Dedicated postpartum IUD inserter

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Across 27 countries, 65% of postpartum women had a prospective unmet need for family planning.

Challenges include:

- No-show rates for postpartum visits where desire for contraception was previously expressed.
- Access to postpartum family planning (PPFP) services, particularly in rural areas.
- Schedule of postpartum visits not conducive to initiation of some methods.
- Perception about conflicts with breastfeeding.
FP in immediate postpartum period

- Immediate PPFP = provided within 48 hours of delivery
  - Postplacental = after placental expulsion and before patient leaves delivery room
- Women offered FP immediately postpartum are more likely to be using FP six months later
  - Lactational amenorrhea method can work up to 6 months
- Rates of PPFP use increase with each additional method offered to women and couples
- Offering a wide range of methods increases likelihood that one will meet a woman’s particular needs and desires
Immediate PPIUD services: Advantages

- Immediate PPIUD insertion offers several advantages over interval insertion:
  - We **KNOW** the woman is not pregnant!
  - Provider and patient both present
    - “One-Stop Shopping” convenience for women
  - Minimal time investment for insertion
  - Cervix is open
  - Less equipment than for interval insertion
  - Many of the side effects in the early post-insertion period (cramping, heavier menstrual bleeding) are masked by postpartum status
Immediate PPIUD services: Challenges

- Due to the shape and size of the uterus postpartum:
  - Conventional IUD inserters are not long enough to reach the postpartum uterine fundus
    - As a workaround, providers use forceps, removing IUD from inserter sleeve, placing it at the tip of the forceps and then inserting into the uterus
      - Could increase infection rate
      - Not simple or intuitive
      - Special instruments not always available
  - Conventional IUD strings too short to be visible postpartum
    - 25-40% of strings seen at follow-up
    - May require ultrasound or X-Ray to find out if IUD has been expelled
PPIUD technique with forceps
Solution: Dedicated PPIUD inserter

Copper T 380A IUD with Standard Inserter

- Extra-long “sleeve” to ensure that IUD can reach fundus
- Stiff yet flexible “sleeve” can be bent slightly to accommodate shape
- Blue flange keeps strings taut and stabilizes IUD orientation until deployment
- Extra-long string ensures visibility in cervix after insertion

Copper T 380A IUD with Dedicated PPIUD Inserter
Dedicated inserter demo video

https://www.youtube.com/watch?v=1NnNaDlJV_4
Dedicated PPIUD inserter: Advantages

- Strings extra long
- Insertion steps intuitive and are similar to conventional IUD insertion, especially Multiload
- Easier to use for Morning After Delivery Insertion than Forceps since sleeve is narrower
- Flexible but stiff sleeve
- Easily reaches fundus
- Inexpensive: ~ $1.00
- No special instruments
Proof of Concept in India (n=80)

- **Methods**
  - Enrolled 80 women who presented for PPIUD insertion at 2 government hospitals
  - Used dedicated PPIUD inserter in all cases
  - Follow-up and ultrasound at 6 to 8 weeks post-insertion
  - Client and provider surveys

- **Results**
  - Use of dedicated inserter found to be safe
    - High fundal placement in 82% of cases
    - Complete expulsion for 7.5%
    - Asymptomatic partial expulsion for 10%
    - No perforations, infections or other complications
  - 93% of providers found insertions to be easy
  - 74% of clients reported no change in pain level

Sharad et al., Global Health Science and Practice, 2016
Initial results from India RCT (n=186)

- Acceptability: 95% of providers thought insertion was “Easy” (80%) or only had “slight difficulty” (14%)
- Expulsion rate 6%-9%
  - Expulsion associated with distance from fundus
  - 16% including partial expulsion
  - Spontaneous complete expulsion ~6%
- Strings seen at follow-up in 100% of cases in which IUD was present
- >90% of patients satisfied
- NO complications
  - No infections
  - No perforations

Blumenthal et al., Global Health Science and Practice, in press, 2016
Second India RCT: Comparison with forceps

- Non-inferiority study
  - Then will leave it to the market to decide which PPIUD insertion technique is used
- Past midway through recruitment
- Still blinded – no results yet
- Data Safety Monitoring Board examined data thus far and recommended continuing the study
  - No safety issues have emerged
- Plan to present findings at the Federation of Obstetric and Gynaecological Societies of India (FOGSI) in January 2017
How much does expulsion matter?

- Expulsions of PPIUD are generally neither dangerous nor painful
- In many settings the IUD costs less than $1
  - Does not represent a large waste of resources if the IUD is expelled
- Clients nor providers expended any significant extra effort at time of insertion
  - Minimal wasted opportunity costs
- **Continuation** is more important than expulsion
  - “a woman simply cannot continue to use an IUD that she never got”
    - Blumenthal and Goldthwaite, Obstetrics and Gynecology, 2015
Dedicated inserter: Next steps

- Demonstration projects ongoing in 7 countries (India, Mali, Myanmar, Guatemala, Nicaragua, Indonesia, Pakistan)
- Interest in Vietnam, Haiti
- UNFPA procured 20K inserters for Afghanistan
- Incorporation into standards - prequalification
- Scale up
- USA? – Would need corporate partner since IUD in existing product not FDA approved
Conclusions

- Safe and effective
- Clients motivated
- Convenient
- Lots of worldwide experience
- Task sharing opportunities
- Expands options for postpartum women
Guatemala and Nicaragua have among the lowest rates of modern contraceptive use in Central America, with high levels of unmet need
- Guatemala has one of the highest population growth rates in the Western Hemisphere of about 2.4% a year
- Nicaragua, the modern contraceptive prevalence rate is particularly low among young people aged 15-24 (30%)

Worked with PSI network member PASMO to introduce the dedicated PPIUD inserter
Post-Placental IUD Training

- Master Trainers (Ob Gyns)
  - Guatemala
    - 7 Trainers
    - 2 Clinical Sites
  - Nicaragua
    - 5 Trainers
    - 3 Clinical Sites
Training process and materials

- 2-hour PowerPoint plus video
- Reference Manual – updated for dedicated inserter
- Modified checklists for steps with dedicated inserter
- Hands-on training with Mama-U anatomic model
- Observed placements in clinical sites
What we learned

- PPIUD using the dedicated inserter is easy to teach

- The Mama-U model is the best simulator for PPIUD training

- Following the training, clinicians were able to place PPIUDs with the dedicated inserter successfully 100% of the time.
Potential Challenges

- Field Placements Numbers
- Establishing what is competency
- Ensuring availability of Product
- Outcomes Tracking?
Thank you!

Questions?
Comments?
Demonstration project in Mali

- Trained trainers including MOH, regional divisions, PSI technical staff
- Trained 17 midwives and one obstetric nurse in 10 public sector sites to use dedicated inserter
- Since Feb 2016:
  - 82 women have opted to receive PPIUD following balanced counseling and eligibility screening
  - All 82 PPIUD insertions done with dedicated inserter
- No complications or expulsions to date
- Providers enthusiastic about the dedicated inserter
  - Ease of use and convenience
- Ongoing: supportive supervision, whole-site orientations for other staff