Medical Male Circumcision as HIV Prevention

Follow the Evidence:
The case for aggressive scale up

Center for Global Health Policy
A project of the Infectious Diseases Society of America’s Education and Research Foundation and the HIV Medicine Association

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About the Center for Global Health Policy

The Center for Global Health Policy, established by the Infectious Diseases Society of America’s Education and Research Foundation and the HIV Medicine Association in 2008, supports and promotes U.S. efforts to combat HIV/AIDS and tuberculosis around the world. The Center provides scientific and policy information to U.S. policymakers, federal agencies, nongovernmental organizations and the news media, linking decision-makers to the latest evidence-based input and guidance from physician/scientists and other professionals from both developing and developed countries.

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INTRODUCTION

More than 33 million people around the world are infected with HIV, the virus that causes AIDS. Nearly 70 percent of those infected live in sub-Saharan Africa, home to only 12 percent of the world’s population. In nine of these countries, more than 10 percent of adults are estimated to be HIV-infected.

Every year, approximately 2 million people die from AIDS worldwide and 2.7 million people are newly infected with HIV. Sub-Saharan Africa accounted for 72 percent of the world’s AIDS-related deaths in 2008.

These deaths are beginning to decline. But living with HIV/AIDS requires lifelong treatment and care, and currently, fewer than one-third of the people worldwide who meet the World Health Organization’s (WHO) clinical eligibility recommendation for HIV treatment, have access to it. HIV prevention is an essential component of the response to the HIV pandemic and should include a combination of evidence-based behavioral and biomedical interventions and additional scale-up of HIV treatment.

The case for medical male circumcision (MC) is strong. Medical MC is a proven, one time, low-cost biomedical intervention that could save millions of lives and significant resources if fully implemented.

SECTION ONE: The Case

Medical male circumcision is effective in reducing HIV transmission to men through vaginal intercourse by as much as 60 percent. This protective benefit lasts over time.

Three randomized, controlled trials, the gold standard of scientific evidence, conducted in South Africa, Uganda and Kenya between 2002 and 2006, demonstrated that medically-performed MC is safe and can reduce a man’s risk of HIV infection during vaginal sex by as much as 60 percent. In each trial, uncircumcised men were randomly assigned to either a group that was offered immediate circumcision or to a control group where circumcision was offered after the trial. During regular follow-up visits, each participant received HIV testing and counseling, condoms and safe sex counseling. More than 10,000 men participated in the three clinical trials.

The results in each of the trials revealed a much lower rate of new HIV infections among men in the groups that were immediately circumcised compared to the men in the groups where circumcision was deferred. All three trials were stopped early because the evidence of a protective effect from circumcision was so strong it was viewed as unethical to delay circumcision for the men in the control groups. An ongoing, follow-up study to the Kenya trial confirmed the protective effect of medical MC was sustained over a 42-month period.

U.S. Global AIDS Coordinator Eric Goosby, MD, on scaling up medical male circumcision:

“We expect a drop in [HIV] prevalence. It will look like a vaccine has entered the community.”
Medical male circumcision must be provided along with comprehensive prevention counseling and services.

In parallel with the Uganda trial, investigators undertook a randomized controlled trial of MC in HIV-infected men and enrolled their female partners. Circumcision of HIV-infected men did not reduce transmission of the virus to uninfected female partners, and more HIV infections occurred in the female partners of the men who were circumcised early than in the control group. There was an association between resumption of sexual intercourse before complete wound healing and increased risk of male-to-female HIV transmission, despite the fact that men and their female partners were repeatedly counseled to abstain from sexual intercourse until healing was complete, as certified by a healthcare provider.

Prevention counseling is essential to educate men that medical MC is only partially protective, so they do not increase high-risk sexual behavior by reducing condom use or increasing their numbers of sexual partners. With prevention counseling, almost all studies to date have shown that risk compensation, also known as behavioral disinhibition, is not a major factor in circumcised populations compared with those that were not circumcised. With appropriate counseling, circumcised men can learn that although MC decreases HIV risk, they are still susceptible to HIV infection if they have unprotected intercourse with HIV-infected or status-unknown partners. It is also important to note that males undergoing medical MC must wait at least six weeks after the procedure before resuming sexual activity. Sexual activity prior to complete healing of the penis can increase the risk of HIV acquisition.

WHO has identified a minimum package of MC services that includes HIV testing and counseling, screening for sexually transmitted infections (STIs) and treatment, risk reduction counseling and condom promotion, in addition to the MC surgery itself.

Medical male circumcision is safe and has few complications when performed in a sterile environment by well-trained health providers. Adverse events associated with medical MC such as procedural complications are rare, usually minor and quickly resolved when the procedure is performed by well-trained and well-equipped medical staff in sterile conditions. Moreover, several studies have found that most men report improvement or no change in sexual function post-procedure, as well as static or improved sexual pleasure among their female partners.

Medical male circumcision is in demand among uncircumcised men and their female sexual partners. Acceptability studies in parts of sub-Saharan Africa have shown a significant demand for MC services among uncircumcised men. In KwaZulu-Natal, South Africa, 51 percent of the uncircumcised men surveyed and 68 percent of the women favored male circumcision for themselves or their sexual partners, while half of the men and 73 percent of the women indicated a willingness to circumcise their sons.

Forty-five percent of men surveyed in Harare, Zimbabwe, expressed interest in circumcision, and more than 80 percent of men in a large survey in Botswana also expressed a willingness to be circumcised. Most men reported their interest in medical MC was related to hygiene, infection control and for some, an acknowledgment that condom use is easier for circumcised men.

Research in some areas of Africa has shown that women prefer partners with circumcised penises to those that are uncircumcised, as is the case in Kisumu, Kenya, where 73 percent of women in a random household survey indicated a preference for a circumcised partner. This same study also showed that as the prevalence of circumcised men in the community increased over time, so did the preference in favor of circumcision in both women and men. One study investigating female satisfaction found more than 97 percent of women reported either no change or improved sexual satisfaction after their male partner was circumcised.

INTEGRATING TRADITIONAL MALE CIRCUMCISION IN SOUTH AFRICA

The Bophelo Pele Project in Orange Farm, South Africa, worked to incorporate traditional initiatives into their medical MC program. The same surgery method was used for this group, but it was conducted in groups and could only be performed by a male, with a traditional circumciser present.
**Medical male circumcision has a community-wide impact.**

MC has the potential to drive down infection rates at the community and country level. As fewer men become infected, HIV risk for women also decreases. MC provides a long-term, positive indirect impact on women at the population level due to the lowered prevalence of male HIV infection if at least five percent of the male population is circumcised. Mathematical models confirm that in places where HIV infection rates are high, women benefit from expanded MC through a lower risk of exposure to infected men. Over time, the benefit will increase, with subsequent reductions in rates of mother-to-child transmission. The United States Agency for International Development (USAID) estimates as many as 36.5 percent fewer infections among women from 2009 to 2025 in the case of Zimbabwe, assuming 80 percent coverage of MC in five years.

However, it is important to note that medical MC does not directly protect women exposed to HIV from infected sexual partners. Therefore, the search for effective preventive technologies that women can control, such as the use of oral or topical antiretroviral medications for prevention, known as pre-exposure prophylaxis and microbicides, must be accelerated in order to optimally protect at-risk women.

**Medical male circumcision has additional benefits, offering men and their female partners protection against other STIs.**

In addition to HIV infection, circumcised males are less likely to acquire some STIs such as genital ulcer disease (GUD), herpes simplex virus type 2 (HSV-2), urinary tract infections and penile cancer than their uncircumcised counterparts. There is also evidence that medical MC reduces the chance of the female partner contracting certain STIs, such as trichomoniasis, GUD and bacterial vaginosis, the latter of which has been associated with low birth weight and other adverse pregnancy outcomes. MC also reduces a man’s risk of contracting and transmitting human papillomavirus (HPV), which can lead to cancer of the cervix in women.

What is more, STIs like syphilis are more common in uncircumcised men and these can increase susceptibility to HIV infection.

**Medical male circumcision provides a conduit to health care for men.**

As an intervention, medical MC includes a package of services: voluntary HIV testing, pre- and post-test counseling, STI screening and treatment, condom distribution, post-procedure counseling, and linkage to care and treatment services for those who test positive for HIV infection.

Medical MC provides an opportunity to introduce adolescent and adult males into the health care system for reproductive health services, including HIV testing and treatment, as well as links to care for other health issues. According to a recent WHO report, the proportion of people globally that reported ever having had an HIV test is higher among women than men. Also, antiretroviral therapy coverage is higher among women, estimated at 39 percent compared to 31 percent among men. The gender gap likely reflects a woman’s likelihood to be tested and treated during pregnancy, in order to prevent the transmission of HIV to her child, and the absence of comparable programs to reach men.

A number of medical MC programs report very high HIV testing rates. For example in a campaign in Iringa, Tanzania, implemented by Jhpiego, a major PEPFAR implementer, more than 99 percent of the more than 10,000 clients got tested for HIV. This program also offers testing to parents and guardians of adolescents, as well as sexual partners if they accompany the MC patient to the clinic.

**Neonatal medical male circumcision and HIV prevention**

Neonatal medical MC is even safer than both adult and adolescent medical MC because of lower risks for surgical errors, infection and other adverse events. It is also cost effective and remains cost saving even under very low estimates of HIV incidence. Men circumcised as infants are not more likely to engage in high-risk sexual behavior than their uncircumcised counterparts once they become sexually active. Scientists attribute this to exposure to prevention messages, including condom promotion and other HIV risk-reduction strategies, as they grow up, limiting misperception of the protective benefit of medical MC.

Neonatal circumcision should also be prioritized as an HIV prevention intervention. However, given the delay in realizing the HIV prevention benefits in the form of reduced HIV incidence, many argue the emphasis should be on the more immediate gains that can be achieved by prioritizing medical MC services for adult men who are sexually active and adolescents who will become sexually active in the near-term.
SECTION TWO: The Strategy

In 2007 the WHO and the Joint United Nations Program on AIDS (UNAIDS) recommended that medical MC should be considered as a preventive intervention in countries or provinces/regions where:

- HIV is hyperendemic (HIV prevalence is 15 percent or greater in the general population)
- The epidemic is principally heterosexual
- Medical MC rates are low (less than 20 percent)
- And there is a large at-risk population

The President’s Emergency Plan for AIDS Relief (PEPFAR) program, in accordance with the WHO/UNAIDS guidance, currently supports safe medical MC for HIV/AIDS prevention based on requests from host governments and in keeping with their national policies, guidelines and cultural norms.

THE NUMBERS

Mathematical modeling shows that universal medical MC across 14 target areas in Africa, estimated at 29.1 million circumcisions, could prevent up to six million new HIV infections and three million deaths in the next two decades.

PRIORITY POPULATION

The WHO and other groups recommend that medical MC interventions aim to reach all males, noting that the greatest impact will come from prioritizing expansion of services to younger males (12 years old and younger, for example) among whom HIV prevalence may still be relatively low but incidence could be high now, or in subsequent years. With that in mind, the urgent need to curb the spread of the epidemic encourages the targeting of immediately at-risk individuals, including those who are already sexually active.

It is important that each country make its own programmatic decisions about which age range and communities to target in order to have the biggest impact, taking cultural and religious considerations into account. Due to the large benefit to public health, countries should provide MC at no or as little cost as possible to ensure maximum participation.

WHO, PEPFAR and UNAIDS have identified priority countries or specific regions in a country that have a high prevalence of HIV and low rates of MC, where aggressively increasing MC services would have the greatest effect on HIV incidence (see map above).

While some countries have high MC prevalence and low HIV prevalence overall, that might not be true for certain areas of a country. This is the case in the Nyanza province of Kenya, and the Gambella region in Ethiopia, both of which have generalized epidemics. The WHO has identified 13 priority areas, all of which are listed here. The U.S. Agency for International Development (USAID) also has identified Gambella region, Ethiopia, as a target area, which we have included.
IMPORTANT MALE SUBPOPULATIONS

Infants
Through PEPFAR, the U.S. government is also devoting resources to neonatal circumcision in some countries. Cultural and religious sensitivity are imperative when promoting neonatal MC, or there is a risk of slowing uptake of the intervention.34

In a large retrospective study of circumcision in nearly 15,000 infants, investigators found neonatal circumcision highly cost effective, due to the estimated number of averted cases of infant urinary tract infection and lifetime incidence of HIV infection, penile cancer, and other conditions. Postneonatal circumcision was 10-times as expensive as neonatal circumcision.43

HIV-Infected Men
Medical MC is not encouraged for men who are HIV-infected as it does not appear to reduce HIV transmission to their negative partners,44 but those who request the service and are healthy enough for surgery should not be turned away. It is important to be sensitive to possible stigmatization associated with barring HIV-infected males from receiving MC services. Moreover, there is evidence that MC is safe and reduces rates of GUD in asymptomatic, HIV-infected men with CD4-cell counts of 350 cells or more.33,45

HIV-positive men who undergo the MC procedure and resume sexual activity before certified wound healing (approximately six weeks) are more likely to transmit HIV than those who wait until complete wound healing.33 Persons with severe immunodeficiency might experience increased complication rates following surgery.45

Men Who Have Sex With Men
There is no strong evidence that MC reduces the risk of HIV transmission related to anal sex.44

RAPID SCALE UP IN KENYA
While massive scale up of male circumcision seems daunting, it is possible. The government of Kenya launched a Voluntary Medical Male Circumcision program in 2008, committing to circumcising 860,000 men over the next four years. One half of these men live in the Nyanza province, which has the highest HIV rate and the lowest MC rates in the country.

With a slow start up and only about 40,000 circumcisions performed in 2008,39 the Kenyans launched the Rapid Results Initiative in 11 districts in Nyanza in 2009. With a goal of circumcising 30,000 men in 30 working days, program workers engaged in public education and aggressive community outreach. They pushed referrals to MC services from other health clinics and sponsored processions through villages promoting MC services. The initiative surpassed its goal, circumcising more than 35,000 men in 30 days.
SERVICE DELIVERY
Effectively scaling up medical MC will require high-quality service sites with well-trained health professionals working with adequate supplies in aseptic conditions. Countries are developing innovative surgical model designs including task-shifting in order to assign more technical procedures to non-physicians, allowing more medical MCs to be performed in areas facing a shortage of doctors.

In early 2008, the Orange Farm MC scale-up program's medical team developed an efficiency-focused surgical model. Using this model, the WHO developed “Models for Optimizing the Volume and Efficiency of MC Services,” or MOVE. MOVE aims to address physician shortages and time-consuming traditional service delivery models that inhibit performing high volumes of surgery. A number of PEPFAR implementers have begun implementing this and similar service models to effectively scale up safe and cost effective medical MC in high-demand settings.

Research and discussions are also focused on the potential of adult MC devices to make the procedure more acceptable to men, faster to perform, and simple enough to be done by less highly trained providers. There are several devices that are used and well-documented in infants and boys, but the safety, effectiveness and acceptability among adults in Africa is unknown, and has in at least one instance been demonstrated to be inferior. The WHO recently hosted a consultation on manufacturing, clinical and regulatory requirements for MC and is expected to publish a framework for evaluating such devices in the near future.

PART OF A PACKAGE OF PREVENTION INTERVENTIONS
The challenge to adult MC providers and counselors lies in conveying to patients that medical MC is only up to 60 percent effective in thwarting off HIV infection; it is not complete protection. Therefore it is imperative that medical MC be offered with a package of services integrating HIV and STI prevention messages and services, including voluntary HIV testing. Those who elect not to test for HIV are not denied medical MC services, but experience in the field has shown that uptake of HIV testing has been high.

A typical service package includes:
- pre-procedure counseling
- provision of male and female condoms
- voluntary HIV testing and counseling
- STI screening and management (and referral for MC once STI has resolved)
- voluntary medical MC performed under local anesthesia
- post-procedure counseling and advising

A PACKAGE DEAL
MC programs supported by the U.S. government provide a package of services including Pre-Procedure Counseling for those who test HIV-negative OR positive that addresses the following:
- risk compensation behavior
- counseling on correct and consistent condom use
- delayed sexual debut
- reduced number of sexual partners
- avoidance of penetrative sex
- respect for women’s sexual and reproductive health needs and concerns
- couples counseling

For those who undergo medical MC, Post-Procedure Counseling also addresses:
- wound care
- when to seek medical attention
- no sexual intercourse for 6 weeks post-procedure
- risk compensation/behavioral counseling

- a follow-up evaluation within seven days of the procedure, ideally with the provider who performed the MC

MC is combination prevention given its inclusion of a biomedical intervention, as well as risk reduction counseling and provision of condoms. When incorporated as part of a prevention package, which can include couples counseling and other services, the impact MC has on HIV incidence could be even more substantial. A study in 2008 showed that several prevention interventions (in this case medical MC and condom use) tend to operate synergistically. When applied at the same time, the interventions have a much greater impact than either could have in isolation.

“I feel this is important for my son. I don’t want him to be another statistic testing HIV-positive, as I am. As a feminist I support medical male circumcision, because in fact it benefits everyone. We must urgently scale up access not only to MC, but all other prevention measures here in Zambia and elsewhere in the region.”

—Miriam Banda, Community of Zambian Women Living with HIV/AIDS
CURRENT FUNDING FOR MEDICAL MC

The U.S. government supports medical MC programs for the prevention of HIV/AIDS through PEPFAR and its various implementing agencies, including USAID, the Centers for Disease Control and Prevention (CDC), and the Department of Defense.

PEPFAR’s latest report to Congress shows that medical MC accounted for only about one percent of overall planned prevention, treatment and care spending in fiscal year (FY) 2009, totaling $60.8 million and supporting programs in 13 of the 14 target populations. Funding for MC programs in FY 2010 was set at $54.4 million as of November, 2010.

Considering the potential benefit of this intervention, increasing the U.S. government’s allocation of funds to providing MC services is imperative.

Efforts to fund medical MC programs, including health professional training, are also supported by nongovernmental organizations like The Bill & Melinda Gates Foundation as well as international organizations such as the Global Fund to Fight AIDS, Tuberculosis and Malaria. The Fund is now encouraging grantees to include the scaling up of medical MC for prevention in their funding proposals. In January of 2009, the Global Fund updated its technical guidance to include MC in the area of prevention, utilizing recommendations from the WHO, UNAIDS and other key implementing partners.
SECTION THREE: Conclusion

MC IS A ONE-TIME, LOW-COST and COST-EFFECTIVE INTERVENTION\textsuperscript{59,60}

Unlike many prevention strategies, medical MC is a one-time intervention that provides long-term protection.\textsuperscript{58} The cost for medical MC services varies and is less expensive when performed on infants. For example, in Namibia MC services cost approximately $88.50 for adults and $72.30 for newborns.\textsuperscript{56} In contrast, in the Nyanza province of Kenya, the MC package of services costs approximately $37 per adult and $30 per neonatal service.\textsuperscript{59}

This variance has several causes. Due to economies of scale, each procedure becomes less expensive the higher the volume of procedures completed. Moreover, programs that implement models for optimizing volume and efficiency, which utilize clinical officers and nurses in place of surgeons for less-demanding procedures,\textsuperscript{48} can realize even more cost savings.

In high prevalence settings, medical MC is cost effective and even cost saving. Models predict that, using a 10-year time horizon, one new HIV infection can be averted for every five to 15 men newly circumcised.\textsuperscript{58} Using this model, the cost to avert one HIV infection ranges from $150 to $900.\textsuperscript{57} According to UNITAID, treating a patient for one year with today’s recommended first-line AIDS treatment costs between $151 and $1,033.\textsuperscript{69} That does not include any other health-related costs such as treatment of opportunistic infections, or opportunity costs associated with an HIV-infected person missing work or being unable to care for children due to illness.

As the impact of MC grows over time, the number of MCs needed per infection averted declines. USAID estimates that between 2016 and 2025, 3.7 MCs will be required to avert one HIV infection in Lesotho,\textsuperscript{58} while only 1.6 MCs will be needed to avert one HIV infection in Nyanza, Kenya.\textsuperscript{59}

WE HAVE TO ACT FAST

The more quickly we implement this proven prevention intervention, the greater the impact will be on the individual, community and country levels.

Economic models show that scaling up MC to reach 80 percent of all adult and newborn males by 2015 would reduce the number of new adult HIV infections by about 40 percent by the end of 2025.\textsuperscript{40} The impact is directly proportional to the implementation pace and scale.\textsuperscript{37}

What is more, spending $1 billion to achieve this impact will also save $20.3 billion\textsuperscript{37} in the long run.

MOVING FORWARD WITH MEDICAL MALE CIRCUMCISION

Since the WHO/UNAIDS released their recommendations supporting medical MC as a significant HIV prevention intervention, more than 290,000 medical MCs have been performed in Kenya, Swaziland, South Africa, Zimbabwe, Tanzania, and Zambia, more than half of which were done in Kenya.\textsuperscript{23} The governments of Lesotho and Swaziland, in conjunction with the PEPFAR program, are poised to launch a population-wide scale up of medical MC. In Swaziland, where the adult HIV prevalence is more than 26 percent,\textsuperscript{67} the goal is to circumcise 80 percent of 18-49 year old males, or approximately 150,000 HIV-negative males, in one year, and to directly evaluate the impact of the intervention on HIV incidence.\textsuperscript{15}

But the activity to date is not enough and nowhere near the scale that it needs to be. To realize the goal of preventing 6 million HIV infections in sub-Saharan Africa in the next two decades, medical MC scale-up would need to reach 5.9 million males in 2011 and almost 12 million in 2012.\textsuperscript{40} So far, the Office of the U.S. Global AIDS Coordinator (OGAC) has been able to respond with financial and technical resources when a given country has needed.
developed a regulatory framework, a plan, and the will to proceed. Nevertheless, the resources that are being devoted to medical MC constitute a tiny fraction of the U.S. funding for global HIV prevention.

It is vital that the U.S. global AIDS program continues to have resources to support countries in their efforts to implement this lifesaving HIV prevention intervention. In this challenging budgetary environment, it is more essential than ever that HIV prevention resources are directed to programs and strategies that are proven to work. PEPFAR must increase funding for medical MC, along with a package of biomedical and behavioral prevention interventions that also includes continued scale-up of HIV treatment, in order to reduce HIV infections and deaths. Increased financial support for the Global Fund from the U.S. and other donors will also be essential to encourage countries to include bold plans for MC scale-up in their proposals to the Fund. And while the U.S. is making a big investment in medical MC in many countries, more donors need to get involved to meet the need.

The Obama Administration’s Global Health Initiative (GHI) has identified eight GHI Plus countries where they will support health care service integration across HIV, primary health care and other infectious diseases to strengthen health systems. Four of these countries have significant HIV epidemics: Kenya, Malawi, Rwanda and Ethiopia. As the U.S. moves forward in these countries, the scale-up of medical MC should be a major component of the GHI strategy with the potential to link HIV testing and medical MC with TB and STI screening and other health care services.

There are a great number of research studies underway that continue to explore this intervention in a variety of ways – from additional analyses about the impact of rapid MC scale-up on a country, to studies looking at the sexual behavior of circumcised men over time, to operational studies examining how to perform medical MCs quicker, better and safer. In Zambia an ongoing pilot study is looking at the acceptability and methodology of neonatal circumcision in country. The results, which are anticipated in 2011, will help inform Zambia’s future strategic plan.

"Investing in MC as part of a comprehensive HIV prevention package could save on future treatment costs. In Zambia it has been estimated that $96.8 million is needed to scale-up MC over eight years. By comparison the treatment costs for those who would go on to be infected without this added level of protection is estimated at $161.7 million.”

—Cost of Male Circumcision and Implications for Cost Effectiveness of Circumcision as an HIV Intervention, Martin, G.; Stover, J.; Relebohile, T. et al. (2007)
infection since antiretroviral (ARV) drugs were found to prevent the transmission of HIV infection from mother to child during pregnancy, labor and delivery, and breast feeding. But it won’t be the last. Our work today in educating men and their partners about both the benefits and limitations of preventing HIV infection with medical MC will also be helpful in informing our strategies for other potent yet partially protective biomedical prevention interventions, such as topical ARV gels, oral ARV and HIV vaccines.

We now have several effective biomedical tools to reduce new HIV infections significantly including HIV treatment, prevention of mother-to-child transmission, and MC. Science has delivered and more scientific breakthroughs are likely in the pipeline. Now, the United States and other donor nations must work in concert with the hardest-hit African countries to expand access to these lifesaving interventions as quickly as possible. Success will be measured in infections averted and lives saved.

“Scaling up MC to reach 80 percent of adult and newborn males in 14 African countries by 2015 could potentially avert more than 4 million adult HIV infections between 2009 and 2025, yield annual cost savings of $1.4 – $1.8 billion after 2015, and a total net savings of $20.2 billion between 2009 and 2025.”

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