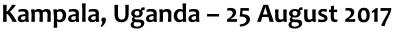
#### But what about...?

Key questions about the ring and PrEP in adolescent girls and young women

Sharon Hillier, Ph.D.

University of Pittsburgh

Meeting the HIV Prevention Needs of Adolescent Girls and Young Women







# What we know about PrEP and the ring



- PrEP is approved for those 18 and older in several countries
- The dapivirine ring could be approved in the near future for women
  18 and older
- Regulatory approvals are based on results of large (Phase III) trials explicitly designed to determine safety and effectiveness
  - Participants are randomly assigned to use either a placebo (with no active drug) or the product with active drug
  - No one knows who is in which group during the study
- PrEP and ring trials had similar results:
  - Both approaches were safe
  - Both effective with consistent use monthly for the ring, daily for PrEP
  - Not effective in younger women ages 18-25 who did not use the products

## We've had longer

				Month	
tol	to learn more about PrEP				
		O			



2 (ongoing)

Don't know yet

(at least 50% or more)

little goes elsewhere

time to get used to

women 18+

Approval Pending – for

Drug delivered into vagina -

Vaginal rings unfamiliar; takes

**Dapivirine Ring** 

Daily PrEP

Drug goes throughout body -

difficult; stigma of HIV meds

**Approved in many countries** 

Daily pill-taking can be

must monitor potential effects

6

20+

Very

for 18+

(more than 90%)

**Phase III Trials** 

**Open-Label Studies** 

How effective with

consistent use?

Where drug goes

**Approval Status** 

Challenges

(with no placebo)

### What do we know about PrEP and the ring in adolescent girls?



• 96 girls in the U.S. ages 15-17 were asked to use a ring for a month at a time for 6 months

- The dapivirine ring was safe and acceptable, and adherence was very high
- What about girls here in Africa?



- A one-year study of 150 boys and girls ages 15-19 from South Africa found:
  - PrEP was safe but adherence became more difficult as level of support was reduced; adherence did not differ between sexes
  - What about girls here in Uganda?

Do we want girls and young women of ALL ages to have access to HIV prevention?







#### **Unanswered Questions**

- Will young women be more inclined to use these products...
  - In studies that don't have a placebo?
  - Knowing that previous studies found them safe?
  - Knowing they can only work with consistent use?
- Is one easier to use than the other?
- Do they like one more than the other?
  Or do they not like either?
- What can we do to help them to use these products?
- What about girls younger than 18? How can we ensure they have access to these products?

#### Discussion

#### DREAM: Key questions

- Will women, including young women, use the ring better knowing that it reduces HIV infection risk?
- What can we learn about the challenges to using the ring, so that if the ring is approved we can help to address these in the "real world"?
- Will information from DREAM help governments make decisions about including the ring in national HIV prevention toolkits?



### Why REACH?







### Unanswered questions about PrEP and the ring in adolescent girls and young women

- Are these approaches safe and acceptable?
- Are they willing to use these products?
- Which one do they prefer?