Summary of Public Comments and CDC Responses to Public Comments for

Information for Providers to Share with Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, Sexually Transmitted Infections, and other Health Outcomes*

**Formerly titled Recommendations for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, Sexually Transmitted Infections, and other Health Outcomes

Introduction: CDC undertook a rigorous review of the comments that were received in response to its request for public comment on the draft "Recommendations for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, STIs, and other Health Outcomes." CDC classified the comments into recurring themes and responded to each theme accordingly. Each comment is prefaced by the word "Comment" and each response by the word "Response." The number of persons that mentioned a particular theme is placed in parentheses next to the word Comment (e.g., n = X). Medical male circumcision has been abbreviated in some places in the document as male circumcision. Full citations are noted at the end in the reference section.

COMMENT (n = 576):

(a) The comments state that the consultation or literature review process or other methods mentioned in policy document were inadequate.

(b) Comments stating that CDC is untrustworthy, shameful, distrustful, etc.

RESPONSE 1:

(a) The CDC recommendations are based on a comprehensive evaluation of scientific data on the health risks and benefits of medical male circumcision. The literature review was systematic in nature and up to date at the time the review was written. The literature review was updated through October 2015 during the process of responding to the peer review and public comments with corresponding updates made to the recommendations statement.

(b) CDC works 24/7 to protect America from health, safety and security threats, both foreign and in the U.S. CDC's pledge to the American people is:

- 1. Be a diligent steward of the funds entrusted to our agency
- 2. Provide an environment for intellectual and personal growth and integrity
- 3. Base all public health decisions on the highest quality scientific data that is derived openly and objectively
- 4. Place the benefits to society above the benefits to our institution

5. Treat all persons with dignity, honesty, and respect

Reference: http://www.cdc.gov/about/organization/mission.htm

COMMENT (n = 537): Comments state that CDC is biased and is presenting one-sided information. They do not reference the studies that have proven that there is no benefit to MC, for example, a study of members of the Navy. The parents need to be presented with pros and cons of circumcising. CDC is a culturally biased organization or is making culturally biased recommendation.

RESPONSE 2: The CDC recommendations are based on a comprehensive evaluation of scientific data on the health risks and benefits of medical male circumcision. The literature review was systematic in nature. The cited Naval study that found that male circumcision has no effect on HIV infection¹ used self-reported responses from participants in the study's HIV-uninfected control arm to document their HIV infection status and circumcision status while it abstracted circumcision status from medical records and conducted HIV testing on participants in the study's HIV-infected case arm. Investigators assumed that because persons in the control arm underwent HIV testing at pre-deployment, that they were all HIV-uninfected at the time of the study. The investigators failed to take into account that men in the control arm may have become HIV-infected after deployment and may have not properly reported their own circumcision status. Such factors limit the validity of the results of the Naval study. The African randomized clinical trials confirmed HIV status through testing of men in both case and control arms and conducted physical exams of the men to ascertain circumcision status, a few of the many steps taken to provide a more definitive answer.

All supporting documents and evidence summaries are to be published in a companion document entitled "Background, Methods, and Synthesis of Scientific Information Used to Inform the "Recommendations for Providers and Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, STIs, and other Health Outcomes."

COMMENT (n = 397): Readers state that additional research is needed that is more generalizable to the population at risk in the U.S. before a conclusion can be reached. Readers state that there is insufficient evidence to make a recommendation for the U.S.

RESPONSE 3: The CDC recommendations are based on a comprehensive evaluation of scientific data on the health risks and benefits of medical male circumcision. Based on this thorough review, CDC concluded that there was sufficient evidence to make recommendations for providers counseling male patients and parents regarding medical male circumcision as it relates to prevention of HIV infection, sexually transmitted infections, and other health outcomes at this time.

Regarding the applicability of the results of the African clinical trials to the U.S., CDC's recommendations state the following:

"Much of the data related to HIV and STI prevention are from RCTs conducted among men in sub-Saharan Africa in regions with high rates of heterosexually acquired HIV infection. In the United States, the prevalence of HIV and lifetime risk of HIV infection are generally much lower than that in sub-Saharan Africa. Also, most new HIV infections in the United States are attributed to male-male sex, a population for whom male circumcision has not been proven to reduce the risk of HIV acquisition. While such factors limit the impact of medically performed male circumcision in reducing the overall HIV epidemic in the U.S., there is epidemiologic data to suggest that some subpopulations in the U.S. are likely to benefit. Eight percent of estimated new HIV diagnoses in the United States are attributed to female-to-male sexual transmission.21 In addition, African-American and Hispanic men have higher risk of HIV infection and lower male circumcision rates than men of other race/ethnicities. Although similar RCTs have not been conducted in the United States, based on evidence from the African trials, uncircumcised heterosexual men living in areas with high HIV prevalence are likely to experience the most public health risk-reduction benefit from elective male circumcision."

COMMENT (n = 692): Many other professional health organizations in western industrialized countries such as the Netherlands, Germany, Norway, Sweden, Finland, and Denmark have taken a stance against neonatal male circumcision.

RESPONSE 4: CDC has developed these recommendations based on a comprehensive evaluation of scientific data on the health risks and benefits of medical male circumcision. Upon its own independent review of the literature, CDC concluded that there was sufficient evidence to make the recommendations for providing information, and if appropriate, counseling, regarding medical male circumcision for the United States.

COMMENT (n = 30):

Miscellaneous recommendations:

a) **COMMENT**: The audience for recommendations should be specified.

RESPONSE 5: The first sentence in the recommendations reads:

"These recommendations are intended to assist health care providers in the United States who are counseling men and parents of male infants in decision making about male circumcision conducted by health care providers (i.e. medically performed) as it relates to the prevention of human immunodeficiency virus (HIV) infection, sexually transmitted infections (STIs), and other health outcomes."

b) **COMMENT:** There should be some mention of how providers will be educated on the recommendations and how to counsel the parents, children, adolescents, and adults regarding MC.

RESPONSE 6: The role of the recommendations document is to provide information for health care providers to share when counseling around medical male circumcision and the issue of training providers is not within the scope of the recommendations or background documents.

c) **COMMENT:** The reasons for recommending MC in infancy vs. adulthood should be specified.

RESPONSE 7: The recommendations document contains the following language:

- o "Considerations for the timing of male circumcision:
 - Neonatal male circumcision is, safer, and heals more rapidly than circumcision performed on older boys, adolescent males, and men, and is less expensive.
 - Most of the health benefits of male circumcision accrue after sexual debut.
 - Male circumcision can also be conducted in adulthood when the individual can make the decision for himself. However, male circumcision after sexual debut could result in missed opportunities for:
 - HIV and STI prevention during the window period between sexual debut and circumcision
 - Prevention of UTIs during infancy."
- d) **COMMENT:** In the recommendations document, recommendations should be for sexually active people and not for infants since they are not at risk of HIV/STIs since they are not sexually active.

RESPONSE 8: While most of the benefits of male circumcision begin at sexual debut neonatal male circumcision is, safer, and heals more rapidly than circumcision performed on older boys, adolescent males, and men, and is less expensive. Therefore some parents may decide to circumcise their infants during the neonatal period so that once they become sexually active they have already undergone the procedure.

e) **COMMENT:** CDC should take into consideration that their recommendations may lead to lawsuits for physicians from circumcised patients once they are adults.

RESPONSE 9: This is outside of the scope of these recommendations.

f) **COMMENT:** CDC should recommend other prevention methods as well.

RESPONSE 10: The current recommendations document includes the following statement "All sexually active adolescent and adult males should continue to use other proven HIV and STI risk-reduction strategies such as reducing the number of partners, and correct and consistent use of male latex condoms, and HIV preexposure or postexposure prophylaxis among others"

g) **COMMENT**: Risks from male circumcision need to be detailed in the guidelines and explained by physicians during counseling session.

RESPONSE 11: The current recommendations document describes the most common risks associated with male circumcision in order that providers share that information with clients. A more detailed description of the risks associated with male circumcision will be published in the companion document entitled "Background, Methods, and Synthesis of Scientific Information Used to Inform the 'Recommendations for Providers and Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, STIs, and other Health Outcomes.'"

h) **COMMENT:** The recommendations document should contain an overview of the biologic plausibility of why MC decreases transmission of HIV and other STDs.

RESPONSE 12: We have added the following sentence to the introductory section of the recommendations document: "The foreskin can serve as a portal of entry for STIs (including HIV), lending biological credibility to the role of circumcision in preventing STI and HIV acquisition through insertive sexual intercourse.²"

 i) COMMENT: The recommendations document should emphasize that although one cannot determine the future transmission risk for HIV or STDs for a neonate who is being circumcised, STDs are quite impactful in today's society, with anogenital HPV being almost ubiquitous across all socioeconomic strata of sexually active persons in the U.S.

RESPONSE 13: We have amended the recommendations document to read as follows:" Other anticipated health benefits derive in part from future prevention of HIV and some STIs acquired through heterosexual sex. STIs are very common with human papilloma virus (HPV) infection of the anus or genitals occurring in nearly all sexually active persons regardless of sociodemographic differences. However, while STIs are currently quite impactful, current risks for either HIV or other non-HIV STIs may not remain constant in the future and the future risk for any individual neonate, child, or adolescent cannot be definitively defined at the time that a circumcision decision is made."

j) COMMENT: In the recommendations document, recommendations for counseling should be limited to well-defined clinical circumstances that warrant such counseling (vs. provision of information), given the growing number of medical priorities which need to be addressed in the course of a patient visits. Perhaps CDC can recommend that the topic of circumcision be incorporated into routine discussions of sexual health.

RESPONSE 14: We have added the following sentence to the introductory section of the recommendations statement: "Counseling around these issues can be incorporated into routine discussions of sexual health, newborn, and child health."

k) **COMMENT:** In the recommendations document, consider a recommendation regarding efforts to educate the American public about current evidence regarding the benefits and risks of circumcision- particularly concerning sexually transmitted HIV infections.

RESPONSE 15: This is beyond the scope of the counseling recommendations.

 COMMENT: In the recommendations document, consider using the commonly used term "medical circumcision" (followed by a clear definition) instead of "medically performed circumcision."

RESPONSE 16: We prefer the term "medically performed circumcision" and already define it in the introductory paragraph: "These recommendations are intended to assist health care providers in the United States who are counseling men and parents of male infants in decision making about male circumcision conducted by health care providers (i.e. medically performed)".

m) **COMMENT:** Consider defining certain technical terms in the recommendations statement: balanitis, oncogenic, legally emancipated, sexual debut, window period, high-risk HPV strains, e.g.)

RESPONSE 17: We have added the definition as follows:

- i. Circumcised boys are less likely than uncircumcised males to experience balanitis (inflammation of the head of the penis) and balanoposthitis (inflammation of the head of the penis and foreskin).
- ii. ...oncogenic (i.e. cancer causing)
- iii. Legally emancipated is now defined as: "Minors may be deemed emancipated, giving them sole authority to make health care decisions on their own behalf under certain circumstances, which vary by state law; for example, if the minor 1) lives independently and is self-supporting, 2) is married, 3) is pregnant or a parent, 4) is in the military, or 5) is declared emancipated by a court as defined in the mature minor section."
- iv. after sexual debut (i.e. after becoming sexually active).
- v. window period (i.e. period of time)
- vi. "high-risk" (i.e. oncogenic) (this term is used in the introductory paragraph so is not further defined as it this text is directed to health professionals, not the lay public)
- vii. observational studies (i.e. A type of study in which individuals are observed or certain outcomes are measured but no attempts are made to affect the outcomes)
- n) **COMMENT:** In the recommendations document, the phrase "high quality" medically performed circumcision is unclear.

RESPONSE 18: The term "high quality" has been removed.

o) **COMMENT:** In the recommendations document, it is unclear if "serious adverse events" are equivalent to "adverse events".

RESPONSE 19:

a) The phrase in the recommendations document including the term adverse events has been clarified as follows:

In the adult/adolescent section:

"The rate of adverse events, not including severe adverse events, in persons 10 years of age and older between 2% and 4 is 5%, with pain, bleeding, infection and unsatisfactory post-surgical appearance most commonly reported. While severe and/or long-term complications have been reported, they are so rare that they have not been precisely established."

In the neonate, infant, child, section:

"The rate of reported adverse events, not including severe adverse events* is as follows

- 1. 0.23% in males (overall)
- 2. 0.2% in infants (aged birth 3 months)
- 3. 0.4% in infants (aged < 12 mo.)
- 4. 9.1% in children (aged 1-9 years)
- 5. 5.3% in persons (aged 10 years and older)

* Severe adverse events include outcomes such as permanent disabilities, disfigurements, and death"

p) **COMMENT:** In the recommendations document, "correctional procedures" are listed as adverse events and should be noted as "adhesions that require correctional procedures"

RESPONSE 21: The sentence has been reworded as follows: "Most commonly reported complications in all age groups include bleeding and inflammation of the penis, and incomplete wound healing and adhesions requiring correctional procedures"

q) **COMMENT:** In the recommendations document, terms "Box" and "Box 1" are used interchangeably; need for editing.

RESPONSE 22: The recommendations document has been edited to use the term "Box 1" throughout the document.

r) **COMMENT:** In the recommendations document, recommendation 3-B refers to data about circumcision (without reference) rather than on focusing on the recommendation per se.

RESPONSE 23: The recommendations document for section 3-B has been updated to include the following recommendation at the beginning of the section: "Healthcare providers should explain that the data regarding male circumcision as it relates to the acquisition of HIV and other STDs among MSM has a number of limitations and results differ based on predominance of insertive or receptive sexual practice." In addition, the following citation

has also been added: Wiysonge CS, Kongnyuy EJ, Shey M, et al. Male circumcision for prevention of homosexual acquisition of HIV in men. *Cochrane Database Syst Rev.* 2011(6):CD007496

s) COMMENT: Recommendation 4-B refers to circumcision of children "according to accepted standards of clinical care and with appropriate use of anesthesia." Recommend rewording to read "using appropriate (or standard) infection control and anesthetic practices," and provide suitable references defining what these are.

RESPONSE 24: The recommendations document has been edited to read as follows: "4-B. Medically performed neonatal, pediatric, or adolescent male circumcision should be done by trained clinicians using appropriate (or standard) infection control, analgesia, and anesthetic practices." Citation: American Academy of Pediatrics Task Force on Circumcision. Circumcision Policy Statement. Pediatrics. 2012; 130(3):e756-785.

COMMENT (n = 588): Readers do not believe or understand the scientific evidence or make a statement that directly contradicts the evidence, e.g., "Male Circumcision does not prevent HIV." "CDC concluded that circumcision magically prevents spread of HIV and STIs."

RESPONSE 25: The CDC recommendations are based on a comprehensive evaluation of scientific data on the health risks and benefits of medical male circumcision. RCT trials in Africa provide the strongest level of scientific evidence needed regarding the effectiveness of male circumcision to reduce heterosexual HIV transmission and transmission of other STDs.

COMMENT (n = 17): Risk of death is not mentioned in the recommendations statement.

RESPONSE 26: The recommendations document states "The incidence of severe adverse events associated with male circumcision performed by clinicians, such as permanent disabilities, disfigurements, and death, is so low that rates have not been precisely established; these events have occurred, but are rare."

COMMENT (n = 1): Comment suggests MC is protective for male-to-female HIV transmission.

RESPONSE 27: Male circumcision reduces the risk of transmission of HIV from an HIVpositive female to an HIV-negative male. There is currently little evidence to suggest that male circumcision protects a female from acquiring HIV from a male partner. Circumcision of HIVnegative men may offer benefit to women in high-prevalence settings to the extent that it contributes to a decline in the overall prevalence of HIV in the male population, and thus fewer HIV-infected sexual partners.³

COMMENT (n= 1): Is there a basis to consider the biological plausibility of MC in reducing risks to the receptive partner for other non-HIV STIs? Perhaps this may inform some discussion in the recommendations document around the potential value of MC in protecting receptive partner from non-HIV STIs during penile-anal intercourse in the MSM counseling section.

REPONSE 28: Based on data from the African RCTs, female partners of circumcised men compared with female partners of uncircumcised men experienced statistically lower prevalence of high risk (HR) HPV DNA viral load,⁴ higher prevalence of incident HR-HPV DNA viral load,⁵ lower prevalence of T. vaginalis,⁶ lower incidence of syphilis,⁷ lower prevalence of bacterial vaginitis,⁶ and lower prevalence of genital ulcer disease.⁶ Also, because circumcised men are less likely to transmit high-risk HPV subtypes to their female partners, their partner's risk of developing cervical cancer is reduced.

Observational studies have evaluated the association between MC and non-HIV STDs in MSM, but most, with one exception, have not found an association.⁸⁻¹³ For example, in Seattle, there was no association between MC status and syphilis, HSV-2, urethral GC, urethral Chlamydia for men practicing only receptive anal sex, only insertive anal sex, or men practicing both insertive and receptive anal sex in the past year.¹² In Sydney Australia, MC was not associated with prevalent or incident HSV-1, HSV-2, self-reported genital warts, incident urethral gonorrhea, or chlamydia. However, in this same study, being circumcised was associated with reduced incident, but not prevalent syphilis, with a protective association for predominantly insertive men, not predominantly receptive men.¹³ Based on the conflicting evidence currently on hand, we are unable to comment about the biologic plausibility of a protective effect for receptive MSM for non-HIV STDs in relation to MC.

COMMENT (n = 271): Commenters suggest another procedure or surgery as a way to prevent disease or suggest that if CDC recommends MC, why not recommend another preventive surgery as well? Examples: Breasts should be removed to prevent cancer; appendix should be removed to prevent appendicitis.

RESPONSE 29: Medical male circumcision is an accepted elective medical procedure that can confer a number of health benefits with a low risk of adverse events. CDC recommends that "health benefits and risks of elective neonatal, adolescent, or adult medically performed male circumcision should be considered in consultation with medical providers while taking into account factors associated with decision-making around male circumcision including religion, societal norms and social customs, hygiene, aesthetic preference, and ethical considerations."

COMMENT (n = 539): Commenters suggest that CDC is recommending, encouraging, or promoting male circumcision in the recommendations document.

RESPONSE 30: The male circumcision counseling guidelines do not advocate for males to be circumcised, but rather aim "to assist health care providers in the United States who are counseling men and parents of male infants in decision making about male circumcision conducted by health care providers (i.e. medically performed) as it relates to the prevention of human immunodeficiency virus (HIV) infection, sexually transmitted infections (STIs), and other health outcomes." The CDC recommendations outline counseling topics for medical

providers when discussing medical circumcision so that individuals considering the procedure for themselves or their children can make an informed decision while taking into account factors associated with decision-making around male circumcision including religion, societal norms and social customs, hygiene, aesthetic preference, and ethical considerations. The counseling messages include information on potential health benefits and risks of circumcision in infants, children, adolescents, and adults. The CDC recommendations do not encourage or discourage medical male circumcision.

COMMENT (n = 207): The CDC recommendations document does not explicitly list all risks associated with MC. Guidelines should list all adverse risks, long term and short term, in the recommendations document.

RESPONSE 31: CDC has carried out a careful examination of adverse events related to circumcision and concluded that in the U.S., medical male circumcision is associated with a complication rate of 0.23% among all men circumcised, most of which are very mild and easily treated.¹⁴ The most common documented risks are described in the recommendations document, and a more thorough analysis of risks and potential health benefits can be found in the literature review that was used to inform the recommendations (See: "Background, Methods, and Synthesis of Scientific Information Used to Inform the 'Recommendations for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV infection, STIs, and other Health Outcomes."). CDC informs the reader in its background document of the risk of penile cancer, heterosexual HIV transmission, and UTIs. A CDC report provided an estimate of complications association with male circumcision in the U.S. and is cited in the CDC male circumcision counseling recommendations.¹⁴

COMMENT (n=341): Readers note that evidence from Africa doesn't apply to U.S. situation due to cultural, epidemiological, or other differences. States that findings are not generalizable and therefore findings from studies conducted on adult males in Africa cannot be applied to infant males in USA.

RESPONSE 32: In the United States, the prevalence of HIV and lifetime risk of HIV infection are generally much lower than that in sub-Saharan Africa, where the randomized clinical trials were conducted. While this may limit the impact of medically performed male circumcision in reducing the overall HIV epidemic in the United States, uncircumcised heterosexual men living in areas with high HIV prevalence are likely to experience the most public health risk-reduction benefit from elective male circumcision. In addition, the 3 RCT trials in Africa provide the strongest level of scientific evidence needed regarding the effectiveness of male circumcision to reduce heterosexual HIV transmission.

COMMENT (n=341): Cultures are different in Africa and US. Common cultural practices more common in Africa compared to US which is a melting pot of multiple cultures. Therefore, Africa will have more cultural influence on people than US will. References made in regards to how

living conditions are better in US compared to Africa, example: developing nation vs. developed country.

RESPONSE 33: Male circumcision is a biomedical intervention that has been shown to reduce a man's risk of acquiring HIV and other STIs through heterosexual sex. In the United States, uncircumcised heterosexual men living in areas with high HIV prevalence are likely to experience the most public health risk-reduction benefit from elective male circumcision.

COMMENT (n=3): Condoms and HIV/STD education/counseling not readily available in Africa.

RESPONSE 34: In global settings, adult male circumcision is delivered within the context of comprehensive HIV prevention messages and services including: the provision of HIV testing and counseling services; treatment for sexually transmitted infections; the promotion of safer sex practices; the provision of male and female condoms and promotion of their correct and consistent use.(See: WHO Male Circumcision Information Page, http://www.who.int/hiv/topics/malecircumcision/en/).

COMMENT (n =341):: In Africa, heterosexual transmission is the predominant mode of HIV transmission, whereas transmission between men who have sex with men is the predominant mode of HIV transmission in the U.S. High risk groups are different in the U.S. and Africa. HIV and STI disease prevalence is higher in African countries compared to US.

RESPONSE 35: In the United States, the prevalence of HIV and lifetime risk of HIV infection are generally much lower than that in sub-Saharan Africa. While this may limit the impact of medically performed male circumcision in reducing the overall HIV epidemic in the U.S., there is epidemiologic data to suggest that some subpopulations in the U.S. are likely to benefit. In the United States, uncircumcised heterosexual men living in areas with high HIV prevalence are likely to experience the most public health risk-reduction benefit from elective male circumcision.

Based on evidence from the African trials, uncircumcised heterosexual men living in areas with high HIV prevalence are likely to experience the most public health risk-reduction benefit from elective male circumcision. While such factors limit the impact of medically performed male circumcision in reducing the overall HIV epidemic in the U.S., there is epidemiologic data to suggest that some subpopulations in the U.S. are likely to benefit. The CDC male circumcision counseling recommendations state that blacks and Hispanics who are disproportionately affected by HIV, and who have lower circumcision rates than white non-Hispanics, are likely to benefit the most from being circumcised.

STIs other than HIV are among the most common communicable diseases in the United States, and interventions that prevent STIs would result in substantial reductions in morbidity and cost of health services. In addition to HIV, In the randomized controlled trials for which data are available, reductions in the 1) prevalence of genitourinary disease (GUD),^{6,15,16} 2) incidence of herpes simplex virus type 2 (HSV-2),^{17,18} and 3) prevalence,^{5,17,19,20} incidence,^{21,22}

and clearance^{5,22} of high-risk oncogenic human papillomavirus (HR-HPV), 4) prevalence of Trichomonas vaginalis,^{6,23} 5) incidence of syphilis,⁷ 6) prevalence of bacterial vaginosis,⁶ and 7) prevalence of mycoplasma genitalium²⁴ were also demonstrated.

COMMENT (n = see totals below): The scientific evidence used by CDC is flawed (n = 897).

RESPONSE 36: The CDC recommendations are based on a comprehensive evaluation of scientific data, which includes but is not limited to data from several randomized clinical trials, ^{7,15,25,26} the strongest and most robust scientific data which can be obtained.

i. **COMMENT (n=95):** CDC cites the policy statement from the American Academy of Pediatrics which bases its data on flawed data. It is unclear how the American Academy of Pediatrics (AAP) developed their most recent stance on MC, concluding that the benefits outweigh the risks. Their stance on MC has waffled back and forth over the years.

RESPONSE 37: The AAP based its recommendations on best available scientific evidence. Updated AAP recommendations were published in 2012 and were based on published scientific studies that found that the health benefits of newborn male circumcision outweigh the risks and that the procedure's benefits justify access to this procedure for families who choose it.²⁷ (http://pediatrics.aappublications.org/content/130/3/585). CDC concurs with this stance.

ii. **COMMENT (n = 86):** Circumcision does not prevent HPV. In light of the HPV vaccine, MC is not needed to prevent HPV infection or HPV-related cancers.

RESPONSE 38: Based on the scientific evidence, circumcision reduces the prevalence, ^{5,17,19,20} incidence, ^{21,22} and clearance^{5,22} of high-risk oncogenic human papillomavirus (HR-HPV) and protects both men and women from HPV infection. Circumcised men are less likely to transmit high-risk HPV subtypes to their female partners, thereby reducing their partner's risk of developing cervical cancer. Although an HPV vaccine is available, it does not confer immunity to all HPV viral types that can cause HPV-related cancer and other HPV disease. In addition, HPV vaccine uptake has not been universal in the United State among persons for whom it is recommended. HPV vaccination does not preclude the benefits of male circumcision in reducing HPV transmission, particularly in boys who are not vaccinated.

iii. **COMMENT(n = 15):** The American Cancer Society's stance on whether MC is associated with cancer prevention, specifically penile cancer, is not in agreement with CDC's stance.

RESPONSE 39: The American Cancer Society states that male circumcision early in life is associated with a lower risk of penile cancer, due to decreased risk of phimosis and smegma accumulation, and decreased risk of becoming infected with HPV or having a persistent HPV infection. (see http://www.cancer.org/cancer/penilecancer/detailedguide/penile-cancer-riskfactors)

iv. **COMMENT (n = 80):** The perceived benefits of MC in reducing penile cancer rates are diminished by the fact that penile cancer is rare.

RESPONSE 40: Penile cancer is rare in the United States, but may be prevented by male circumcision prior to sexual debut.

v. COMMENT (n = 456): Data from African randomized clinical trials were flawed. There were limitations associated with the African RCTs. Limitations can include but not limited to bias, loss to follow up, terminated early, statistical results are not accurate or overestimated (relative vs. absolute measure), condom use was not obtained, requested participants not to have sex, etc.

RESPONSE 41: The 3 RCT trials in Africa provide the strongest level of scientific evidence needed regarding the effectiveness of male circumcision to reduce heterosexual HIV transmission.

In 2009, a Cochrane review evaluated the quality of the scientific evidence and potential impact of bias for each of the 3 male circumcision RCTs, and found that potential for significant biases affecting the trial results was low to moderate. The conclusion was that in spite of any potential bias there is "strong evidence" that male circumcision reduces the likelihood of HIV acquisition in men through heterosexual transmission, and that "male circumcision can be considered as an effective measure to partly prevent HIV acquisition in heterosexual men."²⁸

Two of the 3 clinical trials were terminated early by their Safety and Monitoring Boards because of the robust demonstration of the efficacy of male circumcision in preventing acquisition of HIV infection, to allow the intervention to be available all men and not only those in the intervention group of the studies. Early termination of study is unlikely to have significantly compromised study results due to 4 main factors previously described²⁹: a) "predetermined conservative stoppage rules",²⁹ b)"consistency of results" (across trials) and "finding of stronger effectiveness over time in 2 of the trials" may argue that early termination may have resulted in an underestimate of the effectiveness rather than an overestimate,²⁹ c) "decreased risk of overestimation because of a small number of events";³⁰ specifically "the risk of overestimating the treatment effect decreases when the number of events is at least approximately 200, which was

the total number of events in the RCTs",²⁹ and d) "An observed effect of male circumcision that was similar to existing credible observational studies".³¹

The studies controlled for confounding factors such as use of condoms: People were asked about condom use since time of last clinic visit in a way that would minimize recall bias ("never, sometimes, always"). For example, in the South African study, having at least 1 sexual encounter without a condom since last clinic visit is an example of a sexual risk factor that was controlled for without significant change in the effectiveness of the intervention.

Loss to follow-up is unlikely to have biased the study results significantly. Wamai et al.³² have previously responded on the issue of loss-to-follow up in the RCTS. They state:

"...in all 3 RCTs, use of survival analysis accounting for 15% annual loss (in both groups) indicated that such losses did not differ statistically between groups^{15,25,26} and reduced the potential attrition bias in each trial."

For instance, the South African trial reported:

"Even though some participants were lost during the follow-up, and the loss to follow-up rate was greater than the event rate, the impact of missing participants on the overall results of this study is likely to be small not only because the loss to follow-up was small for a cohort study conducted in a general populations, but also because those who were late for at least one follow-up visit were protected by male circumcision just as the other participants".²⁶

vi. COMMENT (n = 412): Getting circumcised will not prevent disease because countries with high MC rates still have high HIV/STI rates. Readers stated that U.S. has higher MC rates, but also higher HIV/STI rates than European and Asian countries.

RESPONSE 42: This ecological evidence does not refute the large body of highquality scientific evidence demonstrating the protective effect of circumcision against HIV. HIV transmission is affected by many factors that differ between the United States and Europe, which include but are not limited to universal access to healthcare, promotion of HIV testing, access to HIV treatment, sex education, condom usage, and primary modes of HIV transmission. Other ecologic data support the association between male circumcision and reduced HIV prevalence. For example, among the countries in Africa and Asia with prevalence of male circumcision of < 20% have HIV-infection prevalence several times as high (seroprevalence range: 0.24 - 25.84) than countries where > 80% of men are circumcised (seroprevalence range: 0.03-11.64).³³ Comparing 2 cities in sub-Saharan Africa with relatively low HIV prevalence (Cotonou and Yaoundé) with 2 cities with high HIV prevalence (Kisumu and Ndola), investigators concluded that differences in rates of male circumcision likely played an important role in differing rates of HIV transmission across Africa.³⁴ A study comparing Israel, a country with high rates of circumcision, with the Netherlands and France, countries with lower rates of circumcision, found that Israel had lower rates of HIV despite having similar risk factors related to other parameters influencing HIV transmission.³⁵ Finally, the CDC male circumcision counseling recommendations states that blacks and Hispanics, who are disproportionately affected by HIV, and who have lower circumcision rates than white non-Hispanics, are likely to benefit the most from being circumcised with respect to lowering risk for heterosexual HIV transmission.

vii. COMMENT (n=102): MC does not prevent UTIs. (n = 160) Men have lower rates of UTIs compared to females, therefore it doesn't make sense to circumcise males to prevent UTIs. (n=90) The fact that antibiotics can be used to treat UTIs means that MC does not need to be performed in males to prevent UTIs.

RESPONSE 43: Scientific evidence supports male circumcision as an effective intervention to prevent UTIs in male infants. UTIs in male infants are serious infections that can cause kidney damage, and rarely death. While antibiotics can be used to treat UTIs if they are diagnosed, UTIs can be prevented with neonatal male circumcision. Typical treatments and long-term impact of infant UTIs vary with severity of infection, and infant UTIs may require more invasive treatment and diagnosis beyond oral antibiotics. Undiagnosed and untreated UTIs can have severe long term consequences.

While UTIs can be treated, UTIs must first be diagnosed in order to be treated. Circumcision can reduce the occurrence of UTIs altogether, providing a sort of primary prevention for UTIs, and reducing the need to be treated for UTIs.

Based on a meta-analysis of 22 studies, most of which were based in the U.S., it is estimated that 32.1% (95% CI = 15.6 - 49.8) of uncircumcised men compared with 8.8% (95% CI = 4.15 - 13.2) of circumcised men will experience a UTI in their lifetime, suggesting that lack of circumcision is associated with a 23.3% increased risk of UTI during a man's lifetime.³⁶

COMMENT (n = 758): Other methods are effective for prevention and treating HIV, STIs, etc. and should be used to the exclusion of MC. Other methods mentioned include PrEP, HPV vaccine, non-surgical methods, behavioral changes, promote clean needles, know partners status, regular testing, and promoting safer practices.

RESPONSE 44: Because no HIV prevention intervention is 100% effective, utilizing a combination of interventions is the most successful approach to prevent HIV transmission. Male circumcision is unique among HIV prevention interventions in that it is a single procedure that confers lifelong protection against HIV, and is a valuable addition to the HIV prevention portfolio.

Male circumcision is an option for prevention of HIV and other STIs. Consistent and correct use of latex condoms is effective in reducing the risk of sexual transmission of HIV and other STIs. While PrEP is highly effective in preventing acquisition of HIV infection, it does not protect against acquisition of STIs. HPV vaccine provides protection against only a subset of all HPV types, and vaccination uptake has not been universal in the United States among those for whom it is recommended. Clean needles can protect against HIV transmission during injection drug use, but do not provide protection against sexual transmission of HIV. While prevention with behavioral interventions can be effective, optimal protection against HIV and STIs can be provided with a combination of prevention interventions that can include male circumcision.

COMMENT (n = 597): Condoms are very effective in preventing HIV/STI/pregnancy, thus obviates the need for circumcision.

RESPONSE 45: Condoms are part of comprehensive HIV and STI prevention. Male circumcision is an option for prevention of HIV and other STIs. Consistent and correct use of latex condoms is effective in reducing the risk of sexual transmission of HIV and other STIs. While prevention with behavioral interventions can be effective, optimal protection against HIV and STIs can be provided with a combination of prevention interventions that can include male circumcision. See Response 44.

COMMENT (n = 279): Education and counseling about the use of other prevention strategies such as abstinence, monogamy, or having fewer sexual partners can prevent HIV transmission, thus obviating the need for circumcision.

RESPONSE 46: HIV and STI education and risk reduction counseling are part of comprehensive HIV and STI prevention. HIV prevention messages include limiting the number of sexual and using condoms correctly and consistently. Male circumcision may provide an additional safety net of protection.

COMMENT [Comments about counseling procedures. (n = 260)] :

a. COMMENT: Providers lack time to counsel patients about male circumcision.

RESPONSE 47: The CDC recommendations document provides recommendations for healthcare providers to counsel patients and parents of males who might benefit from male circumcision. They do not recommend forcing male circumcision.

b. COMMENT: Providers need proper training to deliver counseling messages around male circumcision.

RESPONSE 48: We agree that provider training on counseling is important, and the recommendations note includes evidence-based information for providers in counseling their patients.

c. COMMENT: How does one counsel men whose sexual practices are unknown?

RESPONSE 49: The recommendations document states "Prior to counseling uncircumcised sexually active adolescent and adult males about medically performed male circumcision, their HIV risk behaviors, HIV infection status, and the gender of their sexual partner should be assessed."

d. COMMENT: Counsel patients on proper care of intact foreskin and risks involved with male circumcision.

RESPONSE 50: Counseling for any surgical procedure, including male circumcision, includes a discussion of the risks and benefits of the procedure. A detailed discussion about proper care of intact foreskin is outside the scope of the recommendations statement but should certainly take place in a discussion of well-baby or well-child care or during a routine primary care visit for adults.

e. COMMENT: Counseling guidelines should include benefits of foreskin.

RESPONSE 51: Some men report that they enjoy the sensation that the foreskin provides during sexual intercourse. The loss of this sensation has been added to the recommendations document as a potential adverse event as follows:

When counseling parents or guardians:

"As a potentially sexually active adult in the future, some men enjoy the sensation of the foreskin experienced during sexual relations. This sensation will not be present after circumcision, however, the bulk of scientific evidence states that men on average do not experience a loss of sexual pleasure or function because of circumcision."

When counseling adults:

"On average, adult men who undergo circumcision generally report minimal or no change in sexual satisfaction or function. Those who enjoy the sensation of the foreskin during sexual relations will no longer experience that sensation."

There is a lack of evidence available from rigorous, well-designed scientific studies demonstrating the health benefits of an intact foreskin.

f. COMMENT: Guidelines do not include counseling procedures for teens and teenage parents.

RESPONSE 52: Teens are included in the recommendations document as "adults" and teenage parents as "parents".

COMMENT (n = 116): Regarding issue of risk compensation when counseling adults and adolescents; for example, male circumcision results in decreased protective behaviors such as condom use, monogamy/reducing sexual partners and increased rates of unwanted pregnancies or STDs as a result of a MC.

RESPONSE 53: Risk compensation can result from HIV and STI prevention interventions, however, in most studies of risk compensation among the African RCTs^{25,28,37-39} with one exception during limited time periods of 1 RCT³⁸, and among 2 of 3 observational studies in the U.S., male circumcision was not associated with risk compensation.⁴⁰⁻⁴²

COMMENT (n = 535) Regarding issue of effect of MC on sexual intercourse when counseling adults and adolescents; for example, decreased male sexual sensitivity or satisfaction, loss of nerve endings, risk of erectile dysfunction, premature ejaculation.

RESPONSE 54: Data from 3 systematic reviews of the literature,⁴³⁻⁴⁵, 2 clinical randomized trials,^{46,47} and 3 of 4 observational studies published after the 3 aforementioned metaanalyses⁴⁸⁻⁵¹ did not demonstrate that circumcision is associated with male sexual dysfunction. The data from the scientific literature overwhelmingly indicates that circumcision does not change or reduce sexual satisfaction or function on average.

COMMENT (n = 671): Discuss risk of adverse effects (AEs) associated with male circumcision when counseling adults and adolescents.

RESPONSE 55: the risk of adverse effects are discussed in the counseling recommendations. The risk of adverse events of male circumcision performed during adulthood are greater than when the procedure is performed during infancy. Results from a CDC study of a large longitudinal healthcare reimbursement dataset in the U.S. including1,400,920 circumcised males,¹⁴ indicate that the incidence of probable adverse events (AEs) related to male circumcision vary by age group: 0.4%, 9.06%, and 5.31% for males age <1 year, 1-9 years, and \geq 10 years, respectively. This incidence of AEs was 10 - 20 fold higher for males in older age groups compared to infants. The rate of AEs in persons 10 years of age and older is 5% with pain, bleeding, infection, and unsatisfactory post-surgical appearance most commonly reported. This same study estimated the incidence rate difference (IRD) (subtracting out the

background rate of AEs in uncircumcised newborns) for potential serious probable AEs to range from a low of 0.76 persons (95% CI = 0.10 - 5.43) with stricture of male genital organ per million male circumcisions (PMMC) to a high of 703.23 persons (95% CI =153.92 - 245.66) with repair of incomplete circumcision PMMC. Penile amputations (partial or complete) were very rare and more common in males aged > 9 years of age compared with males aged 9 years or younger.

COMMENT (n = 85): Issues related to how MC has impacted women's health, including effects of decreased female sexual satisfaction when having sexual intercourse with a circumcised compared with uncircumcised male.

RESPONSE 56: Male circumcision protects women from some STIs and HPV-related disease, including oncogenic HPV viral types and genital warts. Based on data from the African RCTs, female partners of circumcised men compared with uncircumcised men experienced statistically lower prevalence of high risk (HR) HPV DNA viral load,⁴ higher prevalence of incident HR-HPV DNA viral load,⁵ lower prevalence of T. vaginalis,⁶ lower incidence of syphilis,⁷ lower prevalence of bacterial vaginitis,⁶ and lower prevalence of genital ulcer disease.⁶ Because circumcised men are less likely to transmit high-risk HPV subtypes to their female partners, their partner's risk of developing cervical cancer is reduced. In addition, in the RCT in Uganda, of 455 female partners of men circumcised as adults, 2.9% reported less sexual satisfaction after their partners were circumcised, 57.3% reported no change, and 39.8% reported an improvement.⁵²

COMMENT (n = 1,045): Issues related to adverse event/risks associated with the MC procedure in infants/children.

RESPONSE 57: CDC provides valid estimates of the incidence of complication rates related to male circumcision in the U.S. in the background document for different ages with estimates of 0.4%, 9.06%, and 5.31% for males aged <1 year, 1-9 years, and \geq 10 years, respectively.¹⁴ Complications related to circumcision are typically easily managed. The benefits and risks of male circumcision are well documented in the background document and provide critical and important information to parents when deciding whether to circumcise their infant or to adults deciding about whether to be circumcised. The most commonly described complications in infants less than 1 year old and children age 1 to 9 years are bleeding, inflammation, and the need for corrective procedures. Delaying age of circumcision from infancy to 1 year of age or older can increase the risk of some complications associated with the procedure. CDC recommends that parents and guardians discuss potential health benefits and risks of circumcision with a medical provider when considering circumcision for a male child. Specific arguments made by commenters against the medical practice of male circumcision apply to many surgical procedures in the U.S. The low rates of serious complications documented in the scientific literature indicate that medical male circumcision in the U.S. is a safe procedure.

COMMENT (n = 243): Issues related to death associated with infant male circumcision.

RESPONSE 58: It is extremely rare for infant medical male circumcision to result in death, and because of its rarity it is difficult to document the frequency with which it occurs. One review article including data from a myriad of sources, estimated that there were 3 deaths due to neonatal male circumcision in the United States between 1954 and 1989.⁵³

COMMENT (n = see totals next to each adverse event): Issues related to acute risks such as bleeding (n = 76), infection (n = 115), or physical harm (n = 739) such as amputation, other disfigurement (n = 971), or pain (n = 881) associated with infant male circumcision; including concerns that only acute risks associated with MC are reported and that the benefits don't outweigh the risks.

RESPONSE 59: In the U.S., reported rates of complications from the largest studies of medical male circumcision in infants from birth to age 1 month, are approximately 0.2%.^{54,55, 56} Based on a meta-analysis of 22 mainly U.S. studies, it is estimated that lack of circumcision is associated with a 23.3% increased risk of UTI during a man's lifetime.³⁶ The most commonly reported complications are acute in nature and include bleeding and infection, which are usually minor and easily managed.⁵⁴⁻⁵⁷ Hemorrhage is a rare complication of medical male circumcision at any age. Intraoperative bleeding, hemorrhage control procedures, or suture of an artery are more common in circumcisions performed on males 1 year of age or older than in infant circumcision.¹⁴ Infections associated with circumcision are usually minor and easily managed, and occur rarely in infants and children. An evaluation of medical billing data of 1.3 million infant medical male circumcisions in the United States reported that circumcised infants did not have a higher incidence of infection than uncircumcised infants.¹⁴

Minimizing pain is an important consideration for male circumcision. Appropriate use of analgesia is considered standard of care for male circumcision at all ages, and appropriate analgesia can substantially control pain for infants, children, and adults during and after the procedure.⁵⁸ The CDC male circumcision counseling guidelines state that "Medically performed neonatal, pediatric, or adolescent male circumcision should be done by trained clinicians according to accepted standards of clinical care, with appropriate use of anesthesia."

In newborns, the rate of amputations of the penis did not differ significantly between circumcised (3 partial amputations/million infants) and uncircumcised infants; (4 amputations/million infants).¹⁴

The recommendations document states "The incidence of severe adverse events associated with male circumcision performed by clinicians, such as permanent disabilities, disfigurements, and death, is so low that rates have not been precisely established; these events have occurred, but are rare."

Male circumcision does alter the appearance of the penis; however, evidence suggests it does not impact sexual satisfaction or function. For example, data from 3 systematic reviews of the literature,⁴³⁻⁴⁵, 2 clinical randomized trials,^{46,47} and 3 of 4 observational studies published after the 3 aforementioned meta-analyses⁴⁸⁻⁵¹ did not demonstrate that circumcision is associated

with male sexual dysfunction. In a medical claims database, while both circumcised and uncircumcised newborns both underwent penile correctional procedures, circumcised infants underwent such procedures more frequently (644 penile correctional procedures/million uncircumcised infants versus 3281 penile correctional procedures /million.¹⁴

More long term potential complications that have been reported in association with male circumcision are also discussed in the background document such as adhesions and meatal stenosis. Adhesions are a rare and usually minor complication of male circumcision. Adhesions generally resolve themselves without intervention prior to or during adolescence. An evaluation of medical billing data of 1.3 million infant medical male circumcisions in the United States reported that children and adults who are circumcised at 1 year of age or later are more likely than infants to require correctional procedures for adhesions.¹⁴ Meatal stenosis may occur very rarely as a result of medical male circumcision, however, one study that evaluated this potential association did not have enough statistical power to link meatal stenosis to medical male circumcision.⁵⁹

Issues related to effects of male circumcision on psychological issues are addressed in other responses.

COMMENT (n=1): An article that was cited about a potential association between meatal stenosis and male circumcision⁵⁹ was critiqued previously.⁶⁰ Consider including this critique in the background document.

REPONSE 60: The background has been edited to reflect the limitation of this study as follows:

Meatal stenosis may be a complication of surgery. In a prospective study, meatal stenosis was documented in 24 of 239 (7.3%) circumcised boys > age 3 years but no uncircumcised boys.⁶¹ However, the study population was not clearly defined, the diagnosed cases were not independently confirmed, and the investigator reported that the low number of uncircumcised boys in the study resulted in a lack of power to demonstrate a significant association between circumcision status and meatal stenosis.

COMMENT (n = 10): Concerns about adverse events associated with ritual male circumcision practices such as Metzitzah b'peh or the oral suction technique used in infant male circumcision.

RESPONSE 61: The CDC recommendations address medical male circumcision only. Oral suction is not considered a medical procedure and is outside of the scope of the document. Any circumcision procedure performed by religious or other lay providers is outside of the scope of the recommendations.

COMMENT (n = 1): Concerns about the impact of neonatal MC on breastfeeding or jaundice.

RESPONSE 62: A case-control study of the effects of circumcision on infant feeding frequency on day 3 of life and serum bilirubin on day 4 of life in 30 circumcised and 30 uncircumcised infants without antenatal or perinatal problems found no statistically significant differences in either of the two outcomes associated with circumcision status.⁶²

COMMENT (n = 283): Concerns about long term psychological effects that may result from infant circumcision.

RESPONSE 63: There is no high-quality evidence in the scientific literature that indicates medical male circumcision results in long-term psychological trauma. We provide a response below to several publications that have been cited in comments about adverse psychological effects of circumcision that do not contain high-quality evidence.

An article cited by Taddio et al⁶³ studying the effect of neonatal circumcision on pain response during later routine vaccination, focuses much of its parental testimony on "ritual circumcision" which is out of the scope of CDC male circumcision guidelines focusing on medical male circumcision. It also focuses on circumcision conducted without any anesthesia which is not the standard of care recommended by the American Academy of Pediatrics.²⁷

Similarly an article cited by Boyle et al.⁶⁴ also focused on psychological effects of circumcision based on performing circumcision without anesthesia, which is not the standard of care recommended by the American Academy of Pediatrics.²⁷

Reports of negative feelings about their circumcision experienced by men who were circumcised as infants have not been assessed in a balanced unbiased manor, and have mainly been conducted by organizations who oppose the practice of circumcision. While CDC does not dispute that some men who were circumcised as infants may have negative feelings about their circumcision, it is unclear from such reports how common such reports are among the population of men who have been circumcised.

The publication by Hammond⁶⁵ describing a preliminary poll of men circumcised in infancy or childhood, lacks a detailed description of its methodology or whether an attempt was made to obtain responses from a representative sample of circumcised men, or simply to men who are against circumcision. The article does report that questionnaires were only mailed to men "requesting information for circumcision-related organizations."

The study by Cansever⁶⁶ on psychological effects of circumcision on 12 children aged 4 - 7 is biased toward finding a psychological effect related to circumcision and ignoring perceptions by the parents that their children had not suffered untoward effects of circumcision, as it is noted by the authors "from the interviews with the mother, it seemed, in general, that they had little understanding into the child's psychological state, regardless of circumcision. the child's needs and anxieties were rarely recognized and little or nothing was done to protect him from despair." Many of the psychological tests used in the study were subject to biases of the psychologist's cultural interpretations of the children's responses.

The book chapter by Ramos and Boyle about the effects of ritual male circumcision of boys in the Phillipines⁶⁷ reports 2 – 3 sentences of results in the results section of the paper without any statistical tests of significance. The reader is unable to determine whether the results showed any statistically significant differences. The paper about psychological adjustment in children after traumatic disfiguring injuries⁶⁸ is limited to injuries due to "boating, lawn mower, or home accident or dog bites", and not applicable to our discussion about male circumcision.

The study by Frisch and Simonsen⁶⁹ concluding that "boys who undergo ritual circumcision" may run a greater risk of developing autism spectrum disorder is not pertinent to the U.S. circumcision counseling recommendations as it relates to "ritual" not "medical" circumcision. In addition, that study has been critiqued for methodological and analytic concerns, making the findings suspect.

The studies cited by readers ^{70 71} about the effects of pain on infant rats as a proxy for the effects of pain on infant's psychological development may not be representative of the experience in humans. Also, the study cited by readers about the effect of neonatal circumcision on pain response during subsequent routine vaccination compared use of topical lidocaine-prilocaine cream (EMLA) with placebo⁷² and did not include a study arm for more effective methods of analgesia such as dorsal penile nerve block (DPNB), or subcutaneous ring block. It is unclear whether the study results would have been the same had another arm with a more effective analgesic modality been included.

COMMENT (n = 343): Comments mentioning how MC impacts or benefits the economy, healthcare industry, pharmaceutical industry, and how MC is not in the best interest of the patients but instead of the healthcare system.

RESPONSE 64: The CDC recommendations are not intended to provide economic benefit to a particular professional group or industry. The recommendations outline counseling topics for medical providers when discussing medical circumcision with adolescent and adult males, and when discussing medical male circumcision with parents and guardians about circumcision for their child.

COMMENT (n = 29): Concerns that male circumcision is unaffordable for people who lack insurance, particularly in places where Medicaid doesn't cover MC.

RESPONSE 65: In the background document for the male circumcision counseling recommendations, it is stated that the CDC Public Health Ethics Committee subcommittee "noted that lack of health care insurance for some groups and lack of coverage for male circumcision by Medicaid in some states raises issues of distributive justice, and because data demonstrate that male circumcision has the potential to reduce the risk of HIV infection and other adverse health conditions, the procedure should be made available to all who want it."

COMMENT (see associated totals for each item of interest):

a) **COMMENT:** Concerns that neonatal MC is unethical. (n = 2, 415)

RESPONSE 66: The CDC recommendations take into account ethical considerations in addition to medical benefits and risk.

i. COMMENT: Comments referring to MC as a barbaric procedure similar to torture. References to archaic and primitive practices. (n = 477)

RESPONSE 67: Minimizing pain is an important consideration for circumcision. Appropriate use of analgesia is considered standard of care for male circumcision at all ages, and appropriate analgesia can substantially control pain for infants as well as children and adults.⁵⁸

ii. COMMENT: Comments suggesting that male circumcision as a cosmetic procedure with no medical value. E.g., circumcision is not medical treatment, cutting healthy tissue. (n = 971)

RESPONSE 68: Medical male circumcision confers health benefits that include lower risk for urinary tract infections in infancy and lower risk of acquiring HIV and other sexually transmitted infections through heterosexual sex.

iii. **COMMENT:** Comment indicating that there is delayed HIV prevention benefit for infant (benefit seen as adult, not as infant).

RESPONSE 69: Medical male circumcision confers health benefits to infants as well as adults. Circumcised infants are at a lower risk for urinary tract infections in infancy.^{73,74} Circumcision during childhood may also be more successful in preventing penile cancer and possibly prostate cancer than circumcision occurring later in life.^{75,76} In addition, circumcision prior to sexual debut ensures the protective effects of circumcision against sexually transmitted infections, including HIV, are present before commencement of sexual activity that put men at risk for these infections.

COMMENT (n=1,124): Concerns about human rights violations associated with MC. Examples of such concerns include: 1) Infant should have right to make decision at older age (Parents don't have right to make decision for baby). 2) Circumcision of infant males violates ethics, Constitutional or human rights, bodily autonomy. 3) The procedure violates medical ethics because it is not a response to a life-threatening situation. 4) Equates circumcision to abuse, assault, rape, or other physical harm. 5) Makes reference to "do no harm" phrase that is part of the medical oath.

RESPONSE 70: The decision about whether to circumcise an infant or child is considered an appropriate exercise of parental or guardian authority. If a child's preference is of particular

importance to parents or guardians, they may opt to delay circumcision until a time when the child can make a decision for himself. Delaying medical male circumcision to adolescence or adulthood has a higher risk of complication than circumcision conducted before one year of age.

COMMENT (n=881): Readers suggest that all male circumcision, regardless of the result of the procedure, is equal to female genital mutilation, an unacceptable and unethical practice. Includes references to forced genital cutting, mutilation.

RESPONSE 71: Medical male circumcision and female genital cutting (sometimes referred to as female circumcision and female genital mutilation) are not comparable procedures. Medical male circumcision carries little risk and provides a number of health benefits for men who have the procedure. Female genital cutting is a traditional practice that can result in serious, lifelong complications for women who have the procedure and has no health benefit.

COMMENT (n = 492): Refers to benefits associated with conducting MC, benefits of foreskin, or how the benefits of MC do not outweigh the risks associated with MC.

RESPONSE 72: CDC recommends that parents and guardians discuss potential health benefits and risks of circumcision with a medical provider when considering circumcision for a child. Medical male circumcision confers a number of health benefits and has an acceptably low risk of adverse events. Health benefits of medical male circumcision include partial protection from HIV and other STIs acquired through heterosexual sex, lower incidence of infant UTIs, and lower incidence of penile cancer. Complications associated with medical male circumcision in infancy or childhood are typically uncommon and easily managed. Severe complications are rare in all age groups.

Based on a meta-analysis of mainly U.S. studies, it is estimated that lack of circumcision is associated with a 23.3% increased risk of UTI during a man's lifetime.³⁶ CDC recommends that individuals discuss potential health benefits and risks of circumcision with a medical provider when considering circumcision for themselves or their male child.

COMMENT (n = 1,085): Readers comment that foreskin is a functional organ that has cells that prevent virus from entering system because it kills the virus and provides sexual sensation. Comments include statements that God or Nature created men with foreskin for a reason.

RESPONSE 73: The foreskin does not protect men from HIV and other sexually transmitted infections. Multiple randomized clinical trials have demonstrated removing the foreskin reduces the risk of men acquiring HIV, HSV-2, and HPV through heterosexual sex. The fact that Langerhans are active in the capture and processing of antigen, such as HIV, means that they are in close proximity to white blood cells which then serve as a portal for HIV to hijack the immune system to produce new HIV virions. Circumcision removes the foreskin, an important portal for HIV to invade the human body in heterosexual men, which has been shown to

provide a 60% reduction in risk of HIV acquisition in heterosexual men, as well as a reduction in risk for acquisition of other STDs.

The preponderance of evidence from the scientific literature, indicates that circumcision does not change or reduce sexual satisfaction or function overall; while it may do so for some men, this is not the experience for men overall based on the scientific literature.

Medical male circumcision confers a number of health benefits and has an acceptably low risk of adverse events. Complications associated with medical male circumcision in infancy or childhood are typically uncommon and easily managed. Severe complications are rare in all age groups. Health benefits of medical male circumcision include partial protection from HIV and other STIs acquired through heterosexual sex, lower incidence of infant UTIs, and lower incidence of penile cancer.

COMMENT (n = 81): Comments are supportive of MC and the guidelines and refer to benefits of MC.

RESPONSE 74: CDC recommends that individuals discuss potential health benefits and risks of male circumcision with a medical provider when considering circumcision for themselves or their male child.

COMMENT (n = 234): Comments refer to how educating people on proper hygiene and washing of foreskin is safer and more beneficial in preventing diseases such as UTIs compared to practicing MC.

RESPONSE 75: The health benefits of medical male circumcision include partial protection from HIV and other STIs acquired through heterosexual sex, lower incidence of infant UTIs, and lower incidence of penile cancer and possibly prostate cancer. These health benefits cannot be obtained by good hygiene practices alone.

COMMENT (n = 5): Physicians need to counsel on care of the penis for those uncircumcised.

RESPONSE 76: While it is important for physicians to educate parents of uncircumcised children and uncircumcised adults about proper hygiene of the penis as part of routine care, the CDC recommendations outline counseling topics for medical providers when discussing medical circumcision with individuals considering circumcision for themselves or their child. The counseling topics include information on potential health benefits and risks of male circumcision in infants, children, adolescents, and adults. Counseling on hygienic care of uncircumcised penis are outside the scope of the CDC recommendations.

COMMENT (n = 123): Reference to the history of MC and that it first began as a way to prevent boys from masturbating.

RESPONSE 77: The CDC recommendations are based on a comprehensive evaluation of current scientific data on the health risks and benefits of medical male circumcision.

COMMENT (n = 68): Some circumcised males have restoration surgery to have skin grafts put back on the penis to restore the foreskin.

RESPONSE 78: The frequency of such restoration surgery is unknown. Parents may choose to delay male circumcision to a time when the child can participate in the decision to circumcise. However, delaying male circumcision to adolescence or adulthood has a higher risk of complication and may be more expensive than male circumcision conducted before one year of age.

REFERENCES

- 1. Thomas AG, Bakhireva LN, Brodine SK, Shaffer RA. *Prevalence of male circumcision and its association with HIV and sexually transmitted infections in a U.S. Navy population* San Diego, CA: Naval Health Research Center;2004.
- 2. Morris BJ, Wamai RG. Biological basis for the protective effect conferred by male circumcision against HIV infection. *Int J STD AIDS*. 2012;23(3):153-159.
- 3. Hallett TB, Singh K, Smith JA, White RG, Abu-Raddad LJ, Garnett GP. Understanding the impact of male circumcision interventions on the spread of HIV in southern Africa. *PloS one.* 2008;3(5):e2212.
- 4. Canadas MP, Darwich L, Videla S, et al. Circumcision and penile human papillomavirus prevalence in human immunodeficiency virus-infected men: heterosexual and men who have sex with men. *Clin Microbiol Infect*. 2013;19(7):611-616.
- 5. Davis MA, Gray RH, Grabowski MK, et al. Male circumcision decreases high-risk human papillomavirus viral load in female partners: a randomized trial in Rakai, Uganda. *Int J Cancer.* 2013;133(5):1247-1252.
- 6. Gray RH, Kigozi G, Serwadda D, et al. The effects of male circumcision on female partners' genital tract symptoms and vaginal infections in a randomized trial in Rakai, Uganda. *Am J Obstet Gynecol.* 2009;200(1):42 e41-47.
- 7. Pintye J, Baeten JM, Manhart LE, et al. Association between male circumcision and incidence of syphilis in men and women: a prospective study in HIV-1 serodiscordant heterosexual African couples. *Lancet Glob Health.* 2014;2(11):e664-671.
- 8. Millett GA, Flores SA, Marks G, Reed JB, Herbst JH. Circumcision status and risk of HIV and sexually transmitted infections among men who have sex with men: a meta-analysis. *JAMA*. 2008;300(14):1674-1684.
- 9. Mor Z, Kent CK, Kohn RP, Klausner JD. Declining rates in male circumcision amidst increasing evidence of its public health benefit. *PloS one.* 2007;2(9):e861.
- 10. Lafferty WE, Hughes JP, Handsfield HH. Sexually transmitted diseases in men who have sex with men. Acquisition of gonorrhea and nongonococcal urethritis by fellatio and implications for STD/HIV prevention. *Sex Transm Dis.* 1997;24(5):272-278.
- 11. Tabet S, Sanchez J, Lama J, et al. HIV, syphilis and heterosexual bridging among Peruvian men who have sex with men. *AIDS*. 2002;16(9):1271-1277.
- 12. Jameson DR, Celum CL, Manhart L, Menza TW, Golden MR. The Association Between Lack of Circumcision and HIV, HSV-2, and Other Sexually Transmitted Infections Among Men Who Have Sex With Men. *Sex Transm Dis.* 2010;37(3):147-152.
- 13. Templeton DJ, Jin F, Prestage GP, et al. Circumcision and risk of sexually transmissible infections in a community-based cohort of HIV-negative homosexual men in Sydney, Australia. *J Infect Dis.* 2009;200(12):1813-1819.
- 14. El Bcheraoui C, Zhang X, Cooper CS, Rose CE, Kilmarx PH, Chen RT. Rates of Adverse Events Associated With Male Circumcision in US Medical Settings, 2001 to 2010. *JAMA Pediatr.* 2014;168(7):625-634.

- 15. Gray RH, Kigozi G, Serwadda D, et al. Male circumcision for HIV prevention in men in Rakai, Uganda: a randomised trial. *Lancet.* 2007;369(9562):657-666.
- 16. Mehta SD, Moses S, Parker CB, Agot K, Maclean I, Bailey RC. Circumcision status and incident herpes simplex virus type 2 infection, genital ulcer disease, and HIV infection. *AIDS*. 2012;26(9):1141-1149.
- 17. Tobian AA, Serwadda D, Quinn TC, et al. Male circumcision for the prevention of HSV-2 and HPV infections and syphilis. *N Engl J Med.* 2009;360(13):1298-1309.
- 18. Sobngwi-Tambekou J, Taljaard D, Lissouba P, et al. Effect of HSV-2 serostatus on acquisition of HIV by young men: results of a longitudinal study in Orange Farm, South Africa. J Infect Dis. 2009;199(7):958-964.
- 19. Serwadda D, Wawer MJ, Makumbi F, et al. Circumcision of HIV-infected men: effects on high-risk human papillomavirus infections in a randomized trial in Rakai, Uganda. *J Infect Dis.* 2010;201(10):1463-1469.
- 20. Auvert B, Sobngwi-Tambekou J, Cutler E, et al. Effect of male circumcision on the prevalence of high-risk human papillomavirus in young men: results of a randomized controlled trial conducted in Orange Farm, South Africa. J Infect Dis. 2009;199(1):14-19.
- 21. Gray RH, Serwadda D, Kong X, et al. Male circumcision decreases acquisition and increases clearance of high-risk human papillomavirus in HIV-negative men: a randomized trial in Rakai, Uganda. *J Infect Dis.* 2010;201(10):1455-1462.
- 22. Senkomago V, Backes DM, Hudgens MG, et al. Acquisition and persistence of human papillomavirus 16 (HPV-16) and HPV-18 among men with high-HPV viral load infections in a circumcision trial in Kisumu, Kenya. *J Infect Dis.* 2015;211(5):811-820.
- 23. Sobngwi-Tambekou J, Taljaard D, Nieuwoudt M, Lissouba P, Puren A, Auvert B. Male circumcision and Neisseria gonorrhoeae, Chlamydia trachomatis and Trichomonas vaginalis: observations after a randomised controlled trial for HIV prevention. *Sex Transm Infect.* 2009;85(2):116-120.
- 24. Mehta SD, Gaydos C, Maclean I, et al. The effect of medical male circumcision on urogenital Mycoplasma genitalium among men in Kisumu, Kenya. *Sex Transm Dis.* 2012;39(4):276-280.
- 25. Bailey RC, Moses S, Parker CB, et al. Male circumcision for HIV prevention in young men in Kisumu, Kenya: a randomised controlled trial. *Lancet.* 2007;369(9562):643-656.
- 26. Auvert B, Taljaard D, Lagarde E, Sobngwi-Tambekou J, Sitta R, Puren A. Randomized, controlled intervention trial of male circumcision for reduction of HIV infection risk: the ANRS 1265 Trial. *PLoS Med*. 2005;2(11):e298.
- 27. American Academy of Pediatrics Task Force on Circumcision. Circumcision Policy Statement. *Pediatrics*. 2012;130(3):e756-785.
- 28. Siegfried N, Muller M, Deeks JJ, Volmink J. Male circumcision for prevention of heterosexual acquisition of HIV in men. *Cochrane Database Syst Rev.* 2009(2):CD003362.
- 29. Wamai RG, Weiss HA, Hankins C, et al. Male circumcision is an efficacious, lasting and cost-effective strategy for combating HIV in high-prevalence AIDS epidemics. *Future HIV Ther.* 2008;2(5):399-405.
- 30. Montori VM, Devereaux PJ, Adhikari NK, et al. Randomized trials stopped early for benefit: a systematic review. *JAMA*. 2005;294(17):2203-2209.
- 31. Klausner JD, Wamai RG, Bowa K, Agot K, Kagimba J, Halperin DT. Is male circumcision as good as the HIV vaccine we've been waiting for? *Futur HIV Ther.* 2008;2(1):1-7.
- 32. Wamai RG, Morris BJ, Waskett JH, et al. Criticisms of African trials fail to withstand scrutiny: male circumcision does prevent HIV infection. *J Law Med.* 2012;20(1):93-123.
- 33. Halperin DT, Bailey RC. Male circumcision and HIV infection: 10 years and counting. *Lancet.* 1999;354(9192):1813-1815.
- 34. Orroth KK, White RG, Freeman EE, et al. Attempting to explain heterogeneous HIV epidemics in sub-Saharan Africa: potential role of historical changes in risk behaviour and male circumcision. *Sex Transm Infect.* 2011;87(7):640-645.

- 35. Chemtob D, Op de Coul E, van Sighem A, Mor Z, Cazein F, Semaille C. Impact of Male Circumcision among heterosexual HIV cases: comparisons between three low HIV prevalence countries. *Isr J Health Policy Res.* 2015;4:36.
- 36. Morris BJ, Wiswell TE. Circumcision and lifetime risk of urinary tract infection: a systematic review and meta-analysis. *J Urol.* 2013;189(6):2118-2124.
- 37. Mattson CL, Campbell RT, Bailey RC, Agot K, Ndinya-Achola JO, Moses S. Risk compensation is not associated with male circumcision in Kisumu, Kenya: a multi-faceted assessment of men enrolled in a randomized controlled trial. *PLoS ONE [Electronic Resource]*. 2008;3(6):e2443.
- 38. Gray R, Kigozi G, Kong X, et al. The effectiveness of male circumcision for HIV prevention and effects on risk behaviors in a posttrial follow-up study. *AIDS*. 2012;26(5):609-615.
- 39. Kong X, Kigozi G, Nalugoda F, et al. Assessment of changes in risk behaviors during 3 years of posttrial follow-up of male circumcision trial participants uncircumcised at trial closure in Rakai, Uganda. *Am J Epidemiol.* 2012;176(10):875-885.
- 40. Xu F, Markowitz LE, Sternberg MR, Aral SO. Prevalence of circumcision and herpes simplex virus type 2 infection in men in the United States: The national health and nutrition examination survey (NHANES), 1999-2004. *Sex Transm Dis.* 2007;34(7):479-484.
- 41. Gust DAK, K.; Gaul, Z.; Pals, S.; Heffelfinger, J. D.; Begley, E.; Chen, R. T.; Kilmarx, P. H. Male circumcision as an HIV prevention intervention in the US: Influence of health care providers and potential for risk compensation. *Prev Med.* 2011;52(3-4):270-273.
- 42. Crosby R, Charnigo RJ. A comparison of condom use perceptions and behaviours between circumcised and intact men attending sexually transmitted disease clinics in the United States. *Int J STD AIDS*. 2013;24(3):175-178.
- 43. Cox G, Krieger JN, Morris BJ. Histological Correlates of Penile Sexual Sensation: Does Circumcision Make a Difference? *Sex Med.* 2015;3(2):76-85.
- 44. Morris BJ, Krieger JN. Does male circumcision affect sexual function, sensitivity, or satisfaction?--a systematic review. *J Sex Med.* 2013;10(11):2644-2657.
- 45. Tian Y, Liu W, Wang JZ, Wazir R, Yue X, Wang KJ. Effects of circumcision on male sexual functions: a systematic review and meta-analysis. *Asian J Androl.* 2013;15(5):662-666.
- 46. Kigozi G, Watya S, Polis CB, et al. The effect of male circumcision on sexual satisfaction and function, results from a randomized trial of male circumcision for human immunodeficiency virus prevention, Rakai, Uganda. *BJU Int.* 2008;101(1):65-70.
- 47. Krieger JN, Mehta SD, Bailey RC, et al. Adult Male Circumcision: Effects on Sexual Function and Sexual Satisfaction in Kisumu, Kenya. *J Sex Med.* 2008;5(11):2610-2622.
- 48. Hoschke B, Fenske S, Brookman-May S, et al. [Male circumcision is not associated with an increased prevalence of erectile dysfunction: results of the Cottbus 10,000-men survey]. *Urologe A.* 2013;52(4):562-569.
- 49. Chinkoyo E, Pather M. Erectile function in circumcised and uncircumcised men in Lusaka, Zambia: A cross-sectional study. *Afr J Prim Health Care Fam Med.* 2015;7(1).
- 50. Homfray V, Tanton C, Mitchell KR, et al. Examining the association between male circumcision and sexual function: evidence from a British probability survey. *AIDS*. 2015;29(11):1411-1416.
- 51. Dias J, Freitas R, Amorim R, Espiridiao P, Xambre L, Ferraz L. Adult circumcision and male sexual health: a retrospective analysis. *Andrologia*. 2014;46(5):459-464.
- 52. Kigozi G, Lukabwe I, Kagaayi J, et al. Sexual satisfaction of women partners of circumcised men in a randomized trial of male circumcision in Rakai, Uganda. *BJU Int* 2009;104:1698-1701.
- 53. Wiswell TE. Neonatal circumcision: a current appraisal. *Focus & Opinions: Pediatrics*. 1995;1(2):93-99.
- 54. Wiswell TE, Geschke DW. Risks from circumcision during the first month of life compared with those for uncircumcised boys. *Pediatrics.* 1989;83(6):1011-1015.
- 55. Christakis DA, Harvey E, Zerr DM, Feudtner C, Wright JA, Connell FA. A trade-off analysis of routine newborn circumcision. *Pediatrics.* 2000;105(1 Pt 3):246-249.

- 56. Gee WF, Ansell JS. Neonatal circumcision: a ten-year overview: with comparison of the Gomco clamp and the Plastibell device. *Pediatrics.* 1976;58(6):824-827.
- 57. Alanis MC, Lucidi RS. Neonatal circumcision: a review of the world's oldest and most controversial operation. *Obstet Gynecol Surv.* 2004;59:379-395.
- 58. Banieghbal B. Optimal time for neonatal circumcision: an observation-based study. *J Pediatr Urol.* 2009;5(5):359-362.
- 59. Van Howe RS. Incidence of meatal stenosis following neonatal circumcision in a primary care setting.[see comment]. *Clin Pediatr.* 2006;45(1):49-54.
- 60. Schoen EJ. Meatal stenosis following neonatal circumcision.[comment]. *Clin Pediatr.* 2007;46(1):86.
- 61. Van Howe RS. Incidence of meatal stenosis following neonatal circumcision in a primary care setting. *Clin Pediatr.* 2006;45(1):49-54.
- 62. Eroglu E, Balci S, Ozkan H, et al. Does circumcision increase neonatal jaundice? *Acta Paediatr.* 2008;97(9):1192-1193.
- 63. Taddio A, Katz J, Ilersich AL, Koren G. Effect of neonatal circumcision on pain response during subsequent routine vaccination.[see comment]. *Lancet.* 1997;349(9052):599-603.
- 64. Boyle GJ, Goldman R, Svoboda JS, Fernandez E. Male circumcision: pain, trauma and psychosexual sequelae. *J Health Psychol.* 2002;7(3):329-343.
- 65. Hammond T. A preliminary poll of men circumcised in infancy or childhood. *BJU Int.* 1999;83 Suppl 1:85-92.
- 66. Cansever G. Psychological effects of circumcision. *Br J Med Psychol.* 1965;38(4):321-331.
- 67. Ramos S, Boyle GJ. *Ritual and Medical Circumcision among Filipino boys: Evidence of Post-traumatic Stress Disorder*. Robina, Gold Coast, Queensland, Australia: Humanities & Social Sciences papers, Bond University; 2000.
- 68. Rusch MD, Grunert BK, Sanger JR, Dzwierzynski WW, Matloub HS. Psychological adjustment in children after traumatic disfiguring injuries: a 12-month follow-up. *Plast Reconstr Surg.* 2000;106(7):1451-1458; discussion 1459-1460.
- 69. Frisch M, Simonsen J. Ritual circumcision and risk of autism spectrum disorder in 0- to 9-year-old boys: national cohort study in Denmark. *J R Soc Med.* 2015;108(7):266-279.
- 70. Anand KJ, Scalzo FM. Can adverse neonatal experiences alter brain development and subsequent behavior? *Biol Neonate.* 2000;77:69-82.
- 71. Victoria NC, Inoue K, Young LJ, Murphy AZ. Long-term dysregulation of brain corticotrophin and glucocorticoid receptors and stress reactivity by single early-life pain experience in male and female rats. *Psychoneuroendocrinology*. 2013;38(12):3015-3028.
- 72. Taddio A, Stevens B, Craig K, et al. Efficacy and safety of lidocaine-prilocaine cream for pain during circumcision.[see comment]. *N Engl J Med.* 1997;336(17):1197-1201.
- 73. Shaikh N, Morone NE, Bost JE, Farrell MH. Prevalence of urinary tract infection in childhood A metaanalysis. *Pediatr Infect Dis J.* 2008;27(4):302-308.
- 74. Singh-Grewal D, Macdessi J, Craig J. Circumcision for the prevention of urinary tract infection in boys: a systematic review of randomised trials and observational studies.[see comment]. *Arch Dis Child*. 2005;90(8):853-858.
- 75. Daling JR, Madeleine MM, Johnson LG, et al. Penile cancer: importance of circumcision, human papillomavirus and smoking in in situ and invasive disease. *International Journal of Cancer*. 2005;116(4):606-616.
- 76. Wright JL, Lin DW, Stanford JL. Circumcision and the risk of prostate cancer. *Cancer.* 2012;118(18):4437-4443.