Research and Sexual and Reproductive Health Course, Geneva 2008

Male Circumcision and HIV Prevention: Research Influencing Action

Bruce Dick
Department of Child and Adolescent Health
World Health Organization
Geneva

Acknowledgements to Tim Farley, RHR, WHO Geneva

Overview of the Presentation

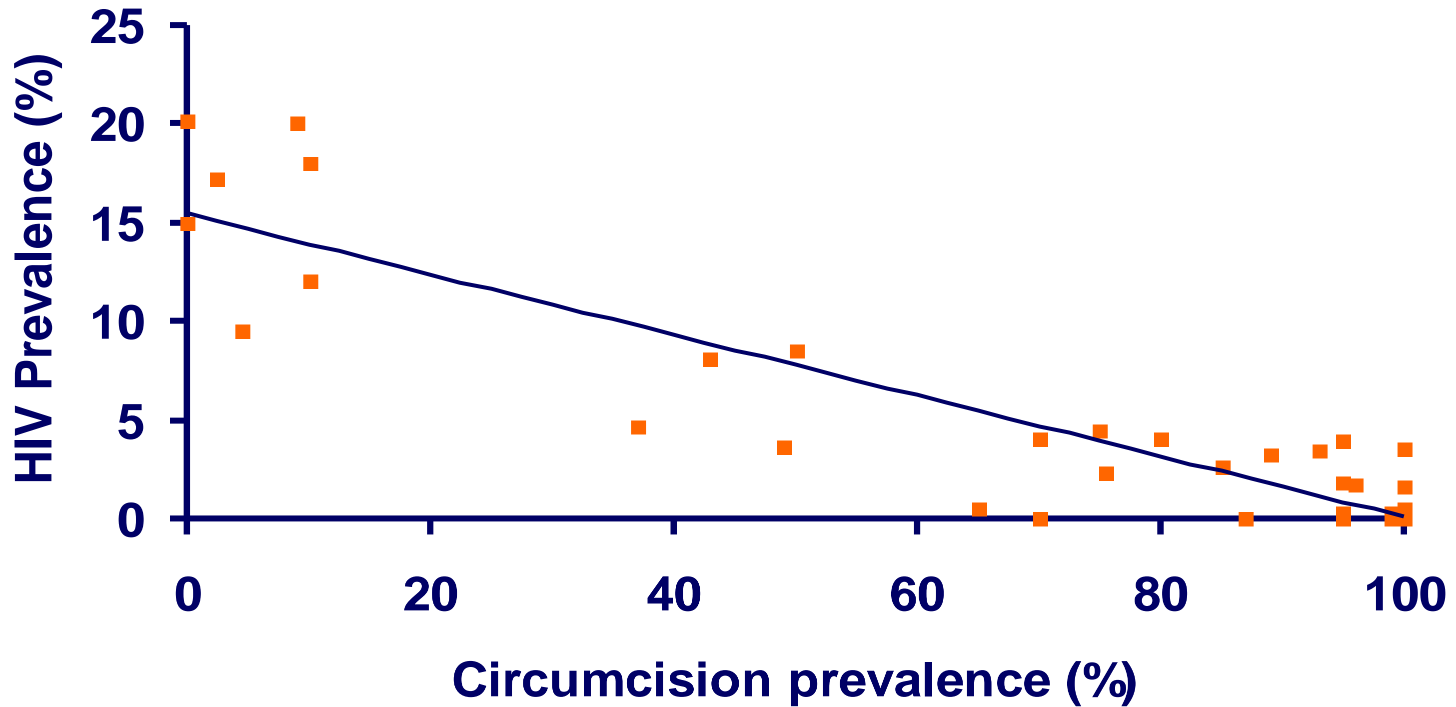
- Building up the evidence to explore the link between Male Circumcision and HIV transmission

- Using the evidence to influence action

- Some reflections/lessons learnt

Male circumcision and HIV infection

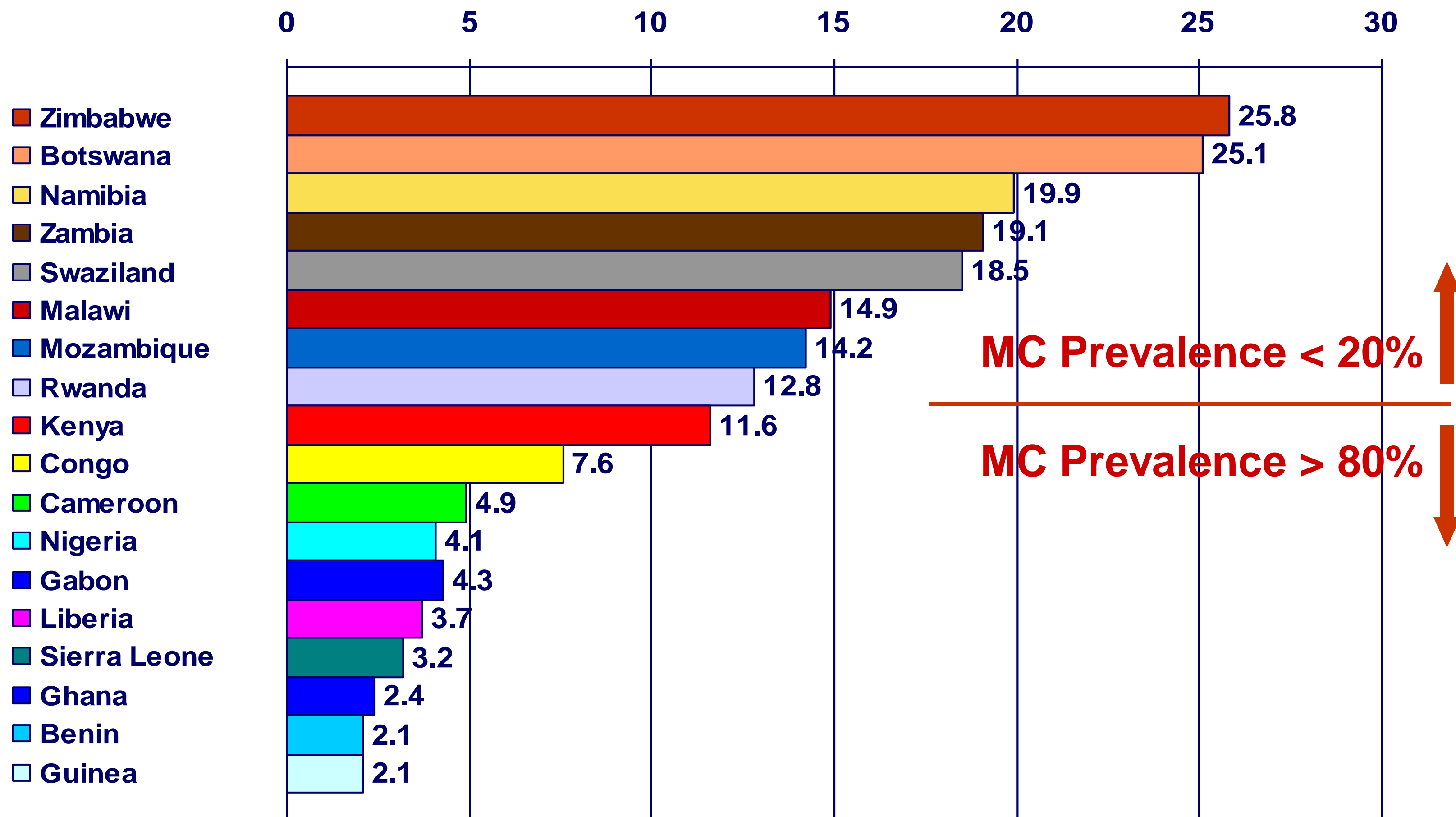
Bongaarts, AIDS 1989



World Health Organization
UNAIDS
unicef
UNFPA

HIV and MC Prevalence – Africa

Adapted from Halperin & Bailey, *Lancet* 1999; **354**: 1813



World Health Organization
UNAIDS
unicef
UNFPA

Biological Plausibility for Male Circumcision's Protective Effect

- Decreased target cells (Langerhan's cells)
- Increased keratin barrier
- Decreased genital ulcer disease
- Decreased micro-trauma to penis
- Decreased warm moist environment

Cochrane review of observational studies

Siegfried, N. et al, 2004

- 35 observational studies met the inclusion/exclusion criteria
- 16 in the general population, 19 in high-risk populations (groups or settings)
- 25 cross sectional, 5 cohort incidence studies, 4 case control
- Meta-analysis not possible because of high variation in results
- Therefore stratified analysis by study type (cohort, cross-sectional) and study population (general or high-risk)

World Health Organization UNAIDS unicef UNFPA

Overall Findings

- Studies from high risk groups report a powerful protective effect of circumcision
- Studies for the general population also indicated preventive effect of circumcision, but results varied more
- Adjusting for confounding variables gave more similar results (note: observational studies can only adjust for known confounding factors, and then only if they are measured accurately)

Overall Conclusion of the Cochrane Review

- *The results from existing observational studies show a **strong epidemiological association between male circumcision and prevention of HIV**, especially among high-risk groups. However, observational studies are inherently limited by confounding which is unlikely to be fully adjusted for*
- ***Insufficient evidence to support an interventional effect on male circumcision on HIV acquisition in heterosexual men***
- *Therefore **Randomized Controlled Trials (RCT) needed** in order to be able to decide whether male circumcision could be recommended as an intervention for HIV prevention*

World Health Organization UNAIDS unicef UNFPA

Emerging Evidence 2005

- July 2005
  - Orange Farm Trial results released
  - Joint press conference ANRS, WHO & UNAIDS
    - "Results very promising"
    - Circumcision should not be promoted for HIV prevention pending results from other two RCTs
  - Concerns
    - Potential for "risk compensation"
    - High complication rates of circumcisions performed in non-clinical settings

Emerging Evidence 2005

- UN Partner Workplan and Actions
  - Priority actions pending availability of further evidence
  - Support countries assess potential impact of new evidence
    - Country stakeholder consultations
    - Human rights dimension
    - Situation analysis tool kit to assess facilities, potential demand
    - Technical guidance on male circumcision techniques, service package and training modules
  - Funded by ANRS, NIH, BMGF, UNAIDS in November 2005

National Consultations on Male Circumcision 2006

- Kenya, Tanzania and Zambia:
  - High circumcision prevalence in selected areas
  - How to extend to non-circumcising groups
  - How to expand safely to meet growing demand
- Swaziland
  - Male circumcision being re-introduced into country
  - High demand in private and NGO sectors
- Lesotho
  - Widespread traditional male circumcision in mountain regions
  - Very limited cutting
  - Huge cultural sensitivities
  - Large tensions between traditional and modern health systems

Regional Consultation, November 2006

- Countries
  - Kenya, Lesotho, Tanzania, Swaziland, Zambia
  - Malawi, Mozambique, South Africa, Zimbabwe
- Challenges
  - Legal, policy, ethical/human rights frameworks
  - How to ensure **safe** male circumcision practices
    - Training needs, types of provider, post-circumcision care, management and reporting of adverse events, risk compensation
  - Whether and how to prioritise (age group, population group, …)
  - Cost and sustainability of services
  - …

World Health Organization UNAIDS unicef UNFPA

Global Technical Consultations

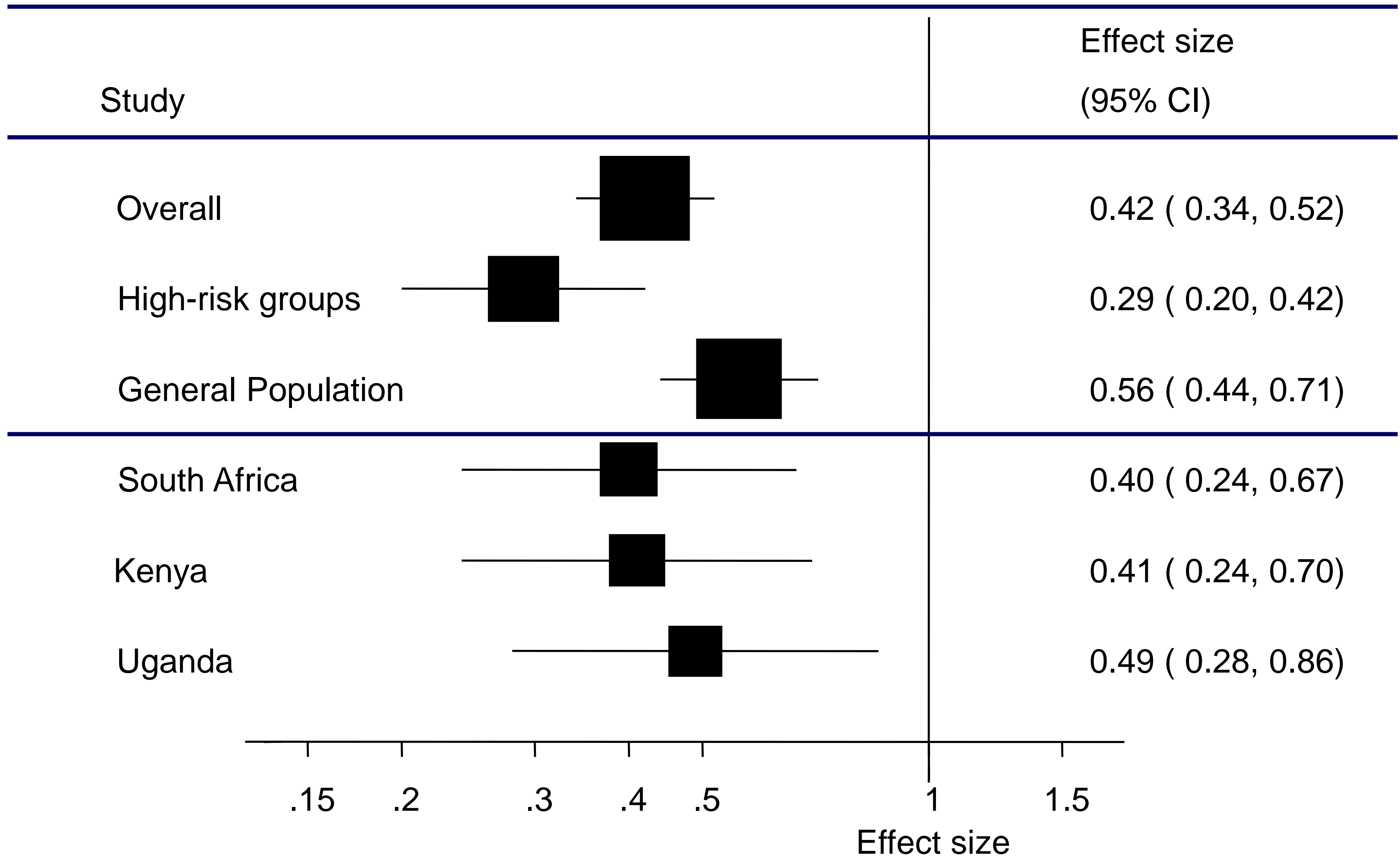
- Strategies and approaches to male circumcision programming (Dec 06)
  - Targeting, models for scale up, minimum package of counselling and services, capitalise on opportunity to reach young men, stigma, …
- Perspectives from social science on male circumcision for HIV prevention (Jan 07)
  - Cultural and ethnographic dimension of promoting MC, potential risk compensation, integration between traditional and clinical circumcision, women's role and perspectives, social change communication, stigma, …
- Male circumcision and adolescent sexual and reproductive health programming (Mar 07)
  - Integrating adolescent sexual health counselling and services, effective programming models, …

World Health Organization UNAIDS unicef UNFPA

New Evidence

- 12 Dec 06
  - Kenya and Uganda trials stopped by DSMB
  - WHO & UNAIDS announced plans for global consultation to review evidence
- 24 Feb 07
  - Publication of results in *Lancet*
- 6-8 Mar 07
  - International Technical Consultation on Male Circumcision and HIV Prevention: Implications for Policy and Programming

Impact on HIV incidence: Evidence from observational studies and RCTs



Conclusions and Recommendations from WHO/UNAIDS Technical Consultation

- 28 Mar 07
  - Conclusions and recommendations released
- 11 key conclusions:
  - "The research evidence is compelling"
  - "Promoting male circumcision should be recognized as an additional, important strategy for the prevention of heterosexually acquired HIV infection in men"
  - "Male circumcision should never replace other known methods of HIV prevention and should always be considered as part of a comprehensive HIV prevention package"

World Health Organization UNAIDS unicef UNFPA THE WORLD BANK

Current Activities to Support Expansion of Safe Male Circumcision Services

- Improve availability, accessibility and safety of male circumcision as part of comprehensive HIV prevention
- UN Partners will provide:
  - Global norms and standards
  - Global advocacy and communications
  - Coordination in setting global research priorities
  - Support monitoring and evaluation of male circumcision services
  - Assessment of legal, ethical and human rights frameworks
  - Technical support through Regional and Country Offices
- UN Partners will support countries to:
  - National programmes to introduce, expand and monitor safe circumcision services
  - National advocacy and communication strategies

World Health Organization UNAIDS unicef UNFPA

Collaborations

- Inter-Agency Task Team on Male Circumcision
  - UNAIDS, UNFPA, UNICEF, WHO (Chair), World Bank
- Key partners:
  - Bill and Melinda Gates Foundation
  - USA National Institutes of Health (NIH)
  - French National Agency for AIDS Research (ANRS)
  - US Agency for International Development
  - Office of the Global AIDS Coordinator
  - Centers for Disease Control and Prevention
  - Clinton Foundation
  - Family Health International
  - Population Services International
  - JHPIEGO Corporation
  - Others …

Conclusions

- We have an effective intervention, but we really don't know how to DO IT
- There will be many unknowns as we move from research findings to practice
- BUT there are also MANY opportunities:
  - **MC and adolescents**
  - **MC as an entry point for sexual and reproductive health**

12 September 2007

MALE CIRCUMCISION: AN INTERVENTION FOR HIV PREVENTION IN THE WHO AFRICAN REGION

An Information Note from the WHO Regional Office for Africa

Nearly two thirds of the people living with HIV reside in sub-Saharan Africa. New HIV infections are occurring at alarming rates despite a range of prevention efforts. Prevention of new infections remains the only realistic hope for stemming the HIV epidemic in the African Region.

The recent WHO and UNAIDS international expert consultation on male circumcision and HIV prevention held in Montreux, Switzerland from 6 to 8 March 2007, concluded that there is unfolding evidence from randomized controlled trials, undertaken in Kenya, South Africa and Uganda, that safe male circumcision reduces the risk of heterosexual transmission of HIV infection from women to men by approximately 60%. The trials also showed that male circumcision performed by well-trained medical professionals in properly equipped facilities is safe.

Safe male circumcision is, therefore, a new additional intervention for HIV prevention that needs to be given due attention. Implementation should take into account a number of specific considerations outlined in the WHO/UNAIDS policy and programme recommendations.

Male circumcision provides only partial protection against HIV. Because of its partial protective effect, male circumcision may be considered as part of a comprehensive package of HIV prevention interventions. Other known effective preventive interventions against sexual transmission of HIV, such as abstinence, delay of sexual relations, faithfulness, correct and consistent use of male or female condoms, reduction in the number of sexual partners, and effective and prompt treatment of sexually-transmitted infections, remain relevant.

Circumcised men can still become infected, and men who are HIV-positive can infect their partners. There is no evidence that male circumcision in men who are already HIV-positive has any protective effect on their female partners. Preliminary data from the Ugandan trial suggests that recently circumcised HIV-positive men who resumed sexual activity before certified wound healing could be more likely to transmit HIV than those who waited until complete wound healing. Also, HIV-negative men who engage in sexual activity before wound healing is certified are also at increased risk of acquiring HIV. Therefore, all men who undergo circumcision should be counseled to abstain from sexual activity until complete wound healing, and thereafter use condoms correctly and consistently.

World Health Organization
UNAIDS
unicef
UNFPA

Reflections …

- A good example of the distillation and generation of evidence
- A good example of "sailing the boat while building it" …
- Ensure the involvement of a range of disciplines
- Involve a range of partners
- Despite the evidence there will be people who disagree: emotive>intellectual
- The questions do not stop with the initial evidence …

World Health Organization UNAIDS unicef UNFPA

Thank You

World Health Organization UNAIDS unicef UNFPA THE WORLD BANK