FHI 360 is a Global NGO working in 60+ countries

Vision
We are working to create a world where opportunity is within reach for all people.

Mission
FHI 360 advances equity, health and well-being through data-driven, locally led solutions — so that humanity thrives.

MAIN OFFICES

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<thead>
<tr>
<th>U.S. Offices</th>
<th>U.K. Office</th>
<th>East and Southern Africa Regional Office</th>
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<tbody>
<tr>
<td>Durham, NC (Headquarters)</td>
<td>London, England</td>
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U.S. Offices: Durham, NC (Headquarters), Washington, DC, New York, NY


Asia Pacific Regional Office: Bangkok, Thailand

East and Southern Africa Regional Office: Pretoria, South Africa

West Africa and Middle East Regional Office: Washington, DC
To expand knowledge about and access to desirable, affordable, quality, voluntary family planning options that better meet people’s changing needs and desires throughout their reproductive lives, with a focus on developing and introducing innovative contraceptive technologies in LMICs.

Product Development and Introduction (PDI) Goal
Beginning with the End in Mind

- Focus on users’ needs and desires
- Understand relevant delivery contexts and issues
- Make evidence-based decisions and learn from past research
- Keep cost in focus to ensure global access
Successful partnership are the core of our model

We engage nearly 100 organizations and consultants globally, and actively manage each project to advance product development goals.
### FHI 360 Contraceptive Product Development Portfolio by Development Stage

<table>
<thead>
<tr>
<th>Early R&amp;D</th>
<th>Development</th>
<th>Pre-Clinical</th>
<th>Clinical Phase 1</th>
<th>Clinical Phase 2</th>
<th>Clinical Phase 3</th>
<th>Regulatory</th>
<th>Introduction/Scale-Up</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Microneedle Patches</td>
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Contraceptive MAP Value Proposition

- Truly innovative, discreet, user-controlled method
- Potential for self-administration or administration by minimally-trained personnel
- Less painful than existing injectable products
- Small packaging simplifies storage and distribution
- No sharps waste eliminates potential for needle reuse
Contraceptive MAPs

• Collaboration with Georgia Tech

• Biodegradable microneedles (MNs) loaded with levonorgestrel (LNG)

• Upon application, MNs break away from patch, embed in skin, and slowly-release LNG over the target duration of 3-6 months

• Considerations for prototype development
  – Formulation for extended drug release of LNG
  – Sharp tips and mechanical strength for insertion into skin
  – Patch backing that facilitates rapid separation from MNs
  – Acceptable size of MN and patch that can accommodate dose of LNG
User Preferences for a Contraceptive MAP

Evidence from India and Nigeria
Study Design

Qualitative Phase

INDIA
- 10 focus groups, 44 women
- 10 interviews with women
- 10 interviews FP providers

NIGERIA
- 10 focus groups, 50 women
- 10 interviews with women
- 10 interviews FP providers

Quantitative Phase

Discrete Choice Experiment (DCE) to quantify the relative importance of MAP attributes

INDIA, N=496
- 22% never used a method
- 28% sterilized, never used
- 50% ever used a method

NIGERIA
- Sample 1, N=530
  50% never used a method
- Sample 2, N=416
  50% never used a method
Study Design: Characteristics/topics discussed in the qualitative phase

- Perceived benefits/drawbacks
- Size
- Administration (self vs provider)
- Pain
- Potential skin reaction
- Location of application
- Wear time

- Frequency of administration
- Side effects
- Packaging
- Disposal
- Storage
- Cost
- Potential for discreet use
Study Design: Attributes and levels included in the DCE survey

**Pain at application**
- No pain
- Like light pin prick
- Like hard pin prick

**Skin reaction at application**
- Rash for one day
- Rash for three days

**Location of application**
- Wrist
- Knee
- Top of foot

**Size of cMNP**
- Small
- Medium
- Large

**Duration of effectiveness**
- One month
- Three months
- Six months

**Effect on menstruation**
- No effect
- Irregular period
- Amenorrhea
Qualitative Findings

- A contraceptive MNP is of interest to women
- Interest in self-use was relatively high, especially in India, but with a preference for application by a provider the first time
- Providers were less supportive of self administration than most women
- Women and providers favored durations at least equivalent to the three-month injectable, and wanted no or minimal side effects
- Views on patch size and location of application were related to the potential for a localized rash and pain, with a desire to permit discreet use and minimize pain
DCE Findings: Relative Importance of Attributes

**INDIA**

- **Menstruation (53%)**
  - Should not impact Menstruation
  - "A lot of time when you take contraceptive methods, it affects the menstruation of that woman. So some gets less bleeding and some bleed a lot. This shouldn't happen."
  - Woman, age 26, never used contraception

- **Duration (14%)**
  - Preference for Longer Duration
  - "If any mother uses this then she would like to be free [of worry about contraception] for six months she doesn’t want to go every month to doctor..."
  - Family Planning Provider

- **Pain (8%)**
- **Rash (8%)**
- **Location (9%)**
- **Size (8%)**

**Desire for Discreet use**
- "The mark (skin reaction) is something that might make it difficult to hide the use of this method. But it can be avoided by applying it at a place that is not visible to others."
- Woman, age 30, condom user

**NIGERIA**

- **Menstruation (42%)**
  - Fear of needles / Pain
  - "Many women are scared of needles. And if we say that needle-prick-pain will happen, many women won’t accept it."
  - Family Planning Provider

- **Duration (24%)**

**Sample 1**
- 6 attributes

**Sample 2**
- 5 attributes
Conclusions

• A contraceptive MNP is of interest to women and may offer women an appealing new contraceptive option.

• Women would prefer a small, long-acting contraceptive MNP to be applied in a discreet location, which would cause minimal skin reaction, and not affect menstruation.

• Desire for no menstrual side effects was the most important driver of product preference in both contexts, though stronger in India.

• Product developers should explore formulations that mitigate potential menstrual side effects and last longer than one month.
Thank You!

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