

Levonorgestrel intrauterine system (LNG IUS): new research in Kenya

David Hubacher, PhD
Senior Epidemiologist



Presentation Outline

- Brief background on technology
 - Development, profile, LNG release, uptake in USA, cost barrier
- New research in Kenya
- Broader questions about future role of product

Mirena[®] - A Levonorgestrel Intrauterine System



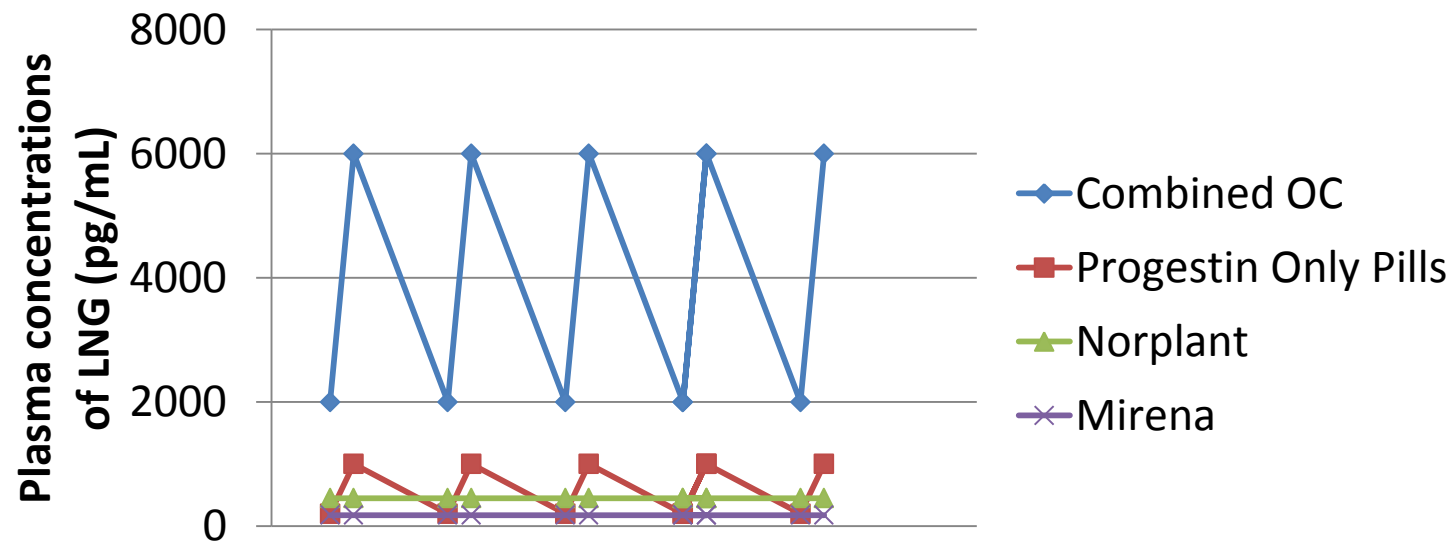
- Basic technology is 40 years old
- 1990 (Finland was first)
- 1990s (Europe)
- December 2000 (USA)
- 2009: USFDA approved Mirena as treatment for heavy menstrual blood loss

Profile of LNG IUS

- 99+ % effective
 - WHO top tier of effectiveness
- Lasts for 5+ years, 80% continuation rate at 1 yr.
- Easy to insert/remove
 - No scalpel or lidocaine needed
- Many non-contraceptive benefits: promotes women's health
 - Generally reduces menstrual blood loss
 - Increases hemoglobin
 - Likely alleviates or prevents anemia
 - Effective treatment for menorrhagia
 - Reduces blood loss from uterine fibroids

Key to Technology: Localized Release of LNG

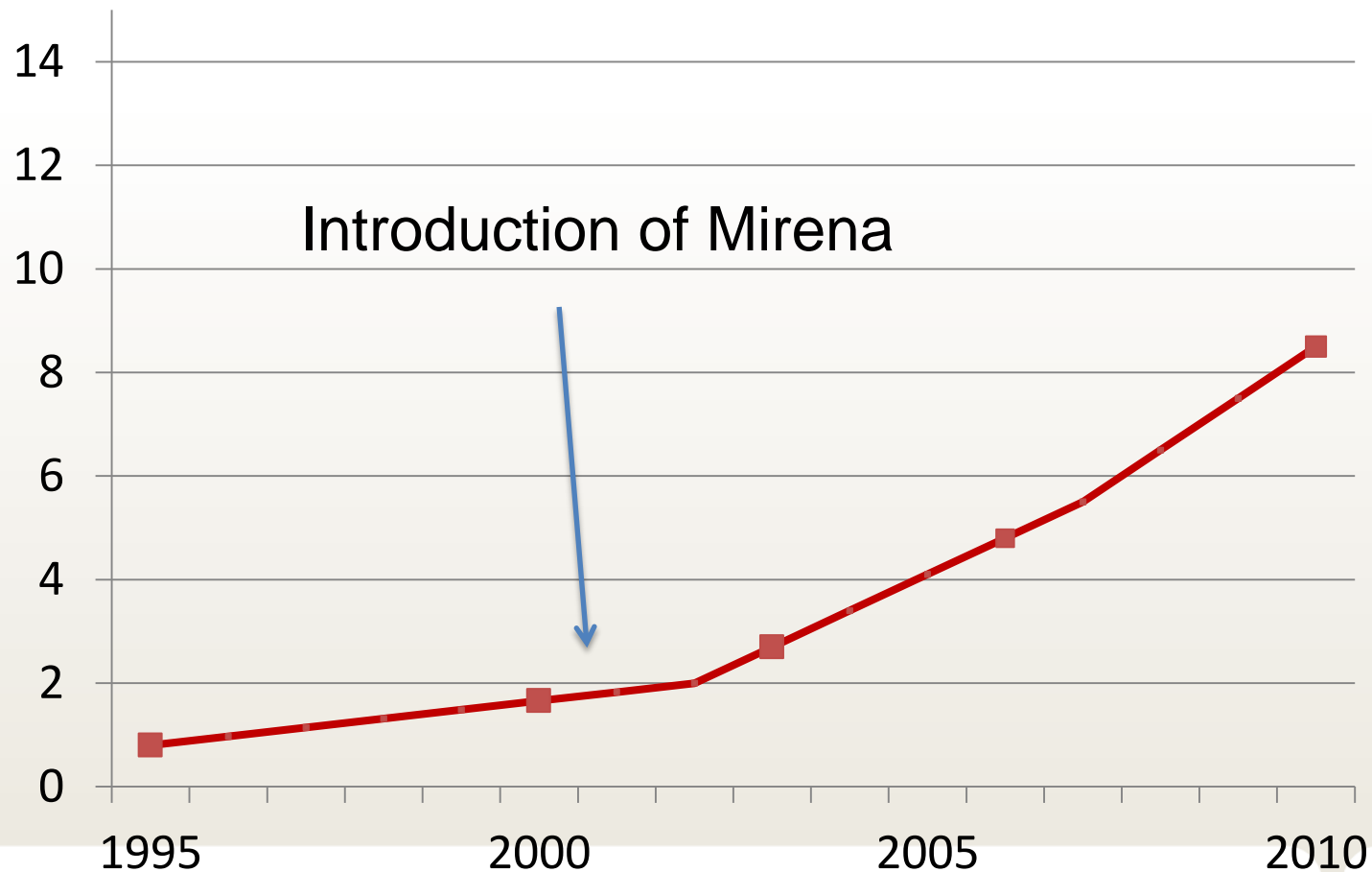
- 20 mcg per day release in uterus
- Not systemic jolt like other hormonal methods
- No peaks and troughs of LNG in plasma
 - steady, low release



After steady state is reached, daily look at levels

Impact of Mirena in USA – Women Like It

Percent of US contraceptors using an IUD



Recap on LNG IUS

- 40-yr old technology
- Proven product
- More than just a contraceptive
- Great potential worldwide

Question:

Why can't women in other countries have it?

Cost as a Barrier for Donor Procurement

- Current price: \$850 in US, \$160 in India, \$200 Kenya
- Donor discounted price: Non-existent
- ICA Foundation (International Contraceptive Access)
 - Partnership between PopCouncil and Bayer
 - Mirena in old inserter system = LNG IUS
 - Donated 47,000 units in 19 countries since 2004
 - Bangladesh, Dominican Republic, Ecuador, El Salvador, Ethiopia, Ghana, Indonesia, Kenya, Nigeria, South Africa, Zambia

ICA Foundation is not the long-term answer

Imagine a \$6 to \$10 LNG IUS

- Would women in Asia/Africa want this product?
- Will LNG IUS attract new users to long-acting?
- What features of LNG IUS are attractive?
- Can demand for product materialize?

New Research in Kenya

- Offer LNG IUS to recent postpartum women
 - (donation of LNG IUS from ICA Foundation)
- Study Objectives
 - Measure uptake relative to other methods
 - Describe participant reasons for choosing or not choosing the LNG IUS
 - Measure and compare continuation rates
 - (Not reporting this aspect today)

Study Details

- Observational prospective cohort study
- Women aged 18-39: offered LNG IUS alongside other options
 - DMPA, POP, subdermal implant, CuIUD
- Population: women at 6-12 weeks postpartum
 - Why this group?
 - Returning for well-baby check
 - Highly effective contraception to avoid short interval
 - Variability in return to menses may hide early LNG IUS hormonal effects
 - Increase hemoglobin, alleviate possible anemia

How Was LNG IUS Described?

- Comparisons:
 - copper IUD is non-hormonal, lasts up to 10 yrs, generally increases menstrual blood loss
 - implant releases hormones in arm, full body (systemic) action, lasts up to 5 yrs
 - LNG IUS: hormonal, lasts up to 5 yrs, generally decreases menstrual blood loss, localized release of hormone in uterus
- All methods: all approved, none are experimental, remove whenever you wish, breastfeeding OK

Recruitment Results

- July 2011 to May 2012
- N=671 enrolled
 - 109 chose LNG IUS (16%)
 - 202 implant (30%)
 - 17 copper IUD (3%)
 - 244 injectable (36%)
 - 99 progestin only pills (15%)

Background characteristics

Background Characteristics	Contraceptive Method Chosen			
	Pills (n=99)	Injectable (n=244)	Subdermal implant (n=202)	LNG IUS (n=109)
Age				
18-19	5.0	9.0	12.4	9.2
20-24	40.4	54.5	44.1	42.2
25-29	33.3	25.8	27.2	32.1
34+	21.2	10.7	16.3	16.5
Number of children				
1	48.5	31.1	30.7	30.3
2-3	45.4	61.9	57.9	61.5
4+	6.1	7.0	11.4	8.3
Education				
Completed primary or less	62.6	78.3	65.9	61.5
Completed secondary	24.2	18.8	29.7	27.5
Higher	13.1	2.9	4.5	11.0

Background characteristics (cont.)

Background Characteristics	Contraceptive Method Chosen			
	Pills (n=99)	Injectable (n=244)	Subdermal implant (n=202)	LNG IUS (n=109)
Unintended last pregnancy (%)	33.3	43.4	49.5	43.1
Ideal timing of next pregnancy				
Not sure	2.0	3.7	5.0	3.7
Within 3 years	26.3	17.6	6.9	11.0
3+ years	49.5	59.4	54.9	56.8
Never	22.2	19.3	33.2	28.4

Why LNG IUS was chosen*, instead of...

Reason LNG IUS was chosen (n=109)	Copper IUD	Subdermal implant
Fewer side effects with LNG IUS	44%	91%
LNG IUS is more effective	24%	6%
Less menstrual bleeding with LNG IUS	43%	4%
The LNG IUS is expensive but free now	3%	1%
Nobody will know I'm using LNG IUS	N/A	23%
Only need a 5-year product	47%	N/A

* multiple reasons allowed; does not sum to 100%

Why subdermal implant was chosen* instead of LNG IUS (n=202)

Reason	Percent*
Fewer side effects	24%
Less pain with insertion/removal	33%
Prefer to expose arm rather than private parts	22%
Implant won't fall out or move	22%
Implant well known and widely used	11%
Does not want device in uterus	11%

* multiple reasons allowed; does not sum to 100%

Method would have chosen if LNG IUS were not available (n=109)

Method	Percent	
Oral contraceptives	2.8	} Short-acting methods
Injectable	25.9	
Condoms	1.8	
Subdermal implant	48.2	
Copper IUD	21.3	
Total	100.0	

Research Conclusions

- Participants cited variety of reasons for choosing particular method
 - Some reasons were accurate others were not
- Without LNG IUS option, 30% would have chosen short-acting method
- LNG IUS acceptors: seeking more than just intrauterine contraception

Next Steps in Kenya Study

- Continued follow-up, thru June 2013
- Record menstrual changes with long-acting methods and user satisfaction
- Document incidence of other side effects
- Tally early removals of long-acting methods

Previous Research in Ghana

- Study by Population Council in 2009
- 71 LNG IUS acceptors
- “Widely acceptable” to both providers and users

- Nyarko et al., Acceptability and promotion strategies for LNG-IUS in Ghana: A Public Health Assessment
- http://www.popcouncil.org/pdfs/2009RH_GhanaLNG_IUSAcceptability.pdf

Future, Broad Discussions

- Is the LNG IUS ready for wider distribution?
- Where will it come from?
 - The ICA Foundation? India? Med360? Bayer?
- Can a good public sector price be negotiated?
- Will donors buy it?
- Can traditional program obstacles to IUD services be overcome?
- Can programs rally around the LNG IUS enthusiasm?
- Promoting substantial health benefits: key to success?