

MTN Scholars Program

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Overview


- Rationale for MTN Scholars Program
 - MTN is committed to research capacity
 - Young investigators are key to MTN mission

- Aspiration for MTN to help train the next generation of investigators
 - To generate questions & participate in analysis

- First year of MTN Scholars Program in 2012

Selection Process - 2012

- Solicited requests for nominations for young investigators from VOICE site PIs
- Nominees submit a study concept with application
- Reviewed by Connie Celum & Jeanne Marrazzo
- 6 participants funded to attend 2 week Principles of HIV & STI Research in Seattle, July 2012



Principles of STI & HIV Research Course, July 2012 & 2013, Seattle

- 2 week course with didactics on pathogenesis, epidemiology, biostatistics, ethics, research design, current topics in HIV & STIs, publication process
- 120 participants, half are international



2012 MTN Scholars & Proposed Topics

- Carolyn Akello, MUHJU, Kampala
 - Predictors of pregnancy among VOICE ppts, Kampala
- Jane Matambo, CIDRZ, Lusaka
 - Intravaginal practices in women in HPTN 035
- Nyaradzo Mgodzi, Univ of Zimbabwe
 - High risk HPV types in women screened for ASPIRE
- Sarita Naidoo, MRC Durban
 - Hormonal contraception & HIV risk, HPTN 035/ 055, KZN
- Krishnaveni Reddy, WHRI
 - Drug resistance & X4 viruses in HIV+ in Hillbrow, SA
- Arendevi Pather, MRC Durban
 - Hormonal Contraception & STI risk, HPTN 035



2013 MTN Scholars Program

- Incorporated lessons learned from 2012
 - Recalibrated expectations about time & resources needed to execute analyses of multi-site databases
 - No linkage of scholar selection to research concept proposals

- 5 scholars selected from South Africa, Zimbabwe & Pune sites for 2 week course on STD/HIV Research Methods



MTN 2013 & beyond

- Constrained resources; currently no funding for MTN Scholars program
- Mentoring & development of those with outstanding potential is critical
 - Realistic expectations of time needed to shape & refine questions, participate in analysis plans, & develop writing skills
 - MTN & sites encouraged to look for resources

Contraceptive use and pregnancy incidence in VOICE participants – Uganda

Carolyn Akello Agwau, MBCChB, MSc Epi
Research Clinician/ Study Coordinator
MU-JHU Research Collaboration
Kampala, Uganda

Regional Meeting - 31 Oct 2013



Background

- HIV incidence remains high in young women (<25yrs) in SSA
- Biomedical HIV prevention trials target women of reproductive age
- Recent clinical trials require use of an effective contraceptive method as an eligibility criteria for enrolment



Rationale

- Impact of this new eligibility requirement on pregnancy incidence is unclear
 - Do new users have similar pregnancy rates as experienced users?
 - How do new users differ from experienced users?
- Identifying participants at high risk of pregnancy will help inform recruitment and contraceptive counseling efforts in future trials



Population and Objectives

Population

- Women enrolled in VOICE trial in Uganda

Objectives

- To compare pregnancy incidence among new users versus continuing users
- To assess correlates of hormonal contraceptive initiation (being a new user)
- Among new users, to identify correlates of contraceptive method choice at enrollment



Population and Objectives

Population

- Women enrolled in MTN-003 trial in Uganda

Objectives

- To compare pregnancy incidence among new users versus continuing users
- To assess correlates of hormonal contraceptive initiation (being a new user)
- Among new users, to identify correlates of contraceptive method choice at enrollment



Methods

- **Primary exposure:** initiation of an effective method of contraception within 60 days of enrolment in VOICE
 - Combined oral contraceptive pills (COCs)
 - Depot medroxyprogesterone acetate (DMPA)
 - Participants initiating other methods excluded due to small numbers
- **Outcome:** first positive pregnancy test result
- **Other covariates of interest:** age, marital status, lives with partner, education, history of termination or miscarriage, # of living children, age of lastborn, and condom use at enrolment



Methods (cont' d)

□ Data collection

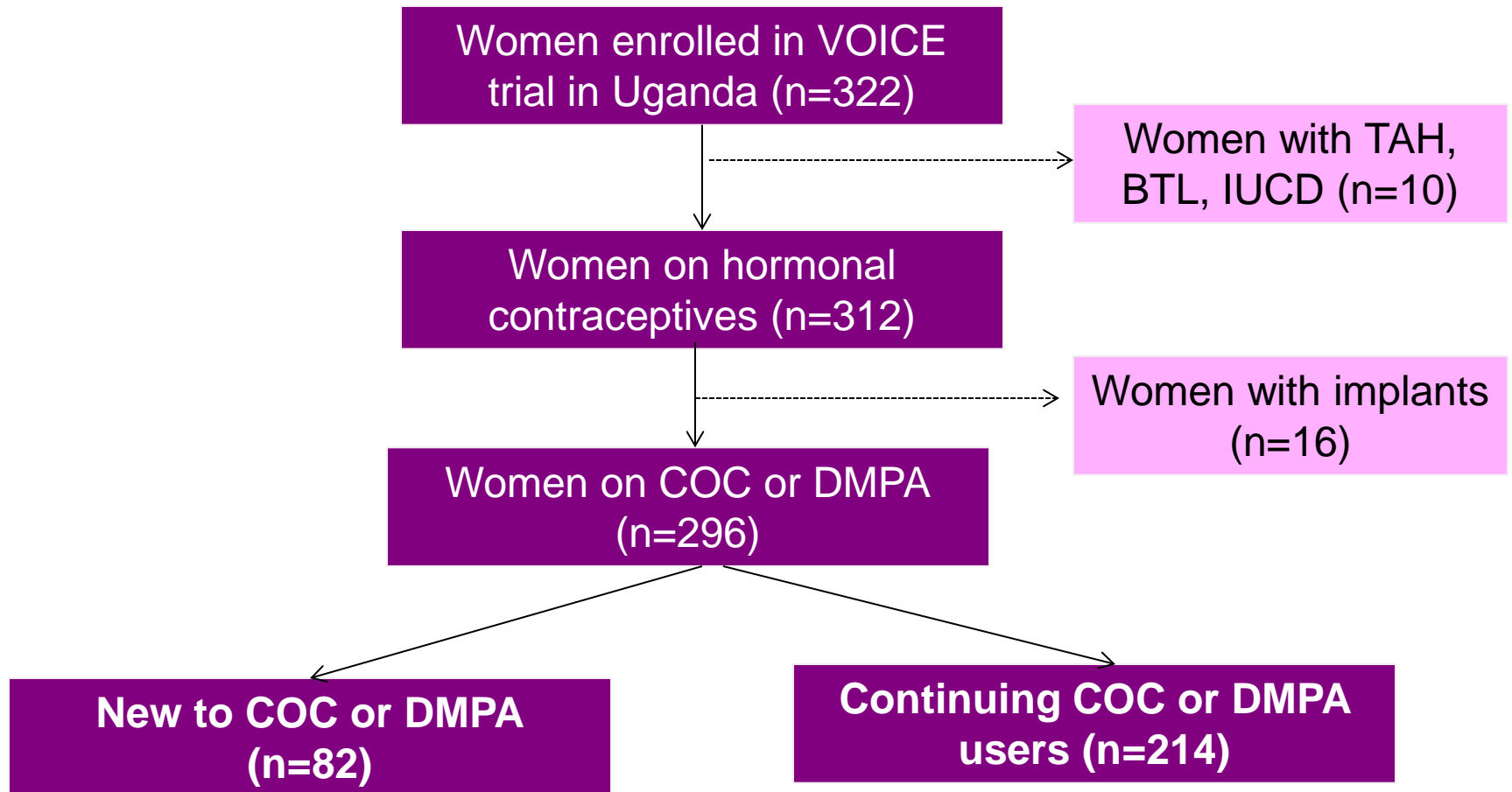
- Baseline covariates and pregnancy data from DataFax database (CRFs)
- Contraceptive initiation data abstracted from the baseline medical & menstrual history form

□ Statistical analysis

- Descriptive statistics and Cox proportional hazards models stratified by baseline contraceptive method
- Data analysis performed by SCHARP



Study Population



TAH = total abdominal hysterectomy; BTL = tubal ligation; IUCD = intrauterine contraceptive device

Baseline Characteristics

Characteristic	New users (n=82)		Continuing users (n=214)		P-value*
Age (years)	30	(24,32)	28	(24,31)	0.11
Education					0.55
None or primary	51	(62%)	125	(58%)	
Secondary or higher	31	(38%)	189	(42%)	
Living with partner	43	(52%)	110	(51%)	0.87
Number of live births					0.03
0-1	20	(24%)	42	(19%)	
2-3	30	(37%)	114	(53%)	
4 or more	32	(39%)	58	(27%)	
Contraceptive method					0.91
DMPA	50	(61%)	129	(60%)	
COCs	32	(39%)	85	(40%)	

*N(%) or median (IQR); *P-value from Chi-squared test or Wilcoxon rank sum test*



Pregnancy Incidence

- 49 incident pregnancies

- DMPA users:
 - 13 pregnancies
 - 5.39 per 100 person-years

- COC users:
 - 36 pregnancies
 - 28.62 per 100 person-years

Pregnancy Incidence among DMPA Users

Variables	Pregnancies/ p-yrs	Incidence (per 100 p-yrs)	Unadjusted HR (95% CI)	
Hormonal contraceptive use				
Continuing user	6/172.56	3.48	1.00	---
New user	7/68.20	10.20	2.56	(0.86, 7.65)
Age (years)				
18 - 24	6/64.38	9.32	1.00	---
25 - 45	7/176.8	3.96	0.46	(0.15,1.37)
Lives with partner				
No	10/123.31	8.11	1.00	---
Yes	3/117.87	2.55	0.32	(0.09, 1.19)
Previous miscarriage or termination				
No	10/206.61	4.84	1.00	---
Yes	3/34.57	8.68	2.10	(0.58,7.71)
Number of live births				
0 – 1	5/42.67	11.72	1.00	---
2 – 3	4/119.79	3.34	0.30	(0.08, 1.11)
4 or more	4/78.72	5.08	0.46	(0.12, 1.71)

P-yrs = person-years; *HR*=hazard ratio; *CI*=confidence interval

Pregnancy Incidence among COC Users

Variables	Pregnancies/ p-yrs	Incidence (per 100 p-yrs)	Unadjusted HR (95% CI)	
Hormonal contraceptive use				
Continuing user	22/92.94	23.67	1.00	---
New user	14/32.81	42.67	1.83	(0.93, 3.60)
Age (years)				
18 - 24	14/24.6	56.91	1.00	---
25 - 34	19/78.89	24.08	0.41	(0.21, 0.83)
35 - 45	3/22.26	13.48	0.22	(0.06, 0.77)
Lives with partner				
No	12/60.22	19.93	1.00	---
Yes	24/65.52	36.63	1.81	(0.90, 3.62)
Education				
None or primary	16/76.5	20.92	1.00	---
Secondary or higher	20/49.25	40.61	2.06	(1.05, 4.01)
Previous miscarriage or termination				
No	22/95.99	22.92	1.00	---
Yes	14/29.76	47.04	2.11	(0.58, 7.71)

P-yrs = person-years; *HR*=hazard ratio; *CI*=confidence interval



Conclusion

- COC users had a 5-fold higher pregnancy incidence compared to DMPA users
- New users had ~2-fold or higher pregnancy incidence than continuing users for both COCs and DMPA
- New users especially those on COCs may benefit from more intensive contraceptive counseling about more effective methods

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