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## **Mainstreaming Voluntary Male Circumcision in HIV Prevention in High Prevalence Settings and for Most-at-Risk Groups**

Master Thesis

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# 1 Abbreviations

ABC – Abstinence, Be Faithful, Use a Condom  
AIDS – Acquired Immunodeficiency Syndrome  
ART – Antiretroviral Therapy  
AVAC – AIDS Vaccine Advocacy Coalition  
cART – Combination Antiretroviral Therapy  
FHI360 – Family Health International (360 degree perspective)  
HIV - Human Immunodeficiency Virus  
HTLV - Human T-cell Leukemia Virus  
IDU – Injecting Drug User  
MSM – Men who have Sex with Men  
MTCT – Mother to Child Transmission  
PMTCT – Prevention of Mother to Child Transmission  
RKI – Robert Koch Institut  
STI – Sexually transmitted infection  
UNAIDS - Joint United Nations Programme on HIV/AIDS  
VTC – Voluntary Counseling and Testing  
WHO – World Health Organization

## 2 Introduction

According to WHO HIV continues to be a major public health issue resulting in an estimated 36 million deaths until today. At the end of 2013 there were approximately 35 million people living with HIV, with Sub-Saharan Africa as the most affected region. Still there is no cure and no vaccination for the HIV infection, but antiretroviral therapy (ART) can be used to control the virus helping patients to live productive and healthy lives despite being infected with HIV. But access to antiretroviral therapy and early detection is still limited. The main public health goal for HIV is therefore prevention of acquiring the virus and the promotion of risk-reducing behavior. Risk factors for acquiring HIV include: unsafe vaginal or anal sexual contact, being infected with another sexually transmitted infection (STI), injective drug use with contaminated needles, and unsafe medical procedures, e.g. blood transfusions/lack of protective devices like gloves.

In high prevalence settings of Sub-Saharan Africa heterosexual transmission through unsafe sexual contacts seem to be the driver of the epidemic. Preventive measures include condom use, testing and counseling for HIV and STIs, ART based prevention, elimination of mother to child transmission (MTCT) as well as harm reduction for drug users. During the recent years there has been growing inclusion of voluntary male circumcision in health interventions to reduce the spread of HIV (WHO 2013: Fact Sheet No. 360). Comprehensive programming includes information, sensitization and stigma reduction. Gender aspects are taken into consideration and sexual networks are addressed, as programmes targeting solely medical aspects have proven to be ineffective (UNAIDS 2013: 14).

UNAIDS/WHO et al. are referring to three randomized controlled trials conducted in South Africa, Kenya and Uganda pointing to a reduction of the risk of heterosexually acquired HIV infection in men by 60%. According to UNAIDS/WHO et al. these studies confirmed hypotheses generated through previous ecological and observational research (UNAIDS/WHO et al. 2009: 1). As a consequence, international organizations, NGOs, multilateral and bi-lateral donors as well as governments of high prevalence countries promote the inclusion of voluntary male circumcision in HIV programming. Despite the wide integration of voluntary male circumcision in prevention programmes regarding HIV transmission there seems to be a lack of knowledge and understanding regarding the exact protecting mechanism and there is ongoing discussion on the possible side effects and related risks of male circumcision campaigns among development practitioners. The longer-term population level effect of expansion or new introduction of male circumcision campaigns in comprehensive HIV programming still remains unknown and there are several ethical, cultural, legal and human rights issues that lead to controversial discussion among stakeholders and prevent governments of high-prevalence countries to integrate voluntary male circumcision in ongoing HIV programming (UNAIDS/WHO et al. 2009: 1).

There seems to be no publication summarizing the current state of research and evidence for the effectiveness of male circumcision as a measure of HIV prevention in high-prevalence settings, also

giving an overview on ethical, legal, and human rights issues as well as formulating recommendations. There is also a lack of a summary regarding the state of research on protective factors arising from male circumcision regarding HIV transmission. As male circumcision is a surgery with possible complications if not performed professionally and the side effects (e.g. inadequate sexual abstinence after surgery, high risk behavior) can be severe there should be careful planning and evidence for interventions. Another area not yet explored is a possible benefit of male circumcision for most-at-risk groups in other contexts than generalized epidemics (e.g. men who have sex with men (MSM), immigrants from Sub-Saharan Africa in Europe).

The master thesis will therefore critically look at publications by research institutes, international organizations etc. and provide an overview on the current state of knowledge and a judgement of evidence provided. An overview on the current practices in public health interventions will also be part of the thesis including new devices for performing male circumcision in low resource settings. The master thesis will in addition analyze the controversial discourse on male circumcision that might prevent the scale-up of male circumcision programming in high-prevalence settings by different stakeholders. It is assumed that especially in Germany critical and sceptical positions dominate the discussion and differ from the global discourse widely accepting evidence provided by WHO and UNAIDS.

Different methodological strategies will be used for the master thesis:

- **Literature review:** For the master thesis a literature review will be conducted. The literature review will include searching international data bases and archives of international organizations to gain an overview on the current state of research.
- **Categorization of studies and publications:** The existing literature and especially existing studies will be categorized according to the methodology and results. The quality, i.e. objectivity, reliability and validity and therefore evidence provided will also be analyzed. Bradford Hill criteria will be used as a benchmark for strength of evidence. With the categorization, an overview on the state of research regarding the protective factors and knowledge, attitude and practices related to male circumcision will be given.
- **Discourse analysis:** A discourse analysis regarding male circumcision as measure of HIV prevention will be conducted. This analysis will help to detect different positions towards male circumcision that either encourage or hinder organizations or state actors to integrate male circumcision in their programming. Ethical considerations regarding the right to physical integrity will be compared to positions regarding potential biomedical benefits of male circumcision. The formulation of messages in current male circumcision programming will be taken into consideration.
- **Formulation of recommendations:** The analysis will result in the formulation of recommendations for health promotion programming. Depending on the results the recommendations can be related to the mainstreaming of male circumcision in ongoing programming, or

to the improvement of ongoing programming, to the elimination of possible risks and harm in voluntary male circumcision in HIV programming, or to rethinking of the inclusion of male circumcision in HIV programming. Specific attention will be given to the current state of knowledge regarding male circumcision as potential beneficial practice for most-at-risk groups in contexts other than generalized epidemics.

Identified study designs for the investigation of male circumcision as a measure of HIV prevention include cross-sectional surveys, case-control studies, cohort studies, randomized controlled trials, mathematical modeling and cost-effectiveness analysis. From the publications it is clear that observational studies triggered further research through randomized controlled trials. The most cited and prominent examples that are also referred to by WHO and UNAIDS as evidence for male circumcision as an effective measure of HIV prevention are three independent randomized controlled trials conducted in South Africa, Kenya and Uganda. Several sub-studies explored related clinical aspects like the effects of circumcision on the penis microbiome and other STIs like HSV-2, HPV or syphilis. Effects of the foreskin surface area on HIV acquisition were also explored. Besides circumcision conducted in medical sites by skilled personnel, traditional male circumcision performed by traditional surgeons in communities was also investigated. Research is also conducted on the possible beneficial or adverse effects of male circumcision during childhood, adolescence and adulthood. The effects of male circumcision on male-to-female transmission are also included in recent study reports. While the experimental study designs are mainly focusing on the medical aspects there are also several publications related to knowledge, attitudes and behaviors among communities. Important aspects like the perception and acceptance of male circumcision in traditionally non-circumcising communities, knowledge on HIV transmission and prevention, risk behavior and compliance to recommended weeks of sexual abstinence after male circumcision are important for establishing good practices regarding voluntary male circumcision as a measure of HIV prevention and reduce possible adverse effects. Evaluation of intervention programmes like text-messaging for compliance to post-circumcision health visits are also available. The results of the behavior oriented studies show to a large extent the necessity of integrating voluntary male circumcision services in comprehensive programmes regarding HIV prevention and point to the fact that male circumcision cannot be a stand-alone but should be complemented by messages on risk reducing behavior, e.g. condom use and reduction of number of sexual partners. The master thesis summarizes the current state of research by analyzing available study results, including aspects of ethical and human rights considerations, as well as giving an overview on ongoing controversial discussion. The thesis shall contribute to a better understanding of voluntary male circumcision as a measure of HIV prevention in high-prevalence settings. Recommendations on good practices regarding public health programming as well as identification of research gaps can contribute to high quality programming in comprehensive HIV prevention.



## 3 HIV/Aids

The following chapter will give an overview on the global epidemic of the Human Immunodeficiency virus (HIV) that will act as background with regard to the biological basics, epidemiology and social impact. It is necessary to have a broad understanding of HIV to judge the importance of solid target group oriented preventive measures.

### 3.1 Origin and Historical Background

The clinical description of the Acquired Immunodeficiency Syndrome (AIDS) dates back to 1981 in the United States in relation to unusual clusters of pneumonia and Kaposi's sarcoma in homosexual men, followed by description of AIDS in other populations like heterosexual patients in Central Africa, injecting drug users (IDU) or blood transfusion recipients (Mindel/Dwyer et al. 2013: 6). The first clinical description of AIDS was followed by the isolation of the Human Immunodeficiency Virus (HIV) in 1983. The virus clearly differed from the earlier discovered Human T-cell Leukemia Viruses (HTLV) but belonged to the same family (Barre-Sinoussi/Chermann et al. 1983: 868). HIV turned out to be a lentivirus belonging to the group of retroviruses (Mindel/Dwyer et al. 2013: 6). One specific lineage of HIV, namely HIV-1 with different subtypes (also referred to as clades), has caused a global epidemic of historical dimension and accounts for the majority of all human HIV infections (Woroby 2008: 13).

While the description of the virus and the history of HIV/Aids since 1981 have been analyzed in detail, the circumstances regarding the spread of the virus into the human population still remain unsolved. To current knowledge the virus seems to have crossed into humans from non-human primates. Mathematical modelling, virology and historical research point to a crossing from non-human primates to humans in central Africa within the 1920s, probably through hunting (Pepin 2011: 210). Earlier theories on the spread of HIV due to a contaminated oral polio vaccine produced with chimpanzee cells seem to be outdated (Woroby 2008: 17/Pepin 2011: 2). The historical frame of colonization, medical practices and urbanization facilitated the spread of HIV to reach a global pandemic (Pepin 2011: 5).

### 3.2 Transmission, Stages of Infection, Testing and Therapy

HIV is transmitted through body fluids of infected persons. Infectious body fluids include semen, vaginal secretions, blood and breast milk. Body fluids have to be exchanged for transmission. To current knowledge it is not possible to become infected through contacts like hand shaking, sharing food, hugging or kissing (WHO 2014: Fact Sheet No. 360). In addition HIV can be transmitted from mother to child in utero, during delivery or breastfeeding, called vertical transmission. Infection with other viral or bacterial STIs increases the risk of transmission as susceptibility is increased when

mucosal linings are damaged. Risk factors for acquiring HIV therefore include: unsafe vaginal or anal sexual contact, being infected with another STI, injective drug use with contaminated needles, unsafe medical procedures, e.g. blood transfusions/lack of protective devices like gloves.

Once the virus enters the human body it is transported from submucosal tissues to the lymph nodes where it targets the CD4 cells (T-cells) and leads to a systematic spread of the infection (Rosenberg et.al. 2008: 59). The virus is replicating within the cells. Within the first 2-4 weeks of infection large amounts of the virus are being produced. This phase is called primary infection or acute phase and may lead to flu-like symptoms like fever, headache, muscle pains and fatigue. As the symptoms remain rather unspecific the individual might not think of an HIV infection at this point in time. The phase following the primary infection is called latency phase and can remain asymptomatic for years. The virus reproduces on very low levels.

After years of latency the immune system of the infected person is damaged to a point that makes the body vulnerable to infections and cancers, referred to as opportunistic infections. Without therapy this stage is on average reached after 10-12 years, but some patients even reach the stage after 2-3 years. This stage is entered when CD4 cells are destroyed to a level that leads to a CD4 count below 200/mm<sup>3</sup> (healthy person 800 to 1200/mm<sup>3</sup>). Typical opportunistic infections include besides others tuberculosis (TBC), fungal diseases and Kaposi's sarcoma. This advanced clinical stage of HIV infection combined with opportunistic infections is still referred to as Acquired Immunodeficiency Syndrome (AIDS), even if the distinction between "Aids" and "no Aids" has become more variable with antiretroviral therapy available (Vermund 2013: 4). Given its long incubation period and the specific challenges for treatment and prevention Vermund suggests to refer to HIV infection also as a chronic disease besides the classification as an infectious disease (Vermund 2013: 10; NIH 2009: online resource). In most cases Aids is leading to death within a few years but treatment can prolong the life of patients. With treatment available during the latency phase a person can even live with the virus for many years without developing Aids.

To detect HIV testing is commonly conducted with an antibody screening test (immunoassay) that can be done as a rapid test or laboratory based. If positive the result is confirmed with a Western blot test or an antibody differentiation test. Testing does have a window of 3-12 weeks starting from infection in which the virus cannot be detected due to the incubation period. Nucleic Acid Tests can shorten the window to ten days but are very costly and therefore not feasible for low resource settings (WHO 2015 a: 91).

There is still no cure for HIV and Aids and no vaccine available. The development of a vaccine is very difficult due to the high genetic variances of the virus and latent viral reservoirs besides other factors. But existing medication can extend the life of infected persons enormously and leads to a better quality of life. There are more than 30 antiretroviral drugs available suppressing the virus to even undetectable levels. The available antiretroviral drugs attack the virus at different stages of its lifetime cycle. The current state of treatment is to use a combination antiretroviral therapy (cART)

with different available drugs suppressing the replication of the virus indefinitely. In settings with adequate resources nearly everyone diagnosed with HIV is treated. In low income countries only patients with a CD4 count of 500/mm<sup>3</sup> and below are eligible to receive medication according to WHO guidelines but often this target is not met due to resource constraints. Immediate treatment should be considered for pregnant and breastfeeding women, children under five years, HIV positive partners in serodiscordant couples as well as HIV-associated Hepatitis B and tuberculosis patients (UNAIDS 2013: 46). Some drugs are especially available for pediatric use and others specifically recommended for pregnant women. Due to side effects and contraindications for specific situations the prescription of cART requires skilled and experienced health care providers (Vermund 2013: 12). The adherence to therapy can not only lead to a better quality of life of the patient but also be an effective way of limiting the risk for transmission including mother to child transmission (MTCT).

### 3.3 Epidemiology of HIV

Unique features of the virus contribute to the spread and historical dimensions of the epidemic. Transmission is highly influenced by human behavior and the long asymptomatic incubation period (Vermund 2013: 3). The likelihood of transmission is correlated with the virus levels within the infected person. The virus level is highest during primary HIV infection. To current research this is the phase a person is most infectious. After primary infection the virus level decreases but rises again over time (Overbaugh 2008: 75-76). Infected persons might spread the virus for years as the HIV infection is often detected only a long time after primary infection.

At the end of 2013, an estimated 35 million people were infected with HIV (UNAIDS 2014: 1), the majority of whom are living in middle- and low-income countries (Vermund 2013: 4). Women are more affected, 52% of people living with HIV in low- and middle income countries are women, with even 57% in sub-Saharan Africa (UNAIDS 2013: 78). Compared to earlier years there is progress reported, pointing to a stagnation or even decline of the epidemic in several parts of the world. It is worthwhile to have a closer look at the epidemiology in different regions because the drivers and high-risk groups differ greatly. The focus will be on sub-Saharan Africa, the Middle East and North Africa as well as Western Europe and North America because these regions will serve as examples throughout the thesis.

***Sub-Saharan Africa:*** The most affected region of the epidemic is sub-Saharan Africa with prevalence rates in adults (15-49) as high as 26.5 in Swaziland, 23.1 in Lesotho, 26.5 and 17.9 in South Africa in 2012 (UNAIDS 2013: A7-A8). The epidemic is driven by heterosexual transmission, and it is likely that this will remain the main transmission way during the next years. MTCT is still a problem with insufficient antenatal care and testing of pregnant women. Iatrogenic transmission is also occurring through contaminated needles, unsafe blood products and lack of protective devices

like gloves. Sexworkers, MSM and IDU do also represent risk groups but the epidemic can clearly be stated as a generalized one, in some countries even hyper-epidemic.

***Middle East and North Africa:*** The region can be described as low-prevalence region but with rising figures (estimated number of people acquiring HIV rose by 50 percent between 2011 and 2013). This might be due to cultural factors like low partner exchange and nearly universal male circumcision rates. IDU seems to be the driver of the epidemic but there are also other factors contributing to rising figures. Several mobile population groups like migrants to the Gulf States and street children have been in focus of current research. As homosexuality is widely not culturally accepted MSM often live in heterosexual marriages with secret contact to men. The virus is then often transmitted unnoticed to women who remain untreated within pregnancy. The presence of suppressive regimes has often limited the research and open communication on the prevalence of HIV within this region (Vermund 2013: 7/UNAIDS 2013 a: 8). Civil war and refugee migration following the Arab spring might be drivers of the infection in recent years.

***Western Europe and North America:*** Adult prevalence rates remain low in Western Europe and North America, but with MSM and IDU at greatest risk. Heterosexual transmission is also occurring, often combined with substance or alcohol abuse and related sexual risk behavior. Some minority and ethnic groups remain vulnerable as, for example, black MSM in the United States. MTCT and blood product contamination is nearly eliminated through various strategies in high-resource health settings (Vermund 2013: 8). Growing numbers of immigrants from high-prevalence countries represent a new high-at-risk group in Western Europe. Within the specific context of Germany that will act as an example for further analysis, immigrants can be referred to as most-at-risk groups. With massive influx of asylum seekers, refugees and people immigrating for a variety of reasons, including economic ones, new challenges arise. Within Germany, MSM are still the most affected group, accounting for 68% of new cases in 2014. Heterosexual transmission accounts for 28% and IDU for 4% of new diagnostics. The second largest group of newly diagnosed HIV patients is from sub-Saharan Africa. An increase from 10% to 15% with regard of all new cases can be seen for this group, with women more affected than men (RKI 2015: 243-246). RKI is stating that the majority of these HIV infections were transmitted in countries of origin. Nevertheless Gräser/Stöver et al. come to the conclusion that Germany might be the country of transmission for one quarter of affected women and one third of affected men (Gräser/Stöver et al. 2013: 21), while experts in Hamburg experience infections in Germany to be most prevalent (Färber 2015, expert interview).

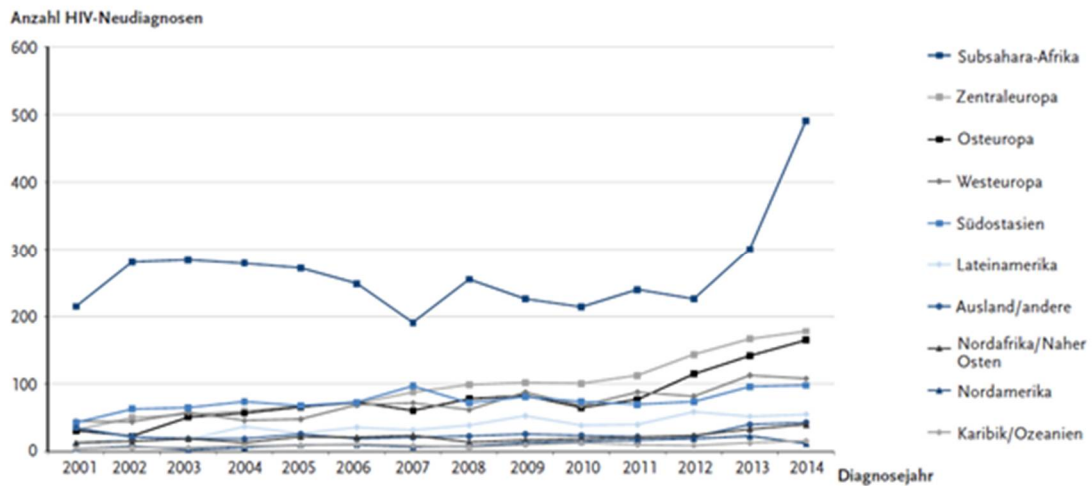


Abb. 7: HIV-Neudiagnosen: Angaben zu nicht-deutscher Herkunft in den Jahren 2001–2014 (n = 9.640)

Figure 1 New HIV Cases in Germany (non-Germans) 2001-2014 (Source: RKI 2015:246)

**Caribbean:** The Caribbean region is the second highest affected region globally but with heterogeneous transmission patterns. Prevalence rates in adults (15 – 49) range from 3.3 in Bahamas to 0.7 in the Dominican Republic in 2012 (UNAIDS 2013: A4). While heterosexual contacts remain the drivers of the epidemic in Haiti and the Dominican Republic, other islands experience concentrated epidemics in MSM and IDUs.

**Central and South America:** The epidemic is diverse but contacts between MSM seem to be the most common way of transmission, and bisexual men are thought to act as bridge groups. IDU is a problem in urban areas and growing substance abuse is leading to risky sexual behaviors. Transgender persons represent a high-risk group, for example in Nicaragua with prevalence rates of 15-19% (UNAIDS 2013: 83).

**South Asia:** MSM seem to be a risk group but heterosexual transmission rates are also rising. Especially transgender persons in Bangladesh, Pakistan and India are at risk. India for example has an adult prevalence rate (15 – 49) of 0.3 in 2012, but due to the large population a massive number of affected persons lives in the country, namely 2,100,000 in 2012 (UNAIDS 2013: A12).

**Southeast- and East-Asia:** The epidemic is less intense than in sub-Saharan Africa but with some vulnerable population groups highly affected. There are diverse patterns of transmission with IDU, MSM and STI patients representing risk groups but also heterosexual transmission on the rise. Iatrogenic transmission has been reported through unsafe blood products (Vermund 2013: 6).

**Eastern Europe and Central Asia:** IDU are the group mostly affected, especially in Russia. The region experience growing prevalence rates, also in MSM and heterosexual population groups. Rigid policies regarding IDU worsen the situation (Vermund 2013: 7).

**Australia and Oceania:** While MSM remain risk groups, especially the risk among IDU has been reduced within the region due to target group friendly approaches like needle exchange programmes.

### 3.4 Most-at-Risk Groups

As with regard to the modes of transmission, several population groups are at highest risk of acquiring HIV. Nevertheless it has to be distinguished clearly between generalized epidemics and concentrated epidemics within subpopulation groups. It is important to know that in generalized epidemics with more than 5% adult prevalence, no person sexually active can be categorized as “low risk”. Within generalized epidemics HIV prevalence among the general population is high enough to maintain the epidemic through sexual networking between serodiscordant couples or within multiple partnerships. In concentrated epidemics the HIV prevalence in sub groups is high enough to drive the epidemic, the subpopulation groups represent the most-at-risk groups, also referred to as high risk groups or key population (UNAIDS 2008: FAQ).

Men having sex with men (MSM) represent a most-at-risk group due to physiological and societal factors. Receiving unprotected anal sex is one way with a very high transmission risk. It is reported that this group is especially vulnerable due to limited access to information, condoms, as well as water-based lubricants and is generally hard to reach with public health interventions. In many countries, especially in North Africa, sub-Saharan Africa, the Middle East, East Asia and Russia, MSM are criminalized and discriminated against, leading to a climate of intolerance and fear, denying MSM of claiming their health rights and access to health services (UNAIDS 2013: 24, 26).

Female, male and transgender sex workers represent another high risk group globally due to multiple sexual partners, marginalization, gender based violence, legal disadvantages and limited access to preventive and healthcare services among other reasons (UNAIDS 2013: 22).

Transgender persons are at high risk globally, especially those who practice receptive anal intercourse (WHO 2014 a: xiii). Higher risk for transgender individuals is also related to denial of basic citizenship rights and accurate personal identification documents, leading to inadequate access to health services. Discrimination, stigma and gender inequalities are underlying societal factors (UNAIDS 2013: 7).

Injective drug users (IDU) are at high risk because of sharing of blood-contaminated injection equipment. Criminalization and non-availability of needle and syringes exchange programmes lead to high transmission rates (WHO 2014 a: xii). People in prisons and other closed settings are specifically at high risk. Risk behaviors like unsafe sexual activities and sexual violence (also between men not linked to homosexual identity), tattooing, and injective drug use in addition to prison infrastructure and overcrowding are contributing factors to increased transmission rates (WHO 2014 a: 5).

In specific contexts several population groups can show high prevalence rates and vulnerability. These can especially include mobile population groups like migrant/mobile workers (e.g. truck drivers, traders or mine workers) or marginalized groups like street children (WHO 2014 a: xii). Refugees are especially vulnerable due to limited access to health services and non-availability of protective devices (UNAIDS 2013: 48).

### 3.5 Social and Societal Dimensions

Only an estimated 51% of infected people globally know their HIV status (WHO 2015: 1) and it is estimated that only 34 percent of affected people living in low income countries are receiving appropriate care and cART for viral suppression (UNAIDS 2013 a: 6). Even in high-income countries only a quarter of HIV positive patients receive the recommended medication. The reasons are multiple and range from frequent non-availability of drugs, limited resources in health systems, psychiatric problems of patients like depression, substance abuse, inadequate and unfriendly treatment in health facilities to stigma within communities. The non-treatment and non-compliance to treatment remain an important driver of the epidemic in all settings. The compliance to therapy can suppress the viral load immensely and limit the risk of transmission. Especially children remain vulnerable as they are dependent on the capability of their parents (Vermund 2013: 20/UNAIDS 2013 a: 6). Results of the insufficient access to treatment and care are leading to an estimated 1.6 million Aids related deaths and 2.3 million new HIV infections globally in 2012 (UNAIDS 2013: 4).

Economic impact and societal implications are severe especially in high-prevalence settings. Millions of children remain orphaned, vulnerable to abuse and left without emotional care, often HIV positive themselves. In many countries key workers become ill, leaving the education, healthcare or social services sector underserved and causing a decline of economic productivity. Societies become less secure and less stable (Sowa 2008: 788-789). While, with the availability of ART and massive investment, HIV is rather becoming a chronic and manageable disease, still millions of people are denied access to medical and preventive services due to resource constraints or restrictive policies. The burden of disease is highest for women and girls, more vulnerable of acquiring the disease due to physiological factors and societal gender inequalities. In addition they often shoulder the care-taking of ill family members, thus being denied educational and economic opportunities (UNAIDS 2013: 79). Gender imbalances also affect men regarding limited design of health services to suit the needs of men and prevailing concepts of masculinity leading to risk-taking behavior. Aids-related mortality is higher for men than for women and men are more likely to enter testing and treatment late (UNAIDS 2013: 80).

HIV patients are especially vulnerable in conflict areas or humanitarian crisis. With collapsing health systems and frequent non-availability of services treatment is interrupted leading to drug resistance and enhancing the risk of further transmission. A prominent example is the Ebola outbreak in Sierra Leone, Guinea and Liberia in 2014 with health posts quarantined or closed for a significant period of time and people afraid of seeking health services (UNADIS 2014 a: 3). The same is applying to immigrants and refugees or internally displaced persons as access to health services like testing and treatment is limited.

### 3.6 Preventive Measures

As there is no cure for HIV and no vaccine available the only way of preventing HIV is preventing

the virus from entering the body. Transmission routes include sexual contacts, blood-borne transmission and MTCT (Gayle 2008: 91). Different strategies exist to be used in different settings for preventing the various transmission ways.

Regarding sexual transmission the use of male or female condoms for vaginal and anal sex is the most protective way. Vaginal microbicides might offer protection but no product is licensed yet with several trials ongoing. In addition, behavioral strategies like the reduction of sexual partners and delayed sexual debut are risk reducing (UNADIS 2013: 13). Treatment of STIs also reduces the susceptibility for the virus. The treatment with ART for infected persons can reduce the viral load immensely and contribute to a reduced risk of transmission. Preventive treatment with ART of uninfected partners in serodiscordant couples is a new preventive measure under current research (UNAIDS 2013: 24) but with risks attached like side effects of medication and the development of resistant viral lines. Male circumcision as a biomedical approach for prevention of sexual HIV transmission will be assessed in detail within the thesis. Several studies point to a reduction of risk of HIV transmission up to 60% (UNAIDS 2013: 12).

Transmission through blood-borne routes can occur in health settings and during injective drug use. Infection control in healthcare settings and the routine screening of blood products is the most effective way to prevent iatrogenic HIV spread (Vermund 2013: 23). The availability and use of protective devices like gloves, goggles and gowns as well as appropriate waste disposal are important strategies. The use of single injection devices and the prohibition of reuse of syringes and needles in health settings reduce the risk of iatrogenic HIV spread. Needle and syringes exchange programmes for IDUs to provide access to clean injective equipment reduce the risk of transmission (Gayle 2008: 94). These measures are often not available in low resource settings.

MTCT can be prevented through ART for HIV positive pregnant women in order to reduce the viral load. Breastfeeding alternatives and cesarean section delivery where appropriate and accessible can reduce the risk of MTCT. Treatment of the newborn with pediatric ART has also been proven to be risk reductive (WHO 2012: 2).

### 3.7 HIV/Aids Prevention Programming

HIV prevention programmes can be distinguished in biomedical, structural and behavioral approaches. Due to the multidisciplinary nature of public health interventions and overlaps in programming, a clear distinction between the approaches is often neither easy nor desirable. But it is worthwhile to explain the concept in order to classify and explain different strategies and identify synergies between the approaches. It is also important to have a look at which societal level the intervention is targeting and what kind of stakeholders are involved.

Biomedical approaches include all measures regarding HIV prevention with medical focus on assessing or impacting the physiological state like STI treatment, testing campaigns, ART as preven-



tion for example for PMTCT or serodiscordant couples, barrier methods like condoms and microbicides. HIV vaccines would fall under this category if available one day. Male circumcision for HIV prevention is also a biomedical approach (Golden/Collins et al. 2013: 4). Biomedical interventions are only successful to a full extent when accompanied by structural and behavioral approaches.

Structural approaches aim at creating changes in policy, programmes and practice to increase availability, acceptability and accessibility of services and goods for HIV prevention and treatment like ART, testing or condoms and lubricants (Golden/Collins et al. 2013: 6). Interventions therefore focus on the political, legal, cultural or economic side of HIV prevention work. Programmes are working on a societal or environmental level.

Behavioral approaches target the individual or small groups to create change in attitude, behavior and beliefs to support HIV prevention and risk reduction. Individual knowledge and skills shall be increased by behavioral approaches to enable the individual to make informed decisions. Programmes fall under the category of social marketing (Golden/Collins 2013: 124).

All three different categories of programming do only work hand in hand to reach maximum impact. To put it in a nutshell it can be said that “[...] effective social-behavioural and structural programmes will not only remain essential in their own right but will also be needed to maximize the efficacy of biomedical approaches.” (UNAIDS 2013: 14) An example is the reduction of viral load through ART for the infected partner in a serodiscordant couple as biomedical intervention strategy but the creation of access, availability and accessibility of medication would fall under the category of structural interventions (Golden/Collins et al. 2013: 6). Prevention programming needs to be combined with continued HIV treatment in order to be effective.

Programme design should be evidence based (Golden/Collins et al. 2013: 4), target group oriented (focusing on key populations/key drivers or wider population groups according to the kind of epidemic) and spread harmonized messages within different intervention approaches (UNAIDS 2013: 14). They should be rigorously evaluated and gender-sensitive as well as youth friendly in design (UNAIDS 2013: 26). Some examples of widely used HIV prevention programming include the roll-out of “abstinence, be faithful and condom use” (ABC) strategies, PMTCT programmes, condom programming and Voluntary Counseling and Testing (VCT). Currently developed strategies include conditional cash transfer programmes.

ABC stands for abstinence, be faithful and condom use. This approach with population specific messages has a long-standing tradition in HIV programming and is used to help individuals identify and reduce risky behaviors. As condom use remains one of the most effective prevention strategies condom programming is still an important part of behavioral approaches. While on the structural side availability of condoms has to be ensured, the individual has to be empowered to negotiate and apply condom use, especially women and youths (UNAIDS 2013: 16). New condom designs (female condoms, Origami condom) might enhance individual acceptability and desirability. Large communication campaigns are often part of condom programming.

PMTCT programmes have been an essential part of HIV prevention work since the 1990s years. With combining structural, behavioral and biomedical approaches pregnant women are reached through antenatal care to reduce the risk of MTCT by testing and ART for mother and newborn. Comprehensive messages of family health and partner testing are often integrated in programming. Antenatal care settings are also an important entry point for sentinel surveys for HIV prevalence monitoring.

VCT approaches are widely used in low- and middle income countries with the integral parts of quality testing, pre- and post-test counseling, partner counseling and linkage to other services. The informed consent of the clients is the main basis to build trust and to offer reliable services. VCT programmes give the opportunity to enable individuals to learn about risk reductive behavior and protect themselves and others from infection (Golden/Collins et al. 2013: 285).

UNAIDS is reporting two examples in Lesotho and Malawi, representing conditional cash transfers as effective strategy to create risk reducing behaviors among young people, respectively school girls. The programme in Malawi reported a reduction of new HIV infections among school girls by 60% (UNAIDS 2013: 18). Notwithstanding the first promising results more research is needed within this area to detect useful strategies and target groups.

Within the specific context of Germany some programmes for the already described high-at-risk group of immigrants exist with the overall targets of spreading culturally sensitive messages on HIV prevention and linking HIV positive immigrants to treatment (e.g. Gräser et al. 2013).

A rather new approach that will be analyzed in detail throughout the thesis is the biomedical approach of voluntary medical male circumcision. According to WHO the risk of acquiring HIV is reduced up to 60% for circumcised men. The following sections will deal with the current knowledge and practice around VMC.

## 4 Male Circumcision

The following chapter will outline basic facts on the practice and recent knowledge on male circumcision focusing on prevalence, procedures and safety of the surgery.

### 4.1 Traditional and Medical Male Circumcision

Male circumcision is one of the oldest surgical practices and is conducted worldwide for medical, religious, social and cultural reasons. First historical mentioning dates back to an Egyptian tomb painting produced around 2300 BC. The practice was conducted among ancient Semitic peoples.

For religious reasons Jews are still nearly universally practicing male circumcision. The tradition is thought to date back to a covenant between Abraham and God. Also referring to the Abrahamic faith, Muslims are practicing male circumcision as part of their relationship with God. Male circumcision is also thought to be a precondition for the hajj to Mecca. Male circumcision among Muslims is not universal but strongly encouraged by religious leaders. For other religions, the practice is not a relevant part of tradition, but with some exceptions like the Coptic Christians in Egypt. For cultural and ethnic reasons male circumcision was and is still practiced by a variety of ethnic groups around the world, including geographical areas of Sub-Saharan Africa, Australia (Aboriginals), America (Mayans and Aztecs), Asian (Philippines, Eastern Indonesia) and Pacific Islands. For the majority of practicing groups male circumcision is a rite for passage to manhood. Social determinants and medical considerations are influencing several groups traditionally non-circumcising, who took up circumcision during the last centuries with advanced surgical methods available and medical benefits promoted. Among them are, for example, the United States of America where the majority of circumcised men report medical, hygienic and social reasons for conforming to the predominant norm as reasons for circumcision. Social desirability is also related to women preferring circumcised men within these societies (WHO/UNAIDS 2007: 3-5).

For religious reasons the time for male circumcision varies. Male circumcision within Jewish religion is carried out on neonates by a traditional practitioner called mohel. Within Muslim faith there is no exact prescribed date and male circumcision is conducted between birth and puberty (WHO/UNAIDS 2007: 19). Male circumcision for cultural reasons as a rite for passage to manhood is carried out between 6 to 35 years depending on the meaning of male circumcision to the respective culture. In societies with other social determinants for male circumcision the procedure is mostly carried out on neonates or young children.

There are several forms of male circumcision with the removal of the male prepuce as predominant practice. The amount of foreskin removed varies between cultures (WHO 2009: 10). Several other more invasive types have been existing in different cultures and might still exist today including peeling of the skin of the penis (tribal practice in South Arabia) or subincision of the urinary tube (Australian aborigines) (Delaet 2009: 411). Some cultural practices only involve incision of the foreskin. The setting for male circumcision greatly varies between cultures. In general it has to be distinguished between traditional male circumcision carried out by a traditional practitioner (often medically untrained) and medical male circumcision carried out in a hospital or other formal health setting including outreach facilities by trained medical staff. It has to be mentioned that a growing number of male circumcisions for religious and cultural reasons also take place in a medical setting (WHO/UNAIDS et al. 2007 a: 2, Insert 3).

Apart from religious, cultural and social reasons male circumcision is conducted for several medical indications, e.g. phimosis, paraphimosis and balanitis xerotica obliterans (WHO/UNAIDS 2007: 14). For years male circumcision has also been conducted for preventive reasons regarding urinary tract

infections, STIs and cancers. A new development is male circumcision for biomedical prevention of female to male HIV transmission that will be discussed in depth throughout the thesis. The following chapters will focus on medical male circumcision, as the majority of programme approaches regarding male circumcision as a measure of biomedical prevention of HIV is conducted in medical settings to ensure safety and quality of services. Some efforts are undertaken to integrate traditional practitioners into programming to enhance cultural acceptability and prevent adverse events from unsafe traditional procedures.

## 4.2 Worldwide Prevalence of Male Circumcision

It is estimated that 30% of males (15 years and older) are circumcised globally (WHO 2009: 10). Estimation is difficult, and WHO calculates figures of practicing population groups (e.g. Jews) and combine those with results from health surveys. Self-reported data are to a high degree unreliable to use within this context, as male circumcision can include different types according to various cultural practices. A man who will perceive himself as circumcised because of passing the traditional rite into manhood with a respective circumcision practice might not necessarily be circumcised in medical terms (e.g. with only subincised foreskin). In addition male circumcision is not coherently documented in hospital settings, and this is true for all age groups. Out of the total 30%, it is estimated that 68,8% are Muslim men predominantly living in North Africa, the Middle East and Asia, 0.8% Jewish men, 12.8% men from the United States of America and 17.6% from other countries with circumcising population groups for non-religious reasons (WHO/UNAIDS 2007: 7-8). It is worthwhile to have a snapshot of different regions because some authors are referring to a possible ecological association of the lower burden of the HIV epidemic within countries with high male circumcision prevalence (see 6.2.1). With massive male circumcision campaigns conducted during the recent years in some countries prevalence might be slightly higher by now especially in Southern and Eastern Africa but consistent figures are missing in most cases. According to the author's knowledge there is no up-to-date publication on the prevalence of male circumcision. WHO estimates from 2007 will therefore act as reference.

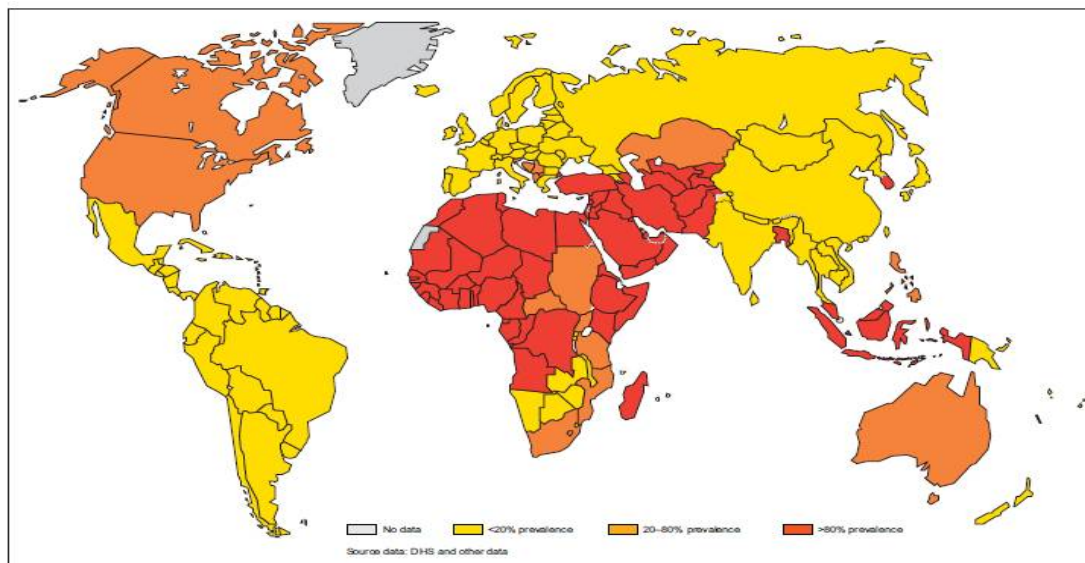
**Africa:** MC is nearly universal in North and most of West Africa. Within Southern Africa prevalence is low with 15% in Swaziland, Zambia, Namibia, Zimbabwe and Botswana. Some countries have higher rates like South Africa 35%, Mozambique 60%, Lesotho 48% and Madagascar >80%. In central and East Africa the picture is also diverse with prevalence ranging from 93% in Ethiopia, 70% in Tanzania, 84% in Kenya to 15% in Rwanda and Burundi.

**Asia and Middle East:** In Muslim countries of the Middle East and Central Asia as well as Pakistan, Indonesia and Bangladesh, male circumcision is nearly universal. The Muslim population in India is

also practicing MC. For non-religious reasons male circumcision is practiced in the Philippines, Malaysia and the Republic of Korea. For these countries figures vary between 60% and 90%.

**North America, Europe, Australia:** In English-speaking industrialized countries male circumcision was on the rise since the 19<sup>th</sup> century following first epidemiological studies on medical benefits and several factors contributing to social desirability of the practice. Prevalence of male circumcision is estimated to be between 70% and 90% within the United States, around 30% to 40% in Canada and 59% in Australia. Within Europe male circumcision is mostly related to Jewish and Muslim religion as well as immigration from traditionally circumcising societies. An exception is a 15.8% prevalence in the United Kingdom for non-religious reasons. The fact that in Europe male circumcision is widely not practiced for cultural, religious or social reasons while in the US the practice is common might have a vast impact on the perception of male circumcision as a potential beneficial practice for biomedical HIV prevention.

**Central and South America:** There is only insufficient information on prevalence of male circumcision in Central and South America. While historically Aztec and Mayan civilizations were practicing male circumcision, today there are only few studies with small sample sizes pointing to low prevalences of 11% in Mexico, Panama, Costa Rica and Colombia, 7% in Brazil and 6% in Peru. (WHO/UNAIDS 2007: 9-12).



Note: National prevalence of male circumcision was estimated using Demographic and Health Survey data where available. For other countries, estimates were made from other published sources. Countries with no published data on male circumcision prevalence are labelled "no data".

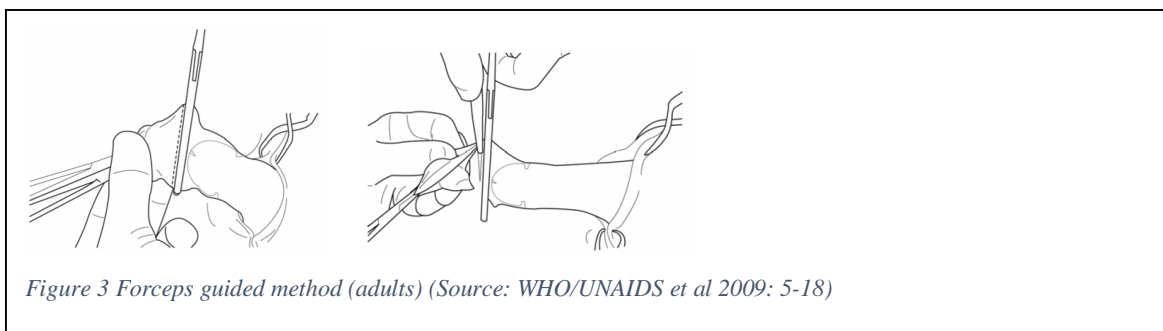
Figure 2 Global map of male circumcision prevalence at country level, as of December 2006 (Source: WHO/UNAIDS 2007: 9)

### 4.3 Medical Surgery and Devices for Male Circumcision

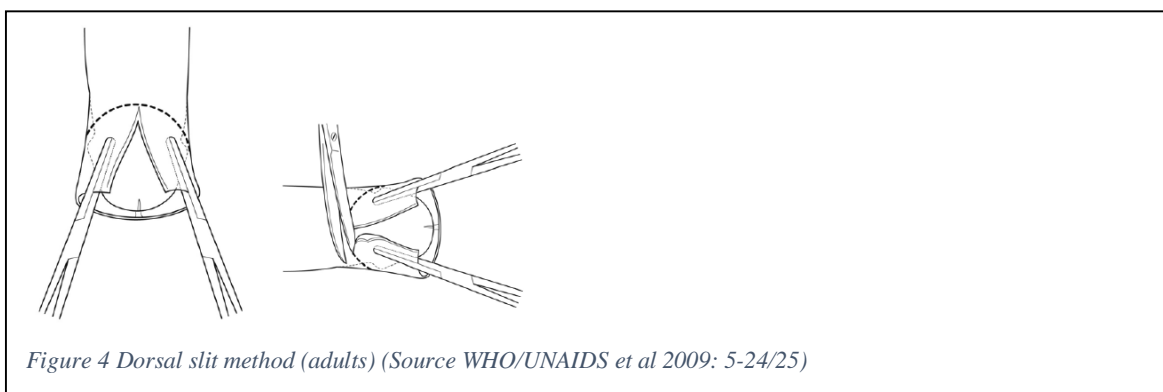
There are different ways how medical male circumcision can be performed, including conventional surgical methods and the use of devices. Differences exist for adult and child male circumcision.

### 4.3.1 Circumcision in Adults

Conventional surgical methods widely practiced for adult circumcision under injectable local anaesthesia include the sleeve resection method, the forceps-guided method and the dorsal slit method.<sup>1</sup> The forceps-guided method is one that is widely used in low-resource settings and can be used by relatively inexperienced surgeons and surgical assistants. An assistant is not necessarily needed to perform the procedure. A forceps is placed to protect the glans and the foreskin is cut away with a scalpel. A disadvantage is that the method leaves 0.5 to 1 cm of mucosal skin.



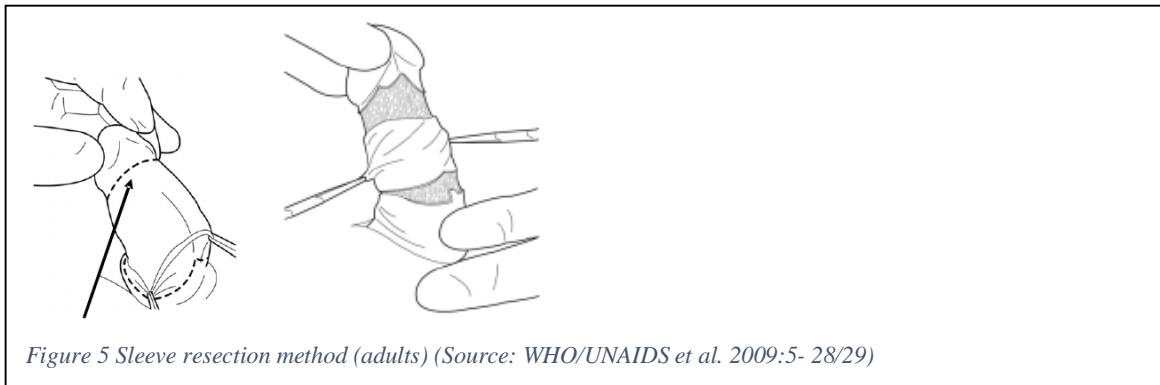
The dorsal slit method is widely practiced worldwide but the surgeon should be more experienced. The presence of an assistant is recommended even if it can be performed without one. Two forceps are placed at the foreskin and a cut is made between the forceps until the previously marked circumcision line. The foreskin is then cut away with dissection scissors. As a disadvantage the method can produce asymmetrical results.



The sleeve resection method produces the best results from a cosmetic point of view but is best performed in a hospital setting by an experienced surgeon. In addition the presence of an assistant is required. Two incisions are done with the retracted foreskin leaving a sleeve of foreskin that is cut away with scissors (WHO/UNAIDS et al. 2009: 5-29).

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<sup>1</sup> Detailed description and illustration of the procedures can be found in WHO/UNAIDS et al. 2009



Sterile conditions and sterile equipment are needed for all described surgical procedures. Wound closing is done with absorbable sutures (WHO 2015 b: 9).

Besides surgical methods several devices are recently available to perform adult male circumcision with some advantages attached especially for low-resource settings. WHO has prequalified a collar clamp device, namely ShangRing™, and an elastic collar compression device, namely Prepex. Due to limited data regarding safety and acceptability, other available devices are not prequalified, e.g. Tara KLamp. The collar clamp mechanism works through tight compression of the foreskin between hard surfaces so that haemostasis is achieved. The foreskin is removed immediately while the device is left on the penis for seven days for prevention of bleeding and healing purposes. Injection of local anaesthesia is needed for pain control as live tissue is removed during the procedure. In comparison the elastic collar compression device<sup>2</sup> works through a slow compression of the foreskin between an elastic ring and a hard surface to achieve necrosis of the tissue. The foreskin is therefore not removed immediately. The necrotic foreskin and the remaining part of the device are removed seven days after device placement. No local anaesthesia is needed for the procedure (WHO 2013: 7-10).



Compared to the surgical methods the use of devices is time-saving and less resource intensive. The procedures can be performed by non-surgical staff (trained mid-level providers) and are acceptable by clients (WHO 2013: 6). No sutures are required and the elastic collar compression device (Prepex)

<sup>2</sup> A video demonstration of the procedure with PrePex device including preparation and removal of the foreskin can be found online: <http://prepex.com/videos/> [02.09.15]

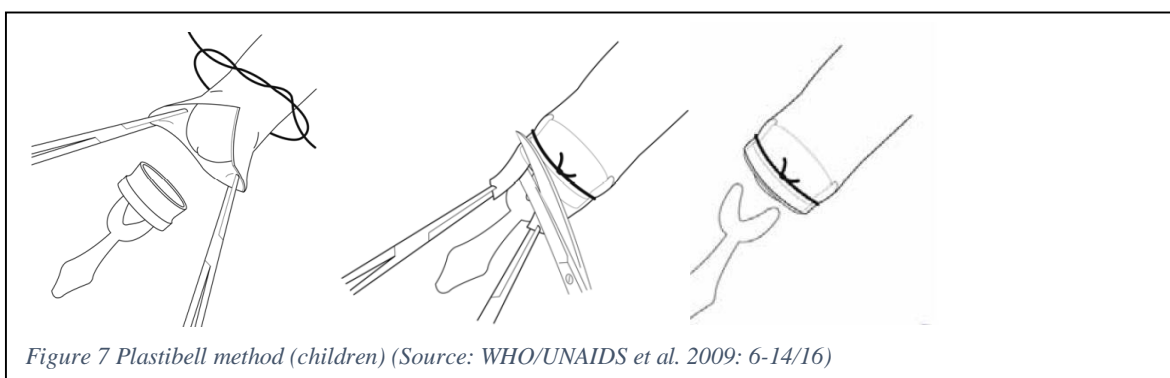
does not need a sterile environment (WHO 2015: 9). The healing time for both devices takes on average one to two weeks longer than following the conventional surgery (collar clamp device 44.1 days, elastic collar compression device 42.3 days), meaning the sexual abstinence period for healing purposes is slightly longer (WHO 2013: 20-21). For male circumcision with devices a second visit of the health facility is mandatory for device displacement while for conventional surgery a follow-up visit is recommended but not mandatory. In comparison to conventional surgery as both devices are disposable no measures for sterilizing equipment have to be taken.

#### 4.3.2 Circumcision in Neonates, Infants and Children

For neonates and infants mainly four methods under injectable local anaesthesia or the use of EMLA anaesthetic cream are performed, including the dorsal slit method, the Mogen clamp, the Plastibell and the Gomco clamp method. Healing takes on average one week for all described procedures.

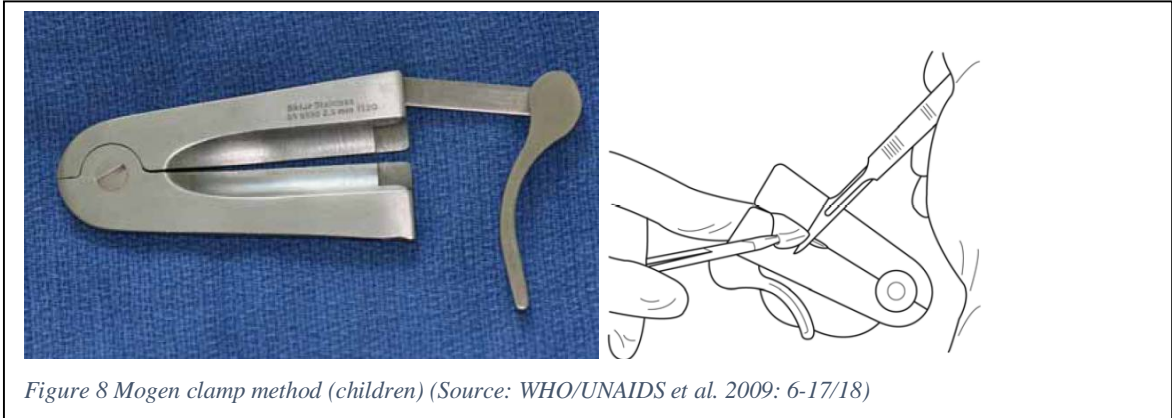
The dorsal slit method (see 4.3.1) is not typically used for paediatric male circumcision and is more suitable for older children. The method does not differ from the dorsal slit method used in adult circumcision but the surgeon needs to be experienced as very small movements are necessary due to the small penis size of an infant. Suturing is necessary for this procedure (WHO/UNAIDS et al. 2009: 6-9).

The Plastibell method is widely used and is also feasible for low resource settings. It can be conducted with EMLA anaesthetic cream. A small dorsal slit is conducted and the Plastibell (disposable ring) is placed over the glans. The foreskin is pulled back over the Plastibell and a ligature is placed in the groove of the plastibell to crush the edge of the foreskin. The foreskin is cut away with scissors and the Plastibell remains on the penis. Bleeding is rare and no sutures are needed. The Plastibell drops off after 5-8 days (WHO/UNAIDS et al. 2009: 6-16).

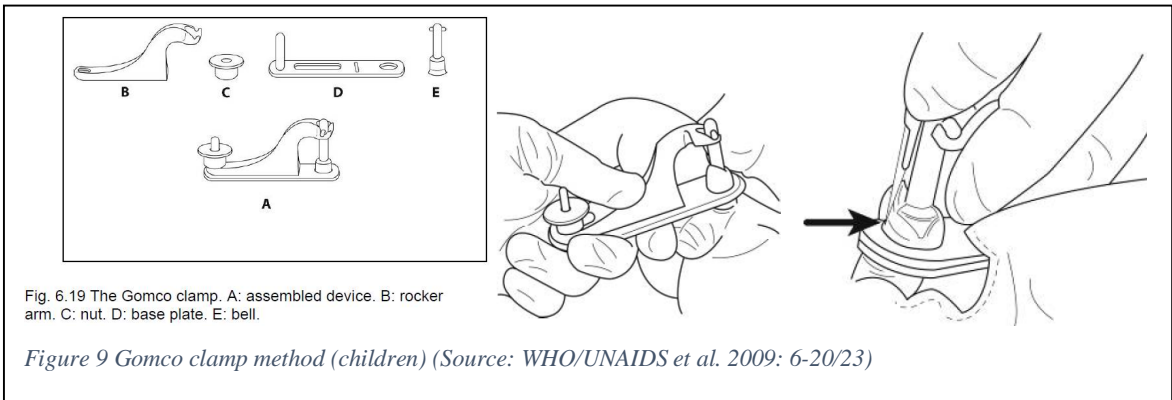


The Mogen clamp is a reusable shield clamp. All adhesions are separated and traction is put on the foreskin that is introduced to the slit of the device. The glans is protected by the clamp and the foreskin is crushed and cut off linear with a scalpel at the outer side of the clamp. In older infants the use of sutures might be necessary (WHO/UNAIDS et al. 2009: 6-16).





In comparison to the Mogen clamp the Gomco clamp consists of four reusable parts (base plate, rocker arm, nut, bell) with different bell sizes. A dorsal slit is conducted and the bell of the clamp placed on the glans. The foreskin is pulled over the bell. The base plate placed over the bell and the rocker arm placed in position to make the clamp ready for tightening. The foreskin is crushed and cut circumferentially. In older infants the use of sutures might be necessary. A disadvantage of the Gomco clamp is that the different parts might be mismatched or lost during sterilization processes (WHO/UNAIDS 2009 et al.: 6-23).



#### 4.4 Complications and Adverse Events

The following section gives an overview on possible complications and adverse events, differentiating circumcision in adults and circumcision in children. The knowledge on adverse events is necessary to balance risk and benefits of the surgery.

##### 4.4.1 Circumcision in Adults

When male circumcision is performed with surgical methods or devices in adult ages, complications are possible as with every surgery. Complications of adult MC can include bleeding, pain, increased sensitivity of the glans penis for several months, meatitis, haematoma, and injury of the penis or the glans, especially when performed by non-trained practitioners. Especially in low-resource settings

wound infection can occur if the procedure is carried out under non-sterile conditions (WHO/UNAIDS et al. 2009: 1-2). Retention of urine and swelling are also cited as complications following male circumcision as well as prolonged wound healing. Recently a risk of acquiring Tetanus especially in low-resource settings has been reported (WHO 2015 b: 4) with rare cases resulting in death. Unpleasant cosmetic results are possible with ragged scars or parts of the foreskin remaining (WHO 2015 b: 7-8). When performed on males previously sexually active a comparison of pre- and post-operational sexuality is possible. With regard to psycho-social effects a possible reduction of sexual sensation and problems with orgasm are reported (Barthlen 2014: 143). Discomfort with erection as a result of removing too much skin can occur (WHO/UNAIDS et al. 2009: 7-8). WHO is referring to trials carried out in Uganda and Kenya resulting in less than one complication in every 50 circumcisions (WHO/UNAIDS et al. 2009:1-2).

#### 4.4.2 Circumcision in Neonates, Infants and Children

Circumcision in neonates, infants and children is especially contested as the child cannot give consent to the procedure. Therefore it was difficult to find neutral literature on complication rates without ethical statements and considerations. There are several possible complications reported regarding circumcision in neonates and older children. Authors are referring to physical and psycho-social problems arising from male circumcision in neonates and infants. But literature is also stating a lack of systematic research and a lot of studies seem to be outdated and the methodological quality of existing studies is often judged to be low. Most of the existing studies were conducted in clinical settings and not in low-resource settings (Schäfer/Stehr 2014: 115; Barthlen 2014: 142).

Complications can be listed with short-term and long-term consequences. Critics of male circumcision emphasize the natural connection between glans and prepuce during the first years of life. According to literature injuries and scars of the glans are possible when separation through surgery on neonates or young infants is conducted. From a medical point of view it is not exactly clear at which point in time the natural separation of glans and prepuce is completed (Schäfer/Stehr 2014: 111; Kupferschmied 2014: 88). High (Schäfer/Stehr 2014: 111) to moderate (Barthlen 2014: 142) rates of secondary hemorrhage are reported. As with every surgery wound infection is possible. In addition Schäfer and Stehr are referring to deviation or torsion of the penis, fistula, obstruction of the urethra and meatal stenosis with possible lesion of bladder and kidney (Schäfer/Stehr 2014: 114-118). Urinary retention can also be listed (Delaet 2009: 412).

As a major and severe consequence an accidental amputation of the glans is possible, especially if the surgery is conducted by untrained or non-medical persons. Necrosis of the penis can also occur (Barthlen 2014: 142). Very rare cases of death mainly through infection are documented (Barthlen 2014: 142, Schäfer/Stehr 2014: 118). As anaesthetization with neonates is not recommended, local anaesthetic through creams is used. Critics are referring to a limited effect of the salves and to pain

during surgery as a result. As a long-term consequence psychological trauma is possible (Kupferschmied 2014: 98-99). Unpleasant cosmetic results of the surgery are also possible, for example with parts of the prepuce remaining (Barthlen 2014: 142).

Further complications can arise from the incorrect use of the devices available for infant circumcision, for example by the use of the wrong size of the Plastibell device. If the bell used is too small pressure necrosis can occur. A too large size may slip onto the shaft of the penis and cause urinary retention and bladder rupture or loss of the glans (WHO/UNAIDS 2009: 6-13).

There are some contraindications to male circumcision like buried (webbed) penis and hypospadia penis. These conditions are often not easy to identify for non-trained persons. In case circumcision is nevertheless conducted consequences can be severe for patients. This also applies as the prepuce can be needed for further cosmetic surgery (Schäfer/Stehr 2014: 113; WHO/UNAIDS 2009 b: 6-2). Quantification of adverse events seems to be difficult from the existing literature and authors draw on different conclusions. Hässler is referring to an analysis of 16 prospective studies resulting in severe complications in 2% of patients and minor complications in 1.5% of cases. Lowest complication rates seem to appear in neonates. Circumcision in three to nine months old boys might show rates up to 30% of complications (Hässler 2014: 154), but this conclusion seems to be a stand-alone and might be due to classification of complications (see also 3.6). WHO is referring to the Australian and Canadian medical society statements concluding on a complication rate of 0.2% to 5% (WHO/UNAIDS 2007: 16).

#### 4.5 Potential Benefits

Several studies report potential benefits of male circumcision other than the partial protection regarding HIV acquisition. The potential protective aspect regarding HIV will be assessed in chapter 6 and therefore not listed here. One of the most cited reasons for circumcision is perceived improved penile hygiene. Glans and inner foreskin require regular cleansing for proper hygiene because secretions can accumulate between foreskin and glans and may act as pathogen host. While few studies have determined the relation between circumcision status and penile hygiene WHO is stating that circumcision might lead to improved penile hygiene in circumstances where men have difficulties to maintain an adequate penile hygiene. But irrespective of circumcision status a proper penile hygiene might reduce the risk of several STI (WHO/UNAIDS 2007: 14).

Several studies have shown circumcised men and male children having a lower risk of urinary tract infections (e.g. Wiswell et al. 2000). According to WHO the likely biological mechanism for the reported benefits is related to the moist and warm environment under the foreskin of uncircumcised men. Especially when penile hygiene is neglected or not possible due to environmental or structural factors pathogens are likely to persist and replicate, including uropathogenic organisms. The pathogens can be found especially at the inner mucosal surface of the foreskin (WHO/UNAIDS 2007: 13).

Within a systematic review Weiss et al. come to the conclusion that circumcised men have a lower risk for syphilis and chancroid (Weiss et al. 2006: 108). The risk for penile cancer seems to be reduced (e.g. Daling et al. 2005). Hässler states, regarding the psycho-social dimension of circumcision, that contrary to often cited feelings of being mutilated following circumcision, uncircumcised men and boys could develop feelings of non-conforming in contexts with high circumcision rates leading to feelings of inferiority (Hässler 2014: 156).

There might also be advantages for female partners of circumcised men, as a reduced risk of *Chlamydia trachomatis* has been found in female partners of circumcised men compared to female partners of non-circumcised men (Castellsague et al. 2005: 907).

#### 4.6 Summary of Safety of Male Circumcision

Comparing the contesting study results on male circumcision with focus on the surgery itself it can be concluded that the procedure seems to be safe in most cases when performed in medical settings by trained personnel under sterile or clean (elastic collar clamp device) environment. Male circumcision seems to cause lowest complication rates in newborns when taking the listed contraindications into consideration. Healing is also completed fastest in neonates and young infants (one week) compared to healing times in adults (up to 44 days). As infants and children are not sexually active, a period of sexual abstinence is not relevant. Another advantage of infant circumcision compared to adult circumcision is the less vascular foreskin (WHO/UNAIDS et al. 2009: 6-1). The main problem remains that a child cannot give consent to the procedure. This point will be elaborated in chapter 7.2.1.1.

#### 4.7 Current Developments in Voluntary Medical Male Circumcision Programming

WHO and UNAIDS recommendation to integrate voluntary male circumcision in HIV programming in high-prevalence countries dates back to 2007. Nevertheless, uptake of male circumcision is still low in many countries prioritized for scale-up.<sup>3</sup> To reach a considerable impact mathematical modelling projected that 80% of uncircumcised adult men would have to be circumcised in countries with high HIV prevalence but low male circumcision rates. While some countries reached considerable progress towards set targets, e.g. Ethiopia with 128% and Kenya with 108% achievement, others are behind schedule, e.g. Malawi with 8% and Namibia with 6% achievement. Total numbers of performed male circumcisions remain in all cases low (WHO 2015 c: 2). Reasons cited include limited human resources, financial constraints and stock-outs of necessary devices (UNAIDS 2013: 19-20).

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<sup>3</sup> WHO priority countries for voluntary male circumcision for HIV prevention: Botswana, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Rwanda, South Africa, Swaziland, United Republic of Tanzania, Uganda, Zambia, Zimbabwe

Challenges regarding policy development, funding, and only slow changing socio-cultural beliefs regarding male circumcision were stated at the beginning of male circumcision programming. Often government health facilities lack the capacities to offer comprehensive voluntary male circumcision packages and implementation of programmes was mostly done by mobile health services implemented by non-governmental organizations (Wamai et al. 2011: 10). The cited low uptake in some countries is pointing to only minor change of the described situation. A lack of understanding of the potential benefits of male circumcision might also contribute to the mentioned situation of slow uptake. A limited coordination between stakeholders might contribute to the low uptake of medical male circumcision in HIV prevention programming. Several non-governmental organizations or other development actors might refrain from promoting the measure due to ethical concerns (see 7.2.1)

## 5 Research Questions and Scientific Methods

The following chapter will outline the methodological base for the analysis. A two-stage analysis will be applied to answer the research questions.

### 5.1 Goals and Research Questions

Since the WHO recommendation to integrate voluntary male circumcision in HIV prevention programming the measure remains contested. While on the one hand WHO priority countries integrated VMC in their public health strategies with massive support from e.g. the US development aid agencies, on the other hand resistance from other developmental actors is persistent, especially in Germany. Actual implementation of VMC strategies in priority countries is slow and programmes remain isolated without linkage to wider population based programmes (see 4.7). WHO is citing evidence from three independent RCTs that heterosexual transmission risk might be reduced by 60% by VMC but statements regarding long-term population effects and behavior of circumcised men remain vague and evidence provided by the RCTs is contested by critics of VMC for HIV prevention. At present, VMC is only considered as a measure in high-prevalence settings and potential integration into programmes for most-at-risk groups in concentrated epidemics is not yet explored. The biomedical approach of VMC is therefore not mainstreamed in HIV prevention programming.

The underlying reasons for the above-described situation are complex and might include limited knowledge of or limited belief in evidence provided regarding a protective effect of male circumcision, ethical concerns as well as limited coordination between stakeholders. A general skepticism can be identified among development and health practitioners, especially within the German context, possibly supported by a wide critical societal discourse on infant male circumcision. This discourse

might prevent the German development aid agencies from integrating male circumcision into their programming and suppress the exploration of male circumcision for most-at-risk groups in concentrated epidemics. The debate on male circumcision seems to be highly driven by ethical and emotional concerns without taking the scientific base into consideration. On the other hand, overpraising the measure might lead to an overestimation of the protective effect of male circumcision by the target group and to increase risk behavior (e.g. neglect of condom use).

The aim of the master thesis is therefore to structure the ongoing controversy and provide guidance for health and development practitioners. The biomedical measure of male circumcision for HIV prevention shall become understandable and acceptable for experts from societies where male circumcision is not widely performed like within the German context. An evaluation of existing evidence on male circumcision as HIV prevention will therefore be conducted and an analysis on the ongoing controversial discourse regarding the surgery provided.

The following questions will guide the analysis:

*Is mainstreaming of voluntary male circumcision recommendable in high-prevalence settings and for most-at-risk groups?*

*Is medical evidence regarding the protective effect of male circumcision strong enough to contest ethical considerations?*

*Is the protective effect of male circumcision for HIV prevention for most-at-risk groups underestimated in Germany as low prevalence and traditionally non-circumcising setting?*

The aim of the analysis is to develop recommendations regarding the mainstreaming of male circumcision in HIV prevention that take the current state of research into consideration. One important aim is to find entry points to support a redefined dialogue within the German public on male circumcision. The following chapters will therefore analyse in detail the current state of knowledge regarding male circumcision as a measure for HIV prevention in high-prevalence settings and will also explore if male circumcision might in addition be a preventive measure for most-at-risk groups in other contexts (e.g. MSM, immigrants from high-prevalence countries). A two-stage analysis will be conducted to answer the research questions. Recommendations regarding mainstreaming of VMC in HIV prevention in high prevalence settings and for most-at-risk groups will be developed in case the analysis shows that there is strong evidence for male circumcision as beneficial practice regarding HIV prevention.

The aim of the two-stage analysis is to give an overview of the current state of knowledge on male circumcision as HIV prevention to decision makers, development practitioners and medical personnel and formulate recommendations regarding further uptake and mainstreaming in HIV programming. It might also help the individual to make an informed decision on preventive behavior. In bringing together the results of the two-stage analysis it will be possible to weigh up the ethical

considerations against the medical side of male circumcision as a measure of HIV prevention and help stakeholders in making “*evidence-based policy and programme decisions*” (WHO 2009: 2).

## 5.2 Literature Review and Evaluation of Evidence

The first part of the analysis will consist of a literature review regarding studies about male circumcision as HIV prevention and an evaluation of evidence provided. Existing studies will be categorized according to methodology and results. The quality of selected studies will be judged regarding objectivity, reliability and validity. Selected Bradford Hill criteria (e.g. biological plausibility) will act as a benchmark of evidence provided. The analysis will result in a summary of potential protecting factors and successful strategies.

The literature review will be conducted through an online search of the scientific database pubmed and the online resources of WHO, UNAIDS and Clearinghouse on Male Circumcision<sup>4</sup> (initiative by WHO, UNAIDS, AVAC and FHI360 to share resources on voluntary male circumcision). The decision to search pubmed was taken as the database is currently the largest and most comprehensive database for health sciences and peer-reviewed literature. It is assumed that the database is providing citations on biomedical literature (online books, scientific journals, MEDLINE) on a neutral basis without preference for or against male circumcision. WHO and UNAIDS as well as Clearinghouse on Male Circumcision as a joint platform have been chosen as these international organizations set standards for HIV and Aids related work of governments, non-governmental organizations and bilateral cooperation. Besides the provision of practical guidance, research is conducted by these organizations and it is assumed that their recommendations have a broad scientific base. Nevertheless it has to be stated that these organizations are positive towards male circumcision and it might turn out that critical positions are neglected within the published and collected material. Therefore it seems to be beneficial to control potential bias through the integration of pubmed search. The search terms *male circumcision AND HIV prevention* will be applied. The search has been carried out in October 2015. The identified studies will be categorized according to type and used methodology. A list is provided in the Annex. Some studies rated to provide the highest level of evidence will be selected for a deeper analysis described in the following section.

According to the literature review, studies will be selected for a deeper analysis of their quality regarding objectivity, reliability and validity to judge the epidemiological evidence for male circumcision as HIV prevention. Bradford Hill criteria will act as a benchmark for evidence provided. It is assumed that with most study designs it will be difficult to differentiate the impact of male circumcision on HIV prevalence from other behavior-related or cultural factors. A randomized controlled trial (RCT) is considered to be the most suitable study design to detect the efficacy of a medical intervention and therefore existing RCTs will be selected for an in-depth analysis. The analysis will

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<sup>4</sup> <https://www.malecircumcision.org/>

be replenished by other studies not conducted with RCT “gold standard” but giving important hints on possible protecting factors, correlating factors, the effects of male circumcision on female to male as well as male to female transmission and long term effects. Specific emphasis will be put on the behavior of men following voluntary male circumcision regarding risk taking and the state of research regarding male circumcision for most-at-risk groups in other contexts than generalized epidemics.

### 5.3 Discourse Analysis

The second part of the analysis will consist of a discourse analysis regarding male circumcision as measure of HIV prevention. This analysis will help to detect different positions towards male circumcision that either encourage or hinder organizations or states to integrate male circumcision in their programming. It is assumed that especially in the German context positions against male circumcision dominate the discussion and hinder the German bilateral development cooperation and non-governmental organizations from formulating a clear position towards male circumcision as HIV preventive measure. The analysis of the discourse regarding male circumcision will be conducted through the methodology of a qualitative critical discourse analysis according to Jäger. The background of the methodology dates back to the theory of discourses by Michel Foucault and can be described as an applied discourse theory (Jäger 2012: 8). The methodology mostly used in social sciences has been chosen as it is useful to detect different discourse lines and their sources of origin.

The methodology can be characterized as interdisciplinary even reaching into natural science. It is possible to identify what kind of statements are “sayable” (Jäger 2012: 81) in different contexts and therefore the methodology is useful to analyse discourses held with a high amount of emotional concerns and contrary positions. As the discourse around male circumcision seems to be influenced to a high degree by cultural and societal ascription and this might have direct impact on the willingness of organizations to either implement or reject programmes regarding male circumcision, the analysis will help to identify the underlying factors. Existing taboos can be identified and addressed accordingly.

Jäger distinguishes between scientific (“special”) discourses and non-scientific (“inter”) discourses while scientific discourses feed into interdiscourses. Other frequently used terminology by Jäger refers to discourse fragments which are texts or pieces of texts referring to a specific issue. Discourse lines consist of discourse fragments referring to the same issue. Discourse lines are overcrossing and influencing each other. Discursive events are events with high public attention influencing or determining different discourse lines. Discursive events are marking the discursive context. Different discourse levels include for example, science, politics, and media. At the end of a discourse analysis,



different discourse positions can be detected. A discourse analysis is identifying different discourse lines on different discourse levels and connecting them (Jäger 2012: 80-85).

The analysed material will include media, scientific, and legal articles gathered through an online search following an open concept. The analysis is a qualitative one and completeness of the picture is achieved as soon as the analysis of further material does not contribute to further understanding of the issue (Jäger 2012: 130). Documents published between 2005 and 2015 are taken into consideration for the analysis as a representative selection of material (Jäger 2012: 94). The analysis will mainly be used to detect different positions within the discourse and to identify hindrances for mainstreaming VMC in HIV prevention. A structural analysis of discourse fragments will be followed by a detailed analysis of selected material to describe and compare different discourse lines (Jäger 2012: 96-109).

## 6 Studies regarding Male Circumcision as HIV Prevention

### 6.1 Overview on Existing Studies and Scientific Articles

The search of the pubmed database resulted in 1030 articles published on “male circumcision” AND “HIV prevention”. The articles were selected according to title examination. 385 remaining articles were selected according to abstract provided within the database. For a deeper analysis, 54 studies regarding the impact of male circumcision on HIV acquisition and behavior of circumcised men were selected. Primary research and systematic reviews were included in the analysis. In addition numerous studies and reviews exist regarding the acceptability and safety of male circumcision, the use of devices compared to surgical methods for male circumcision, health care providers’ knowledge and mathematical modelling regarding a projected impact of male circumcision programmes. Research is also done on the impact of traditional male circumcision on HIV prevalence and the cultural context in several countries of Sub-Sahara Africa. The search of the Clearinghouse on male circumcision as well as WHO and UNAIDS resources did not result in additional studies or systematic reviews. Main additional resources provided by WHO and UNAIDS include guidelines, reports and strategic documents on the scale-up of male circumcision in priority countries.

### 6.2 Existing Evidence for Male Circumcision as HIV Preventive Measure

#### 6.2.1 Ecological and Observational Studies

To judge the available evidence regarding male circumcision as HIV preventive measure for HIV acquisition in men engaging in heterosexual relationships in generalized epidemics it seems to be worthwhile to have a look at the history of evidence provided to understand the full picture. First suggestions of a protective effect of male circumcision regarding HIV infection date back to the

1980s (e.g. Bongaarts et al. 1989). The epidemic in Africa showed differences in strength between and even within countries. Bongaarts et al. analysed ethnographic literature on circumcision and compared the findings with data on HIV seroprevalence existing at that time. They found that *“The average HIV prevalence is 16.4% in the five countries where more than three quarters of males are estimated to be uncircumcised, and in none of the capitals of these five countries is seroprevalence less than 9.5%. In contrast, among the twenty countries where more than 90% of males are circumcised the average seroprevalence is 0.9% and in no case did seroprevalence exceed 4%.”* (Bongaarts et al. 1989: 375). According to the authors the differences could be explained only partly by behavioral patterns. The hypothesis emerged that these variances could be explained to a considerable degree by different circumcision prevalence rates as it was assumed that circumcision status was also associated with acquisition of other STIs like syphilis and chancroid (Weiss et al. 2000: 2361). Ecological association between high HIV infection rates and low circumcision prevalence in African countries was further stated in the early 1990s (e.g. Moses et al. 1990: 696) and again confirmed in 2006 with the analysis of country-specific data from 118 developing countries (Drain et al. 2006: 1). During the 1990s a considerable number of observational studies have been conducted to assess the relationship between male circumcision and HIV acquisition risk.

Two systematic reviews were conducted during the early 2000s, summarizing the results of the research carried out so far (Weiss et al 2000; Bailey et al. 2001). Weiss et al. conducted a systematic literature review that resulted in the analysis of 27 studies published until 1999 that included circumcision as a potential risk factor for HIV infection. The analysis included 5 case-control studies, 3 cohort studies, one partner study, and 19 cross-sectional surveys. 21 studies showed a lower risk for circumcised men to be infected with HIV. In 14 of these studies a statistically significant association occurred ( $P < 0.05$ ). 6 studies included in the review showed a positive association between HIV risk and circumcision but without being statistically significant (Weiss et al. 2000: 2362-2363). To summarize, the risk of circumcised men of HIV infection according to this review was approximately half of that in uncircumcised men (pooled RR = 0.56, CI 0.40-0.68), the association was even stronger in high-risk men (e.g. truck drivers, STD clinic attenders) than within the general population. After adjustment for potential confounders (e.g. sexual behavior) the analysis showed a stronger effect (pooled adjusted RR = 0.42; CI 0.34-0.54) (Weiss et al. 2000: 2363).

Bailey et al. reviewed ecological, prospective and case-control studies, as well as cross-sectional surveys to assess the state of research in the early 2000s regarding male circumcision and HIV risk. Articles on potential underlying biological mechanisms were also reviewed (Bailey et al. 2001: 223). According to this review ecological association between lack of circumcision and high HIV prevalence could be seen in Sub-Saharan Africa and in parts of non-circumcising regions in West-Africa (e.g. around Abidjan, Côte d'Ivoire). This association could not be found in European countries as predominantly non-circumcising societies and the United States, where male circumcision is widely practiced. The authors conclude that this might be due to injecting drug use and receptive anal sex

among MSM being main transmission routes in comparison to heterosexual transmission in generalized epidemics (Bailey et al. 2001: 224). Out of 37 reviewed cross-sectional and case-control studies, 28 showed a significant protective effect of male circumcision regarding HIV acquisition. Eight studies found no positive effect of male circumcision regarding HIV infection. A greater risk for HIV infection among circumcised men was stated by one study (Bailey et al. 2001: 225). Ten prospective studies (cohort studies) were reviewed from the United States, India, Kenya, Tanzania and Uganda. The studies from Kenya, Tanzania and Uganda showed a statistically significant risk in uncircumcised men for HIV infection. The strongest evidence for a potential protective effect of male circumcision was found in a cohort study conducted in Uganda analyzing the HIV acquisition risk of men in serodiscordant couples (Bailey et al. 2001: 115). As this study was very prominent in the history of research regarding male circumcision and HIV acquisition it will be discussed separately during the course of this section. In addition Bailey et al. reviewed biological mechanisms that will be discussed in a separate section (see 6.2.4) with up-to-date state of research.

A prominent example that provided strong evidence for the potential protecting effect of male circumcision was a cohort study conducted in Rakai, Uganda. A sub-cohort assessed the HIV transmission and acquisition risk in serodiscordant couples followed up between 1994 and 1998. This was the first time that the association between HIV acquisition and male circumcision was studied in a prospective way in serodiscordant couples within the general population and not in high risk groups (e.g. truck drivers, STD clinic attendees). The association between male circumcision and HIV acquisition was studied in 187 HIV negative men in serodiscordant partnerships with HIV positive female partners, and association with HIV transmission was studied in 223 HIV positive men in serodiscordant relationships with HIV negative female partners. The analysis was also stratified for religion and age of circumcision, as Muslim religion is widely practiced and circumcision age varied (Gray et al. 2000: 2372-2373). Within the 187 serodiscordant couples with HIV negative men, 50 men were circumcised. Within the group of circumcised men, no seroconversions occurred during the study time, regardless of the viral load of the female partner. Within the group of initially HIV negative uncircumcised men, 40 seroconversions occurred during study time, and the trend towards increased HIV incidence was linked with higher viral loads of female partners (Gray et al. 2000: 2378). For the transmission to initially HIV negative female partners from HIV positive men, a higher viral load appeared to be the decisive factor, regardless of circumcision status. The results suggested a protective effect of male circumcision regarding HIV acquisition of HIV negative men, even with regard to high viral loads of the HIV positive female partner. Circumcision was highly affiliated with Muslim religion and age of circumcision varied, so the authors could not exclude other behavioral patterns varying between population groups to be the main responsible factor for the protective effect regarding HIV acquisition instead of male circumcision (Gray et al. 2000: 2379).

**Table 2. HIV acquisition and transmission by circumcision status in HIV discordant couples in Rakai District, Uganda<sup>a</sup>**

	Couples with circumcised men			Couples with uncircumcised men		
	No	Incident HIV cases/py	HIV incidence/100 py (95% CI)	No	Incident HIV cases/py	HIV incidence/100 py (95% CI)
Male HIV – female HIV +	50	0/106	Male acquisition 0	137	40/239	Male acquisition 16.7 (12.0–21.4)*
Male HIV + female HIV –	29	3/58	Female acquisition 5.2 (0–10.6)	195	46/349	Female acquisition 13.2 (9.6–16.8)*

<sup>a</sup>p<0.001 based on confidence interval of incident rates. py=person years

Figure 10 Summarized results of the sub-cohort study in Rakai (Source: Bailey et al. 2001: 225)

A Cochrane systematic review of 37 observational studies (five cohort studies, 28 cross-sectional studies, four case-control studies) published in 2005 also concluded that the majority of analysed studies showed an association between presence of male circumcision and lower HIV acquisition risk (Siegfried et al. 2005: 165). But likewise the authors concluded that evidence provided by observational studies is not sufficient to include male circumcision as an HIV preventive measure in public health interventions and that results of randomized controlled trials are needed for a definite conclusion. Major concerns included the potential confounders in observational studies (Siegfried et al. 2005: 172) and this concern was shared by other authors: “*The main limitation of observational studies is that the effect of circumcision on HIV infection may be confounded factors that are associated with HIV risk, and that may differ between circumcised and uncircumcised men.*” (Weiss et al. 2000: 2367) Observational studies cannot conclude on a causal association between circumcision and lower risk of HIV infection. Often it is also difficult with the cited study designs, especially with cross-sectional surveys, to establish temporality as it is unclear if male circumcision precedes HIV acquisition (Bailey et al. 2001: 226). A spotlight on the potential confounders should underline the need for definite confirmation of hypotheses generated through observational research on a causal relationship between male circumcision and reduced HIV acquisition risk through experimental studies.

### 6.2.2 Potential Confounders in Observational Studies

The cited reviews identified possible confounders like circumcision age, religion, ethnicity, presence of other STIs, genital hygiene and cultural practices (Bailey et al. 2001: 223; Weiss et al. 2000: 2367–2368). Several correlating factors stated in scientific literature should also be mentioned as they might give additional explanations related to lower HIV rates in settings with high circumcision rates and give important hints on behavioral aspects. A major affiliate for circumcision is religion, and specific norms and behaviors do therefore apply for a considerable number of individuals. Gray and colleagues mention the pre-pubertal circumcision age of Muslim boys and therefore circumcision before sexual debut as predominant norm for this population group. In addition, in some parts of the world polygamous marriage within Muslim population groups might represent closed sexual networks with lower HIV introduction rates. The chance of abstaining from alcohol and the respective

related risk behavior is also thought to be higher in Muslim men. Post-coital ablutions are practiced by Muslim men and women according to religious beliefs (Gray et al. 2000: 2379). Abu-Raddad and colleagues also conclude that besides nearly universal male circumcision Islamic cultural traditions might contribute to the relatively low HIV prevalence rates in the MENA region including closed sexual networks of both polygamous and monogamous marriages, social prohibition of premarital and extramarital sex and limited alcohol consumption (Abu-Raddad et al. 2010: 15).

On the other hand, (unsafe) traditional male circumcision practices present till today in some regions might even increase the risk of HIV transmission. Analysing the Malawian demographic health survey data Mutombo et al. conclude that traditionally circumcised men even have a higher risk of HIV infection possibly related to the involvement in ritual sexual practices before complete wound healing (Mutombo et al. 2015: 8). This study also confirms other findings that traditional male circumcision might not have an equally protective effect like medical male circumcision regarding HIV acquisition. Wamai et al. refer to the example of Tanzania where circumcision is more common in men with higher income and higher educational level. These men tend to have more sexual partners and therefore a higher risk of HIV infection. Demographic and Health Survey data from Tanzania were therefore pointing to a higher HIV infection rate of circumcised men despite being circumcised (Wamai et al. 2011: 4-5).

### 6.2.3 Randomized Controlled Trials

With numerous ecological and observational studies conducted with results showing a high probability of male circumcision being a protective factor regarding HIV acquisition in men, three independent randomized controlled trials in South Africa/Gauteng province (Auvert et al. 2005), Kenya/Kisumu (Bailey et al. 2007) and Uganda/Rakai (Gray et al. 2007) were conducted to assess the potential causal relationship through direct experimental evidence (Auvert et al. 2005: 1113) and to exclude the possibility of confounding (Gray et al 2007: 369).

The South Africa trial assigned 3.274 men (18-24 years) to the study of whom 146 were found to be HIV positive at randomization. HIV positive men were assigned to the study in order to benefit from medical care but excluded from statistical analysis. After randomization the intervention group was offered immediate circumcision and the control group was assigned to delayed circumcision. A period of 21 months for follow-up was planned. Participants received regular counselling regarding risk-reductive behavior and were tested regularly for HIV. Forceps-guided method was applied for the surgery (see also 4.3.1). The trial was stopped early after interim analysis as it turned out that male circumcision was highly protective regarding HIV acquisition. The ethical board decided that male circumcision should be offered immediately to participants of the control group as it was considered to be unethical to withhold a protective measure. The results showed 20 seroconversions within the intervention group and 49 seroconversions within the control group corresponding to a “RR of HIV infection for the intervention group in comparison to the control group [...] of] 0.40

(0.24-0.68),  $p = 0.00059$ ” (Auvert et al. 2005: 1116). The protective effect was therefore calculated with 60%. After controlling for behavioral factors the protective effect was stated with 61% (Auvert et al. 2005: 1112). The rate of adverse events was 3.8% including complications like pain, bleeding, damage to the penis and problems with appearance. For the first time the study demonstrated a causal relationship between male circumcision and a reduced risk of HIV acquisition in men (Auvert et al. 2005: 1119). The authors refer to the termination of the trial and resulting consequences as the main limitation of the study. The short follow-up of participants limited the possibility to establish long-term effects and only participants assigned at the beginning received a full follow-up cycle. The analysis was therefore adjusted for this potential bias (Auvert et al. 2005: 1120).

The Kenya trial assigned 2,784 HIV negative men (18-24 years). HIV positive men were not eligible to participate in the trial but referred to a support group and post-test counselling. Men assigned to the intervention group were offered immediate circumcision and men assigned to the control group were scheduled for delayed circumcision. A period of 24 months for follow-up was originally planned. Participants received regular counselling regarding risk-reductive behavior and were tested regularly for HIV. Forceps-guided method was applied for surgery (Bailey et al. 2007: 645). Exactly as the South Africa trial the Kenya trial was stopped after interim analysis to offer immediate circumcision to the control group. The results show male circumcision to be a protective factor regarding HIV acquisition in men. During the study time 22 men seroconverted in the intervention group. In comparison 47 seroconversions occurred in the control group. These figures correspond to a risk ratio (RR, relative risk) for circumcised men compared to uncircumcised men of 0.47 (95% CI, 0.28-0.78). The risk of HIV acquisition in circumcised men was therefore reduced by 53%. After excluding four men found to be HIV positive at the baseline from the analysis, the risk reduction was stated with 59% (Bailey et al. 2007: 658-650). The rate of adverse events was found to be 1.5%, including e.g. bleeding, swelling and infection (Bailey et al. 2007: 652). Limitations of the study included the surgeries being conducted in a project-owned clinic facility and the low rate of adverse events might therefore not be transferrable to non-study sites (Bailey et al. 2007: 369), the impossibility of blinding medical staff to treatment, and incomplete HIV test results for 9% of study participants. In addition the forceps-guided method leaves a small amount of mucosal tissue that might vary between surgeons (Bailey et al. 2007: 654).

The Uganda trial enrolled 4,996 HIV negative men (15-49) either to immediate or delayed circumcision. A period of 24 months for follow up was originally planned. HIV positive men were enrolled to participate in a separate trial and to a treatment programme. Participants received regular counselling regarding risk-reductive behavior and were tested regularly for HIV. The sleeve method was applied for surgery (see also 4.3.1) (Gray et al. 2007: 657-658). The trial was also stopped after interim analysis to offer immediate circumcision to the control group. During the study time 22 men seroconverted within the intervention group and 45 seroconverted within the control group. These figures correspond to a risk ratio (RR, relative risk) for circumcised men compared to uncircumcised

men of 0.49 (95% CI, 0.28-0.84). The risk of acquiring HIV was therefore reduced by 51% in circumcised men, irrespective of e.g. non-marital relationships, transactional sex, and alcohol consumption. (Gray et al. 2007: 663). The rate of moderate or severe adverse events was 3.6%, including bleeding, infection and wound disruption. All adverse events could be managed and resolved (Gray et al. 2007: 664). Limitations included e.g. the short follow-up time due to termination of the trial. Six men who seroconverted (three in intervention and three in control group) reported no sexual activities, blood transfusions or injections. The authors interpreted these findings as probable under-reporting of sexual activity (Gray et al. 2007: 663).

	South Africa (Orange Farm)	Uganda (Rakai)	Kenya (Kisumu)
<b>Sample size:</b>	3,274	4,996	2,784
Control	1,654	2,522	1,393
Intervention	1,620	2,474	1,391
<b>Age</b>	18-24	15-49	18-24
<b>% lost to study:*</b>	8.0%	9.1%	8.6%
Control	9.5%	9.2%	8.2%
Intervention	6.5%	9.0%	9.1%
<b>Sero-conversions:</b>			
Control	49	45	47
Intervention	20	22	22
<b>% risk reduction</b>	61%	51%	53%**
<b>P-value</b>	P < 0.001	P < 0.005	P < 0.005

Data shown are taken from the published trial reports (Auvert, Taljaard, Lagarde et al, n 2; Gray, Kigozi, Serwadda et al, n 2; Bailey, Moses, Parker et al, n 2).

\* % lost to trial are at 21 months for South Africa and 24 months for Uganda and Kenya.

\*\* Using methods comparable to those applied in Orange Farm and Rakai (ie, modified intent-to-treat), the protective effect of male circumcision was 59% in the Kisumu trial (Robert Bailey, personal communication, 22 February 2012).

Figure 11 Summarized results of the RCTs in South Africa, Uganda, Kenya (Source: Wamai et al. 2012: 123)

#### 6.2.4 Biological Plausibility: Protecting factors

There are several biological explanations for the protecting effect of male circumcision and the assumption that the inner foreskin represents the main entry point for the HI-Virus in men. It is assumed that circumcision removes this specific vulnerable tissue and leaves only less vulnerable skin and a small amount of vulnerable mucosal tissue with the urethral meatus (Kigozi et al. 2009: 2). The graphic is illustrating the anatomical precondition for HIV entry into the male body.

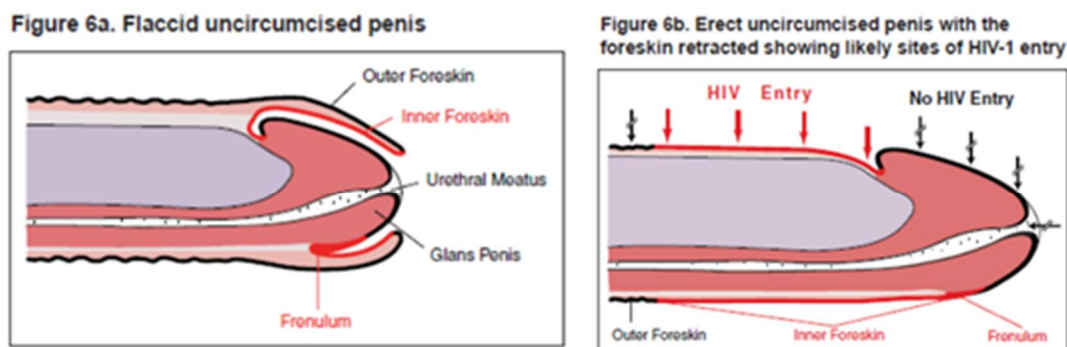


Figure 12 Areas of HIV entry according to anatomy of the penis with intact foreskin (Source: WHO/UNAIDS 2007: 14)

Several plausible explanations are presented to support this assumption. Jayathunge et al. reviewed 29 studies regarding the role of the foreskin in HIV acquisition to establish an overview on the state of research (Jayathunge et al. 2014: 31-32). The review provides a valuable overview on the evidence provided for several possible explanations why the removal of the foreskin represents a protective effect regarding HIV acquisition. In addition to the review primary research is also presented within this section.

One explanation that was believed to be plausible is the possible different keratinization of the outer and inner foreskin. Several researchers concluded that a thick keratin layer might represent a defense line against the entry of the HI-virus. It was thought that the inner foreskin is less keratinized than the outer foreskin and glans penis. Against this explanation that was also listed as possible explanation by WHO and UNAIDS (WHO/UNAIDS et al. 2009: 1-5) the review found mixed results regarding this assumption in different studies. While the evidence provided by different studies is not consistent due to different methods of measurements of the level of keratin, the analysed article also point to differences in keratinization of the inner foreskin due to age, medical history (STIs, urinary tract infections) and genetic constellation. The authors suggest more research regarding this point through laboratory studies with foreskin samples to fully understand the level of keratinization and the possible impact on HIV entry through the inner foreskin (Jayathunge et al. 2014: 40). While there are some hints regarding a possible vulnerability of the inner foreskin resulting from a thinner keratinization, this point seems not to present a stand-alone explanation regarding the biological role of the foreskin in HIV acquisition.

A more plausible and consistent explanation refers to the existence and distribution of HIV target cells within the foreskin, namely CD4 cells and Langerhans cells as cellular receptors. Jayathunge et al. concluded that even if there were differences in measurements and different results in exact distribution of cells there is general agreement on the presence of CD4 and Langerhans cells in the foreskin with higher density of these receptor cells specifically within the inner foreskin. These findings are important as they represent a plausible explanation of HIV entry into the male body through the foreskin and would explain why the removal of the foreskin provides a considerable level of



protection against infection. The Langerhans cells seem to play a main role within this complex mechanism of virus entry (Jayathunge et al. 2014: 40).

Another factor related to the cellular mechanism of HIV acquisition might be related to the penile microbiota. Price et al. assessed the change of the penile microbiome of 12 men before and after surgery. The results suggest that: *“The anoxic microenvironment of the subpreputial space may support pro-inflammatory anaerobes that can activate Langerhans cells to present HIV to CD4 cells in draining lymph nodes.”* (Prince et al. 2010: 1) The removal of the foreskin would therefore be an important factor to reduce the anaerobic microbiome of the penis to decrease the potential of the underlying cellular mechanism to attract HI-virus entry. (Prince et al. 2010: 2) The same mechanism applies as the removal of the foreskin reduces the probability of other STI infection causing mucosal inflammation that supports the activation of HIV receptive cells (Jayathunge et al. 2014: 41).

Several other factors beyond cellular microbiological mechanisms seem to play a role according to one study conducted in relation to the trials in Uganda. Foreskins of initially HIV-negative men enrolled in the trial within the group of delayed circumcision were measured after removal. 956 men were included into the analysis, of whom 48 were infected with HIV within the time prior to the surgery. The main result was: *“The mean foreskin surface area was significantly higher among men who seroconverted [...] compared with men who remained uninfected [...]”* (Kigozi et al. 2009: 3) According to this study uncircumcised men with a larger foreskin area are at higher risk of HIV acquisition. The authors suggest the potential higher amount of receptive cells and the larger area of vulnerable tissue for micro trauma during sexual intercourse might contribute to the results (Kigozi et al. 2009: 4).

In addition the potential moist environment under the foreskin seems to support the mechanisms of HIV acquisition. Studies regarding “wetness” under the foreskin suggest that men with a higher degree of “wetness” were more likely to be infected with HIV. Even if not fully understood, penile “wetness” beneath the foreskin might be a marker for poor penile hygiene. Suggested mechanisms for the risk factor of wetness beneath the foreskin include longer healing-time of micro trauma of tissue resulting from sexual intercourse or inflammatory STIs and in general an immune response from the tissue activating HIV receptive cells. In addition, *“[...] a wet penis might enhance adherence of infective HIV virions to the surface of target cells for longer than a dry penis.”* (O’Farrell et al. 2006: 76) This might support the general WHO statement that circumcision might lead to improved penile hygiene in circumstances where men have difficulties to maintain an adequate penile hygiene. But irrespective of circumcision status a proper penile hygiene might reduce the risk of several STI (WHO/UNAIDS 2007: 14) and therefore the HIV acquisition risk.

According to the state of research outlined above and the understanding of the entry of the HI-virus into the human body the “immunohistochemistry of foreskin tissue” (Bailey et al. 2007: 653) seem to play an important role in HIV acquisition of men. The explanations given by researchers are plausible to current bio-medical knowledge, and it is most likely that several factors interact during the

process of viral entry. It is biologically plausible that the removal of the foreskin acts as reductive regarding the entry point of the HI-virus into the male body. An important Bradford Hill criterion is therefore fulfilled.

#### 6.2.5 Criticism Regarding the Evidence Provided

Criticism regarding the evidence provided by the three RCTs is not widely shared within the scientific discourse around male circumcision. Lie and Miller criticize the non-blinding of the trials and a potentially more intense counseling of the intervention group from the side of the study team to support their hypothesis of reduced HIV risk in circumcised men. From these authors' point of view behavioral factors could have contributed to the lower rates of HIV in the circumcised groups. The HIV infections occurring although men were reporting no sexual partner are for Lie and Miller a sign of other potential risk factors influenced by circumcision not controlled for within the analysis (Lie/Miller 2011: 3). Boyle and Hill see several methodological problems within the three trials, including researcher expectation bias, early termination, inadequate double-blinding and participant expectation bias (Boyle/Hill 2011: 318). These concerns seem to be not widely shared within the scientific discourse. Arguments of Boyle and Hill are also analysed in 7.2.1.1 and 7.2.1.3.

#### 6.2.6 Quality of Evidence Provided

The quality of evidence provided regarding male circumcision as a partly protective factor for HIV acquisition in men can be judged as high. Hypotheses generated through ecological and observational research triggered the conduction of the three RCTs. Objectivity, validity and reliability are given through the three independent RCTs conducted in three different places with divergent populations. Authors and funding of the trials also differed supporting the judgement of independency. Most of the Bradford Hill criteria of causality are satisfied, “[...] *namely strength of association, consistency, temporality, coherence, biological plausibility and experiment*” (Wamai et al. 2011: 1). The RCTs were able to confirm the strong association between male circumcision and a reduced risk of HIV acquisition that was already proposed by ecological and observational studies. The consistency is given as according to Hill the association has “[...] been repeatedly observed by different persons, in different places, circumstances and times” (Hill 1965: 295). A temporality that could not be confirmed by the observational research, especially with regard to cross-sectional studies, could be stated by the RCTs, e.g. circumcision was preceding HIV acquisition (Bailey et al. 2001: 226). Regarding the coherence Hill states that “[...] *the cause-and-effect interpretation of our data should not seriously conflict with the generally known facts of the natural history and biology of the disease [...]*” (Hill 1965: 298). The findings of the trials are in line with current knowledge on the transmission ways and biology of heterosexual HIV transmission. Biological plausibility is given and is outlined in a separate section (see 6.3) to enhance the understanding of the protective effect of removing the

foreskin as the main entry point for the HI virus to the male body. Experimental evidence is given with the three trials conducted in Sub-Saharan Africa (Hill 1965: 295-298). The judgement of high quality of evidence available regarding male circumcision as an HIV preventive measure provided through the three RCTs is shared by several authors (Siegfried et al. 2009; Padian et al. 2010; Wamai et al. 2011) and was translated through WHO/UNAIDS recommendation in 2007 into public health policy.

### 6.3 Research Regarding Impact of Male Circumcision

The current state of research regarding several factors related with male circumcision as an HIV preventive measure will be outlined in the following sections as they have important implications regarding further understanding of the protective effect and give an overview on areas of future research. Some points will give important background knowledge regarding male circumcision programming.

#### 6.3.1 Male to Female Transmission

Not much research has been conducted on the direct impact of male circumcision regarding HIV transmission from men to women. While it is evident that female to male transmission is reduced by up to 60% (see 6.2) the effect seems not to exist the other way around. While observational studies also suggested a direct impact of male circumcision on HIV acquisition to women at least from HIV positive men with lower viral loads (e.g. Gray et al. 2000: 2380) these findings were not confirmed by a randomized controlled trial in Rakai, Uganda (Wawner et al. 2009).

HIV positive men and their consenting female sexual HIV negative partners were enrolled to the trial with one group of men receiving immediate circumcision and one group delayed circumcision. The results did not show a protecting impact of HIV transmission to women, and a negative impact of early resumption of sexual activity with incomplete wound healing could not be excluded. Male circumcision of HIV positive men was also not leading to lower rates of other STI symptoms and bacterial vaginosis in female sexual partners. Nevertheless there were limitations to the study, as being underpowered regarding participants and a slight difference in enrollment motivation of different trial groups was assumed. The findings strongly support the view that male circumcision is only a direct benefit to the insertive sexual partner (see also 6.8) and represents an indirect benefit to women. As the trial was stopped early and men with advanced HIV infection were not eligible, long-term effects could not be established (Wawner et al. 2009: 235-236). The importance of sexual abstinence during wound healing is also underlined by these results.

The importance of post-operative abstinence until wound-healing can also be supported by a recent observational study regarding penile HIV shedding from circumcision wounds in HIV infected men (Aaron et al. 2015). Samples were collected from HIV positive men prior to circumcision surgery

and during follow-up visits. Men with different viral loads and different ART status were included into the study. HIV shedding was highest with incomplete wound healing and fell with healed wounds even below prior circumcision levels. Authors suggest that lower HIV shedding after surgery might be due to the removal of the foreskin and the development of an intact scar. The increase of HIV shedding during the first two weeks of wound healing might be due to the inflammation process and the activation of HIV target cells. Limitations of the study included the self-reported ART status of men and the observational nature of the study that makes it difficult to state causality. The actual impact of penile HIV shedding on female HIV acquisition is not known but these results point to the importance of sexual abstinence until complete wound healing. The authors conclude that the optimal point in time for male circumcision as HIV prevention is before sexual debut to avoid negative impacts on women of early resumption of sexual activity (Aaron et al. 2015: 10-13).

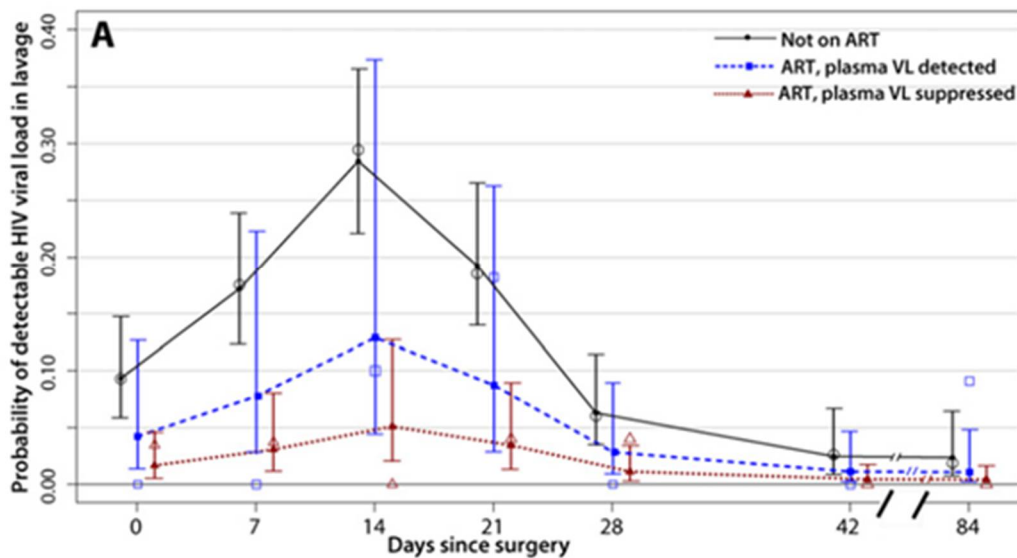


Figure 13 Penile HIV Shedding, Day 0 visit is prior to surgery (Source: Aaron et al. 2014: 9)

### 6.3.2 Circumcision of HIV Positive Men

Several studies already mentioned support the assumption that HIV transmission to the (female) receptive partner is not reduced through male circumcision and that only indirect benefit exists for women (see 6.3.1) or male receptive partners (see 6.3.5) of circumcised HIV positive men. A higher risk for HIV acquisition for the receptive partner of HIV positive men during post-surgery wound healing might exist (Aaron et al. 2015: 10-13; Wawner et al. 2009: 235-236) if abstinence is not adhered to during wound healing. Also, wound healing might be prolonged in HIV positive men, especially if not on ART treatment and depending on the CD4 count (Rogers et al. 2013: 5). WHO and UNAIDS are therefore not recommending promotion of male circumcision of HIV positive men, but is also stating that it should not be denied if necessary from a medical point of view or requested

for by HIV positive men combined with intensive counselling on risks involved and behavioral recommendations. HIV testing should also not be a precondition to circumcision (WHO/UNAIDS 2007c: 11). According to Clearinghouse on Male Circumcision this recommendation is related to stigma reduction and avoidance of HIV negative men seeking services from unsafe providers if denied by an official medical facility (Clearinghouse on Male Circumcision: Male circumcision for HIV positive men, online resource). Indirect benefit for sexual partners of circumcised HIV positive men might exist regarding reduced other STD rates. More research is needed on optimal programming regarding HIV positive men seeking circumcision services, e.g. with regard to optimal counseling, safety and wound healing.

### 6.3.3 Risk Compensation among Circumcised Men

According to the evidence provided, male circumcision does only reduce the risk of HIV acquisition in men and does not eliminate it completely. There are mainly two risk behaviors relevant within the context of male circumcision as HIV prevention – on the one hand the early resumption of sexual activity before complete wound healing (42 days of abstinence are recommended) and risk taking sexual behavior in the false belief of complete protection, also known as risk compensation (Bailey et al. 2007: 654). Depending on the perception of male circumcision within the respective society women might also believe in a complete protection and abstain from condom use or be less able to negotiate it (Westerkamp et al. 2013: 1770).

The probability of a higher risk of HIV acquisition in men before wound healing as well as the probability of a higher male-to-female transmission rate exists. The Kenya trial documented self-reported early resumption of sexual activity of men within the intervention group (4% of whom 2 seroconverted and one potentially during wound healing) (Bailey et al 2007: 654). There is not much literature available with reliable figures on early resumption of sexual activity. In contrast to the findings of the Kenyan trial other studies conclude on rates of early resumption of sexual activity up to 30.7% in a prospective study in Kenya (Herman-Roloff et al. 2012: 6) and 24% in an observational study in Zambia (Hewett et al. 2012: 751). The data suggest that in large-scale circumcision programmes the rates of early resumption of sexual activity might be higher due to the less intense counseling and follow-up of men (Hewett et al. 2012: 755). Kamath and Limaye reviewed the literature regarding the early resumption of sexual activity in circumcised men. According to the review risk factors for the early resumption of sexual activity include being married, alcohol consumption, being older ( $\geq 25$ ), having more than two sex partners during the last year and being HIV positive (Kamath/Limaye 2015: 987). Only one study was found by the review regarding strategies for prevention of early resumption of sexual activity – a positive effect of text messaging for newly circumcised men regarding required abstinence was not given (Kamath/Limaye 2015: 988).

If men overestimate the protective effect of male circumcision they might engage in risk behavior like unprotected sex and multiple partnerships. The Uganda trial did not find different risk behaviors

between the intervention and the control group (Gray et al. 2007: 369) and the Kenya trial did only find minor differences, which was explained by increased safer sex practices within the control groups and not by general increased risk behavior within the intervention group. Risk behavior rather remained stable within the intervention group. (Bailey et al. 2007: 654). Both studies indicate that during the study period risk compensation did not occur. In contrast the South Africa trial found slightly higher rates of risk behavior within the intervention group (Auvert et al. 2005: 1118). All studies can only give information on a short period of time and at the time of data collection it was not publicly known that male circumcision is a risk reductive factor regarding HIV acquisition. The perception might have changed and therefore risk compensation might be more present with large circumcision campaigns rolled out (see also 7.2.2.2). A prospective cohort-study in Kenya assessed the risk behavior of circumcised and uncircumcised men parallel to the roll-out of a large circumcision campaign and found no signs of risk compensation among circumcised men, but a reduced perception of being at risk. Risk behavior decreased within both groups, especially condom use increased (Westerkamp et al. 2014: 1773-1774). A 3-years follow-up study of the Uganda trial also did not point to risk compensation among circumcised men within a context where benefits of circumcision were known among the population resulting from the trial activities (Kong et al. 2012: 884). Auvert et al. come to the same conclusion drawn from a cross-sectional survey conducted among a target population of a male circumcision campaign (Auvert et al. 2013: 9).

In contrast, qualitative research points to the fact that men and also women within target populations of male circumcision programmes might tend to overestimate the protective effect of male circumcision (see also 7.2.2.2). Participants of a qualitative study on women's view on male circumcision reported their belief that circumcised men are protected from HIV, illustrating their opinion with reference to radio sessions, posters and loudspeaker announcements (Layer et al. 2013: 4-5). The authors conclude that overstating the health benefits of male circumcision might not only lead to risk behavior among men but also among women in a false sense of complete protection (Layer et al. 2013: 6). Even if the evidence provided by the cited qualitative study can be judged as low and only perceptions of male circumcision and not actual risk behavior of women is measured, nevertheless the results are pointing to the important fact that with increased messaging on male circumcision the messages of health benefits might lead to misconceptions within the target group.

#### 6.3.4 Long-term Effects of Male Circumcision as HIV Preventive Measure

According to Metha et al. the “[...]long-term follow-up of circumcised men with an appropriate comparison group of uncircumcised men is generally not feasible in programmatic implementation, surveillance of programmatic effectiveness over time will need to rely on regular cross-sectional surveillance of men's circumcision status and HIV status.” (Metha et al. 2013: 2904). There are few studies conducted regarding the long-term effect of male circumcision as roll-out of circumcision as a relatively new biomedical preventive measure, but the research conducted point to the sustainability

of the preventive effect. Metha et al. followed up on participants of the randomized controlled trial in Kenya between 2006 and 2010. The protective effect of male circumcision was sustained at 58% 6 years after the beginning of the trial and therefore corresponding to the results of the trial (Metha et al. 2013: 2904). A post-trial follow-up of the control group of the Ugandan trial with men who decided to get circumcised concluded on a protective effect of 67% (Gray et al. 2012: 4).

The findings suggest that male circumcision is a life-long protective measure for men against HIV acquisition. The population based effect is yet to be established but difficult to measure due to the varying success of the national male circumcision programmes. Mathematical modelling suggests that “one HIV infection being averted for every five to 15 male circumcision performed [...]” (UNAIDS/WHO/SACEMA 2009: 1)

### 6.3.5 Circumcision for Men Having Sex with Men

There are several studies conducted in Western countries and developing countries (e.g. Great Britain/Thornton et al. 2011, China/Zeng et al. 2014, Peru and United States/Sanchez et al. 2011) evaluating a potential protective effect of male circumcision regarding HIV acquisition for MSM as well as acceptability of male circumcision among MSM, but the picture is mixed according to current research. It is not possible to draw a definite conclusion from the studies presented. No clinical trial has been conducted up to now and conclusions are therefore drawn from observational research. Wiysonge et al. reviewed 21 observational studies (Cochrane review) in 2011 regarding male circumcision and HIV acquisition in MSM. “*The pooled effect estimate for HIV acquisition was not statistically significant (20 studies; 65,784 participants; OR 0.86, 95% CI 0.70 to 1.06) and showed significant heterogeneity ( $I^2=53%$ ). In a subgroup analysis, the results were statistically significant in studies of men reporting an insertive role (7 studies, 3465 participants; OR 0.27, 95% CI 0.17 to 0.44;  $I^2= 0%$ ) but not in studies of men reporting a receptive role (3 studies, 1792 participants; OR 1.20, 95% CI 0.63 to 2.29;  $I^2 = 0%$ ).*” (Wiysonge et al. 2011: 2) The authors mention several factors that differ between anal sex practices among MSM and vaginal intercourse contributing to heterosexual HIV acquisition. The receptive anal partner is involved in acquisition routes that are most likely not influenced by male circumcision and in addition it is possible that rectal secretions contain higher viral loads than vaginal secretions. Unprotected insertive anal sex might therefore be related to a higher transmission risk per act compared to unprotected vaginal sex. In addition Wiysonge et al. draw the conclusion from available research that most MSM are versatile instead of solely practicing the receptive or insertive anal sex role (Wiysonge et al. 2011: 5). Armbruster et al. also conclude that sex role specific interventions are needed for biomedical HIV prevention among MSM and that more research within this area is needed (Armbruster et al. 2013: 4).

Studies published after 2011 and therefore not captured by the Cochrane review also still show a mixed picture. Doerner et al. found no association between circumcision status and HIV infection in

men who exclusively or predominantly practiced the insertive anal sex role in a cross-sectional survey, but limitations are valid for observational research including self-reported data and sample selection through an online survey (Doerner et al. 2013: 1324). Zhou et al. also found no association in a cross-sectional study between circumcision status and HIV infection in MSM preferring the insertive anal sex role (Zhou et al. 2013: 1280). In contrast, Qian et al. conclude from the results of a cross-sectional survey a considerable lower risk of circumcised MSM practicing the insertive sex role regarding HIV acquisition (Qian et al. 2015: abstract).

Acceptability of male circumcision as a potential preventive measure is also mixed. While Thornton et al. 2011 found uncircumcised MSM in Great Britain unwilling to take part in trial research regarding male circumcision as a potential preventive measure as no benefits were ascribed to the procedure (Thornton et al. 2011: 931), Zeng et al. found more than half of their uncircumcised study participants willing to undergo male circumcision (Zeng et al. 2014: 3).

The mixed findings suggest that the results of the RCTs conducted in South Africa, Kenya and Uganda among heterosexual men cannot be easily transferred to MSM, even for MSM practicing predominantly the insertive anal sex role. Research is needed on behavior regarding sex roles and acceptability of male circumcision among MSM to better understand a potential impact of male circumcision regarding HIV acquisition. MSM might also show very different behaviors among different societies. Even if there are indications that male circumcision might be a protective factor regarding HIV acquisition for MSM practicing the insertive anal sex role, definite conclusions could only be drawn from a randomized controlled trial not yet conducted.

### 6.3.6 Male Circumcision as HIV Prevention for Most-at-risk Groups other than MSM

Male circumcision as a protective factor has been researched in most-at-risk groups among heterosexual men within generalized epidemics (e.g. truck drivers, STD clinic attendees) but only partly for most-at-risk groups within settings with concentrated epidemics. Most-at-risk groups among heterosexual men might include immigrants from high-prevalence settings to low-prevalence settings with multiple partners or sexual networks within the respective immigrant community, clients of sex workers, migrant workers within countries with low prevalence of HIV or men engaging in any other risky heterosexual behavior. The literature review resulted in two studies conducted in China regarding acceptability of male circumcision as HIV preventive measure among drug users and migrant workers in China (see 6.3.7).

### 6.3.7 State of Research for Regions other than Sub-Saharan Africa

Male circumcision as an HIV preventive measure has been recommended by WHO and UNAIDS for high-prevalence settings with predominant heterosexual transmission and low circumcision rates. 14 countries in Sub-Saharan Africa have therefore been prioritized for scale-up of male circumcision



programming. As evidence is provided regarding a protective effect of male circumcision for men up to 60%, research is going on in several other countries regarding a possible integration of male circumcision in HIV prevention programming. Research is mainly conducted regarding acceptability and perception of male circumcision for children and adults among different population groups. Scientific articles about China, India, Papua New Guinea, Jamaica, and the Dominican Republic were gathered from the literature review.

According to the literature reviewed, medical male circumcision seems to be an acceptable strategy for HIV prevention in settings other than Sub-Saharan Africa, but only in combination with sensitive educational approaches. A non-blinded, single-arm, pragmatic clinical trial in the Dominican Republic resulted in high acceptability and feasibility of male circumcision as an HIV preventive measure. The main interest of the study was to assess the feasibility and safety of male circumcision in outpatient settings (Brito et al. 2015: 8-9).

A qualitative study among circumcising and non-circumcising communities as well as health professionals in India found strong association of male circumcision with Muslim religion among community members and was perceived as acceptable practice for religious reasons. Among non-circumcising communities male circumcision was found to be acceptable according to medical advice from health professionals. Health professionals were sceptical towards trial results from “foreign” countries. The authors conclude that while the procedure is acceptable in general as a religious and medical practice education has to be conducted to frame it as a preventive measure regarding HIV acquisition among men (Sahay et al. 2014: 10-11).

A cross-sectional study in Jamaica found low levels of knowledge among uncircumcised men about male circumcision, but increased rates of acceptance (47% of participants) after an information session. Male circumcision was associated more with beliefs about pleasure during sexual intercourse but not with medical benefits. The authors conclude that male circumcision especially for children might be an acceptable strategy in Jamaica if combined with intensive health education (Walcott et al. 2013: 7-10).

A cohort study assessed the impact of different educational interventions among migrant workers in China regarding acceptability and uptake of male circumcision as an HIV preventive measure. The intervention resulted in uptake of male circumcision in 9.2% among all participants and in 14.6% among those who received the most successful communication strategy. Even if HIV rates among the participants were low the authors refer to migrant workers as a most-at-risk group due to unstable family situations, involvement in commercial sex and inaccessibility to the national HIV prevention programme. The authors suggest studies to be conducted about the potential long-term effect of circumcision programmes among migrant workers (Ning et al. 2013: 6-7). Another study conducted in China assessed the acceptance of male circumcision as HIV preventive measure among IDUs who are thought to be at risk not only through reuse and sharing of needles but also through risky sexual behaviors. 45.2% of participants were found to judge male circumcision as an acceptable measure

for HIV and STD prevention. The authors conclude that male circumcision might be a suitable additional strategy for HIV prevention among IDUs besides ongoing needle-exchange programmes (Huang et al. 2013: 541, 546).

An example worthwhile to mention within this context is Papua New Guinea as a country with extensive traditional foreskin cutting practices. In some regions of Papua New Guinea dorsal longitudinal foreskin cuts are practiced as a cultural tradition. These cuts result in an appearance of the penis closely to medical male circumcision but with some skin remaining undersurface and at the sides of the penis shaft. In most cases the glans is exposed after the procedure. MacLaren et al. found in a recent ecological study correlations of prevalence of longitudinal foreskin cuts with HIV prevalence in different regions of Papua New Guinea (MacLaren et al. 2015: 502-504).

In summary, research regarding male circumcision as an HIV preventive measure in settings other than Sub-Saharan Africa is conducted but yet with limited options to generalize the results. As only countries from Sub-Saharan Africa are prioritized by WHO for up-scale of male circumcision the interventions and studies conducted in other countries are not yet supported by national strategies and therefore remain comparatively limited in reach. The sample sizes are small and data on population impact scarcely exist.

#### 6.3.8 Gaps in Research

There are several areas identified for further research to understand the full potential of medical male circumcision as HIV preventive measure. As evidence is dating back to 2005 and 2007 respectively and interventions in priority countries are ongoing, the long-term effect of medical male circumcision on HIV prevalence in countries and the long-term protective effect remains an area for intensive research. Population based effects are to be measured apart from calculation through mathematical modelling. The long-term population effects will only be clear if targets of male circumcision programmes are met to reach a considerable number of men. Continuous follow-up, e.g. through ex-post-evaluations of programmes or post-trial studies, can provide important knowledge on the long-term protective effect and behavioral factors of circumcised men.

The exact cellular mechanism of HIV entry to the male body through the (inner) foreskin should be an area of further research. Even if already plausible cellular mechanisms are explained in scientific literature the microbiological confirmation through various researchers would contribute to further understanding of the protective effect and might be an entry point for research on potential additional preventive measures (e.g. penile wipes, vaginal microbicides).

On the behavioral side it is not very clear yet from the literature if male circumcision and potential overestimation of the protective effect is leading to increased risk behavior among men and women. Systematic research and testing of messages is needed in order to reduce potential harm of male circumcision programmes.

The protective effect of male circumcision for MSM is not understood to a full extent yet. There are hints that a protective effect might exist for MSM practicing predominately insertive anal sex. Limited understanding of a possible protective effect is also due to limited design of studies to capture sex roles and sexual behavior of MSM in different contexts. Some authors request for a randomized controlled trial to understand the effect of male circumcision with regard to HIV prevention in MSM (e.g. Qian et al. 2015: abstract).

The acceptability and feasibility of male circumcision in other (cultural) contexts than Sub-Saharan Africa is an area with increased research activities in the recent years. Related research regarding traditional circumcision practices, knowledge and attitudes of different population groups and healthcare providers as well as potential beneficial impact of the measure in different contexts is to be established to understand the potential of male circumcision as an HIV preventive measure in countries other than priority countries of WHO. The same applies to research regarding male circumcision for most-at-risk groups in low prevalence settings or rather concentrated epidemics.

Areas for qualitative research to inform programme and service design include the potential of male circumcision to establish male friendly health services, the role of women with regard to male circumcision – as partners and mothers, as well as the acceptability of neonatal male circumcision as potential beneficial practice with regard to better wound healing, lower rates of adverse events and the advantage of male circumcision before sexual debut.

## 6.4 Discussion

According to the literature reviewed there is compelling evidence for male circumcision being a protective measure regarding HIV acquisition for heterosexual men in generalized epidemics. The evidence provided can be judged as high according to objectivity, validity and reliability given and causal association confirmed by a majority of Bradford Hill criteria. Biological plausibility is given through various cellular and physiological explanations. The WHO and UNAIDS recommendation to integrate the biomedical approach of voluntary medical male circumcision into comprehensive HIV programming within generalized epidemics is therefore justified. According to recent research the measure might also be suitable to other contexts than generalized epidemics, e.g. heterosexual most-at-risk groups in concentrated epidemics. One important point to mention is that overestimation of the protection offered by male circumcision can lead to risk behavior among men and women, and this should be taken into consideration very carefully within programming. Risk reduction through consistent condom use and reduction of sexual partners must be recommended. The compliance to sexual abstinence during wound healing is a crucial factor and more effective ways of supporting men during abstinence time need to be found.

## 7 Global Discourse on Male Circumcision as HIV Prevention

During the process of analyses of collected material for the discourse analysis it became clear that it is not possible to reduce every piece of information (online publications, media articles etc.) to one main statement as recommended by Jäger as an appropriate way during structural analysis. This was a first indication regarding the mixing up of arguments from legal, medical, religious and psychological perspectives. It was therefore decided to collect the main arguments stated, put them into a matrix and define the different discourse lines from this base. The result is a structured analysis of the discourse lines. The discourse around male circumcision can be characterized as an interdiscourse as it consists of a variety of opinions from the scientific and the public sphere. The following sections will outline the main arguments given within the discourse that will be put into relation with the existing biomedical evidence available regarding male circumcision as a preventive measure regarding HIV acquisition in heterosexual men outlined in Chapter 6.

### 7.1 Discursive Events

Two main discursive events were identified from the research. These two events will be described as entry points to the following analysis of discourse lines. They act as reference points in a variety of publications and statements. A quantitative increase in publications can be identified around these dates. One of the discursive events mainly triggered a scientific debate while the other one facilitated a general discourse and therefore broad societal debate. It is worthwhile to have a closer look at these two events to understand the dynamics of the discourse around male circumcision as an HIV preventive measure.

#### 7.1.1 WHO Recommendation on Male Circumcision as HIV preventive Measure

WHO and UNAIDS facilitated an international expert consultation between 6<sup>th</sup> and 8<sup>th</sup> March 2007 in Switzerland to draw conclusions on evidence provided on male circumcision as HIV preventive measure by the three randomized controlled trials conducted in South Africa, Kenya and Uganda. The consultation was attended by a variety of stakeholders (e.g. researchers, governments, non-governmental organizations, human rights activists). The attending experts concluded that evidence provided by the RCTs and supported by results from observational studies is strong enough to integrate male circumcision in HIV programming. The decision to recommend male circumcision for HIV prevention was published in form of a press release on 28<sup>th</sup> March 2007. The decision was described as a “*significant step forward in HIV prevention*” with an “*immediate benefit to individuals*” (Dr Kevin De Cock, Director, HIV/AIDS Department in WHO). The measure was recommended for settings with generalized heterosexual epidemics with low rates of male circumcision. Male circumcision was communicated as only partly protective and only to be considered within comprehensive HIV prevention packages (condom use, reduction of sexual partners etc.). Several areas for further

research were identified, e.g. the impact of male circumcision on women`s health regarding HIV and other STIs, the impact of male circumcision for the insertive partner regarding anal sexual intercourse and the longer-term behavior of circumcised men (WHO 2007: Press Release). The recommendation was supported by UNAIDS, also framing the decision as a milestone in HIV prevention: “*The efficacy of male circumcision in reducing female to male transmission of HIV has been proven beyond reasonable doubt. This is an important landmark in the history of HIV prevention.*” (WHO/UNAIDS 2007c: 2). A historical dimension was also emphasized by the statement: “*Male Circumcision is the most compelling evidence-based prevention strategy to emerge since the finding that antiretroviral medication can reduce mother-to-child transmission of HIV.*” (WHO/UNAIDS et al. 2007 b: 2) Therefore the two main international health players set new standards for biomedical HIV prevention with wide implications for HIV programming and research. The publishing of the results of the RCTs starting in 2005 combined with the WHO/UNAIDS recommendation triggered a broad scientific dialogue. Since 2006 numerous scientific articles have been published concerning acceptability of and access to medical male circumcision, behavior and attitudes of men and women regarding circumcision, safety and quality of circumcision services and devices and evaluation of ongoing programmes. The WHO/UNAIDS recommendation was also the starting point for several priority countries to integrate male circumcision as HIV prevention into their public health strategies (e.g. Uganda, Swaziland). Development agencies provided massive funding for programmes.

### 7.1.2 German Court Decision and Law on Infant Male Circumcision

In Mai 2012 a German court (Cologne) decided that religious motivated male circumcision performed on children is to be judged as bodily harm. This was the first time a German court decided on religious circumcision as an offence. A Muslim physician circumcised a four-year old boy according to the religious motivated wish of the parents without medical indication. The mother presented the child two days later at a hospital because of secondary hemorrhage that could be stopped. The public prosecutor`s office followed up the case and the doctor was accused of bodily harm. The court decided that the parents` rights regarding free exercise of religion do not outweigh the right of the child to bodily integrity and self-determination. From this point of view male circumcision represents an irreversible change to bodily appearance. While in general stating that the circumcision was a bodily harm the court acquitted the physician as he was acting without knowledge that the procedure might present an offence (LG Köln 2012: III/15-16). But the judgement of the court regarding male circumcision performed on children in general was outstanding compared to prior dispensation of justice and created a broad societal debate in Germany that can be classified as a general discourse. Many different actors ranging from media, politicians, jurists, religious organizations and physicians commented on the court decision. To end the resulting legal uncertainty the German government adopted a law regarding male circumcision performed on children. According to this law male circumcision on children is legal if performed by a physician under anaesthesia. Male infants

under six months can be circumcised by non-medical persons if trained and therefore equally qualified as a physician to perform the procedure (Bürgerliches Gesetzbuch §1613d/Deutscher Bundestag 2012: 5). The decision did not end the debate in Germany and many arguments can be extracted from the discourse.

## 7.2 Discourse Lines

The following section will describe the identified discourse lines and provide a selection of quotations that illustrate the language used within the discourse around male circumcision. Several analysed articles referred to different discourse lines and are therefore quoted in different sections. The mixing of arguments will be described as part of the discussion.

### 7.2.1 Discourse Lines Opposing Male Circumcision

#### 7.2.1.1 *Circumcision of male neonates and children as a violation of basic human rights*

Within the debate about male circumcision, especially regarding infant male circumcision one discourse line is referring to the procedure as a violation of basic human rights including “*the right to be free of torture, the right to liberty and security of person, the right to privacy, the right to enjoy the highest standards of physical and mental health, and, in very rare cases, the right to life.*” (Delaet 2009: 412). Especially the rights defined in the Convention of the Rights of the Child are ignored according to critics of the procedure (Barthlen 2014: 145). While these statements refer to international treaties, in addition it is stated that male circumcision performed on children is an assault to rights defined in national laws, including the right to bodily integrity and the right to violence-free education (*Erziehung*) defined in German Basic Law (Barthlen 2014: 145). Terre des Femmes as a women’s rights organization is of the opinion that the legality of male circumcision on infants and children for non-therapeutic reasons is a threat to the right of equal treatment of boys and girls as female circumcision is banned under German law (Terre des Femmes 2012: online). The rights debates about male circumcision seem to be held on an intellectual level and referring to human rights as a theoretical frame. Mainly scientific articles are referring to the potential violation of basic rights of the child when evaluating ethical concerns about male circumcision. This discourse line is not very dominant on the international level and Delaet is stating a “*virtual silence of the international community*” (Delaet 2009: 406) regarding male circumcision as human rights violation. In comparison to this “*silence*” on the international level about human rights concerns the debate is even more predominant in Germany with a specific connotation on a comparison of male and female circumcision (see 7.2.1.2).

A majority of critics of male circumcision is referring to circumcision in neonates and children and to the fact that children cannot give informed consent to the surgery and therefore to the different rights violated from this point of view (see above). Boyle and Hill see problems of informed consent

even regarding adult male circumcision especially with regard to the participation in the RCTs but their views can be projected to ongoing circumcision campaigns. In this view the process of data collection regarding male circumcision was unethical. In the view of the authors men decide pro male circumcision in “*a false sense of security*” and “*impoverished men [...were] submit to amputation of a normal functional sexual body part in the absence of any pre-existing pathology*” (Boyle/Hill 2011: 328). It can be assumed that the authors judge African men to be unable to understand the consequences, benefits and risks of a surgical procedure and participation in a medical trial. Statements like “[...] *poor, black African men as an expendable resource to be exploited*” during clinical trials raise the connotation that ongoing circumcision campaigns are a large medical experiment of the “*United States medical establishment*” (Boyle/Hill 2011: 329).

#### 7.2.1.2 *Male circumcision as mutilation and trauma*

Also related to the rights debate but even more radical and emotionally loaded one strong discourse line is referring to male circumcision as mutilation and therefore as comparable to female genital mutilation. As this argumentation is widely used and expressed with vigor it is analysed in a separate section from the rights debate. „Amputation” (Herzberg 2014: 270) is a term widely used by critics of the practice. It is even stated: “*Die Vorhautamputation aus nichttherapeutischen Gründen wird von nicht wenigen Betroffenen als eine Form von sexualisierter Gewalt wahrgenommen.*”<sup>5</sup> (Christian Bahls/Mogis, in Fraczek/Fuchs 2013, Deutsche Welle) It is stated that a part of the body that is functionally important to men is irreversibly removed (e.g. Von Loewenich 2014: 76-77). Boyle and Hill see the foreskin as “*a highly erogenous part of the penis*” and male circumcision as “*significant bodily injury caused by the irreversible amputation and the resultant possible long-term adverse psychosexual effects*” (Boyle/Hill 2011: 328-329)

Delaet, for example, concludes that there are “*...sharp differences between the most extreme forms of female genital mutilation and male circumcision... [but] that the most common forms of male and female circumcision are not sufficiently divergent practices to warrant a differential response from the international community and that there are more similarities between the two practices than is typically acknowledged.*” (Delaet 2009: 405) The argument of comparing female and male circumcision is therefore framing male circumcision as a practice without medical benefits that is a threat to physical and mental well-being of the circumcised boy. The language and comparisons used in this context are usually very harsh: “*Just as we call sex without consent 'rape', circumcision without consent or reasonable justification should be called 'mutilation'.*” (Robbins 2012: The Guardian). Even in scientific discussions comparisons can be found: “*First, there is some evidence of a 'possible anatomical explanation for the epidemiologically observed protective effect of male circumcision',*

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<sup>5</sup> Translation: The amputation of the foreskin for non-therapeutical reasons is perceived as sexual violence by a considerable number of persons affected.

concerning the susceptibility to HIV in Langerhans cells in the inner foreskin, and a protective keratinisation that occurs after circumcision. Yet, Langerhans cells occur in the clitoris, the labia and in other parts of both male and female genitals, and no one is talking of removing these in the name of prevention.” (Dowsett/Couch 2007: 36) Polemical criticism of the RCTs in Sub-Saharan Africa is even leading to statements like: “Indeed, ‘[a] lowered risk of HIV infection among circumcised women’ has even been reported. Why weren’t trials also undertaken into the alleged HIV-preventive efficacy of female circumcision to test how randomly allocating women to immediate versus delayed circumcision groups could ‘benefit’ women by showing that female circumcision is an effective HIV preventive measure?” (Boyle/Hill 2011: 327) While the authors are not supposed to be understood to make a serious statement promoting female genital mutilation within HIV prevention it is very clear that they see male circumcision as comparable to female genital mutilation.

Several sources refer to the surgery as a traumatic event in childhood. In most cases extreme pain is given as the main reason for assumed trauma in persons circumcised as children. The impact of EMLA cream as anaesthesia is doubted by advocates of the trauma hypothesis. This discourse line might go back to times when male infants were medically circumcised without anaesthesia as it was assumed that infants do not have a sensation of pain. This view is currently outdated and WHO guidelines refer to anaesthesia for infants to be circumcised but still critics are referring to the practice to be carried out in medical settings without eliminating the pain with incomplete reference to sources from the 1990s: “You will never know what happens to your baby in the circumcision room. Some circumcision rooms are sound insulated so parents can’t hear their babies screaming. Most newborns do not receive adequate anesthesia. [...] Who would want to hear that his or her baby was screaming in agony? Only 45% of doctors who do circumcisions use any anesthesia at all.” (Intaction.org: online, 10 common myths about circumcision)

“Die Entfernung der Vorhaut stellt ein Trauma dar und kann zu erheblichen körperlichen, sexuellen oder psychischen Komplikationen und Leidenszuständen bis ins Erwachsenenalter führen!”<sup>6</sup> (Franz, Matthias, in Herzberg 2012: Die Zeit) is stated by a physician for psychosomatic medicine from a German clinic. Activists against the practice do often cite anonymous affected persons to underline their views. “I wanted it covered up. I felt mutilated. I also felt that my parents had abandoned me; why had they let someone do that to me? I had such a feeling of helplessness and abuse due to my circumcision.” (Philip, in Robbins 2012: The Guardian) Numerous statements of this kind can be found in articles and on websites against infant and child male circumcision, often with the argument that circumcised boys and men feel ashamed and non-conforming in contexts with low circumcision rates.

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<sup>6</sup> Translation: The removal of the foreskin constitutes a trauma and can cause severe physical, sexual or mental complications and suffering reaching even into adulthood.



### 7.2.1.3 *Male circumcision as medically irrelevant*

Several arguments constantly used refer to male circumcision as not medically relevant and therefore unnecessary. There are two different argumentation lines around this issue. One is doubting the evidence provided regarding a preventive effect of male circumcision regarding HIV and other medical conditions. The other one is referring to the availability of other non-invasive measures of HIV prevention like condoms (Barthlen 2014: 141). Especially male circumcision of infants and children is seen as not relevant within this context, as they are not sexually active (Schäfer/Stehr 2014: 119). Robbins even comes to the conclusion that male circumcision “[...] shares more in common with ancient coming-of-age rituals than responsible medical practice.” and has therefore “[...] no place in a modern society.” (Robbins 2012: The Guardian) Delaet is writing in this context “[...] the rationales that have been used to justify male and female circumcision/genital mutilation suggest that they both can be characterized as primarily cultural practices rather than medically warranted procedures (Recent scientific findings about the HIV-preventive benefits of male circumcision do not change the fact that culture and religion have been driving forces leading to the prevalence of the procedure for most of the history in which it has been practiced)” (Delaet 2009: 420) Delaet is therefore stating that a potential beneficial medical effect of male circumcision does not outweigh the framing of infant and child circumcision as a human rights issue.

Boyle and Hill raise several concerns in a critical article on the RCTs with regard to the medical rationale of male circumcision. Specifically two points shall be mentioned here as they are often cited from critics of the surgery. “*What is the purpose of male circumcision, if condom use is still needed to prevent sexual transmission of HIV?*” (Boyle/Hill 2011: 317) This view is supported by expressions of opinions from other authors: “*For highly exposed men, such as men living in southern Africa, the choice is either using condoms consistently, with extremely low risk of becoming infected, or being circumcised, with relatively high risk of becoming infected. This is quite similar to women’s choice to either use a highly efficacious contraceptive method or use a folk method. [...] Is there a rationale for promoting the idea of circumcision when better choices are available?*” (Garenne 2006: 143)

In addition, the predominant mode of heterosexual transmission in Sub-Saharan Africa is doubted by Boyle and Hill assuming a considerable number of homosexual men participating in the trials: “*The RCTs were premised on the untested assumption that men who have sex with men are extremely rare in Africa and that the HIV epidemic is primarily heterosexual in nature. Evidence suggests this is not the case [...]*” (Boyle/Hill 2011: 324-325) and “*The trials did not report on non-sexual transmission of HIV from use of non-sterile surgical and other skin-piercing instruments such as re-use of contaminated scalpels, contaminated injection syringes, contaminated blood transfusions [...] likely to occur in any real-life scaling up of male circumcision*” (Boyle/Hill 2011: 326) While these transmission ways might be present in African settings the authors seem to doubt the predominant driver

of heterosexual transmission in generalized Sub-Saharan HIV epidemics and therefore the relevance of male circumcision for prevention of female to male transmission.

## 7.2.2 Discourse Lines Supporting Male Circumcision

### 7.2.2.1 *Male circumcision as ethical requirement and fulfillment of right to health*

In comparison to the discourse line referring to male circumcision as a violation of rights defenders of the surgery judge withholding of male circumcision as a violation of the right to health. *“Since the benefits of male circumcision in HIV prevention are now proven, the question as far as ethics is concerned is not that advocating male circumcision is a violation of ethical principles or human rights, but rather that failure to advocate male circumcision to help protect against infection by HIV, or indeed the other STIs and other infections, might be deemed a dereliction of duty by any medical practitioner or health authority. Ethical analyses have emphasized that it is unethical in medical practice to not offer a proven intervention such as male circumcision for HIV prevention. Such a failure to offer a beneficial procedure has previously resulted in the needless loss of thousands of lives.”* (Wamai et al. 2012: 93)

### 7.2.2.2 *Male circumcision as surgical vaccination*

In literature and media statements male circumcision as a preventive measure regarding HIV, but also regarding other conditions, e.g. urinary tract infections, is often compared to vaccination. On the one hand the comparison is used to judge male circumcision from an ethical point of view but on the other hand male circumcision is sometimes considered to provide an equal level of protection like a vaccine. Auvert et al. conclude in the discussion part of the South Africa trial: *“MC provides a degree of protection against acquiring HIV infection equivalent to what a vaccine of high efficacy would have achieved.”* (Auvert et al. 2005: 1120) While not stating that male circumcision is actually a vaccine the comparison can be found in numerous scientific and media articles. One year after the WHO/UNAIDS recommendation researchers concluded in a discussion paper: *“MC works: it is at least as good as the HIV vaccine we have been waiting for, praying for and hoping to see in our lifetimes.”* (Klausner et al. 2008: 6) Wamai et al. close an article evaluating the evidence regarding male circumcision as an HIV-preventive measure with the following statement: *“Not only is MC highly efficacious against HIV acquisition, but it also confers multiple other health benefits, thus making it quite rightly a ‘surgical vaccine’ for the 21st century.”* (Wamai et al. 2011: 17). This position was also supported by often cited public statements around the publication of a report by the American Academy of Pediatrics: *“Infant circumcision should be regarded as equivalent to childhood vaccination. As such, it would be unethical not to routinely offer parents circumcision for their baby boy. Delay puts the child's health at risk and will usually mean it will never happen.”* (Brian

Morris, in e.g. CBS News 2014) Within English-speaking Western countries the term “surgical vaccine” is often used in media articles to explain benefits of male circumcision (e.g. Pacific Standard 2011).

While these statements are extracted from scientific discourses and general discourses around policy implementation of voluntary male circumcision programming, similar perceptions seem to exist in priority countries for male circumcision programmes pointing to a predominant discourse line within the “development scene”. While voices from the target group of male circumcision campaigns are often not represented in scientific or media discourses, qualitative studies regarding the perception of male circumcision offer an important insight. Statements by participants of a qualitative study in Tanzania support the assumption that the target group of male circumcision might frame male circumcision as equal to vaccination: “*So after my husband’s circumcision, I know that I am safe from diseases.*” and “*It reduces the rate of HIV transmission in a sense that if a man is circumcised and he is not HIV-positive then he cannot become infected ... For example, I am HIV positive. If I have sex with an uncircumcised man and I refuse to use a condom, I will surely transmit the disease to him. But if he is circumcised he will not get HIV.*” (Layer et.al. 2013: 4). The statement “*Because even in the radio they mentioned that [circumcised men] will not get HIV*” (Layer et al. 2013: 5) is pointing to a discourse line that is supporting the perception of male circumcision as equivalent to vaccination.

#### 7.2.2.3 *Male circumcision as religious right and tradition*

Besides the discussion around the medical benefits and the controversy about the rights aspect of male circumcision in infants and children one strong discourse line is referring to male circumcision as religious right and tradition. Especially in Germany the discussion about religious circumcision of boys was held intensively after the court decision in May 2012. The discourse line is referring to religious male circumcision and not to male circumcision as a preventive measure but is important to be mentioned to understand the perception of male circumcision in Germany. The Zentralrat der Muslime in Deutschland (Central Committee of the Muslims in Germany) judged the Cologne court decision in 2012 to be a threat to religious and parental rights. “*Der Zentralrat der Muslime in Deutschland (ZMD) sieht in dem Urteil des Kölner Landgerichts, in dem die Beschneidung auch als Körperverletzung gelten soll, einen eklatanten und unzulässigen Eingriff in das Selbstbestimmungsrecht der Religionsgemeinschaften und in das Elternrecht.*”<sup>7</sup> (Zentralrat der Muslime in Deutschland 27.06.12: Pressemitteilung) In addition, the Zentralrat der Muslime in Deutschland is referring to medical benefits of the practice for children and adults to underline their position. The Zentralrat der Juden in Deutschland (Central Committee of the Jews in Germany) is also referring to religious

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<sup>7</sup> Translation: The central committee of the German Muslims sees the court decision of the Cologne court that judges male circumcision as bodily harm as a striking and inadmissible interference to the right to self-determination of religious communities and to parental rights.

rights: „Diese Rechtsprechung ist ein unerhörter und unsensibler Akt. Die Beschneidung von neugeborenen Jungen ist fester Bestandteil der jüdischen Religion und wird seit Jahrtausenden weltweit praktiziert. In jedem Land der Welt wird dieses religiöse Recht respektiert.“<sup>8</sup>(Gaumann, Zentralrat der Juden in Deutschland 26.06.12: Pressemitteilung) Circumcision is seen as an integral part regarding the association with god within Jewish religious belief and an important sign of religious denomination.

### 7.3 Positioning of German Stakeholders

This section will briefly outline the positions taken by German actors involved in HIV prevention in development cooperation as well as on the German national level. While international organizations (e.g. WHO, UNAIDS, ILO) as well as the US bilateral aid (e.g. UNAIDS, PEPFAR) are actively promoting male circumcision as an HIV preventive measure and provide funding as well as technical support to priority countries, the German bilateral development aid seems to be hesitant. The German Ministry for Economic Cooperation and Development (BMZ) states: *“Ziel der Bundesregierung ist es zudem, nationale Gesundheitssysteme so zu stärken, dass medizinische Präventionsmaßnahmen wie [...] die präventiv wirksame Beschneidung entsprechend der jeweiligen Richtlinien der WHO gefahrlos und professionell begleitet und umgesetzt werden können“.*<sup>9</sup> (BMZ 2012: 11) The GIZ as implementing branch of the German bilateral aid adds: *“Eine Studie von WHO und UNAIDS weist zudem für beschnittene Männer ein um bis zu 60 Prozent geringeres Risiko einer HIV-Infektion nach (WHO, UNAIDS, 2007) [sic!]. Die deutsche Entwicklungszusammenarbeit vertritt die Position, dass es unerlässlich ist, die männliche Beschneidung mit anderen HIV-Präventionsmethoden, insbesondere mit Aufklärung und Kondomgebrauch, zu kombinieren. Sie kann keine dieser Methoden ersetzen.“*<sup>10</sup> (GIZ 2011: 1) As not referring to the trials and observational studies conducted as primary research it is not clear if the scientific base is assessed to a wide degree by the GIZ. The statement does not oppose male circumcision but as it is more or less the only published statement regarding the measure an active promotion of male circumcision is not very likely. No examples of programming regarding male circumcision as an HIV preventive measure from the side of the German bilateral aid has been found according to online publications. The reasons might be diverse and ranging from a general skepticism regarding the surgery to a fair amount of reserve with regard to external

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<sup>8</sup> Translation: This dispensation of justice is an incredible and inconsiderate act. The circumcision of newborn boys is a regular feature of Jewish religion and has been practiced worldwide for thousands of years. This religious right is respected in every country of the world.

<sup>9</sup> Translation: It is the target of the German Government to strengthen national health systems to a degree that medical prevention measures as [...] the preventive circumcision can be professionally accompanied and conducted according to the respective WHO guidelines.

<sup>10</sup> Translation: A study of WHO and UNAIDS is in addition showing a reduced risk of HIV infection up to 60% in circumcised men. The German bilateral aid takes the position that it is essential to combine male circumcision with other HIV preventive measures, especially with condom use and awareness raising. Male circumcision cannot replace any of these measures.

communication in the light of a controversial discourse within the German population with loud voices opposing the surgery.

Apart from German bilateral aid German non-governmental organizations also seem to avoid working on male circumcision or widely promoting it. Besides positioning of Terre des Femmes (see 7.2.1.1) no mentioning of male circumcision as HIV preventive measure has been found from the side of German non-governmental organizations engaged in development cooperation during the research process for the discourse analysis.

For the German national level the Bundeszentrale für gesundheitliche Aufklärung (BZgA/Federal Centre for health education) as health educational initiative of the German health system is also taking tentative position. *„Von der Weltgesundheitsorganisation (WHO) wurde die Beschneidung der Vorhaut 2007 in den Katalog der Präventionsmaßnahmen aufgenommen. Hintergrund dieser Entscheidung waren die Ergebnisse von in Afrika durchgeführten Studien, denen zufolge das HIV-Infektionsrisiko für den beschnittenen Mann beim ungeschützten Vaginalverkehr um etwa 60 Prozent geringer ausfällt. In einigen Ländern des südlichen Afrikas gilt die männliche Beschneidung daher als Element der bevölkerungsbezogenen Prävention. Allerdings ist sie auch hier nur in Verbindung mit dem Angebot weiterer Maßnahmen hinreichend wirksam. Es wird befürchtet, dass beschnittene Männer aufgrund zu hoher Erwartungen an die Schutzwirkung häufiger Risikokontakte eingehen könnten. Hierdurch könnte die durch eine Beschneidung erzielte Schutzwirkung letztlich aufgehoben oder sogar in ihr Gegenteil verkehrt werden.“*<sup>11</sup> It is also stated that male circumcision cannot be a standalone, and that MSM practicing receptive anal intercourse and women are not protected by the measure. *“In Ländern, in denen andere effektive Maßnahmen zur Verringerung des Übertragungsrisikos zur Verfügung stehen, ist die Beschneidung als Element der bevölkerungsbezogenen Präventionsmaßnahmen daher vielfach umstritten.“*<sup>12</sup> (BZgA: online, Häufige Fragen, HIV-Übertragung) The BZgA is making a clear point that the WHO recommendation is referring to countries with generalized epidemics and not to countries with concentrated epidemics, as the main drivers of HIV transmission in Germany are related to MSM and IDU. Potential new heterosexual high-at-risk groups like immigrants from high-prevalence settings are not captured by the statement. A general scepticism can be assumed with the statement regarding the potential adverse effects of risk compensation of circumcised men as kind of a conclusion. This statement can be interpreted as relativizing the evidence provided for male circumcision as an HIV preventive measure.

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<sup>11</sup> Translation: WHO included male circumcision into the catalogue of preventive measures in 2007. The background of the decision were the results of studies conducted in Africa according to which the HIV infection risk of the circumcised man during unsafe vaginal sexual intercourse is reduced up to 60%. In some countries of Southern Africa male circumcision therefore is part of the population based prevention. Nevertheless also within this context the measure is only effective in combination with others. It is feared that circumcised men do more often engage in risk contacts due to an overestimation of the protective effect. The protective effect of circumcision could therefore be abolished or reversed.

<sup>12</sup> Translation: In countries with other effective measures available for the reduction of transmission risks, circumcision as a population based preventive measure is often contested.

In a position paper published after the results of the African trials became available the Robert Koch Institut (RKI), the BZgA and the Deutsche AIDS Hilfe (DAH/German AIDS Service Organisation) stated: *“Auf bevölkerungsbezogener Ebene stellt die Beschneidung in Deutschland kein taugliches Mittel zur Reduktion der HIV-Neuinfektionen dar. Deshalb wird die Beschneidung der Vorhaut in Deutschland nicht als präventive Maßnahme beworben. Im individuellen Fall, kann sich die Situation anders darstellen, wenn z.B. aufgrund besonderer Lebensbedingungen die Beschneidung als (zusätzliche) Maßnahme der Risikoreduktion gewünscht wird.”*<sup>13</sup> (Deutsche AIDS Hilfe 2007: 3-4) While the surgery is not opposed as a preventive measure for settings with generalized epidemics the position paper additionally states that potential risk compensation of circumcised men have to be monitored carefully (Deutsche AIDS Hilfe 2007: 3-4) The information available from the side of the German AIDS Hilfe are not easy to find, therefore it can be assumed that the position here referred to has not changed much since the publishing of the cited position paper.

#### 7.4 Discussion

The analysis shows that the discourse around male circumcision is highly driven by ethical and emotional concerns. The comparison of the main identified discourse lines shows that judgement of the surgery is done between two extreme ends, ranging from demonizing the procedure as mutilation to overpraising it as a surgical vaccine.

<b>Discourse lines opposing male circumcision</b>	<b>Discourse lines supporting male circumcision</b>
Circumcision of male neonates and children as a violation of basic human rights	Male circumcision as ethical requirement and fulfillment of right to health
Male circumcision as mutilation and trauma	Male circumcision as surgical vaccination
Male circumcision as medically irrelevant	Male circumcision as religious right and tradition

The discourse is highly emotionalized and arguments are often stated without taking the scientific base into consideration. From the analysis it is very clear that arguments from different approaches (rights, natural science, psychology, religion) are used to frame male circumcision. Different potential dangers are attached when drawing conclusions from single pieces of the discourse. The framing of male circumcision as a violation of human rights undermines the potential of the measure to be an effective population-based HIV prevention strategy. Especially the comparison of male circumcision

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<sup>13</sup> Translation: At the population based level male circumcision is not an appropriate tool for the reduction of new HIV infections. Therefore male circumcision is not promoted as a preventive measure in Germany. In individual cases the situation can be different if for example due to specific living conditions circumcision as (additional) measure for risk reduction is desired.

with female genital mutilation without taking the evidence for male circumcision being an HIV preventive measure into consideration is introducing an argument that has the potential to create a taboo within the discourse. Especially development practitioners not knowledgeable about the medical and biological side of male circumcision who work within a context guided by human rights as the underlying norm might jump to the conclusion that male circumcision is equally harmful as female genital mutilation. On the other hand overpraising the measure as a vaccine might lead to an overestimation of the protective effect of male circumcision by the target group and provoke increased risk behavior (e.g. neglect of condom use, multiple partnerships). From the discourse analysis it is clear that information widely spread by media and representing only discourse fragments often leads to one-sided arguments. It might be difficult to gain access to neutral information about male circumcision as a biomedical approach of HIV prevention apart from scientific literature, especially if one is not intensively educated in health issues and biomedical research.

It is important to note that the German discourse differs from the discourse held outside of Germany. On the international level the discourse seems to be triggered by the medical side of the procedure (e.g. potential medical benefits versus potential harm) and arguments are - while on the one hand being emotionalized - on the other hand nevertheless referring to scientific or pseudo-scientific findings on medical benefits or harms. In comparison to this finding, the discourse in Germany is a very specific one. Triggered by the court decision on male circumcision and the law passed later on, the discourse seems to have brought the issue of male circumcision on the public agenda in Germany as a predominately non-circumcising society for the first time. Not surprisingly, as the trigger was a court decision on religious circumcision, the discourse is mainly held from two points of view - seeing male circumcision only as a tradition without medical benefits violating children's rights or seeing the execution of male circumcision as an integral part of religious freedom. The medical side of the procedure seems to be "inaccessible" to the German public probably as circumcision does not have a stand within the German health system. Male circumcision might be seen by greater parts of society as a major threat to bodily integrity. Stakeholders engaged in HIV prevention either in development cooperation or on the national level acknowledge the evidence provided by the RCTs, but this acknowledgement is not translated into programme work or exploration of the potential of male circumcision for new most-at-risk groups. It turns out that the potential of the measure might be underestimated in a predominantly non-circumcising society with low HIV prevalence rates, and ethical concerns frame the debate. The gained knowledge on concerns and predominant arguments from critics of male circumcision will find entry to the answering of the research questions and conclusion that will result in recommendations for development and health practitioners.

## 8 Limitations

### 8.1 General Limitations of Data Regarding Male Circumcision and HIV Prevalence

Global estimations of prevalence of male circumcision remain vague. Estimations are done according to assumptions on religious practices (referring to nearly global circumcision rates for Muslims and Jews) combined with country estimations on non-religious circumcision (e.g. for traditional or medical reasons). Also, these estimations do not reflect regional or in-country variations due to ethnic or religious multiplicity (WHO/UNAIDS 200: 7-9). There are several limitations regarding data on circumcision status. Often country data is gathered through self-reporting of survey participants. It is stated by researchers that self-reported circumcision status does often not correlate with the status of penile examination. This can be due to the fact that different circumcision styles exist with some of them having parts of the foreskin remaining, or circumcision is done in early ages of childhood so participants are not able to remember the operation. Reporting according to social desirability is also possible. WHO is also referring to studies that result in a high proportion of participants not knowing their circumcision status (WHO 2007: 9).

Data on HIV prevalence within the general population are often gathered from sentinel surveillance among pregnant women in antenatal care according to WHO recommendation for generalized epidemics with a prevalence of over 1% in the general population. Pregnant women are seen as a good proxy for the general population and in addition, access is easy through antenatal care (WHO/UNAIDS 2003: 7). Limitations are, for example, the under- and overestimation of prevalence due to the age of the pregnant women. Young pregnant women with HIV positive status may not be representative for all women in that age group as they have been sexually active and others may have not and therefore not exposed to HIV transmission risk. An overestimation of HIV prevalence in young women may be a consequence. HIV prevalence in older pregnant women can lead to an underestimation of HIV prevalence in women of the same age group as women with HIV are less likely to become pregnant (WHO/UNAIDS 2003: 8). Moreover, women attending antenatal care in a setting with low attendance rates might not be representative for the whole population. Bias can also occur in the selection of sites, the use of data collection forms and the eligibility of patients to participate in the sentinel surveillance. Data of sentinel surveillances are usually compared to those of the general HIV reporting system. Several problems can arise as a large variety of stakeholders of the health sector and non-profit sector in low-resource settings report on the results of HIV testing campaigns. Without going into details, some of the problems are related to frequent unavailability of data collection forms and double testing of patients as no proper coding system exists. The quality of data on the prevalence of HIV in the general population can therefore often be judged as limited and careful reading on data gathering of reports is necessary to judge the limitations of published reports.



Data on HIV prevalence in high-risk groups, often gathered through behavioural surveys, is also prone to bias. High risk groups may include brothel based sex-workers, non-brothel based sex-workers, men having sex with men, injective drug users, transport workers and members of the armed forces and police. First of all, reporting bias is very probable as the interviewees might have answered due to social desirability. The second limitation is related to the access to high-risk groups as well as the sample size and selection. Difficulties are possible regarding access to the high-risk groups due to stigma and fear of legal consequences. In many countries this is especially the case for men having sex with men, sex workers and injecting drug users. Due to the mentioned limitations the methodological validity and evidence of reports regarding the prevalence and sexual behaviour among high risk groups can be perceived as low. But nevertheless, reports on high risk groups can give important information on the interaction of high-risk groups with the general population and show trends in behavior and HIV prevalence. The findings can be used for further research and identification of gaps in knowledge.

## 8.2 Limitations of the Presented Two-stage Analysis

The presented two-stage analysis has some limitations. Both the literature review and the discourse analysis might be incomplete. With regard to the literature review (first stage) the selection of studies was done according to titles and abstracts. Studies with unclear titles and abstracts might have been excluded from the analysis and therefore selection bias might be present. The likelihood of bias in favour of a positive judgement of male circumcision is diminished as several systematic reviews were included into the analysis which also come to the conclusion that male circumcision is partly protective regarding HIV acquisition in heterosexual men. Critical scientific articles were included into the review but do present a minority in comparison to the numerous studies supporting the evidence provided with different epidemiological study designs. An additional meta-analysis was not conducted through the thesis but results of meta-analysis used to illustrate the strength of evidence provided for male circumcision as an HIV preventive measure.

The discourse analysis was conducted according to Jäger's instruction that completeness of the picture is achieved as soon as the analysis of further material does not contribute to further understanding of the issue (Jäger 2012: 130). Therefore the guiding approach was not to identify every actor who is taking a specific position but rather to concentrate on main arguments stated. Some actors might therefore not be represented within the analysis and others overrepresented. As a qualitative approach is guiding the second stage of the analysis quantitative aspects are only important, for example, with regard to the identification of discursive events. A quantitative increase in statements can be observed around the two discursive events identified. The aim of the second stage analysis was not to gain an absolutely complete picture but to identify main controversial aspects and entry points for a redefinition of the dialogue around male circumcision. Information on positioning of

German stakeholders was gathered through online research and not through direct contact. Ongoing programmes not reported on in online publication or unpublished positions are therefore not captured by the review. But as online publications is widely used to clarify positions and enhance transparency it can be assumed that the cited positions are representative to a high degree.

One important point to mention is that several assumptions not specifically reviewed by the thesis are underlying the analysis. These include the findings regarding drivers of the HIV epidemic in different contexts and transmission ways of HIV. They are taken as confirmed by research and widely acknowledged in science. Especially the predominantly heterosexual transmission in generalized sub-Saharan African epidemics is an underlying assumption widely supported and only contested by a minority of researchers (e.g. Boyle/Hill 2011).

## 9 Conclusion and Recommendations

The results of the two-stage analysis provide a broad base to answer the research questions and to formulate recommendations regarding the mainstreaming of voluntary medical male circumcision in HIV prevention.

*Is mainstreaming of voluntary male circumcision recommendable in high-prevalence settings and for most-at-risk groups?*

According to evidence available on male circumcision as a partly protective measure regarding heterosexual female to male transmission of HIV the mainstreaming of voluntary medical male circumcision is recommendable. The HIV acquisition risk is reduced by up to 60% in circumcised men and this is confirmed by a broad scientific base. The evidence provided by the three independent randomized controlled trials is compelling and supported by ecological and observational research. The hierarchy of evidence provided makes male circumcision one of the best documented and proven HIV prevention strategies. Plausible biological mechanisms on a cellular and physiological base explain the removal of the foreskin as a feasible way to remove the main entry point of the HI-virus to the male human body. The strength of evidence provided can be judged as high by applying Bradford Hill criteria. In high-prevalence settings with generalized heterosexual transmission male circumcision is an acceptable and effective way to provide a direct partly protective measure to men with indirect benefit to women.

Specific features of the biomedical approach of voluntary medical male circumcision make it “*although not a ,magic bullet‘, [... but] a critical component in the ,tool box‘ of HIV prevention approaches.*” (Wamai et al. 2011: 1) The measure is a single intervention with low risk of adverse effects if performed in an appropriate medical setting, providing a life-long partial protection to men against HIV acquisition according to recent research. In combination with behavioral and structural approaches for risk reduction, especially the promotion of condom use and the reduction of sexual

partners, it can contribute in the longterm to decreased HIV prevalence in settings with generalized epidemics and low circumcision rates if performed consistently among target groups. While the promotion of condom use and risk reductive behavior is inevitable, the measure provides an additional protection in potential times of non-availability of protective measures like condoms and inaccessibility of health services including ART for HIV positive female partners to suppress the viral load, e.g. due to humanitarian crisis, instability and displacement. *“In the area of sexuality, which many empirically believe to represent purely voluntary behaviors under individual control, for too long we have neglected structural approaches to prevention... high-risk sex may have more to do with environments that promote risk behavior and the limited accessibility of condoms than with individual knowledge, attitudes, and beliefs.”* (Golden/Collings et al. 2013: 18) As this is true for structural interventions this conclusion can also be drawn for male circumcision as a biomedical approach of HIV prevention.

The mainstreaming of voluntary medical male circumcision in HIV prevention programming for adult men and, in the longer term, for neonates and children should be considered as integral part of preventive work like other widely accepted measures, especially condom use. While providing male circumcision services to sexually active men has priority to reduce the risk of HIV acquisition, the circumcision of boys before sexual debut is a practice to be considered. Rates of adverse events are lower in children and wound healing is faster. Problems with abstinence during wound healing are not relevant within the context of neonatal male circumcision or circumcision of boys.

The potential of male circumcision for most-at-risk groups other than heterosexual men in generalized epidemics is not explored to a full extent yet. Observational research is pointing in the direction that male circumcision might offer benefits for MSM practicing exclusively or predominantly the insertive anal sex role, but the observational research is not confirmed by experimental study designs. In addition, several studies do not show this association, and behavior of MSM is not fully captured by studies and large variety of behaviors exist in different societies.

The research regarding male circumcision as a preventive measure for heterosexual most-at-risk groups (e.g. migrant workers, IDUs, immigrants from high-prevalence settings) in concentrated epidemics is only on the threshold. There might be potential for a beneficial impact of offering male circumcision services to heterosexual most-at-risk groups if embedded in comprehensive HIV prevention work.

*Is medical evidence regarding the protective effect of male circumcision strong enough to contest ethical considerations?*

The evidence provided regarding voluntary medical male circumcision as a partly protective measure in HIV prevention for men is compelling. The provision of male circumcision services should therefore be framed as a right to health issue with the provision of male circumcision services as integral part within HIV prevention work and not as a violation of human or especially children’s rights to

bodily integrity. If offered in medical settings by skilled medical providers under (local) anaesthesia the procedure can be considered as safe and pain experienced during wound healing as moderate. The removal of the foreskin is not comparable to female genital mutilation, as according to available research the removed foreskin is not an essential functional part of the male sexual organ. In the vast majority of cases full functionality and sexual sensitivity is maintained after the surgery. The procedure is in most cases not putting men's or boy's health at risk.

As no cure and no vaccine exist against the HI-virus and, in addition, treatment is not available to all affected persons and the disease has extensive negative social and economic impacts on individuals and societies, prevention of new HIV infections remains the sole way of stemming the epidemic. All available tools not harmful to the individual should be considered to be integrated into HIV prevention work. This is especially true for voluntary medical male circumcision as a proven strategy for risk reduction of HIV acquisition in men. Moreover, in comparison to other available measures male circumcision is a cost-effective measure with minor side-effects.

The often cited potential adverse effect of risk compensation among circumcised men with possible negative impact on female partners is according to research not as widespread as often thought. Most studies conducted within this area do not come to the conclusion of increased risk behavior among circumcised men. This is partly not the case for the early resumption of sexual activity before complete wound healing and therefore men need to be supported more effectively to comply with recommendations of abstinence to protect female partners and themselves. The perception of male circumcision as a surgical vaccine and the overestimation of the protective effect might present future problems with growing awareness of and false beliefs in protection among the target group of male circumcision campaigns. A redefinition of messages accompanying male circumcision campaigns might be necessary in some cases documented by qualitative research.

*Is the protective effect of male circumcision for HIV prevention for most-at-risk groups underestimated in Germany as low prevalence and traditionally non-circumcising setting?*

According to the results of the discourse analysis the protective effect of male circumcision as a biomedical approach in HIV prevention might be underestimated. The discussion of male circumcision is mainly held as a controversy around religious circumcision within a human rights frame. This can be explained by the Cologne court decision on religious circumcision to be judged as bodily harm and later on redefined by a law as legal, as the trigger of the discourse and main discursive event. The WHO and UNAIDS recommendation did not have a comparable trigger effect to the German public and it can be assumed that this is due to the fact that Germany is a low-prevalence setting with regard to HIV and a predominantly non-circumcising society. As a high-resource setting other preventive non-invasive measures like condoms and ART are widely available and the epidemic is mostly concentrated in MSM and IDUs. Not surprisingly, male circumcision is not considered to be a population based preventive measure which is true regarding the German context, but

this perception seems also to be translated to other contexts. Male circumcision does not seem to be not considered as an important tool for HIV prevention within the context of development cooperation. On the national level the potential of male circumcision for new most-at-risk groups like immigrants from high-prevalence settings is not explored. The medical side of the practice seems to be “inaccessible” to the German public even reaching into specialist circles, and male circumcision as HIV preventive measure can be considered as a taboo subject in Germany. A redefinition of the German discourse is necessary and the compelling evidence available for male circumcision as an HIV preventive measure should be the entry point to frame a re-perception of male circumcision within the discourse that is stuck in deadlocked positions. Biomedical evidence outlined in the first stage of the analysis of this thesis can provide this base.

### *Recommendations*

- Mainstreaming of voluntary medical male circumcision as an HIV preventive measure in high-prevalence settings with low circumcision rates in comprehensive HIV prevention programming should be acknowledged and supported by all stakeholders within development cooperation (bilateral development cooperation, international organizations, non-governmental organizations, governments of high-prevalence countries). Financial as well as technical support should be provided to ensure the provision of safe and high-quality services for men and boys in order to ensure that priority countries reach the targets set for male circumcision to be an effective population-based measure.
- Mainstreaming of voluntary medical male circumcision in HIV prevention work is to ensure that the measure is not provided as a stand-alone but as a tool in comprehensive programming. Supportive environments should be created for men to enhance uptake of services (e.g. workplace programmes, male and youth friendly health services). The family and the couple should be considered to be an important target of male circumcision campaigns – also with regard to the uptake of neonatal male circumcision and circumcision of boys as beneficial practice according to research results. Male involvement in ante- and postnatal care can be an entry point for uptake of adult and neonatal male circumcision services.
- Messaging regarding male circumcision as an HIV preventive measure should be subject of intensive research, monitoring and evaluation in order to avoid misperceptions and overestimation of the protective effect. The comparison of male circumcision with vaccination is not useful within this context. Intensive counselling and appropriate information should support men in abstaining from risk compensation and early resumption of sexual activity before wound healing in order to protect female sexual partners and themselves.
- German actors in development cooperation should consider playing a pioneering role in redefining the specific German dialogue on male circumcision and create a supportive climate within the development scene and on the national level to explore the potential of the measure within

development cooperation and for most-at-risk groups. The scientific base and evidence provided by experimental, ecological and observational research should be the base for the discussion. Ethical considerations should be taken from a rights to health perspective rather than from perspectives comparing male circumcision with female genital mutilation.

- German actors of HIV prevention on the national level should consider exploring the potential of male circumcision for new heterosexual most-at-risk groups, especially immigrants from high-resource settings, and at least provide detailed and target group friendly information on the measure to the public.

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## 11 Declaration of Independent Work

“I hereby declare that I wrote this thesis without any assistance and used only the aids listed. Any material taken from other works, either as a quote or idea have been indicated under ‘Sources’.”



## 12 Appendix

### Studies and Scientific Articles Included in Stage 1 of the Analysis

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