Q: What contraceptive method is most commonly used in Indonesia?

(Hint: It is also the most commonly used in Kenya - another family planning “success story”)

SEE BELOW

Space so you are not tempted to look at the answer too soon.

A: Injectables. Injectables are clearly the up-and-coming method globally. According to the 1997 DHS, 21% of married women in Indonesia were using injectables. (Overall modern method prevalence was 55%.) In Kenya in 1998, 12% were using injectables, while total modern method prevalence was 32%. Interestingly, in both countries pills were second (15% in Indonesia and 9% in Kenya.)
Q: In helping clients select their contraceptive method, I’ve noticed that most clients already have a method in mind when they come for services. Recently several clients with acne have told me they want to try oral contraceptives to improve their acne. Can acne really improve when women take OCs?

A: Yes, though not always. For one of the newer OCs marketed in the United States containing the progestin norgestimate, the improvement in acne has actually been demonstrated in a careful placebo-controlled trial. Other studies however have also found an average improvement in acne with other OC formulations, including the OC formulation USAID provides. Not all women have their acne improve on OCs however, and for some it actually gets worse. So clients have to see for themselves if OCs help their acne.
Q: My girlfriend and I are having an argument. She says that LAM (Lactational Amenorrhea Method) is a more effective contraceptive than the pill. I can’t imagine where she got that idea. The pill has to be more effective. Who’s right?

A: You both are. It depends upon whether you are talking about “Perfect Use” (Used correctly and consistently) or “Typical Use” (As commonly used.) With perfect use, OCs have a lower failure rate - 0.1% for 12 months for OCs vs. 0.5% for LAM for 6 months. On the other hand as commonly used LAM has a lower failure rate (2%) and the failure rate for OCs is surprisingly high (6-8%). Thus in the “real world” situation, LAM is actually more effective.

Of course the main point is not which is more effective, they are used in different situations. Importantly, BOTH are effective, especially when good counseling is provided.
Q: OK, you’ve convinced me that LAM is an effective method, but very few women in my country exclusively breastfeed for very long, so I can’t see that it has much place here.

A: Actually, that’s part of the beauty of LAM. Women DON’T have to be exclusively breastfeeding – only “fully,” or “nearly fully” breastfeeding. As long as breastfeeding is the predominant source of nutrition for the infant, that’s enough. Of the three LAM criteria, actually amenorrhea is the most important. Of course exclusive breastfeeding provides major child survival benefits. And some evidence indicates that promoting LAM also tends to improve breastfeeding practice (increasing exclusive breastfeeding as well as more “full” or nearly full breastfeeding,) but exclusive breastfeeding is not a precondition of LAM.
Q. My sister told me she heard that a new pill for emergency contraception was approved by the U.S.F.D.A. Is that true?

A. Yes. It is called “Plan B.” It is a progestin-only formulation with two 0.75 mg tablets of levonorgestrel. As with other ECPs, the first dose needs to be taken within 72 hours of unprotected intercourse and the second tablet is taken 12 hours later. Based on a WHO randomized comparative trial, this formulation is more effective and has fewer side effects (nausea and vomiting) than the conventional “Yuzpe” regimen (e.g. 4 + 4 low dose combined OCs.)

Like the Yuzpe regimen, Plan B’s effectiveness decreases over time, so it is best to take EC as soon as possible after unprotected intercourse.
Q: My cousin was in the U.S. last month and bought some spermicidal contraceptive film. She thinks it’s wonderful. I’ve never heard of it before. Is it for real?

A: Yes, Vaginal Contraceptive Film or VCF has been marketed in the U.S. for a number of years. It contains the same spermicide (nonoxynol-9) commonly found in many other over-the-counter (OTC) spermicidal products such as the Conceptrol vaginal foaming tablets that AID provides to programs. VCF is a very thin 2X2 inch nonoxynol-9 impregnated square of film. It is folded over by the client and inserted into the vagina at least 15 minutes prior to intercourse. As with many spermicidal products, it does not have the best contraceptive effectiveness. On the other hand it has a number of important advantages - OTC availability, safety, consumer control etc.
Q: In your last response about Vaginal Contraceptive Film (VCF) you said it does not have the “best” contraceptive effectiveness. But how effective is it really in preventing pregnancy?

A: Actually relatively poor compared to a number of other contraceptive methods, but still much better than no method. Family Health International recently completed an eight-site international study comparing VCF to Conception vaginal foaming tablets (VFT.) The 6-month typical use failure rate for VCF was 24.9% versus 28% for the VFT group (the rates for the two products were not statistically different.) These rates were somewhat higher than expected, which may have been partly due to characteristics of couples selected for the study (e.g. fairly sexually active and prospectively willing to accept the generally low efficacy of spermicidal methods.) Moreover, those few women in the study who reported they did not desire any more children had a failure rate of less than 10% within 6 months.

While these pregnancy rates are high compared to many other contraceptive options, they are considerably better than theoretically expected with no method of contraception - 61%. So these products have a place as a contraceptive option, especially for couples who cannot use other methods or who find other methods unacceptable.
Q: OK, now I know that Vaginal Contraceptive Film (and other spermicides) are relatively less effective than other contraceptive methods. But what about the acceptability? How much do clients like it?

A: At least as well as vaginal foaming tablets and perhaps better. FHI conducted an acceptability study of VCF compared to the Conceptrol vaginal foaming tablets in three developing countries and found that on balance, clients tended to prefer VCF a bit over VFTs. The VFTs were judged a bit more messy and the film more difficult to insert (sometimes sticking to the fingers during insertion.) Of course individual clients’ preferences varied.
Q: This vaginal contraceptive film you have been talking about sounds as if it might be a good substitute for the foaming tablets that USAID currently provides. It seems more acceptable and at least no less effective. Why not change from the tablets to the film?

A: The Agency may. A major additional consideration will be cost, since the current foaming tablets cost the Agency almost twice as much as a condom. Also, changing spermicidal methods would inevitably cause some disruption to clients and programs, so any proposed switch should be carefully considered. USAID’s Office of Population will be consulting soon with missions and others to get their views.
Q. My cousin had Norplant inserted 4 years ago and really likes it. But she can’t remember when it’s supposed to be removed. What is the effective use life of Norplant?

A. Still officially 5 years, but actually 7 years according to the latest clinical data. The Population Council has now accumulated a large amount of clinical trial data showing that Norplant (the current soft-tubing version which has been in use for a number years) is very highly effective through seven years. The Council will be applying to the USFDA shortly to change Norplant labeling to reflect the latest results.
Q. I’m glad to know that the use-life of Norplant is now known to be 7 years, but isn’t there a new version of Norplant? What can you tell me about it?

A. Norplant II or “Jadelle” is very similar to Norplant, but consists of two slightly larger, low-dose progestin-releasing “rods” rather than the 6 “capsules” of regular Norplant. It has actually been approved by the USFDA, but only marketed on a limited basis and not as yet in the US. While the insertion and removal process is essentially the same, the two rods may be somewhat easier to insert and remove than the six capsules, and a newly developed inserter may also improve insertion. The use-life of Jadelle is only 5 years however. The public sector price remains uncertain.

It appears likely that Schering/Leiras (the manufacturer) will want to shift over to Jadelle over the next few years. While Jadelle is very similar to Norplant, such a shift would mandate some significant transitional activities for programs – including training. Actually, however, it is conceivable USAID might want to continue to provide Norplant in view of its longer use life and depending on price. In the meantime it will behoove us to undertake some simple familiarization or Operations Research to better understand the programmatic ramifications of a transition to Jadelle.
Q. While I know about the USAID supported implant contraceptives, NORPLANT and NORPLANT II (Jadelle), I keep hearing something about a single implant contraceptive. What can you tell me about it?

A. The Organon Company has developed and tested a single implant contraceptive for women, called Implanon. It is currently under review for marketing approval with the USFDA. Like the NORPLANT products, Implanon works by constantly releasing a progestin, in this case desogestrel. The duration of effectiveness is currently 3 years.

A recent Chinese study compared Implanon with Norplant. Implanon comes with a new innovative inserter for the single implant, so insertion and removal time were markedly faster with Implanon. Overall, bleeding patterns were fairly similar (often irregular,) but with a bit more amenorrhea with Implanon and higher incidence of “frequent bleeding” with Norplant.

Indications are thus far that Implanon will be more expensive than Norplant, though it is hoped that the availability of Implanon will increase choice and competitiveness of the implant market and help drive product prices down.

(This contraceptive pearl submitted by Dr. Felice Apter)

Q: I’m interested in Natural Family Planning. I understand there may be a simpler version under development. Can you tell me about it?

A: Yes, the “TwoDay” algorithm under development, shows promise as a simpler, easier approach compared to other cervical mucus methods such as the Billings method. Like other cervical mucus methods, it builds on the rather narrow window of a few fertile days during the cycle, and well-established ability of women to learn to perceive secretions coming from the vagina.

The woman asks herself two questions:
1) Did I note secretions today?
2) Did I note secretions yesterday?

If the answers to both of these is NO, it is very probable she is not fertile.

The approach was developed based in part on analysis of over 7,000 historical cycles charted as part of an earlier large WHO study. It appears simpler and easier to learn than previous approaches and avoids “charting” the cycle. It was developed and is being further evaluated by Georgetown University and collaborators.

Q: I know that use of various contraceptive methods varies a lot around the world. But, what country has the greatest number of married (repeat married) women taking Oral Contraceptives? (Hint – since this refers to the number of users, population size is a factor here.)

(Space to prevent inadvertent peeking)

A: Germany, with 7.1 million women using according to an upcoming Population Report on OCs. (If you said Brazil or the U.S. – Good for you too! They are second and third with 6.1 million and 6.0 million respectively.)
Q: I’ve been breastfeeding for 5 months and just recently started taking progestin-only pills (POP’s) for contraception. My neighbor told me that I should switch to combined oral contraceptives (COCs) when I reach 6 months. But I really like the POPs and would like to keep on taking them. Can I continue to take them after 6 months?

A: Yes, as long as you are breastfeeding. In fact, if you are very conscientious about your pill-taking, you can take them indefinitely. While you are breastfeeding, the synergy between the breastfeeding and the POPs results in very high efficacy beyond 6 months. After breastfeeding stops, contraceptive effectiveness declines, but for women who take them consistently and at the same time every day the effectiveness is very good.

Q: The three-month injectable contraceptive Depo-Provera is very popular among the clients we see in our health clinic, but I’ve heard there is also a one-monthly. Is there such an injectable?

A: Yes. Actually there are at least three. An older formulation (sometimes known as Deladroxate) has been manufactured and used in Latin America for many years. Two newer ones have been developed with help from WHO and are being increasingly marketed around the world. The most popular of these is Cyclofem (or Cycloprovera.) It contains the same progestin as Depo-Provera (but at a substantially lower dose) along with a small amount of fairly short acting estrogen. Since these injectable have both a progestin and an estrogen, they are termed “combined” monthly injectables.

Though these injectables require the client to return to the service site on a monthly basis, the addition of the estrogen helps provide more regular bleeding patterns, with less irregular bleeding and amenorrhea.
Q: These monthly injectables sound promising. Are any of them approved by the USFDA?

A: No, but Cyclofem may be approved soon. FDA approval requires that a drug company or some other “sponsor” apply for approval. The Pharmacia & Upjohn company is interested in marketing Cyclofem under the brand name “Lunelle” in the United States and has applied to the FDA for approval. While exact timing is always uncertain with regulatory approval, my reading is that FDA approval should be forthcoming relatively soon.
Q: If Cyclofem or “Lunelle” is approved by the US FDA, does that mean that USAID will supply it, as it does other contraceptive commodities?

A: Not necessarily. Proper introduction of a new method of contraception requires significant care and resources, and USAID “central procurement” of contraceptive commodities requires significant advance planning. In all likelihood, the cost of a single-month dose of Cyclo-Provera would cost in the same neighborhood as a three-month dose of Depo-Provera - with additional service delivery costs and inconvenience to clients. We would need to be assured of a significant improvement in advantage to the client and demand from programs to justify the additional effort and resources in order to add it as a major procurement activity.

But the advent of such a new method certainly merits consideration, including its possible evaluation in “introduction” studies. And even if USAID didn’t provide it, we could still support various programmatic efforts that include it, including social marketing.
Q: Which of the following factors materially related to women’s continuation of the Depo-Provera injectable contraceptive, according to a recent study from Bolivia? (Could be more than 1)

a) Client’s age  
b) Client’s education  
c) Client’s marital status  
d) Type of provider  
e) More than 3 children  
f) Client told about side effects such as amenorrhea  
g) Client told to return to clinic if having problems  
h) Client believed menstruation is necessary for good health


A: e, f, g and h are correct. In this study age, marital status, and education didn’t matter for continuation. Neither did type of provider. As found in a number of other studies, however, whether the client was told about side effects was strongly correlated with continuation. However this study went beyond that variable, to whether the client was specifically told to return to the clinic if having problems (strongly positively correlated) and whether the client believed menstruation is necessary for good health (strongly negatively correlated.) (The correlation with increasing parity probably just reflects increased motivation.)

Take home lesson: Addressing bleeding side effects is crucial for injectable provision including:
1. finding out and addressing clients’ views and feelings about bleeding;  
2. discussing the bleeding side effects, including amenorrhea;  
3. inviting the client to return to the service site if she has problems.
Q: In my country program, we’re doing everything we can to promote condoms, including promoting the concept of “dual protection” against both unwanted pregnancy and STI’s. Some men find condoms very acceptable, but others say they really don’t like the feel of them. Are there any improved male condoms on the horizon?

A: Yes. One seemingly good alternative has been developed by Dr. AVK Reddy of Chennai, India. His initial product, called “Inspiral” has an enlarged portion at the tip end designed to slide back and forth to create added sensation during intercourse. It is FDA approved and marketed in the US, UK and a few other countries. Whether it actually represents a major improvement in sensation remains to be seen, but the product does appear to be selling well. In any case, it represents a “different” product and is likely to attract additional men.
Q: Those new condoms with the expanded end sound interesting. Can I obtain them in the US? What’s the possibility we can get them into our country program?

A: The Inspiral condoms are available for sale in the U.S., though marketing is fairly limited. You might want to have a look at the Condomania web site – www.condomania.com.

Regarding use in programs, since they are not made in the U.S. it is not likely USAID will be providing them directly. However, they might be provided by other donors or bought directly by country programs. Also, use in social marketing programs might be possible wherein a private sector or other partner might provide the condoms and USAID might support the promotion.

And there is more to come! Inspiral is the first of a family of condoms with expanded ends. Three additional FDA-approved condoms - part of a series called “supernaturals”- are in the pipeline.
Q: In my country, IUDs seem to be increasing a bit in popularity, particularly in a number of our clinics where an especially strong emphasis is on quality provision of IUDs. Some of our clinics recommend follow-up every 3 months after the insertion but other providers say so many follow-up visits aren’t needed. So we are wondering, when is it most appropriate to advise clients to return to the clinic for follow-up?

A: At approximately 1 month and also any time the client has problems or questions, or has need of other offered services. While Pelvic Inflammatory Disease (PID) is actually uncommon as a result of IUDs and only increased in women at risk of STIs, the incidence of PID is highest within the first month or so after insertion and falls off very rapidly after that. Other problems such as pain, bleeding and expulsion also tend to cluster within the first month. So it is important to put the emphasis on the 1 month visit and then encouraging and making it easy for clients to return when and if they have specific felt needs. Additional routine scheduled follow-up visits are of low utility and resources can be better used for other services.

References:
Q: Our program receives USAID support for family planning and we are implementing the new certification requirement on abortion resulting from USAID’s Year 2000 appropriation. We’re wondering, however, are our efforts on Postabortion Care (PAC) affected by the legislation?

A: No. USAID’s policy and commitment to PAC remains unaffected. Saving women’s lives from complications of abortion and linking women with needed family planning and other health services remains a high priority, and the program guidance remains the same.
Q: Despite extensive provider training and retraining efforts in the IUD and good supply, few clients receive IUDs in our country. However, we suspect that potential demand for IUDs is high because a few providers have large followings of satisfied IUD clients. Interestingly a “mystery client” study found that most of the time providers don’t even mention the IUD to new clients. Are there reasons why providers avoid the IUD?

A: Yes. Your question points out the importance of the “provider perspective” for programs.

See how many reasons you can think of. (Scroll down for my list. Let me know reasons I may have missed.)

(Scroll down)

(Scroll down)

Possible reasons:

- More work. For example, IUD insertion takes a lot more effort including the preparation than providing pills, injections or condoms.

- Paraphernalia, supplies, equipment are more complex. Getting them all together may be challenging.

- Proper training. Many providers may not have it.

- Low frequency of IUD insertion can contribute to a lack of confidence and lack of competence in IUD insertion skills and contributed to a “vicious cycle” of avoidance.
- Misconceptions. We think of “rumors” among clients in this regard, but providers may have misconceptions of their own. One example may be exaggerated perception of client’s risk of infection with IUDs.

- “Accommodating” perceived client wishes. Clients very often come to a service site with a selected method in mind. Providers may feel it isn’t worthwhile raising many alternatives.

- Social distance. In many cultures differences between the provider and client such as gender, class and caste may discourage the kind of intimate contact required for IUD insertion.

- Personal risk. For example providers may fear they would be exposed to risk of HIV or other infection.
Q: What additional reasons did you hear from Pearl readers as to why providers might avoid IUDs?

A: I got a great response from Pearl readers, with many additional ideas beyond what I came up with. I’ve listed some below. (I’ve taken the liberty to synthesize and recast them. Hope I’ve done them justice.)

- Providers may have a single bad experience with a client receiving IUD such as pain or bleeding and thereafter shy away from IUDs.
- When IUDs are not popular and infrequently requested, it requires a lot of effort to explain the IUD and risks steering clients away from their preferred method. After a while, providers may not make the effort.
- Assuming that everyone is at high risk of STIs/HIV.
- Fear of being blamed (and sued in the case of the U.S.) for PID and later infertility, whether or not the IUD was responsible.
- Residual “stigma” from the Dalkon Shield etc., which just tends to make IUDs less attractive in general.
- Some providers just don’t like clinical procedures.
- Provider shyness about the intimate aspect of the procedure.
- Fear of spousal disapproval (directed to provider.)
- Avoiding even the relatively minor discomfort that some clients have with IUD insertion.
- Service delivery guidelines or common practice that unnecessarily restrict IUD provision (eligibility criteria, when to insert etc.)
- Religious concerns (e.g. that IUD might be an abortifacient)

Really good responses. Thanks to all!
Q: I’ve heard that some of the newer oral contraceptive pills may have a higher risk of thromboembolic disease. Is that true?

A: Yes, it appears so. However, the risk of cardiovascular disease related to low-estrogen OCs is very low and both the older and newer formulations are very safe.

Recall that combined OCs have both an estrogen and progestin component. Relatively recently, some OCs have been introduced containing so-called “third generation” progestins (desogetsrel and gestodene.) These newer progestins were developed, in part, because they offered the prospect of lower cardiovascular risk. Ironically, the preponderance of epidemiologic evidence finds that the risk of venous thromboembolic disease (abnormal excess clotting in the veins) is about twice as high with these newer progestins. However, cardiovascular disease related to the pill is very rare, and the other cardiovascular risks related to OCs (heart attack and stroke) do not appear to be increased more for the third generation progestins. So, even though this difference appears real, it is extremely small in the large scheme of things and no regulatory agency that I am aware of has viewed it important enough to prompt a product withdrawal.

P.S. USAID OCs contain the second generation progestin -- norgestrel.

Q: I know that oral contraceptives reduce the risk of cancer of the ovary, but is that true of the newer lower-dose OCs as well?

A: Yes, according to a recent U.S. study of ovarian cancer. Because of the long incubation period for ovarian cancer, up to now it has been difficult to study the effect of the lower-dose OCs introduced in the 1980s. Now, however, a large “case-control” study of ovarian cancers diagnosed from 1994-99, has sufficient size and time to assess the effect of the low-dose OCs. In the study, low-dose OCs provided the same risk reduction of 50% (odds ratio 0.5, with 95% confidence interval: 0.4-0.6.) that was provided by the older, higher-dose OCs. So, the reduction in risk is both substantial and highly statistically significant.

Q: I understand that there is concern that the common spermicide Nonoxynol-9 (N-9) might actually increase the rate of HIV transmission. Is that true?

A: At the recent AIDS meeting in Durban, South Africa, preliminary data were presented from a UNAIDS trial of an N-9-containing gel in commercial sex workers (CSWs.) Rates of HIV transmission were indeed higher with the product than with a placebo gel. These higher rates were associated with higher rates of vaginal lesions. N-9 is a detergent and is known to be irritating. Some but not all data from other studies among CSWs tend to support such a higher risk of HIV transmission with N-9. However it is not clear that these findings from CSWs (with average intercourse episodes of 3.6 per day in the study) are at all relevant to more typical women using spermicides for family planning on a less frequent basis and thus less irritation. Previous irritation studies of the spermicidal gel had not found significant vaginal irritation under those conditions.

Various health agencies are reevaluating their position on N-9 spermicides, but for the time being none has recommended removal of N-9 products or is discouraging their use among typical family planning users. My own view is that spermicides continue as a valid method, especially if used with other barriers. Diaphragm use with spermicides can be especially effective and theoretically may offer physical protection against HIV. Consistent condom use with or without spermicide is also effective against HIV. On the other hand, spermicides alone are decidedly among the least effective contraceptive methods.