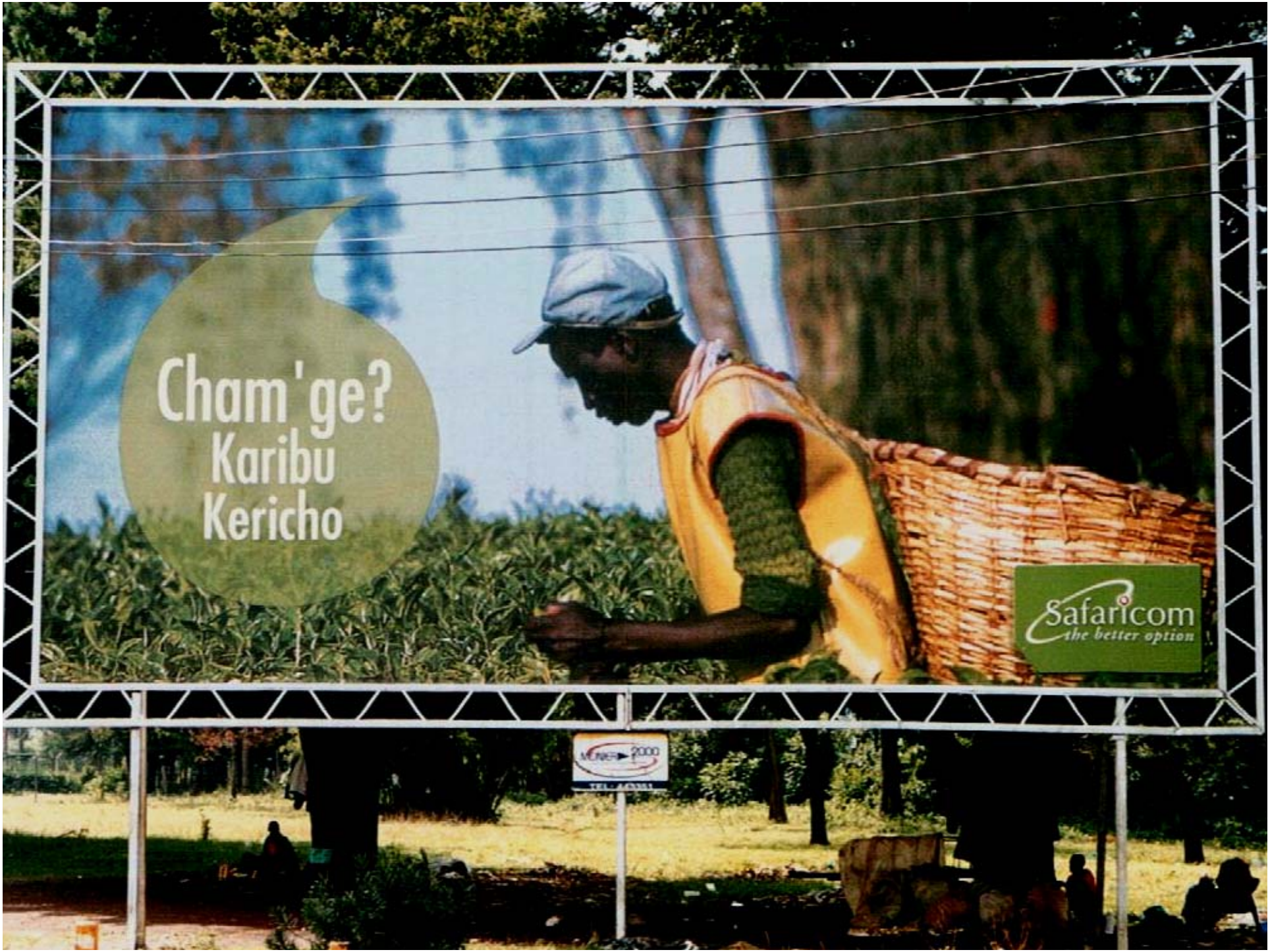
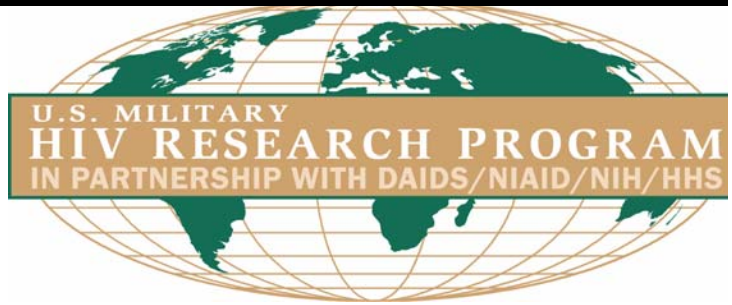

Cham'ge?
Karibu
Kericho
Safaricom
the better option

Male Circumcision and HIV Infection Among Tea Plantation Residents in Kericho, Kenya: Incidence Results After 2 Years of Follow-up

XVI International AIDS Conference
August 15, 2006

Douglas N. Shaffer, MD, MHS
Walter Reed Project HIV Program
Kericho, Kenya



Outline

- United States Military HIV Research Program (USMHRP) / Walter Reed Project (WRP) – Kenya Medical Research Institute (KEMRI) Collaboration
- HIV and Malaria Cohort Study
- “Male Circumcision Cohort”
- 24 Month HIV / Circumcision Data
- Conclusions

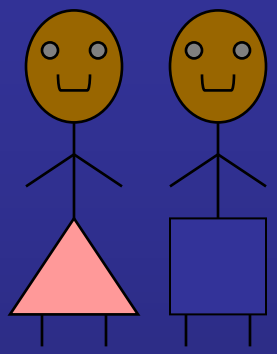
USMHRP / WRP – KEMRI Collaboration

- USMHRP Mission - prevention of HIV disease through
  - Development of a globally effective HIV vaccine
  - Targeted HIV surveillance, prevention, and treatment
- KEMRI Collaboration & HIV Research
  - Built upon long standing (40 years) relationship in Kenya with US DOD/WRP
  - Collaborative HIV vaccine research began in 1998 and is conducted among the rural African highlands of the southern Rift Valley Province in Kericho

HIV & Malaria Cohort Study

- 3 ½ year prospective, natural history cohort study following 2801 adult tea plantation workers & dependents twice a year since June 2003
- Primary Objectives
  - Establish HIV prevalence/incidence
  - Characterize HIV risk behaviors
- Secondary Objectives
  - Profile HIV co-morbidities
  - Establish area/population “normal” laboratory values
  - Ascertain volunteers’ willingness to participate in future HIV vaccine trials

"Male Circumcision Cohort"



18-50 y/o consenting

6 mo recruitment

plantation workers and dependants

Baseline Cohort n=2801

Methods:
1. Followed q 6 mo
2. Baseline & follow-up questionnaires
3. Baseline & follow-up HIV testing

Exclusions:
1. Female (n=1081, 36%)
2. HIV positive men (195, 7.0%)
3. Lost to follow-up (146, 5.2%)
4. Missing data (1, 0.03%)

Male Circumcision Cohort n=1378 & 2689 person-years

Analyses:
1. Routine simple statistics
2. Incidence calculations (per 100 py)
3. Hazard/regression analyses

Baseline Characteristics

	Uncircumcised (n=270, 19.6%)	Circumcised (n=1108, 80.4%)
Age (yrs)	32.1 (+/- 9.6)	30.9 (+/- 8.5)
Tribe ††		
Kalenjin	1.1%	39.8%
Kisii	0.4%	32.3%
Luhya	5.2%	19.4%
Luo	74.1%	2.8%
Other	19.3%	5.7%
Education †		
≥ High School	40.3%	50.8%
Primary	57.4%	47.3%
None	2.3%	1.9%

† $p < 0.05$ †† $p < 0.001$

Baseline Characteristics cont.

	Uncircumcised (n=270)	Circumcised (n=1108)
Marital History †		
Never married	21.5%	23.2%
Married once	55.2%	60.1%
Married ≥ twice	23.3%	16.6%
Sexual Activity (yrs) †		
≤ 6	22.7%	18.8%
7 – 11	19.3%	26.3%
12 – 18	24.6%	27.0%
≥ 19	33.3%	27.9%
Sex With CSW		
Yes	14.2%	12.3%
No	85.8%	87.7%

† $p < 0.05$

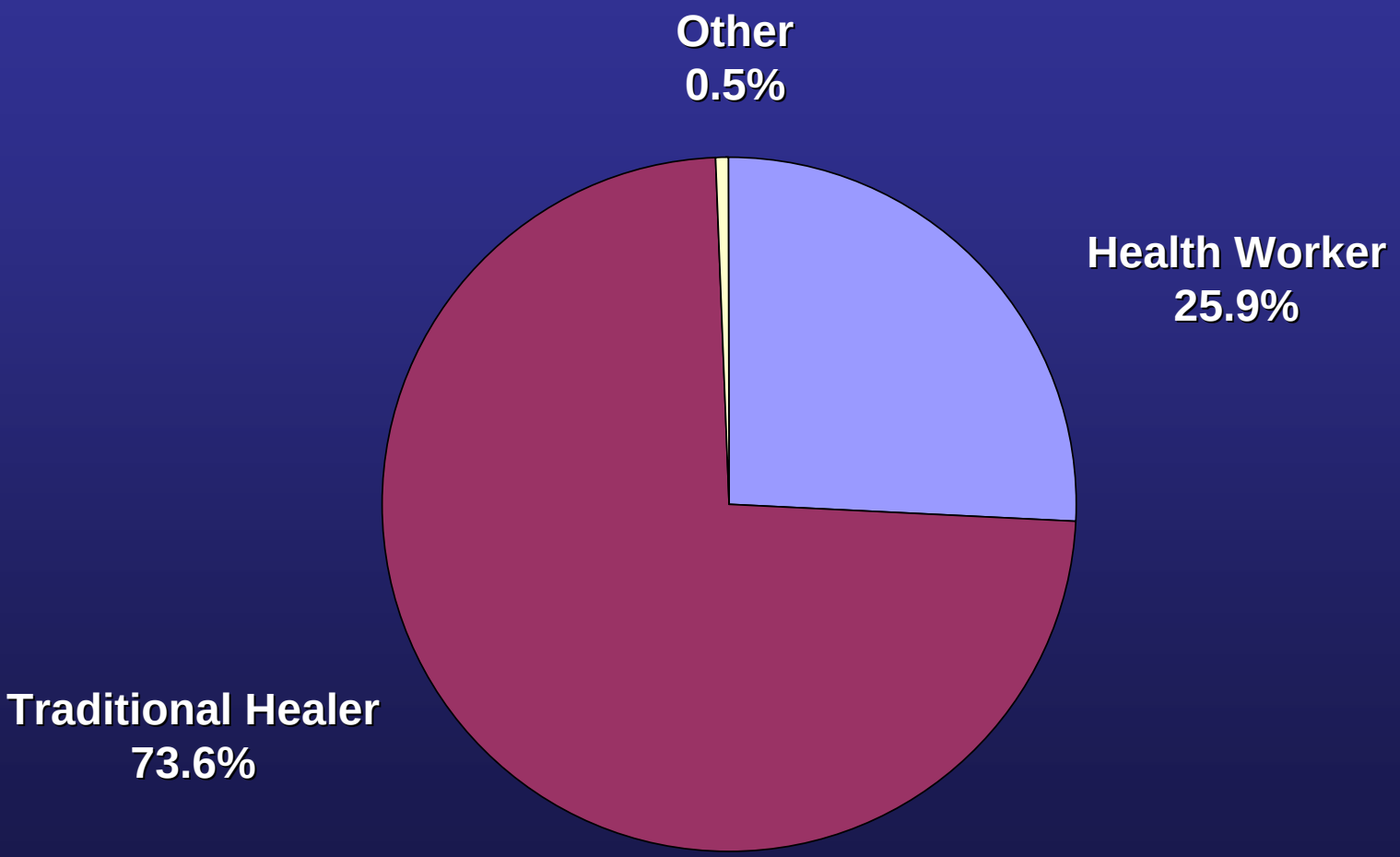
Baseline Characteristics cont.

	Uncircumcised (n=270)	Circumcised (n=1108)
STI Last 6 Mo		
Yes	5.9%	5.3%
No	94.1%	94.7%
Penile Sores/Ulcers Last 6 Mo		
Yes	7.1%	6.3%
No	92.9%	93.7%
Sexual Acts Last Mo		
None	22.9%	23.2%
1 – 4	25.9%	31.8%
5 – 8	28.6%	24.2%
≥ 9	22.6%	20.8%

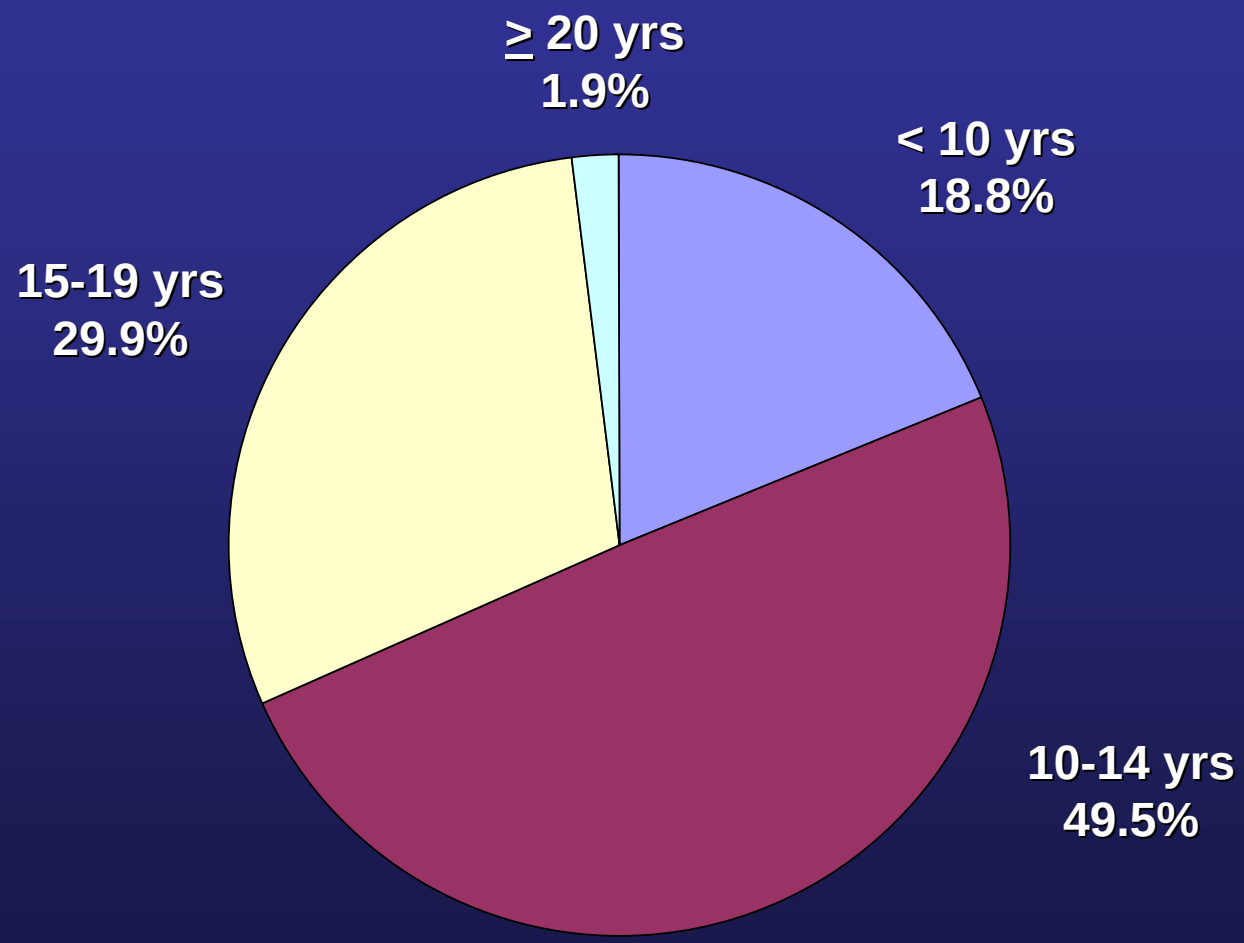
Baseline Characteristics cont.

	Uncircumcised (n=270)	Circumcised (n=1108)
Blood Transfusion (5 yrs)		
Yes	1.5%	1.8%
No	98.5%	98.2%
Condom Use		
Always	11.2%	8.5%
Sometimes	12.3%	13.8%
Never	76.5%	77.7%

Who Performed Circumcision



Age At Circumcision



Circumcision & 24-Month Incident HIV

	Incident Cases	Person-Years	Incidence Rate * (95% CI)	Hazard Ratio (95% CI)
Overall	30	2689	1.12 (0.75-1.59)	
Circumcised	17	2165	0.79 (0.46-1.25)	**0.31** †† **(0.15-0.64)**
Uncircumcised	13	524	2.48 (1.33-4.21)	ref

* per 100 person-years

†† p = 0.001

Circumcision & 24-Month Incident HIV Hazard Ratios

	Circumcised : Uncircumcised Hazard Ratio (95% CI)
Univariate Model	0.31 (0.15-0.64)
Multivariate Model 1 (demography)	0.54 (0.20-1.47)
Multivariate Model 2 (behavioral)	0.32 (0.16-0.67)

Model 1: age, education, & tribe
Model 2: marital history, STI past 6 mo, yrs sexual activity, sexual acts/mo, & penile ulcer

Study Strengths

- Prospective cohort
- 24 months follow-up
- Availability of sociodemographic data
- General, rural population
- Pre and post-test HIV counseling
- Comprehensive HIV care and treatment

Study Limitations

- Self reported circumcision
- Not designed or statistically powered to detect small differences within circumcised vs. uncircumcised strata when considering potentially confounding variables
- Risks and harms of circumcision not addressed
- Hazard ratios presented may be biased by HIV risks highly correlated with circumcision status.

Conclusions

- Our study suggests circumcision offers a degree of protection from HIV infection in adult men living in the rural African highlands of the southern Rift Valley in Kenya.
- Additional controlled, randomized studies designed to describe the relationship of confounding variables (both risks and sources of HIV infection) to circumcision status and incident HIV are needed.
- Careful attention must be given to the risk-benefit profile of circumcision as an HIV prevention measure alone as well as in relation to other HIV prevention measures (e.g. abstinence, faithfulness, condoms, vaccines, microbicides).

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Kenyan HIV Cohort Study Volunteers

WRAIR Human Use Protocol #855, KEMRI SSC #590: "*HIV and Malaria Cohort Study Among Plantation Workers and Adult Dependents in Kericho, Kenya*."

Disclosure: Opinions, interpretations, conclusions, and recommendations are those of the authors and not necessarily endorsed by the Kenya Medical Research Institute or US Army.