Depo-subQ in Uniject: Long Road to a Game-Changer
2011 International Conference on FP
November 30, 2011

Jeff Spieler
Senior Technical Advisor for Science and Technology
Office of Population and RH
Bureau for Global Health
USAID/Washington
Program:

- Introduction, Overview and History – Jeff Spieler
- Family Planning Use and Need in Africa
- Facilitating Country Introduction – Sara Tifft
- Acceptability Research (planned) in Senegal and Uganda – Holly Burke and Bocar Mamadou Daff
- Home and Self-Injection: A Game Changer? – Bonnie Keith and John Stanback
- Discussion
New formulation of Depo-Provera: Depo-subQ Provera 104, for delivery with Uniject

Potential “home run”

Depo-subQ Provera 104:
- New formulation for subQ injection
- 30% lower dose (104 mg vs. 150 mg)
- Rapid onset of action
- Same effectiveness, same length of protection (>3 months)
- Approved by USFDA (2005) and EMA/UK

Uniject:
- Single dose, single package
- Prefilled, sterile, non-reusable
- Short needles for subQ injection (easier use by non-clinical personnel/CHWs)
- Compact; easy to use and store
- Potential for home- and self-injection
- Approval by EMA and LDC registration forthcoming
- PK study completed for injection in arm; Acceptability studies to begin in early 2012; Available for roll-out in late 2012-2013
The LD Formulation of Depo-Provera Is Efficacious at Lower Peak Concentrations

Pharmacokinetic Profiles of the LD Formulation of Depo-Provera and Depo-Provera Contraceptive Injection

MPA Serum Concentration (ng/mL)

Time (days)

Depo-Provera (n=8)
LD Formulation of Depo-Provera (n=42)

LD = lower dose.

Data on file.
DMPA IM vs. depo-subQ in Uniject

**DMPA IM 150**
- 150 mg MPA
- Delivered every 3 months
- Glass vial with auto-disable syringe
- 1” needle
- Intramuscular injection
- Site: deep muscle tissue
- 99% contraceptive efficacy
- Depo-Provera brand: manufactured by Pfizer
- Generic equivalents

**Depo-subQ Provera 104**
- 104 mg MPA
- Delivered every 3 months
- Prefilled in Uniject injection system
- 3/8” needle
- Subcutaneous injection
- Site: subcutaneous fat
- 99% contraceptive efficacy
- Pfizer product: Patent until 2020
- No other manufacturer
Non-clinic access using depo-subQ in Uniject

Features
- Single, exact dose, all-in-one presentation
- Subcutaneous injection
- Simplified injection procedures
- Simpler, shorter training
- Eliminates mismatch of syringe/vial supplies

Benefits
- Reduced weight and volume
- Non-reusable
- Easier to transport and store, less waste to dispose
- Improved injection safety

Value
- Increased acceptability and use by lower-level health care workers
- Uniquely suited to home and self-injection
## Depo subQ in Uniject Timeline - Development Milestones

<table>
<thead>
<tr>
<th>Year</th>
<th>Uniject Milestones</th>
</tr>
</thead>
<tbody>
<tr>
<td>1989</td>
<td>• PATH licenses Uniject design to Horizon Medical, Inc.</td>
</tr>
<tr>
<td>1992</td>
<td>• FDA approved Depo-Provera on October 29, 1992</td>
</tr>
</tbody>
</table>
| 1995 | • Initial business analysis/feasibility of Depo Provera in Uniject was started  
      • Pharmacia AB and The Upjohn Company merge to form Pharmacia & Upjohn |
| 1996 | • PATH and Horizon Medical jointly license Uniject to BD |
| 1997 | • PATH and USAID begins early work with Pharmacia & Upjohn to package DMPA 150 mg in Uniject |
| 2000 | • Pharmacia & Upjohn merge with Monsanto and Searle creating Pharmacia  
      • Initial efforts by Pharmacia to package DMPA in Uniject were suspended due to problems associated with reaching acceptable shelf life stability  
      • Pharmacia begins work to incorporate Uniject into reformulation of DMPA for subcutaneous administration |
| 2003 | • Pharmacia merges with Pfizer, Inc. |
| 2004 | • Clinical studies establish depo-subQ provera 104’s contraceptive efficacy in prefilled glass syringes |
## Depo subQ in Uniject Timeline - Development Milestones

<table>
<thead>
<tr>
<th>Year</th>
<th>Uniject Milestones</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2005</strong></td>
<td>• Depo-subQ provera 104 in prefilled glass syringes approved by USFDA</td>
</tr>
<tr>
<td><strong>2007</strong></td>
<td>• Sayana® (depo-subQ provera 104 in prefilled glass syringe) approved by Medicines and Healthcare Products Regulatory Agency (MHRA) and the European Medicines Agency (EMA)</td>
</tr>
<tr>
<td><strong>2009</strong></td>
<td>• PATH, with BMGF funding assesses eight potential early introduction countries, and with global TAG, identifies five focus countries: Kenya, Malawi, Pakistan, Rwanda, and Senegal</td>
</tr>
</tbody>
</table>
| **2010** | • Pfizer submits depo-subQ provera 104 in Uniject to MHRA/EMA for regulatory approval  
• With funding from BMGF and USAID, PATH and FHI360 develop collaboration to plan for the conduct depo-subQ in Uniject acceptability and operational research in Uganda and Senegal  
• JHU SPH develops research project to compare Depo subQ in Uniject with Depo IM in HIV+ women in Rakai, Uganda – to begin in early 2012 |
## Depo subQ in Uniject Timeline - Development Milestones

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<tr>
<th>Year</th>
<th>Uniject Milestones</th>
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</table>
| 2011    | • FHI undertakes a pharmacokinetic (Pk) study of depo-subQ provera administered in the back of the upper arm  
          • Conditional MHRA/EMA regulatory approval received in mid-2011; final approval conditioned on completion of online training materials and completion of process validation (PV) batches; anticipated date TBD.  
          • Country-level registration submissions begin following final EMA approval  
          • Acceptability studies and operational assessments approved for conduct in Uganda and Senegal |
| 2012-2013| • EMA approval expected  
          • Acceptability studies conducted and completed  
          • Country registrations begin  
          • Product rollout anticipated in 2013 |
Facilitating country introduction of depo-subQ in Uniject

Sara Tifft, MBA
Senior Program Officer, Reproductive Health Global Program

2011 International Conference on Family Planning

Depo-subQ in Uniject: Long Road to a Game Changer
Facilitating country introduction

- Country introduction planning
- Demand modeling
- Logistics assessment
- Identifying target markets
- Opportunities and challenges
- Next steps
Country introduction planning

Eight initial assessment countries
Bangladesh
Kenya
Ethiopia
Rwanda
Senegal
Nigeria
Malawi
Pakistan

Five early introduction countries
Kenya
Rwanda
Senegal
Malawi
Pakistan

Criteria for five early introduction countries identified

Support
• Government supports family planning and product.
• Supporting sponsors and partners in country.

Access
• Country conditions enable depo-subQ in Uniject to support community-based and broader access to injectable contraceptives:
  – Government policies support CBD.
  – Product may influence CBD acceptability or policies.
Country assessments: Lessons learned

• Strong interest in product among ministries, nongovernmental organizations, and donors.

• High levels of price sensitivity:
  – Growing demand for injectables putting pressure on limited reproductive health commodity budgets.
  – Worldwide market reference prices falling.

• Evidence needed:
  – With expansion of non-clinic delivery of DMPA IM, what is the added value of the depo-subQ provera 104™ in the Uniject™ injection system (depo-subQ in Uniject)?
    ▪ Improve access by accelerating non-clinic access to injectables?
    ▪ Reduce delivery costs?
    ▪ Open up new delivery paradigms—home-self-injection?
Demand modeling

Depo-subQ in Uniject uptake variables:

- **Displacement** (cannibalization) of DMPA IM.
- **Switching** from other methods.
- Community-based **distribution**.
- International procurement **price**.

Introduction dynamics:

- Depo-subQ in Uniject alone not a game changer, but could accelerate existing trends in family planning uptake.
- Highlights strategies for highest impact:
  - New users.
  - Non-clinic settings.
  - Home and self-injection.

**Depo-subQ Provera 104™ in Uniject**
**Market Estimation Model**

Projection of depo-subQ in Uniject Use in Five Countries

Prepared by Futures Institute
For PATH
November 2009–May 2010
Demand model estimates for depo-subQ in Uniject use derived from market growth and displacement.
Demand model limitations

- Do not distinguish clinic and non-clinic delivery channels:
  - In markets with adequate distribution of DMPA IM, depo-subQ in Uniject’s greatest value may be in non-clinic settings.

- No accounting for supply constraints:
  - Depo-subQ in Uniject production capacity will increase gradually.
  - Displacement strategy not feasible or desirable.
  - Procurement price acts as a supply constraint.

- No accounting for donor and government funding constraints:
  - More realistic to compare potential market size with the availability of funds for injectable contraceptive procurement.
Comparative analysis

by PATH and John Snow, Inc. logistics team
Logistics assessment

- Conduct a quantitative and qualitative analysis comparing logistics differences between depo-subQ in Uniject and DMPA IM with needle and syringe.
  - Quantitative model for global shipping costs.
  - Qualitative data on in-country logistics benefits.
Bundling and syringe availability

- Most key informants: syringe availability at point-of-use not a major issue.
- But, evidence of continuing problems in Ethiopia, Malawi, Madagascar, Nigeria, Senegal, and Rwanda.
- “Integrated” injection system ensures syringe and needle availability at point-of-use.
Freight savings (international)

For 200,000 vials packed with AD syringes and safety boxes/200,000 units of depo-subQ.

- 62% lighter
- 25% smaller

Depo subQ  Depo-Provera
Freight (international) savings for different proportions of DMPA as depo-subQ in Uniject for 2009

<table>
<thead>
<tr>
<th>Country</th>
<th>Proportion of DMPA as depo-subQ in Uniject</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>100%</td>
</tr>
<tr>
<td>Kenya</td>
<td>$130,346</td>
</tr>
<tr>
<td>Malawi</td>
<td>$120,157</td>
</tr>
<tr>
<td>Pakistan</td>
<td>$56,911</td>
</tr>
<tr>
<td>Rwanda</td>
<td>$33,048</td>
</tr>
<tr>
<td>Senegal</td>
<td>$49,722</td>
</tr>
<tr>
<td>Global</td>
<td>$3,276,891</td>
</tr>
</tbody>
</table>

Reproductive Health Initiative shipment data; savings vary due to share of air/ocean.
In-country distribution savings

- There will be economic cost savings, but they cannot be easily quantified.
- Most in-country supply chains charge per value of goods.
- So savings will accrue but to whom?
- In Zimbabwe:
  - Distribution costs = US$289 /m³.
  - So to ship 1,000,000 vials as depo-subQ = US$10,000 savings (25%).
Other in-country logistics savings

<table>
<thead>
<tr>
<th>Function</th>
<th>Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procurement and forecasting</td>
<td>Marginal since almost always done together.</td>
</tr>
<tr>
<td>Storage</td>
<td>Lighter, smaller: save on space, lighter pallet racking, easier handling.</td>
</tr>
<tr>
<td>Inventory management and LMIS</td>
<td>Fewer items to manage (ordering, recording, etc.): Substantial benefit if program manages few items.</td>
</tr>
<tr>
<td>Distribution</td>
<td>Economic savings due to weight and volume.</td>
</tr>
<tr>
<td>Vial caking</td>
<td>No possibility.</td>
</tr>
</tbody>
</table>
Community-based distribution

- As for service delivery for community-based distribution, benefits here may be substantial:
  - Community health workers often carry their products.
  - Storage space is likely limited.
  - Important to minimize number of items; eliminating one item is potentially significant.
  - Injection safety.
- Product is more likely to not be left behind!
Identifying target markets: Country and delivery settings for depo-subQ in Uniject

2011 International Conference on Family Planning

*Depo-subQ in Uniject: Long Road to a Game Changer*
Identifying target markets for impact

**DEMAND**
- Strong current and future demand for injectables.
- Non-clinic access helps fill the gap: new users, improved continuation.

**DELIVERY**
- Constraints to non-clinic access: Service points, policies.
- Depo-subQ in Uniject: Part of the solution to non-clinic access constraints.

**MARKETS**
- Country market opportunities: Need, market size, non-clinic access stage.
Current injectable prevalence and number of users

![Graph showing current injectable prevalence and number of users for various countries with specific data points for countries like Kenya, Ethiopia, and Nigeria. The graph includes prevalence rates and the total number of injectable users.]

*All modern methods except injectables (yellow bar).
Intent to use in the future:
Number of potential new injectable users

*Potential new users of all methods except injectables (yellow bar), ^Potential new users of injectable data is not available for Pakistan.
Need for non-clinic access: Limited service points, human resource constraints

Among the 47 countries in sub-Saharan Africa:

- These 47 countries have 33% of the global burden of maternal, newborn, and child disease.
- But have less than 3% of the global health workforce.

Worldwide, there is a **4.2 million shortage**\(^1\) of skilled, motivated, and supported health workers:

- Rural populations have few service delivery points.
- Urban poor have limited access to skilled providers.

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Non-clinic access stage

- Reviewed non-clinic and community delivery systems for family planning.
- Categorized by stage of non-clinic access to injectables specifically.

<table>
<thead>
<tr>
<th>National</th>
<th>Pilot/Scaling</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>Benin, Cameroon, DRC, Liberia, Mali Mozambique, Senegal*, Tanzania, Zimbabwe</td>
<td>Benin, Cameroon, DRC, Liberia, Mali Mozambique, Senegal*, Tanzania, Zimbabwe</td>
</tr>
<tr>
<td>Pakistan</td>
<td>None</td>
<td>None</td>
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</tbody>
</table>

- Established national-level systems for non-clinic access to family planning.
- Delivery of injectables through national system in place and scale-up are underway.
- Clear policies and guidelines.

- Established national and/or regional NGO systems in place, not delivering injectables at scale; or injectable pilots completed and evaluated.
- Policies and guidelines variable.

- No national non-clinic access systems for FP and/or injectables.
- Policies and guidelines unclear or generally not supportive of non-clinic access to injectables.

*Senegal MOH approved CBD of injectables through a national CBD program, but it has not yet been piloted or rolled out.
Analysis

Data from 21 countries

Access framework

- Market size
- Need
- Non-clinic access

Highest impact country and delivery settings
Non-clinic access stage: Pilot/scaling

- National community health worker (CHW) program for family planning by province. One CHW/20 households (100 people). Under USAID APHIA III project.
- Pills, condoms: door-to-door.
- Referrals for injectables.
- 31 CHWs allowed to deliver injectables on pilot basis.
- Scale-up recommended per pilot evaluation.

Country example: Kenya key statistics

Population
(Women 15-49)
9.4 Million

CPR*
39.4%
3.7M

No Use
60.6%
5.7M

Injectable
55%
2M

Other
45%
1.7M

Intend to use
55%
3.1M

Intend to use injectables
52%
1.6 Million

Injectable Prevalence: Urban/Rural

22%
24%
21%

Total Injectable
Urban
Rural

Injectable Prevalence: Wealth Quintile

22%
12%
23%

Total Injectable
Lowest Quintile
Highest Quintile

Intent to Use Injectables

52% of potential new users

* Modern methods only
Opportunities and challenges

• Depo-subQ is a new product—but is not differentiated from the current standard.
  – Price continues to be a challenge.

• What benefits would merit differential pricing?

• Will non-clinic access continue to change so that depo-subQ in Uniject offers less value over time?
  – Data needed?

• Would depo-subQ in Uniject be of more benefit in low-injectable prevalence settings?
Next steps

• Continue work toward win-win price and volume scenarios with Pfizer.

• Complete regulatory steps to country registration.

• Undertake rigorously evaluated initial market introductions: document costs, benefits, and impact on new and continuing users.
Conclusions

- Country assessments, demand modeling, and logistics assessments: information for developing market identification framework.
- Depo-subQ in Uniject is expected to add the most value in non-clinic access, including community-based distribution and potentially home/self-injection.

Thank you!
Acceptability of depo-subQ in Uniject in Senegal and Uganda

Holly Burke, PhD, MPH, FHI 360
Bocar Mamadou Daff, MD, MPH, MSc, Ministry of Health, Senegal
Anthony Mbonye, MD, PhD, Ministry of Health, Uganda
John Stanback, PhD, FHI 360
Research question

- Is Depo-subQ in Uniject acceptable to family planning (FP) providers and clients?
Objectives

- Measure the acceptability of Depo-subQ in Uniject among DMPA IM family planning clients;

- Measure the acceptability of Depo-subQ in Uniject among family planning providers—both clinic-based and community health workers (CHWs);

- Assess family planning providers’ (clinic-based and CHWs) training materials
Inclusion criteria for receiving Depo-subQ in Uniject

• Age 18-40 years
• Using DMPA continuously for at least 9 months
  – New users may react to side effects of DMPA, not to the Uniject compared with IM delivery
• Received their most recent DMPA injection 3 months ago at a study facility or from a study provider
• Desires to be re-injected with DMPA
• Willing to receive Depo-subQ in Uniject instead of DMPA IM
Study sites

- Senegal: 1 health center and 3 health posts in the Thies, Mbour and Tivaouane Districts (total 12)
- Uganda: 2 health facilities in Mubende District and 3 facilities in Nakasongola District (total 5)

Aissatou Coly, 2011
Recruitment

- Study providers will recruit their own DMPA clients
- Exception: Senegal CHWs don’t have DMPA clients
- Senegal CHWs will participate in the study at one of the 9 health posts under the supervision of the nurse/mid-wife at that post
- Senegal CHWs will administer Depo-subQ in Uniject to DMPA clients who are recruited by a clinic-based study provider
Study design: Senegal

**Study Designflow:**

**Baseline**
- CHWs: n = 40
- Clinic Providers: n = 20

**Training**
- Interview

**Offer Depo-subQ**
- CHW Clients
  - Refuse: n = 50
  - Receive Depo-SubQ: n = 240
    - (~3 injections/CHW, ~6 injections/clinician)

**Follow-up**
- >3 Months Interview

**Confirmation**
- 3 Months Interview
Study design: Uganda

- CHWs
  - n = 40
  - Both programs
    - Training
      - Baseline
        - Post-training evaluation and interview
      - Interview
    - Follow-up
      - >3 Months
        - Interview

- CBD clients
  - Both programs
    - Offer Depo-subQ
      - Refuse
        - n = 50
      - Receive Depo-SubQ
        - n = 120
          (~3 injections/CHW)
      - Confirm Choice
        - 3 Months
          - Interview

Pre-Injection Measure
Post-Injection Measure
Measurement: Client acceptability

- 3 months after trying Depo-subQ in Uniject, % of clients who declare they would select Depo-subQ in Uniject for their next injection if it was available
- Reason(s) for selecting one method over the other
- Number and type of advantages and disadvantages expressed about the method
- Level of ease/nervousness prior to the injection
- Degree of pain (if any) felt during and after the injection
- Degree of skin irritation and soreness (if any) at the injection site
Measurement: Provider acceptability

- Number and type of advantage and disadvantages expressed about method
- Level of ease or anxiety administering method
- Preference for administering one method over the other
Results will inform product introduction planning

• Global and Country levels
  – Provide evidence to donors and governments about provider and end-user acceptability
  – Provide experience with the product

• Community levels
  – Outreach and communication

• Health facility levels
  – Training, logistics planning and counseling messages
Home and self-injection using depo-subQ in Uniject: A game changer?

Bonnie Keith, MPH, Reproductive Health Global Program, PATH
John Stanback, PhD, PROGRESS Project, FHI 360

2011 International Conference on Family Planning

Depo-subQ in Uniject: Long Road to a Game Changer
Home and self-injection

- Administration of depo-subQ in Uniject:
  - By a third party (e.g., a family member) delivering the injection in a woman’s home.
  - By the woman herself through self-injection.

A way to transform injectable contraception?
- May represent ideal delivery mechanism for depo-subQ in Uniject.
- Increases women’s independence and control over their family planning options.
- Multiple market options and distribution approaches.
- May have a positive effect on uptake and continuation.
PATH literature review

- Review literature on subcutaneous DMPA.
- Compare the subcutaneous and intramuscular (IM) formulations of DMPA.
- Review literature on home administration of injectable contraception:
  - Focus on feasibility and acceptance of self-injection.
  - Emphasis on low-resource countries.
- Identify evidence and knowledge gaps.
- Describe future research needs regarding home and self-injection of depo-subQ in Uniject.

Subcutaneous vs. intramuscular injection

Subcutaneous injection offers benefits over IM:

- Fewer landmarks required for targeting injection sites
- Shorter needles can be used (3/8 to 5/8 inch)
- Readily self-administered
- Muscle mass not an issue

Existing evidence

- Self-injection is common for patients with conditions such as diabetes, multiple sclerosis, and infertility.

- Three studies reviewed home delivery of medicines in Uniject in Indonesia:
  - Researchers found the delivery system to be simple, easy to learn, acceptable to recipients, practical, cost effective, and safe.¹⁻³

Women can self-inject correctly and safely with Uniject

Brazil (1997)
88 women were trained to use Uniject to self-administer Cyclofem

- 90% were able to correctly self-inject with Uniject monthly for three consecutive months.
- 57% reported they wished to continue after the end of three months.

Depo-subQ in Uniject is uniquely suited to home and self-injection.

Considerations for use

• Training
• Storage
• Safe injection and waste management
• Supply infrastructure
• Policy environment
Literature review findings

- Home and self-injection of depo-subQ in Uniject may be both feasible and acceptable.

- Research needs (gaps) identified:
  - Assess the acceptability of home and self-injection using depo-subQ in Uniject.
  - Assess the training, systems, policies, and infrastructure necessary to sustainably implement a home-based delivery program for depo-subQ in Uniject, including self-injection.
  - Assess storage and waste disposal requirements and options for depo-subQ in Uniject in a home setting in developing countries.
Home and self-injection: Qualitative assessment objectives

• To explore perceptions of home and self-injection of depo-subQ in Uniject.

• To understand the home and self-injection policy environment, and explore how it will support or hinder home and self-injection options for depo-subQ in Uniject.

• To identify the key considerations and optimal conditions for effective training, storage, systems management, and waste disposal of depo-subQ in Uniject.
Data collection methods

Methods:
Individual interviews and focus groups.

Populations:
• Family planning users and non-users.
• Health care providers.
• Key informants.
Country identification process

Status of community-based access to injectables (CBA2I)

1. Active community-based distribution of injectables.

2. Policies in place allowing community health workers to provide injectables.


Sub-Saharan Africa
Identified country

Ethiopia

• Nationalized, government-supported CBA2I program.
• Innovative non-clinic access policies.
• High volume potential.
• Policy change may be feasible.
• Research process manageable and support available.
## Timeline and next steps

<table>
<thead>
<tr>
<th>Activity</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submit application to PATH Research Determination Committee</td>
<td>November 2011</td>
</tr>
<tr>
<td>Submit to PATH Research Ethics Committee</td>
<td>December 2011</td>
</tr>
<tr>
<td>Select research firm and consultants in country.</td>
<td>December 2011</td>
</tr>
<tr>
<td>Finalize study sites and assessment tools.</td>
<td>December 2011</td>
</tr>
<tr>
<td>Submit study design and instruments to in-country IRB</td>
<td>December 2011–January 2012</td>
</tr>
<tr>
<td>Training and data collection.</td>
<td>February 2012</td>
</tr>
<tr>
<td>Data analysis.</td>
<td>March–June 2012</td>
</tr>
<tr>
<td>Disseminate report.</td>
<td>September 2012</td>
</tr>
</tbody>
</table>
Rapid assessments

Kenya, Senegal

- Urban settings.
- Explore private sector provision.
- Variation in community access status.
- Focus countries for PATH’s depo-subQ in Uniject project.
Ongoing research “Late-Breakers”

- Prabhakaran & Sweet: “Self Administration of Subcutaneous Depot Medroxyprogesterone Acetate: A Pilot Observational Study of Feasibility and Acceptability”
  - Located – Florida, USA
  - Sample size = 50
  - Results –
    - DMPA-SC continuation at injection three: 86%
    - Preliminary conclusion: “Continuation was high with DMPA-SC self-injection. Subjects found injection easy, convenient, and are likely to recommend self-injection to other women. A 15-20 minute education session is adequate to allow for successful self-administration.”
### Participant attitudes toward self-injection (by injection)

<table>
<thead>
<tr>
<th>Easy</th>
<th>Convenient</th>
<th>Recommendable</th>
</tr>
</thead>
<tbody>
<tr>
<td>94%</td>
<td>98%</td>
<td>98%</td>
</tr>
<tr>
<td>80%</td>
<td>93%</td>
<td>93%</td>
</tr>
<tr>
<td>98%</td>
<td>98%</td>
<td>98%</td>
</tr>
</tbody>
</table>

- **Injection 1**: Easy - 94%, Convenient - 98%, Recommendable - 98%
- **Injection 2**: Easy - 80%, Convenient - 93%, Recommendable - 93%
- **Injection 3**: Easy - 98%, Convenient - 98%, Recommendable - 98%
Ongoing research “Late-Breakers”

- Rahman et al.: “Assessing acceptability of subcutaneous contraceptive injection Depo-subQ provera 104™ (Depo-subQ)/SAYANA®, mode of administration and its convenience among the Bangladeshi married women of reproductive age”

- Located – Bangladesh
- Sample size = 606
- Results –
  - Data collection underway
  - Final results expected September 2012
Ongoing research “Late-Breakers”

Beasley, et al.: “Self versus Clinic Administration of Depot Medroxyprogesterone Acetate: A Randomized Controlled Trial”

- Located – Columbia University, New York, USA
- Sample size = 138
- Results:
  - Data collection complete, analysis ongoing
  - Preliminary conclusion: “Self-administration of DMPA-SC is an acceptable and feasible option”
Self versus Clinic Administration of Depot Medroxyprogesterone Acetate: A Randomized Controlled Trial

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INTRODUCTION AND OBJECTIVES

Introduction: In 2001, 49% of pregnancies in the U.S. were unintended, and annually, more than 6 million women are at high risk of unintentional pregnancy because of gaps in contraceptive use. Depot medroxyprogesterone acetate (DMPA) is highly effective, but due to the need for provider administration, access remains a problem. The advent of subcutaneous (SC) DMPA makes administration outside of the clinical setting possible.

Objectives: To evaluate the acceptability and feasibility of self-administration of SC DMPA

METHODS

Eligible women presenting to a Title X family planning clinic who desired to initiate, restart, or continue DMPA use were offered study entry. Participants were randomized to self or clinician administration of SC DMPA. Those randomized to self-administration were taught how to self-inject by the research study coordinator using the “Instructions for Use of depo-subQ provera 104” found in the US Physician Prescribing Information. The participants were supervised in performing the initial injection. Participants able to correctly administer SC DMPA were provided with a second injection for home use in 12 weeks.

RESULTS

229 eligible women were invited to participate and 138 (60%) participated. 91 were randomized to self-administration and all attempted self-injection. 98.9% were able to correctly self-administer SC DMPA.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n (%)</th>
<th>Characteristic</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Racial Group</td>
<td></td>
<td>Highest grade in school</td>
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</tr>
<tr>
<td>White</td>
<td>8 (9)</td>
<td>Grade 0-8</td>
<td>12 (13)</td>
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<tr>
<td>Black</td>
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<td>Some HS</td>
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<tr>
<td>Multiple races</td>
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<td>HS grad/GED</td>
<td>43 (47)</td>
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<tr>
<td>Other</td>
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<td>Some college</td>
<td>15 (16)</td>
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<tr>
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<td>6 (7)</td>
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<tr>
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<td></td>
<td></td>
</tr>
<tr>
<td>Not Hispanic</td>
<td>10 (11)</td>
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CONCLUSIONS

- Self-administration of SC-DMPA is an acceptable and feasible option
- Investigation of continuation rates, patient satisfaction, and predictors of discontinuation is ongoing

REFERENCES

Conclusions

Home and self-injection of Depo subQ in Uniject likely to be:

- Safe
- Acceptable
- Feasible
- A “Game-Changer”