

Depo-Provera in Uniject

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Hi I'm Jim, Science Advisor for the Bureau for Global Health, USAID, and I want to talk to you today about Depro Provera in Uniject.

Office of Population New Technical Priorities

- 1. Contraceptive security**
- 2. Long-term and permanent methods**
- 3. Birth-spacing (HSTP)**
- 4. FP/HIV integration**
- 5. FP/MCH integration**
- 6. Community-based FP (especially Depo)**

To start us off I would first like to list off some of the Office of Populations new technical priorities. They are an innovative and organic organization and they do have new priorities from time to time. I don't want to go through all of them but I want to make the point that the sixth one is community based family planning, especially Depo Provera, and that of course would include public sector provision in the community but also social marketing and even the commercial sector.

Background: Injectable Use

- **Injectable contraception popular and growing**
- **12 million using in 1995, 32 million in 2005**
- **Unmet need is great, especially in Africa**
- **Access is a huge issue**

Now for some more background on injectable use in general. Many of you already know this, but injectable use is really quite popular and it is growing. For example there were 12 million people using injectables in 1995 and that grew to 32 million in 2005. The unmet need for family planning in general is great, especially in Africa, but of course injectable use is quite popular in Africa as well.

CBD Depo

- **Successful experience with community workers in Uganda, Madagascar, Ethiopia, Malawi etc. providing Depo using conventional IM injection**
- **Community worker's provision is just as good quality as higher level workers**
- **Use provider checklist for screening**

There in lies our interest in community distribution of Depo and so far we've had successful experiences with community workers in Uganda, Madagascar, Ethiopia, Malawi, providing Depo using intra-muscular injection. And we found through our research that community workers provision is just as high quality as higher level workers can provide. One of the key parts of that though is to use a provider checklist for screening for eligibility.

Uganda – Community Injection Worker with Clients



Here we have our happy community injection worker with her happy clients.

Madagascar

Supervisor Traveling to Depo CBD Worker



Here is a supervisor in Malawi, traveling to reach her Depo CBD worker. Obviously this is pretty remote.

Sub-Cutaneous Depo

- Easier injection (SC) than IM
- Lower administered dose (104 mg vs. 150)
- Essentially identical effects (e.g. ovulation suppression, return to ovulation)
- FDA approved, but not marketed in U.S.
- Studies of SC Depo for FDA approval were done with conventional syringes

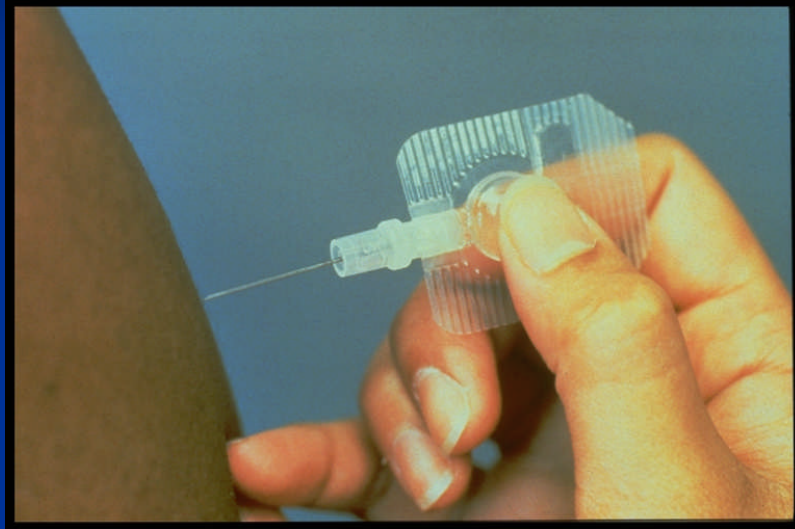
Our story continues now with the development of Sub-Cutaneous (SC) Depo. The idea is to provide it sub-cutaneously, not intra-muscularly. The advantage of that is that it is an easier injection. Many people are able to do sub-cutaneous injections, for example insulin is usually injected sub-cutaneously by diabetics themselves. The way the formulation was developed it actually ended up being a lowered administered dose, 104 mgs vs. 150 mgs. However the effects are essentially the same in that it inhibits ovulation in the same way and return to ovulation is basically the same. This approach was FDA approved by Pfizer but not marketed in the US by Pfizer as yet. The studies for SC Depo for FDA approval were done with conventional syringes, so we are not yet there to the Uniject story.

Depo for SC is a Different Formulation

You can't take regular Depo which has been formulated for IM injection, and just inject a smaller amount SC.

Now please bear in mind that Depo for SC injection is actually a different formulation. You can't just take the regular Depo which has been formulated for IM injection and just inject a smaller amount SC, it doesn't work that way. So that is good for Pfizer because that helps them differentiate their market.

Depo-Provera in Uniject



So now we are going to be talking about Uniject itself, this is a picture of it. Notice that it is just a small little plastic container and a little needle coming out. But there is a little valve in there so that the fluid can only flow in one direction.

Advantages of Uniject

- **One-time use**
- **Simplicity**
- **Used for SC injection**
- **One “thing” vs. vial + syringe**
- **Easier logistics, saves space**
- **Safety (Real and perceived)**
- **Disposal**

Let's talk about the advantages of Uniject. As we have already mentioned there is this one time use feature which is very important. It has a certain simplicity. It can be used for SC injection. You are only dealing with “one thing,” if you will. Rather than having a vial and a syringe and having to load up the syringe, the Depo actually comes in the Uniject. So that gives you easier logistics, and it helps save space. Related to all of this there is also a real safety advantage, but in my view there is also a perceived safety advantage; this cannot be used for IM injection and it just looks fairly unthreatening. Lastly, disposal is easier.

SC Depo in Uniject

- Pfizer strategy to market SC Depo only in Uniject.
- Allows for market differentiation.
- Should be similar price for public sector as current Depo for IM use which includes vial and syringe.

So what is Pfizer's strategy with respect to SC in Uniject? Because they have already got it approved for SC use through syringes, but they have made the decision to only market it in Uniject. That allows them to have really good market differentiation. Now of course price is always an important issue, but we are assuming that price should be very similar for the public sector, and that would include the social marketing sector, as we are currently paying for Depo use IM, partly because we no longer need to have a vial and syringe.

Depo in Uniject Expected in 2010

Awaiting:

- Manufacturing line development
- Additional FDA requirements

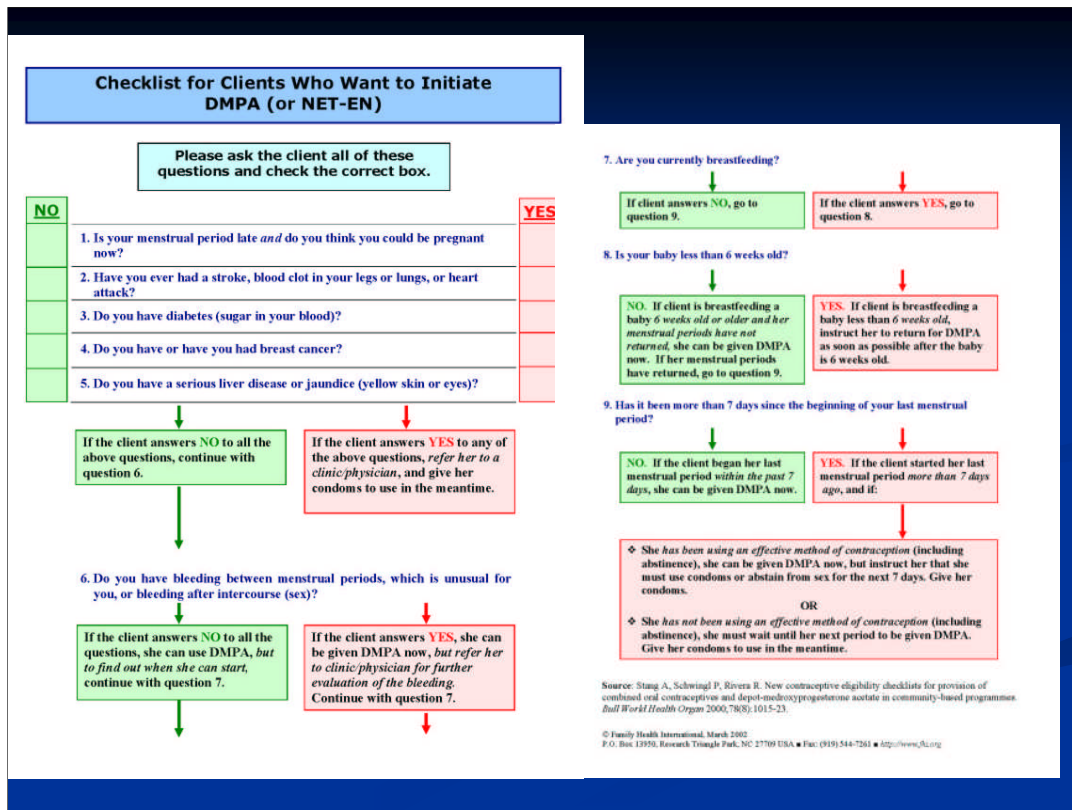
(This is a realistic time projection)

So where is this long expected Depo in Uniject? We are expecting it in the year 2010. We are waiting for two things: first of all Pfizer has decided to have a dedicated manufacturing line, and that really takes a lot of development and quality control, but secondly the FDA is requiring additional human studies just to show the SC use of Depo with Uniject is the same as with a syringe. Based upon my conversations with Pfizer this is a realistic time projection.

Depo in Uniject Ideal for Social Marketing

- Safe
- Effective
- Easy product to keep and store
- Good demand
- Reasonably priced
- Can be provided by trained “lay” providers using checklist
- Counseling about bleeding disturbance side effects is key

So what about social marketing? Our view is that this really is an ideal product for social marketing. It's safe, effective, easy to keep and store, there is good demand for it, it should be reasonably priced, and it could be provided by a trained “lay” provider – as long as they use the checklist and that could include a pharmacist or a chop keeper and the like. Of course a really key thing about providing Depo Provera is counseling the clients about the potential bleeding disturbances that do often occur with its use.



This is a slide of the famous checklist. Notice that it is divided into two parts. The first part is the eligibility criteria, things like breast cancer or jaundice which are really not very common. The second part has to do with determining in a reasonable way that the client is not pregnant, the so-called “pregnancy checklist” part, and it’s actually fairly simple.

What now?

- **Pfizer is currently negotiating marketing agreements (e.g. Senegal)**
- **Social Marketing Programs should be making preparations for Depo in Uniject.**

What now for social marketing? One of the really nice things about this is that it does Pfizer is going to be fairly assertive or you might even say aggressive, about trying to market Depo in Uniject, and we understand that they are already currently trying to negotiate marketing agreements, for example we heard that in terms of Senegal. But the bottom line is that social marketing programs should be making the preparations for Depo in Uniject.

I look forward to discussing all this with you in the discussion area.

Thank you!