



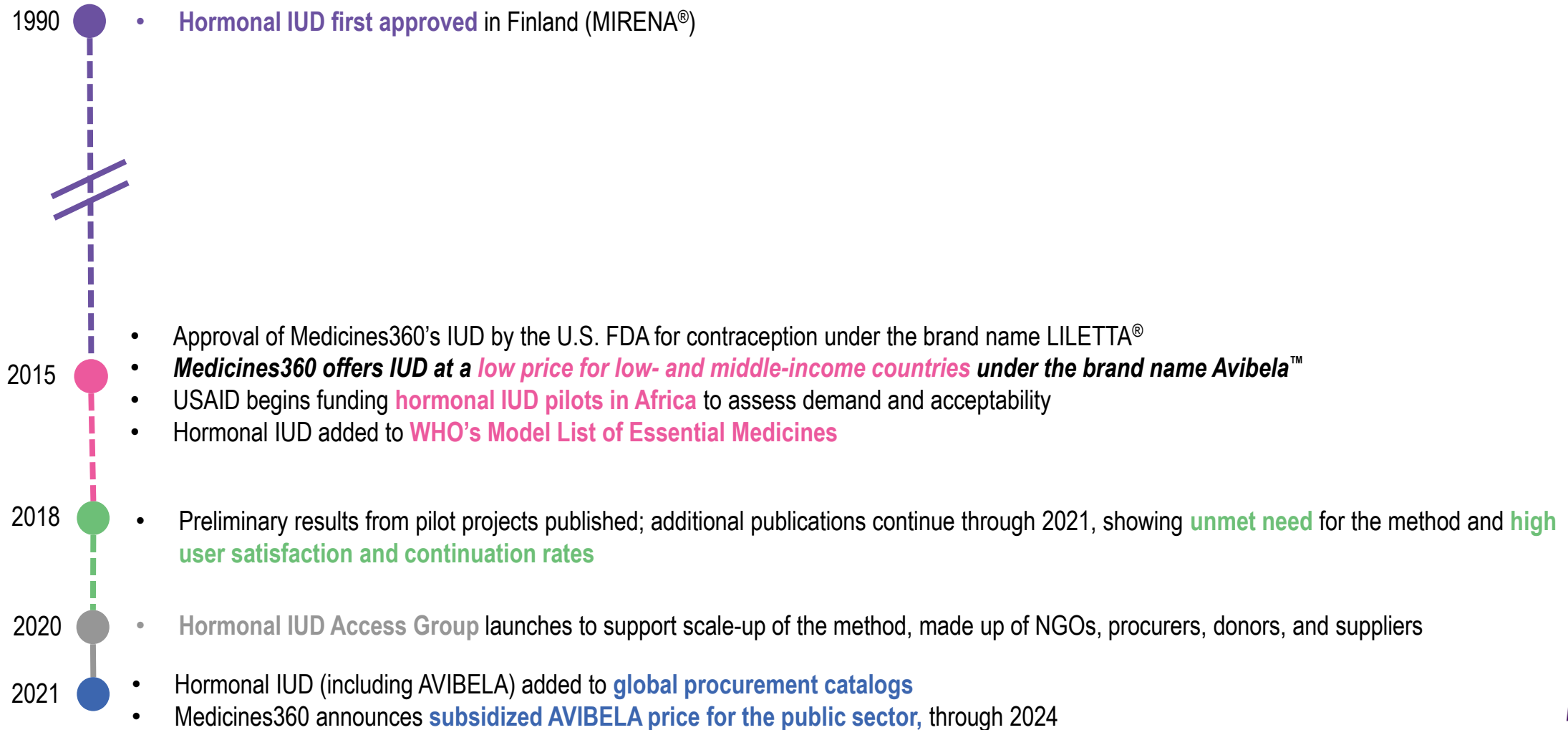
Evidence from clinical trial data addressing common misconceptions about the hormonal IUD

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The hormonal IUD is being introduced at scale in low- and middle-income countries for the first time







ACCESS IUS:

*A Comprehensive
Contraceptive Efficacy
and Safety Study of an
IUS*

- Medicines360 conducted the ACCESS IUS trial in the U.S. to evaluate the levonorgestrel 52 mg IUD for contraceptive efficacy and safety for up to 10 years with a secondary goal of addressing misconceptions related to IUD use
- **We hypothesized that rigorous clinical trial data could adequately address common misconceptions**

The ACCESS IUS trial included a diverse U.S. cohort, including 58% nulliparous women

 Age	 Race/Ethnicity	 BMI	 Parity Status																
<p>16 to 45 years N = 1751</p> <p>Efficacy was evaluated among women aged 16 to 35</p>	<table border="0"> <tr> <td>White</td> <td>78.4%</td> </tr> <tr> <td>Black</td> <td>13.3%</td> </tr> <tr> <td>Asian</td> <td>3.9%</td> </tr> <tr> <td>Other</td> <td>4.4%</td> </tr> </table> <p>14.7% of women indicated Hispanic ethnicity</p>	White	78.4%	Black	13.3%	Asian	3.9%	Other	4.4%	<p>Mean: 26.9 kg/m²</p> <p>Overall Range: 15.8 to 61.6 kg/m²</p> <p>25.1% obese* 5.3% morbidly obese†</p>	<table border="0"> <tr> <td>Nulliparous</td> <td>58%</td> </tr> <tr> <td>N=1011</td> <td></td> </tr> <tr> <td>Parous</td> <td>42%</td> </tr> <tr> <td>N = 740</td> <td></td> </tr> </table>	Nulliparous	58%	N=1011		Parous	42%	N = 740	
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Successful IUD placement in 1714 women (98%)

*BMI ≥ 30 kg/m²

† BMI ≥ 40 kg/m²

ACCESS IUS protocol and outcomes evaluated

Protocol

- **Chlamydia screening:** at study entry and yearly if age ≤ 25 years
- **Baseline gonorrhea screening:** if testing had not been performed since starting current sexual relationship
- **Additional STI testing:** if new sexual partners during the trial
- **Follow-up visits with pelvic exam:** 3 times in the first year and twice yearly thereafter

Outcomes evaluated

- Pelvic infection (defined as any clinical diagnosis of endometritis or PID) risk with insertion at initial visit prior to having STI testing results
- Expulsion rates
- Amenorrhea (defined as no bleeding or spotting for 90 continuous days) rates with extended use
- Return of menses and fertility after IUD discontinuation

STI treatment, when required, was successful without IUD removal

- 80% of participants did not have STI test results available before IUD placement
- Of 1684 participants with testing during IUD placement, 23 had positive results; all were treated without IUD removal, and none developed pelvic infection
- Nine (0.5%) participants were diagnosed with pelvic infection within 2 years after placement: 3 participants within 7 days, 1 at 39 days, and 5 at ≥ 6 months
 - The four early diagnosis infections had successful outpatient antibiotic treatment; one elected to have IUD removal after treatment

Expulsion occurred in 65 (3.8%) of participants over 6 years and occurred more frequently in parous users

- 50 (76.9%) expulsions occurred within the first year
 - Expulsion occurred more frequently in parous users through one year (parous 4.6%, nulliparous 1.7%, $p < 0.001$) and 6 years (parous 5.9%, nulliparous 2.2%, $p < 0.001$)

**98% of participants
evaluated had a
menses after
discontinuation**

- Amenorrhea occurred in 19% of users at one year, 27% at 2 years, 37% at 3 years, and remained ~37-42% through 8 years of continuous use
- Of 664 participants evaluated for return of menses after IUD discontinuation, 651 (98.0%) had a menses with 647 (99.4%) within 3 months
 - Excluding 12 participants with known reasons for not having menses (pregnancy, hysterectomy, and ovulatory dysfunction), 651/652 (99.8%) had menses within 3 months

86% of participants desiring pregnancy conceived within 12 months of IUD removal

- Among 165 participants who attempted to conceive after up to 5 years of IUD use, 142 (86.1%) conceived within 12 months (median time 92 days)
- The 12-month conception rates did not differ between nulligravid (66/76 [86.8%]) and gravid (76/89 [85.4%]) users ($p=0.83$)
- Conception rates did not differ based on duration of use (92% if ≤ 1 year and 89% if 4+-5 years, $p=0.28$)

The ACCESS IUS trial data addresses misconceptions that serve as barriers to hormonal IUD use

STI and pelvic infection risk

- Patients without clinical evidence of active infection can have STI screening at the time of IUD placement, if indicated based on standard screening guidelines
- IUD users who are found to have a positive STI test after placement can be safely treated with outpatient antibiotics and typically do not require IUD removal

Expulsion

- IUD expulsion over 6 years of use is infrequent, occurs most commonly during the first year, and is more common in parous than nulliparous patients

The ACCESS IUS trial data addresses misconceptions that serve as barriers to hormonal IUD use

Menstrual bleeding and return to menses

- The potential benefit of decreasing menstrual flow is maintained continuously at the same rate with extended use
- Menses return relatively quickly for almost all patients who discontinue a hormonal IUD

Return to fertility

- Fertility rates are normal within one year after IUD removal and did not differ by gravidity, parity, or duration of IUD use

Overall, these findings address misconceptions related to STI and pelvic infection risk, expulsion rates, return of menses and fertility after IUD discontinuation, and especially demonstrate the utility of the hormonal IUD in nulliparous users

Thank you!

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