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**Progress in Voluntary Medical Male Circumcision for HIV
Prevention**
**Supported by the United States President's Emergency Plan
for AIDS Relief through 2016:
10 Years of Program Data**

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PEPFAR circumcisions through 2016

**Progress in Voluntary Medical Male Circumcision for HIV Prevention
Supported by the United States President's Emergency Plan for AIDS Relief through 2016:
10 Years of Program Data**

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1 PEPFAR circumcisions through 2016
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4 **ABSTRACT:**
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9 **OBJECTIVE** This article provides an overview and interpretation of the performance of PEPFAR's
10 male circumcision program, which has supported the majority of voluntary medical male circumcisions
11 performed for HIV prevention, from its 2007 inception through 2016, and client characteristics in 2016.
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14 **DESIGN** Longitudinal collection of routine program data and disaggregations.
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17 **SETTING** 14 countries in sub-Saharan Africa with low baseline male circumcision coverage, high HIV
18 prevalence, and PEPFAR-supported voluntary medical male circumcision programs.
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21 **PARTICIPANTS** Clients of PEPFAR-supported voluntary medical male circumcision programs
22 directed at males aged 10 years and above.
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25 **MAIN OUTCOME MEASURES** Numbers of circumcisions performed and disaggregations by age
26 band, HIV test uptake and result, procedure technique, and follow-up visit attendance.
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29 **RESULTS** PEPFAR supported a total of 11,886,276 circumcisions in 14 countries in southern and
30 eastern Africa. In 2016, 46% of clients were under 15 years of age, 9% were not tested for HIV and 1%
31 of those tested were HIV+, and 78% returned for a follow-up visit within 14 days of circumcision.
32
33

34 **CONCLUSIONS** Recruiting older, sexually active clients continues to be a challenge despite targeted
35 efforts. The substantial proportion of clients not testing for HIV is expected and may be reassuring that
36 testing is not being presented as mandatory for access to circumcision. While VMMC is extremely safe,
37 achieving the highest possible follow-up rates for early diagnosis and intervention on complications is
38 crucial, and programs continue to work to raise follow-up rates. The VMMC program has achieved
39 rapid scaleup but continues to face challenges, and new approaches may be needed to achieve the new
40 UNAIDS goal of 27 million additional circumcisions through 2020.
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STRENGTHS AND LIMITATIONS OF THIS STUDY:

- The large dataset covers ten years of virtually complete program data on nearly 12 million men.
- PEPFAR-supported clients constitute a large majority of all voluntary medical male circumcision clients, making client characteristics reported here likely to be representative of the program as a whole.
- The multicountry nature of the data allows determination of client characteristics common across settings.
- The routine reporting system is aggregate only, and collected data does not support analyses of associations between client characteristics.
- Data are not complete for all client characteristics (disaggregations) in all countries.

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INTRODUCTION:

Male circumcision, the removal of the foreskin, reduces a man's risk of acquiring HIV through heterosexual exposure by approximately 60 percent.^{1,2,3} Since its adoption as a recommended HIV prevention strategy by the World Health Organization (WHO) and Joint United Nations Programme on HIV/AIDS (UNAIDS) in 2007,⁴ voluntary medical male circumcision (VMMC) has become a core component of the global HIV prevention portfolio through support by national and global programs, such as the United States (U.S.) President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis and Malaria. The WHO/UNAIDS's guiding document for VMMC from 2012-2016 recommended scale-up of VMMC in 14 countries in southern and eastern Africa with high HIV prevalence, low circumcision coverage and primarily heterosexual HIV transmission,⁵ with an initial goal of circumcising 20 million men to achieve 80% coverage among males aged 15-49 years in the 14 countries by 2016. As a one-time biomedical intervention conferring lifelong partial protection from HIV, and the only prevention method specifically targeted at HIV-negative heterosexual men, VMMC complements other behavioral and clinical prevention interventions such as condom promotion, reduction in number of sex partners, pre-exposure prophylaxis, and treatment-as-prevention.

VMMC services were launched progressively in each of the recommended 14 countries between 2007 and 2011, primarily with PEPFAR support. PEPFAR-supported VMMCs are surgical or procedural interventions often lasting 5-15 minutes,⁶ provided by physicians or nurses under local anesthesia. They are offered with the WHO-recommended minimum package⁷ of accompanying services, including the offer of HIV testing and linkage to care and treatment for HIV-positive individuals, HIV risk-reduction education, condom provision, and sexually transmitted infection (STI)

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4 screening and treatment or referral. Over the lifetime of the program, several additional key innovations
5
6 have also been incorporated. These include the introduction of WHO-prequalified circumcision devices
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8 as alternatives to conventional surgery; the introduction of WHO “Models for Optimizing Volume and
9
10 Efficiency”;⁸ the identification of the 15-29 year age group as the focal demographic for rapidly
11
12 reducing population-level HIV incidence through VMMC;⁹ enhancement of safety measures based on
13
14 accumulating data, particularly for adolescents based on their unique surgical safety requirements;
15
16 introduction of policies on tetanus vaccination prior to VMMC;¹⁰ and increased emphasis on linking
17
18 clients testing HIV-positive to care and treatment,¹¹ to support WHO/UNAIDS treatment scale-up
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20 goals.¹²
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26 All PEPFAR-supported VMMC programs report on key program outcomes, including the total
27
28 VMMCs performed in each country and select disaggregations: circumcision technique (device or
29
30 surgical), client age range, HIV test results among VMMC clients tested at VMMC sites, and adherence
31
32 to routine post-operative follow-up. These indicators provide an overview of the accomplishments and
33
34 key current attributes of the PEPFAR VMMC program. This article presents PEPFAR-supported
35
36 VMMC achievements since program inception in 2007, compares key disaggregations from U.S. fiscal
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38 year 2016 with those from 2015, and discusses future challenges and directions for the program.
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40 Because PEPFAR supports the majority of VMMCs conducted globally (approximately 82% through
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42 2016)¹³, client characteristics described here are expected to be reasonably representative of the global
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44 VMMC clientele to date.
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METHODS:

Data reported by PEPFAR-supported VMMC programs are drawn initially from site-level client registers and records, and reported by the implementing partners to PEPFAR in each host country, Data are then cleaned in-country; and then reported to PEPFAR's central coordinating body, the Office of the Global AIDS Coordinator. Implementing partners also report to their host country governments, following procedures agreed upon in-country; this may occur independently or may use the same data stream. Data are currently reported to PEPFAR on a quarterly basis, and then grouped by U.S. Government fiscal year, which runs October 1st through September 30th, rather than by calendar year. These numerical data are now available online¹⁴ and were used here to calculate percentages where relevant. Monitoring trends across years is possible, but prior to 2015, fewer VMMC disaggregations were collected.

The disaggregations reported for VMMCs performed, and definitions where needed, are listed in table 1. Their rationales and context are summarized below.

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Table 1: Disaggregations and Categories for PEPFAR-supported VMMC program reporting on VMMCs performed, 2016

Disaggregation	Client Categories
Age	<ul style="list-style-type: none"> - < 61 days (early infant male circumcision) - 2 months-<10 years (not funded by PEPFAR due to safety concerns) - 10-14 years - 15-19 years - 20-24 years - 25-29 years - 30-49 years - 50+ years
Result of HIV test offer at VMMC site	<ul style="list-style-type: none"> - HIV+ - HIV - - Unknown: includes clients with undocumented or indeterminate status and those not tested at the VMMC site for any reason
Technique	<ul style="list-style-type: none"> - Surgical - Device-based
Post-operative Follow-up status	<ul style="list-style-type: none"> - Returned for at least one post-operative follow-up visit within 14 days of surgery - Did not return within 14 days

- 1) Client age category: PEPFAR's prioritization of, or "age pivot" to, the 15-29 year age range began in fiscal year 2016. Ages below 15 years constitute the largest combined proportion of VMMCs performed, but will have delayed impact on the HIV epidemic due to the delay until sexual debut and other risk behaviors. These age bands are collapsed together in this report.
- 2) Result from client HIV test offered at VMMC site: Under PEPFAR¹⁵, UNAIDS¹⁶ and WHO¹⁷ guidance active in 2016, HIV testing at the VMMC site should be encouraged but is not required for access to VMMC, and clinically eligible clients choosing to test may proceed with VMMC regardless of their test results. As a disaggregation within the cohort of clients receiving VMMC, this reporting does not include men who were tested at VMMC sites but

PEPFAR circumcisions through 2016

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4 then decided against VMMC after receiving a positive HIV test result, as men testing
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6 positive are counseled that circumcision will not affect the course of their HIV infection and
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8 may choose not to proceed.
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11 3) Circumcision technique used: Circumcision devices offer an alternative to surgery, and
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13 advantages include faster procedures and potentially avoiding the injection of anesthesia and
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15 incision of living tissue. Initially, PEPFAR-supported circumcision was exclusively surgical,
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17 using one of three WHO-recommended techniques: forceps-guided, dorsal slit, and sleeve
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19 resection.¹⁸ With WHO prequalification of the PrePex device in 2013¹⁹ and ShangRing in
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21 2015,²⁰ some ministries of health have introduced device-based services as additional options
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23 for clients. Both PrePex and ShangRing devices remain on the penis for seven days and are
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25 removed by a provider during a follow-up visit. Anatomic and age-based eligibility criteria
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27 vary between devices and can be stricter than surgical eligibility criteria, restricting the pool
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29 of eligible clients.²¹ Numbers of circumcisions performed using a device therefore reflect
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31 national policies and eligibility for, as well as availability and client uptake of, these
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33 alternative methods. They also reflect the impact of tetanus mitigation policies as discussed
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35 below.
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41 4) Follow-up status: PEPFAR-supported programs follow fixed schedules for routine
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43 postoperative follow-up set by national ministries of health to ensure client safety. These
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45 often include a return visit at days two and seven after surgery, or day seven after device
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47 placement (for device removal). In 2016, the PEPFAR follow-up indicator was only reported
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49 among surgical cases, which therefore constitute the denominator for determining follow-up
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51 percentage.
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PEPFAR circumcisions through 2016

RESULTS:

From PEPFAR fiscal year 2007 through 2016, a total of 11,886,276 PEPFAR-supported VMMC's were performed in 14 countries in southern and eastern Africa. From 2010 through 2014, annual VMMC numbers approximately doubled annually, reaching 2,794,808 in 2014. In 2015, 2,573,273 VMMC's were performed, followed in 2016 by 2,290,200; these represented the second- and third-highest annual totals. Nearly two thirds (64%) of PEPFAR-supported circumcisions performed since the program's inception were performed in 2014-2016 (Figure 1, Table 2). In 2016, PEPFAR-supported VMMC's constituted 80% of all VMMC's reported by WHO, and 55% or more of reported VMMC's in all individual countries except Rwanda.¹³

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Table 2: Annual PEPFAR-funded VMMCs performed by country, 2007-2016*

Country	2007-2009	2010	2011	2012	2013	2014	2015	2016	Total
Botswana	5,180	534	0	8,590	12,464	13,893	7,712	24,201	72,574
Ethiopia	0	3,110	8,236	12,445	16,393	11,831	11,307	14,335	77,657
Kenya	45,657	112,574	182,788	158,278	214,851	229,390	233,813	264,490	1,441,841
Lesotho	0	0	199	6,971	36,418	39,175	28,909	31,709	143,381
Malawi	0	0	778	13,314	67,384	68,334	90,820	82,381	323,011
Mozambique	0	4,009	18,946	79,002	129,581	160,660	187,186	241,793	821,177
Namibia	117	1,229	5,379	6,121	0**	785	9,927	15,116	38,674
Rwanda	0	896	3,922	17,639	36,441	74,803	65,048	50,204	248,953
South Africa	18,100	14,956	72,004	170,849	294,977	327,473	472,047	355,917	1,726,323
Swaziland	3,802	19,728	13,399	14,456	9,708	11,934	12,156	16,003	101,186
Tanzania	262	21,581	117,351	151,915	381,394	554,673	615,089	519,437	2,361,702
Uganda	0	9,052	57,132	352,039	742,978	906,615	466,650	330,343	2,864,809
Zambia	0	21,236	63,444	103,517	199,372	239,464	216,394	185,028	1,028,455
Zimbabwe	0	9,811	30,608	36,765	88,114	155,778	156,215	159,243	636,534
Total	73,118	218,716	574,186	1,131,900	2,230,075	2,794,808	2,573,273	2,290,200	11,886,276

* Fiscal years

** PEPFAR support for VMMC in Namibia was paused for strategic planning in 2013.

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Twelve countries provided >85% data completeness across all disaggregations in 2016. Where data completeness for a given disaggregate in a country (sum of all VMMC categories for that disaggregate, divided by total VMCMCs performed) was less than the 85% threshold we selected for this analysis, values are bolded (Table 3).

In total, 46% of VMMC clients were within the 15-29 years age range, to which PEPFAR shifted focus that year, down from 48% in 2015, with wide variation among countries, ranging from 32% in Swaziland to 85% in Rwanda. In contrast, 46% of PEPFAR VMMC clients were within the 10-14 years range, up from 42% in 2015. Of the 13 countries reporting age data for 2015 and 2016, 10 experienced an increase in the proportion of males circumcised in the 10-14 year age group between 2015 and 2016. Among high-volume programs, this shift toward circumcision of 10-14 year olds was largest in Kenya (48% in 2015, then 56% in 2016) and Tanzania (45% in 2015, then 52% in 2016).

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Table 3: Numbers and Characteristics of PEPFAR-funded Voluntary Medical Male Circumcisions, Fiscal Year 2016 (Oct. 1, 2014-Sept 30, 2016) by country and 2015 totals

Country	VMMCs	Client Age in Years (%)*						HIV status (%)		Device Method Used (%) (vs. Surgical)	Follow-up Visit **(%)
		<15	15-19	20-24	25-29	30-49	50+	HIV+ among tested clients	Unknown *		
Botswana	24,201	45	15	14	11	14	1	4	33	28	83
Ethiopia	14,335	32	34	18	7	9	0	0	48	7	97
Kenya	264,490	56	26	9	5	3	0	3	32	1	74
Lesotho	31,709	56	22	8	6	8	1	3	6	3	83
Malawi	82,381	49	30	10	5	5	0	5	31	0	75
Mozambique	241,793	42	32	14	6	5	0	0	0	0	70
Namibia	15,116	12	32	20	15	20	2	1	0	0	99
Rwanda	50,204	5	46	27	12	9	0	1	0	53	100
South Africa	355,917	51	19	10	8	11	1	1	12	1	50
Swaziland	16,003	65	22	7	3	3	1	1	5	5	98
Tanzania	519,378	52	26	11	5	6	0	0	14	0	88
Uganda	330,343	38	27	13	8	8	7	1	2	3	76
Zambia	185,028	34	28	17	11	9	1	3	17	0	94
Zimbabwe	159,243	37	30	13	9	10	1	0	7	27	107***
Total in 2016	2,290,141	46	27	12	7	7	1	1	9	4	78
Total in 2015	2,573,238	42	28	13	7	8	1	1	7	5	72

Bolded entries indicate <85% data completeness.

* Includes clients with undocumented or indeterminate status and those not tested at the VMMC site for any reason

** Percent of clients who returned for at least one post-operative follow-up visit within 14 days of surgery

*** In some countries, reported numerators may not have been confined to surgical followup visits as intended, inflating followup rates even above 100%.

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Overall, 9% of clients had “unknown” HIV status, as compared to 7% in 2015, with individual country values ranging between 0% in Rwanda and 48% in Ethiopia. Among clients tested for HIV, 1% were positive, essentially unchanged from 2015, with individual country positivity varying between 0% in Zimbabwe, Tanzania, Mozambique and Ethiopia, and 5% in Malawi.

Device-based circumcision techniques constituted a small percentage of circumcisions in all countries in 2016, accounting for 4% of VMMCs across countries (down from 5% in 2015), ranging between 0% in several countries and 53% in Rwanda, with Botswana and Zimbabwe following at 28% and 27%, respectively.

Post-operative follow-up rates were 78% overall, an increase from 72% in 2015. These ranged between 50% in South Africa and 107% in Zimbabwe, falling at or above 75% in 11 countries. Because followup reporting in 2016 was based on percent of surgical clients only who returned for followup, calculated followup rates may be lower than true rates in countries with substantial numbers of device-based VMMCs, which would be expected to have high followup due to the necessity of returning to remove the device. However, in some countries, reported numerators may not have been confined to surgical followup visits as intended, inflating reported followup rates even above 100%.

CONCLUSION:

VMMC has undergone a scale-up of historic proportions within global health, comparable to the scale-up of HIV treatment.²² Nearly 12 million PEPFAR-supported VMMCs were performed, out of a sub-Saharan African total of nearly 15 million,²³ between 2007 when support began and 2016, making

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5 VMMC an essential prevention intervention for achieving the PEPFAR goal of an AIDS-free generation
6 through epidemic control in sub-Saharan Africa.²⁴ Models estimate that global VMMCs conducted
7 through 2016 will avert 500,000 infections by the end of 2030.¹³ Scale-up has been enabled not only by
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9 dedicated resources, totaling over \$1.5 billion through 2016 from PEPFAR alone, but also through
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11 leadership from ministries of health, rapid expansion of surgical skills and responsibilities to non-
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13 physician health cadres, and public outreach campaigns. It has provided millions of men with lifelong
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15 partial protection from HIV and some STIs, and connected them with additional HIV and other health
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17 services through testing, STI screening, and referrals for other health conditions. Infections averted in
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19 men through VMMC also help prevent new HIV infections among women and girls,^{25,26,27} and male
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21 circumcision is also associated with lower prevalence of a range of STIs in women.²⁷
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28 PEPFAR committed in 2015 to supporting at least 13 million VMMCs through 2017,²⁸ and has
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30 remained on track to achieve that target. In light of the high proportion of global VMMCs supported,
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32 PEPFAR client data is also expected to provide a reasonably representative view of the global VMMC
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34 clientele to date. References to achievements and characteristics below refer to the PEPFAR program
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36 except where otherwise stated.
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40 All VMMC implementing countries continue to scale up VMMC. However, in 2015 and 2016
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42 there were substantial declines in PEPFAR VMMC achievements in Uganda (the largest contributor to
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44 VMMC results); these were mirrored by declines in total VMMCs achieved in Uganda.¹³ Service
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46 delivery and policy were impacted by the identification of tetanus as a risk among VMMC clients in the
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48 Ugandan setting, due to limited historical tetanus immunization coverage.^{29,30,31} WHO issued global
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50 recommendations that additional visits for tetanus vaccination be performed prior to circumcision using
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52 device-based VMMC methods associated with increased risk of tetanus,³² and the Uganda National
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PEPFAR circumcisions through 2016

VMMC Program ultimately required an additional visit for tetanus vaccination prior to VMMC. This shift may have also impacted performance in several other countries. Additionally, a PEPFAR policy issued in late 2014 discontinued the use of the forceps-guided surgical technique in young adolescents to avoid the associated risk for injury to the immature glans, causing some country programs to decrease VMMC provision to this age group until they could retrain their VMMC workforces in a more appropriate method. In 2016, Tanzania, South Africa and Zambia also experienced declines, possibly due to these same reasons, some exhaustion of their ‘early adopter’ populations, and strategic shifts in program geography and funding.

VMMC client populations in 2016 were young, with males aged 10-14 years representing 46% of all PEPFAR VMMCs (virtually all VMMCs in clients <15 years are in the 10-14 year range), as compared to 12% of the combined male general population of the 14 implementing countries.³³ This represents a change from the program’s historical client age distribution; from 2010 through 2013, clients in the 10-14 years age range characterized no more than one third of all clients in any year.³⁴ The 2015 distribution (42% of clients were aged <15 years) served as the baseline prior to implementation of the “age pivot”; yet the actual age balance shifted further toward the younger range in 2016 despite this focus. In some countries, this shift may partially reflect the maturation of the VMMC program: ‘exhaustion’ of this age band and replacement with younger males.

VMMC clients also have low HIV positivity compared to the general population, 1.2%, vs. 5.5 (95% confidence interval 4.9-6.0% prevalence among males aged 15-49 years in the southern and eastern Africa region in 2016.³⁵ The young age of the client population is almost certainly the major underlying factor; pre-adolescents and early adolescents have less exposure to sex and consequently less HIV risk and lower HIV prevalence than older age groups. Because HIV test results are not

PEPFAR circumcisions through 2016

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5 disaggregated by age group, this effect cannot be controlled for in PEPFAR routine reporting data.
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7 Lower HIV prevalence among VMMC clients could also reflect self-selection of men with health-
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9 protecting behaviors into the pool of VMMC clients and/or the effects of messaging promoting VMMC
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11 for HIV prevention, leading to the self-exclusion of men who know they are HIV-positive (including
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13 any who learn they are HIV-positive at the VMMC site and consequently opt out of VMMC). Despite
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15 this low prevalence, it should be noted that men in sub-Saharan Africa have lower HIV testing uptake
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17 than women³⁶ and the VMMC program provides an opportunity to reach men who might not otherwise
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19 undergo testing. The substantial proportion of clients with ‘unknown’ test results is expected, and is
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21 likely to reflect the voluntary nature of HIV testing in VMMC, as well as the frequency of HIV test kit
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23 stockouts.
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28 The fact that only 4% of all 2016 circumcisions were performed by device methods reflects the
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30 relatively short period that device-based circumcision has been available, as well as the rigorous
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32 country-level vetting process which new devices undergo when being introduced in a new country,³⁷
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34 prior to nationwide rollout. It may also reflect current preferences of clients and programs. As of
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36 publication, all countries implementing PEPFAR-supported VMMC except Ethiopia and Namibia have
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38 begun the evaluation process for at least one device, although scale-up of device-based service delivery
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40 can take time even after evaluation is completed and policy is in place. Although devices offer several
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42 advantages over surgical circumcision, they require more intense post-market safety monitoring tailored
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44 to their mechanisms of action, until more VMMCs have been done using these methods. Most recently,
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46 uptake of the most commonly-used device has also been negatively impacted by the WHO advice and
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48 PEPFAR policy related to tetanus vaccination prior to device placement.³⁸
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5 Most countries with low follow-up proportions also have low follow-up data completeness,
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7 making these results difficult to interpret. However, there is evidence that adverse events (AEs) are
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9 actually more common among males who do not return for follow-up than among those who do.³⁹ While
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11 VMMC is extremely safe,⁴⁰ achieving high follow-up rates to allow early AE diagnosis and intervention
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13 is crucial for program safety.
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17 The findings in this paper are subject to several limitations. These data reflect results supported
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19 by PEPFAR, rather than country totals. Additionally, cross-tabulations between disaggregations are not
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21 reported, and therefore it is not possible to determine associations between age group, HIV status and
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23 procedure technique. Data are not complete for all disaggregations in all countries. Data entry errors
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25 such as those discussed above for followup, and variations in reporting practice, are possible. Category
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27 definitions combine some disparate groups (e.g. “unknown” test results include men who were not tested
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29 at VMMC sites for any reason, whether preference, test kit shortage, or documentation of recent outside
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31 testing.)
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36 The global VMMC program’s achievements to date have demonstrated the feasibility of rapid
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38 scale-up of circumcision coverage, but program strategy will need to continue evolving to maximize
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40 impact, achieve revised targets, maintain safety, and meet broader UNAIDS and PEPFAR objectives.
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42 Attracting more 15-29-year-old clients, and ideally other high-risk clients who will benefit most from
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44 VMMC, may require new demand creation approaches and service delivery models. Though current
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46 achievements have passed the halfway mark to the initial global target, this target was recently revised
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48 under the new UNAIDS Fast Track framework to include 27 million additional circumcisions by the end
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50 of 2020 beyond those conducted through 2015,⁴¹ to reach 90% coverage among 10-29-year-olds.⁴²
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52 Reaching these VMMC targets is a key component of the Fast Track strategy: the overall impact
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PEPFAR circumcisions through 2016

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4 projection for achievement of Fast Track goals – 28 million HIV infections averted by 2030 – depends
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6 in part on achieving and maintaining this coverage. Finally, the updated 2016 WHO/UNAIDS
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8 framework for VMMC calls for circumcision programs to shift from largely stand-alone service delivery
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10 toward greater integration within a broad platform of adolescent and adult male reproductive health.
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12 Strategies that reached “early adopters” predisposed to uptake VMMC rapidly may differ from those
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14 needed to reach the remaining uncircumcised men, and to do so within this integrated platform. To
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16 achieve the ambitious goals in this framework, substantial engagement and increased resource
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18 commitments from stakeholders other than PEPFAR, including national ministries of health, will be
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20 needed.
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48 Prevention, the US Agency for International Development, or the United States Government.
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4 **CONTRIBUTORSHIP:** Stephanie M. Davis drafted and finalized the manuscript.
5

6 Jonas Hines, Melissa Habel, Jonathan M. Grund, Renee Ridzon, Jonathan Davitte, Anne Thomas,
7 Valerian Kiggundu, Caroline Cooney, and Naomi Bock revised the manuscript.
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9

10 Brittney Baack and Paran Pordell revised the data and manuscript.
11

12 Carlos Toledo conceived of the paper, obtained the data, and revised the manuscript.
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17 **DATA SHARING:** As described in this article, the dataset underlying the tables and results is
18 publically available at <https://data.pepfar.net/quarterlyData/> .
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26 **ETHICAL STATEMENT:** Use of this routinely collected, aggregate-only program data was reviewed
27 and approved by CDC Human Subjects Protection.
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34 **RESEARCH REPORTING CHECKLISTS:** Because this manuscript is based on routinely collected
35 program data and does not examine associations between risk factors and outcomes, none of the
36 standard checklists are applicable, including per EquatorWizard.
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PEPFAR circumcisions through 2016

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PEPFAR circumcisions through 2016

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Figure Legend

Figure 1: Cumulative Number of PEPFAR-supported Voluntary Medical Male Circumcisions by Country, 2007-2016

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2007-2009

PEPFAR circumcisions through 2016

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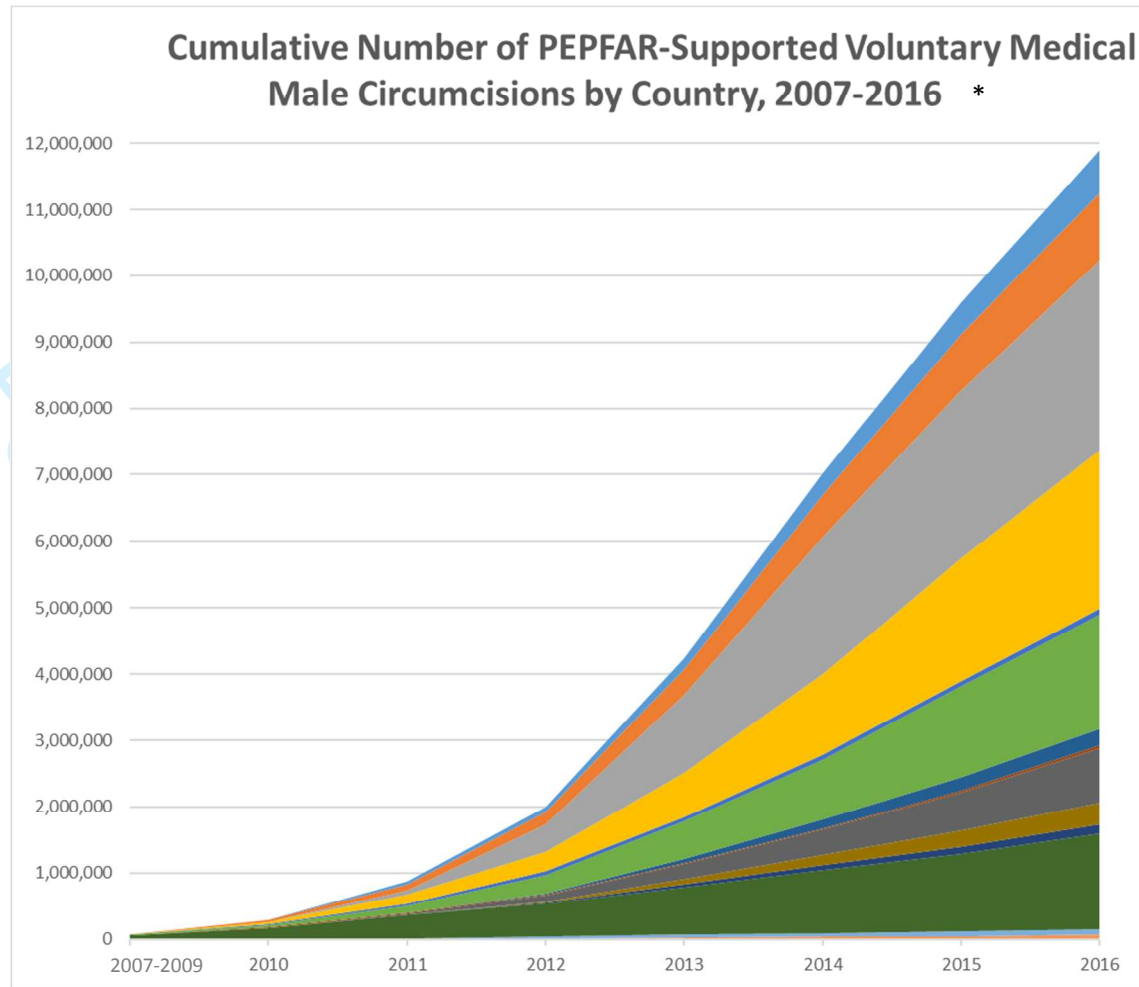
PEPFAR circumcisions through 2016

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Figure 1:



* Fiscal years

BMJ Open

**Progress in Voluntary Medical Male Circumcision for HIV
Prevention
Supported by the United States President's Emergency Plan
for AIDS Relief through 2017:
Longitudinal and Recent Cross-sectional Program Data**

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7 **Progress in Voluntary Medical Male Circumcision for HIV Prevention**
8 **Supported by the United States President's Emergency Plan for AIDS Relief through 2017:**
9 **Longitudinal and Recent Cross-sectional Program Data**

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ABSTRACT:

OBJECTIVE This article provides an overview and interpretation of the performance of PEPFAR's male circumcision program, which has supported the majority of voluntary medical male circumcisions performed for HIV prevention, from its 2007 inception through 2017, and client characteristics in 2017.

DESIGN Longitudinal collection of routine program data and disaggregations.

SETTING 14 countries in sub-Saharan Africa with low baseline male circumcision coverage, high HIV prevalence, and PEPFAR-supported voluntary medical male circumcision programs.

PARTICIPANTS Clients of PEPFAR-supported voluntary medical male circumcision programs directed at males aged 10 years and above.

MAIN OUTCOME MEASURES Numbers of circumcisions performed and disaggregations by age band, result of HIV test offer, procedure technique, and follow-up visit attendance.

RESULTS PEPFAR supported a total of 15,269,720 circumcisions in 14 countries in southern and eastern Africa. In 2017, 45% of clients were under 15 years of age, 8% had unknown HIV status, 1% of those tested were HIV+, and 84% returned for a follow-up visit within 14 days of circumcision.

CONCLUSIONS Over 15 million VMMCs have been supported by PEPFAR since 2007. VMMC continues to attract primarily young clients. The nontrivial proportion of clients not testing for HIV is expected, and may be reassuring that testing is not being presented as mandatory for access to circumcision, or in some cases reflect test kit stockouts or recent testing elsewhere. While VMMC is extremely safe, achieving the highest possible follow-up rates for early diagnosis and intervention on complications is crucial, and programs continue to work to raise follow-up rates. The VMMC program has achieved rapid scale-up but continues to face challenges, and new approaches may be needed to achieve the new UNAIDS goal of 27 million additional circumcisions through 2020.

STRENGTHS AND LIMITATIONS OF THIS STUDY:

- The large dataset covers eleven years of program data on over 15 million men.
- PEPFAR-supported clients constitute a large majority of all voluntary medical male circumcision clients, making client characteristics reported here likely to be representative of the program as a whole.
- The multicountry nature of the data allows determination of client characteristics common across settings.
- The routine reporting system is aggregate only, and collected data does not support analyses of associations between client characteristics.
- Data are not complete for all client characteristics (disaggregations) in all countries.

INTRODUCTION:

Male circumcision, the removal of the foreskin, reduces a man's risk of acquiring HIV through heterosexual exposure by approximately 60 percent.^{1,2,3} Since its adoption as a recommended HIV prevention strategy by the World Health Organization (WHO) and Joint United Nations Programme on HIV/AIDS (UNAIDS) in 2007,⁴ voluntary medical male circumcision (VMMC) has become a core component of the global HIV prevention portfolio through support by national and global programs, such as the United States President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis and Malaria.⁵ The WHO/UNAIDS's guiding document for VMMC from 2012-2016 recommended scale-up of VMMC in 14 countries in southern and eastern Africa with high HIV prevalence, low circumcision coverage and primarily heterosexual HIV transmission,⁶ with an initial goal of circumcising 20 million men to achieve 80% coverage among males aged 15-49 years in these countries by 2016. As a one-time biomedical intervention conferring lifelong partial protection from HIV, and the only prevention method specifically targeted at HIV-negative heterosexual men, VMMC complements other behavioral and clinical prevention interventions such as condom promotion, reduction in number of sex partners, pre-exposure prophylaxis, and treatment-as-prevention.

VMMC services were launched progressively by ministries of health in each of the recommended 14 countries between 2007 and 2011, primarily with PEPFAR support. PEPFAR-supported VMMCs are surgical or procedural interventions often lasting 5-15 minutes,⁷ provided by physicians or nurses under local anesthesia. They are offered with the WHO-recommended minimum package⁸ of accompanying services, including the offer of HIV testing and linkage to care and treatment for HIV-positive individuals, HIV risk-reduction education, condom provision, and sexually transmitted infection (STI) screening and treatment or referral. Over the lifetime of the program, several additional key innovations with potential to impact the volume and client demographics of the program have also been incorporated. These include the introduction of WHO-prequalified circumcision devices as

1 alternatives to conventional surgery; the introduction of WHO “Models for Optimizing Volume and
2 Efficiency”;⁹ the identification of the 15-29 year age group as the focal demographic for rapidly
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4 reducing population-level HIV incidence through VMMC;¹⁰ enhancement of safety measures based on
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6 accumulating data, particularly for adolescents based on their unique surgical safety requirements;
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9 introduction of policies on tetanus vaccination prior to VMMC;¹¹ and increased emphasis on linking
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11 clients testing HIV-positive to care and treatment,¹² to support WHO/UNAIDS treatment scale-up
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13 goals.¹³
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18 All PEPFAR-supported VMMC programs report on key program outcomes, including the total
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20 VMMCs performed in each country and select disaggregations for all clients: client age range, result of
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22 HIV test offer, circumcision technique (device or surgical), and adherence to routine post-operative
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24 follow-up. These indicators provide an overview of the accomplishments and key current attributes of
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26 the PEPFAR VMMC program. This article presents all PEPFAR-supported VMMCs performed since
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28 program inception in 2007, compares key disaggregations from U.S. fiscal year 2017 with those from
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30 2015 and 2016, and discusses future challenges and directions for the program. The primary objective
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32 of this paper is to describe PEPFAR’s VMMC program, and identify in which aspects the program is
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34 performing well and in which gaps and challenges remain and should be prioritized. Making key
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36 demographic data on VMMC clients available may also support refining projections around impact.
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38 Client characteristics described here are expected to be reasonably representative of the global VMMC
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40 clientele to date because PEPFAR supports the majority of VMMCs conducted globally (approximately
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42 82% through 2016)¹⁴, and because VMMC donors operate under the common WHO minimum package
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44 service structure.
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51 **METHODS:**

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55 Data reported by PEPFAR-supported VMMC programs are drawn initially from site-level client
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57 registers and records, and reported by the implementing partners at the site level to PEPFAR in each
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1 host country. Data are then cleaned in-country; and then reported to PEPFAR's central coordinating
2 body, the Office of the Global AIDS Coordinator. Implementing partners also report to their host
3 country governments, following procedures agreed upon in-country; this may occur independently or
4 may use the same data stream. Data are currently reported to PEPFAR on a quarterly basis, and then
5 grouped by U.S. Government fiscal year, which runs October 1st through September 30th, rather than by
6 calendar year. These numerical data are now available online¹⁵ and were used here to calculate
7 percentages where relevant. Monitoring trends across years is possible, but prior to 2015, fewer VMMC
8 disaggregations were collected.

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21 The disaggregations reported for VMMCs performed, and definitions where needed, are listed in
22 table 1. Their rationales and context are summarized below. Not all sites are able to collect and report
23 circumcision data by each disaggregate for all clients. Therefore, percentages presented here for each
24 disaggregate are calculated only among clients for whom data on that disaggregate were reported.

Table 1: Disaggregations and Categories for PEPFAR-supported VMMC program reporting on VMMCs performed, 2016

Disaggregation	Client Categories
Age	<ul style="list-style-type: none"> - < 61 days (early infant male circumcision) - 2 months-<10 years (not funded by PEPFAR due to safety concerns) - 10-14 years (this and younger categories are collapsed here as '<15') - 15-19 years - 20-24 years - 25-29 years - 30-49 years - 50+ years
Result of HIV test offer at VMMC site	<ul style="list-style-type: none"> - HIV+ - HIV - - Unknown: includes clients with undocumented or indeterminate status and those not tested at the VMMC site for any reason
Technique	<ul style="list-style-type: none"> - Surgical - Device-based
Follow-up visit attendance	<ul style="list-style-type: none"> - Returned for at least one post-operative follow-up visit within 14 days of surgery - Did not return within 14 days

- 1) Client age range: Age ranges represent those selected for PEPFAR routine reporting to support fine analysis of client age patterns. PEPFAR's prioritization of, or "age pivot" to, the 15-29 year age range began in fiscal year 2016. Ages below 15 years constitute the largest combined proportion of VMMCs performed, but will have delayed impact on the HIV epidemic due to the delay until sexual debut and other risk behaviors. These age ranges are collapsed together in this report.
- 2) Result of HIV test offer at VMMC site: Under PEPFAR¹⁶, UNAIDS¹⁷ and WHO¹⁸ guidance active in 2016, HIV testing at the VMMC site should be encouraged but is not required for access to VMMC, and clinically eligible clients who do test may proceed with VMMC regardless of their results. As a disaggregation within the cohort of clients receiving VMMC, this reporting does not include men who were tested at VMMC sites but then decided against VMMC after receiving a positive HIV test result. This may not be unusual, as men testing

1 positive are counseled that circumcision will not affect the course of their HIV infection and
2 may choose not to proceed.
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6 3) Circumcision technique used: Circumcision devices offer an alternative to surgery, and
7 advantages include faster procedures and potentially avoiding the injection of anesthesia and
8 incision of living tissue. Initially, PEPFAR-supported circumcision was exclusively surgical,
9 using one of three WHO-recommended techniques: forceps-guided, dorsal slit, and sleeve
10 resection.¹⁹ With WHO prequalification of the PrePex device in 2013²⁰ and ShangRing in
11 2015,²¹ some ministries of health have introduced device-based services as additional options
12 for clients. Both PrePex and ShangRing devices remain on the penis for seven days and are
13 removed by a provider during a follow-up visit. Anatomic and age-based eligibility criteria
14 vary between devices and can be stricter than surgical eligibility criteria, restricting the pool
15 of eligible clients.²² Numbers of circumcisions performed using a device therefore reflect
16 national policies and eligibility for, as well as availability and client uptake of, these
17 alternative methods. They also reflect the impact of tetanus mitigation policies as discussed
18 below.
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36 4) Follow-up visit attendance: PEPFAR-supported programs follow fixed schedules for routine
37 postoperative follow-up set by national ministries of health to ensure client safety. These
38 often include a return visit at days two and seven after surgery, or day seven after device
39 placement (for device removal). In 2015 and 2016, the PEPFAR follow-up indicator was
40 only reported among surgical cases, which therefore constituted the denominator for
41 determining follow-up percentage; in 2017 it was calculated among all circumcisions.
42 Followup was only reported on if it took place, so that clients who did not follow up cannot
43 be distinguished from those whose followup status is unknown.
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1 Comparison data on country-specific total annual VMMC volume (including both PEPFAR-
2 supported and non-PEPFAR supported procedures) is drawn from the most recent WHO VMMC
3 Progress Brief, covering 2007-2016.¹⁴ Data on PEPFAR's 2017 country-level VMMC targets is drawn
4 from annual PEPFAR Budget and Target reports.²³

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11 *Patient and public involvement:* Because this manuscript reports program data rather than
12 research data, no research question or study design was formulated for data collection. Data collected
13 instead consists of indicators designed to monitor program achievements. VMMC clients were
14 beneficiaries choosing to uptake a public health interventions, not research participants. However,
15 satisfied VMMC clients are sometimes involved in recruiting peers for VMMC. Results are publically
16 available online as referenced above.

26 RESULTS:

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29 From PEPFAR fiscal year 2007 through 2017, a total of 15,269,720 PEPFAR-supported
30 VMMCs were performed in 14 countries in southern and eastern Africa. From 2010 through 2014,
31 annual VMMC numbers approximately doubled annually, reaching 2,794,808 in 2014. In 2015,
32 2,573,273 VMMCs were performed, followed in 2016 by 2,290,200; these represented the third- and
33 fourth-highest annual totals. The year 2017 saw an increase to 3,665,866, the highest annual total to
34 date. Over half (54%) of PEPFAR-supported circumcisions performed since the program's inception
35 were performed in 2015-2017 (Figure 1, Table 2). In 2016, the latest year for which WHO national-
36 level data is available, PEPFAR-supported VMMCs constituted 80% of all VMMCs reported by WHO,
37 and 55% or more of reported VMMCs in each individual country except Rwanda.¹⁴ VMMCs conducted
38 in 2017 achieved 92% (3,664,531/3,665,866) of PEPFAR targets for that year, with nine countries
39 reaching 90% or more of their targets.

1
2 Twelve countries provided >85% data completeness across all disaggregations in 2017 for which
3 completeness was calculable. By disaggregate, 3,278,130 clients had age data (387,736 missing =
4 12%); 3,309,077 had result of HIV test offer (including unknown status; 356,789 missing = 11%);
5
6 3,282,987 had technique data (382,879 missing = 12%); of whom 2,736,851 had a reported follow-up
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8 within 14 days. Because programs only reported the number of clients who received follow-up in 2017,
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10 and did not separately report the number which did not, we are unable to assess completeness for this
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12 disaggregate (but see table 2 footnote). Where data completeness for a given disaggregate in a country
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14 (sum of all VMMC's across categories for that disaggregate, divided by total VMMC's performed) was
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16 less than the 85% threshold we selected for this analysis, values are bolded (Table 3).
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23 In 2017, 48% of VMMC clients were within the 15-29 years age range, to which PEPFAR
24 shifted focus that year, a relatively stable proportion from 46% in 2016 and 48% in 2015. There was
25
26 wide variation among countries, ranging from 25% in Botswana to 68% in Rwanda. In contrast, 45% of
27
28 PEPFAR VMMC clients were within the 10-14 years range, representing a stable increase, along with
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30 46% in 2016, from 42% in 2015. Eight countries experienced an increase in the proportion of clients in
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32 the 10-14 year age range from 2016 to 2017. This shift was largest in Rwanda (5% to 28%), Botswana
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34 (45% to 66%), and Namibia (12% to 34%), all relatively small programs. However other programs, like
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36 South Africa, did successfully achieve the reverse (43% in 2017, from 51% in 2016). Countries which
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38 had previously shifted in 2016 toward younger clientele included several large programs which also
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40 showed decreases in overall achievements in that year, such as Tanzania, South Africa and Zambia,
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42 though in the first two cases this trend reversed in 2017.
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PEPFAR circumcisions through 2017

Table 2: Annual PEPFAR-funded VMMCs performed by country, 2007-2017, and PEPFAR 2017 VMMC targets*

Country	2007-2009	2010	2011	2012	2013	2014	2015	2016	2017	2017 PEPFAR Target	Total
Botswana	5,180	534	0	8,590	12,464	13,893	7,712	24,201	22,645	20,911	95,219
Ethiopia	0	3,110	8,236	12,445	16,393	11,831	11,307	14,335	13,782	17,184	91,439
Kenya	45,657	112,574	182,788	158,278	214,851	229,390	233,813	264,490	227,272	240,010	1,669,113
Lesotho	0	0	199	6,971	36,418	39,175	28,909	31,709	25,445	40,573	168,826
Malawi	0	0	778	13,314	67,384	68,334	90,820	82,381	99,435	109,348	422,446
Mozambique	0	4,009	18,946	79,002	129,581	160,660	187,186	241,793	315,239	427,536	1,136,416
Namibia	117	1,229	5,379	6,121	0**	785	9,927	15,116	27,736	34,746	66,410
Rwanda	0	896	3,922	17,639	36,441	74,803	65,048	50,204	175,902	95,936	424,855
South Africa	18,100	14,956	72,004	170,849	294,977	327,473	472,047	355,917	460,668	428,486	2,186,991
Swaziland	3,802	19,728	13,399	14,456	9,708	11,934	12,156	16,003	15,071	18,616	116,257
Tanzania	262	21,581	117,351	151,915	381,394	554,673	615,089	519,437	696,572	696,449	3,058,274
Uganda	0	9,052	57,132	352,039	742,978	906,615	466,650	330,343	753,198	1,011,964	3,618,007
Zambia	0	21,236	63,444	103,517	199,372	239,464	216,394	185,028	323,180	271,260	1,351,635
Zimbabwe	0	9,811	30,608	36,765	88,114	155,778	156,215	159,243	227,299	252,847	863,833
Total	73,118	218,716	574,186	1,131,900	2,230,075	2,794,808	2,573,273	2,290,200	3,383,444	3,665,866	15,269,720

PEPFAR circumcisions through 2017

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* Fiscal years

** PEPFAR support for VMMC in Namibia was paused for strategic planning in 2013.

PEPFAR circumcisions through 2017

Table 3: Numbers and Characteristics of PEPFAR-funded Voluntary Medical Male Circumcisions, Fiscal Year 2017 (Oct. 1, 2016-Sept 30, 2017) by country and 2015-2016 totals

Country	VMMCs	Client Age Range in Years (%)*						Result of HIV test offer at VMMC site (%)		Technique: Device Method Used (%) (vs. Surgical)	Follow-up Visit Attendance **(%)
		<15	15-19	20-24	25-29	30-49	50+	HIV+ among tested clients	Unknown status*		
Botswana	22,645	66	10	9	7	7	1	0	18	0	72
Ethiopia	13,782	47	26	14	6	7	0	0	32	0	96
Kenya	227,272	60	23	9	5	3	0	0	2	1	80
Lesotho	25,445	56	18	8	6	10	1	2	50	0	90
Malawi	99,435	42	28	15	8	6	0	1	0	0	89
Mozambique	315,239	45	30	13	6	5	1	2	6	0	81
Namibia	27,736	34	21	15	13	16	1	1	44	0	99
Rwanda	175,902	28	48	15	6	4	0	0	0	53	100
South Africa	460,668	43	22	12	10	11	1	2	20	0	59
Swaziland	15,071	54	29	10	3	3	1	3	1	0	99
Tanzania	696,572	46	26	15	6	6	1	0	13	0	92
Uganda	753,198	46	26	13	8	6	1	1	3	0	86
Zambia	323,180	38	27	16	10	9	0	0	4	0	94
Zimbabwe	227,299	47	25	13	8	7	0	0	0	5	***
Total in 2017	3,383,444	45	27	13	8	7	1	1	8	3	84
Total in 2016	2,290,141	46	27	12	7	7	1	1	9	4	78
Total in 2015	2,573,238	42	28	13	7	8	1	1	7	5	72

Bolded entries indicate <85% data completeness.

* Includes clients with undocumented or indeterminate status and those not tested at the VMMC site for any reason

** Percent of clients who returned for at least one post-operative follow-up visit within 14 days of surgery or device placement

*** Followup rate in Zimbabwe unknown for 2017. Facilities representing 46% of all Zimbabwe circumcisions did not report followup data, due to delays in adoption of the new follow-up reporting method.

PEPFAR circumcisions through 2017

Overall, 8% of clients had “unknown” HIV status in 2017, as compared to 9% in 2016 and 7% in 2015, with individual country values ranging from 0% in Rwanda and Zimbabwe to 50% in Lesotho; other countries with high “unknown” rates were Ethiopia at 32% and Namibia at 44%. Among clients tested for HIV, 1% were positive, essentially unchanged from 2015-2016, with individual country positivity varying between 0% in Zimbabwe, Tanzania, Mozambique and Ethiopia, and 5% in Malawi.

Device-based circumcision techniques constituted a small percentage of circumcisions in all countries in 2017, accounting for 3% of VMMCs across countries (down from 5% in 2015 and 4% in 2016), ranging between 0% in many countries and 53% in Rwanda. Botswana and Zimbabwe showed substantial respective drops from 28% to 0% and 27% to 5%.

Post-procedure follow-up rates among all clients were 84% overall (excluding Zimbabwe), higher than the 72% in 2015 and 78% in 2016. These rates ranged between 59% in South Africa and 100% in Rwanda, falling at or above 75% in 11 countries.

DISCUSSION:

VMMC has undergone a scale-up of historic proportions within global health, comparable to the scale-up of HIV treatment.²⁴ This manuscript demonstrates that overall program volume is high and increasing, but there is progress to be made in increasing volume further to pursue Fast Track targets, attracting older clients with higher HIV risk and, in some places, raising postoperative follow-up rates to ensure complications are managed promptly.

PEPFAR circumcisions through 2017

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5 With respect to program volume, over 15 million PEPFAR-supported VMMC were performed
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7 between 2007 when support began and 2017, making VMMC a major prevention intervention for
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9 achieving the PEPFAR goal of an AIDS-free generation through epidemic control in sub-Saharan
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11 Africa.²⁵ PEPFAR had committed in 2015 to supporting at least 13 million VMMCs through 2017,²⁶
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13 and exceeded that target. Models estimate that global VMMCs conducted through 2016 alone will avert
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15 500,000 infections by the end of 2030.¹⁴ Scale-up has been enabled not only by dedicated resources,
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17 totaling over \$1.5 billion through 2017 from PEPFAR alone, but also through leadership from ministries
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19 of health, rapid expansion of surgical skills and responsibilities to non-physician health cadres, and
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21 public outreach campaigns. It has provided millions of men with lifelong partial protection from HIV
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23 and some STIs, and connected them with additional HIV and other health services through testing, STI
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25 screening, and referrals for other health conditions. Infections averted in men through VMMC also help
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27 prevent new HIV infections among women and girls,^{27,28,29} and male circumcision is also associated
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29 with lower prevalence of a range of STIs in women.²⁹
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35 In light of the high proportion of global VMMCs supported, PEPFAR client data is also expected
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37 to provide a reasonably representative view of the global VMMC clientele to date. References to
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39 achievements and characteristics below refer to the PEPFAR program except where otherwise stated.
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43 All VMMC implementing countries continue to scale up VMMC. However, in 2015 and 2016
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45 there were substantial declines in PEPFAR VMMC achievements in Uganda (the largest contributor to
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47 VMMC results); these were mirrored by declines in total VMMCs achieved in Uganda.¹⁴ Service
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49 delivery and policy were impacted by the identification of tetanus as a risk among VMMC clients in the
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51 Ugandan setting, due to limited historical tetanus immunization coverage.^{30,31,32} WHO issued global
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53 recommendations that additional visits for tetanus vaccination be performed prior to circumcision using
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PEPFAR circumcisions through 2017

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4 device-based VMMC methods associated with increased risk of tetanus,³³ and the Uganda National
5 VMMC Program ultimately required an additional visit for tetanus vaccination prior to VMMC. Similar
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7 policies may have also impacted performance in other countries with significant device contributions
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9 (not shown) like Botswana and Rwanda. Additionally, a PEPFAR policy issued in late 2014
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11 discontinued the use of the forceps-guided surgical technique in young adolescents to avoid the
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13 associated risk for injury to the immature glans, causing some country programs to decrease VMMC
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15 provision to this age range until they could retrain their VMMC workforces in a more appropriate
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17 method. In 2016, Tanzania, South Africa and Zambia also experienced declines (Uganda had not
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19 previously reported age data), though these were accompanied by *increases* in client proportions in the
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21 10-14 age group, and were followed in 2017 by increases in overall performance and shifts toward older
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23 clientele. These 2016 declines may thus be due to strategic shifts in program geography and funding.
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25 Total program performance then increased substantially in 2017, with nine countries showing increases
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27 over 2016, including these largest programs. We attribute this recovery to resolution of the challenges
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29 described above, combined with increases in available resources.
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38 Country-level PEPFAR VMMC targets are set each year for the following year, based on
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40 previous years' achievements, available resources, overall ministry of health targets, and remaining
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42 unmet need to achieve saturation. In 2017, overall performance was well-matched to targets (92%),
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44 with variations including some countries with marked overperformance (Rwanda and Zambia) and
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46 others with high absolute performance but even more ambitious targets (e.g. Uganda, with the highest
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48 national PEPFAR VMMC performance ever reported). In addition to the policy factors discussed above,
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50 reasons for variation in performance against targets can include implementing partner capacity and
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PEPFAR circumcisions through 2017

ambition (partners may choose to surpass their targets once achieved, if funding remains) and unexpected external factors such as civil unrest and health care strikes.

VMMC client populations in 2017 were young, with males in the 10-14 years age range representing 45% of all PEPFAR VMMCs (virtually all VMMCs in clients <15 years are in the 10-14 year range), as compared to 12% of the combined male general population of the 14 implementing countries.³⁴ This represents a change from the program's historical client age distribution; from 2010 through 2013, clients in the 10-14 years age range characterized no more than one third of all clients in any year.³⁵ The 2015 distribution (42% of clients were aged <15 years) served as the baseline prior to implementation of the "age pivot"; yet the actual age balance shifted further toward the younger range in 2016 (46%), with only slight recovery in 2017, despite this focus. In some countries, the shift toward younger ages may partially reflect the maturation of the VMMC program: 'exhaustion' of older age ranges and replacement with younger males. Additional potential barriers which may apply disproportionately to older males include reluctance to abstain from sex for the 6-week healing period, perception of low risk due to having established partners, the opportunity cost of lost wages during recovery, and fear of creating perceptions in a stable partner that they intend to seek other sexual partners.^{36,37} Age ranges 30 years and above represented a small (8% in 2017) percentage of VMMC clientele, despite being a sexually active group at risk for HIV, possibly for similar reasons. However, some countries and individual partners did successfully make modest shifts toward older clientele, and identification and broader adoption of their best practices are called for.

VMMC clients also have low HIV positivity compared to the general population, 1% among all clients in 2015, 2016 and 2017, as compared to 5.5% (95% confidence interval 4.9-6.0%) prevalence among males aged 15-49 years in the southern and eastern Africa region in 2016.³⁸ The young age of

PEPFAR circumcisions through 2017

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4 the client population is almost certainly the major underlying factor; pre-adolescents and early
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6 adolescents have less exposure to sex and consequently less HIV risk and lower HIV prevalence than
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8 older age groups. Because HIV test results are not disaggregated by age group, this effect cannot be
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10 controlled for in PEPFAR VMMC reporting data. Lower HIV prevalence among VMMC clients could
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12 also reflect self-selection of men with health-protecting behaviors into the pool of VMMC clients and/or
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14 the effects of messaging promoting VMMC for HIV prevention, leading to the self-exclusion of men
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16 who know they are HIV-positive (including any who learn they are HIV-positive at the VMMC site and
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18 consequently opt out of VMMC). Despite this low prevalence, it should be noted that men in sub-
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20 Saharan Africa have lower HIV testing uptake than women³⁹ and the VMMC program provides an
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22 opportunity to reach men who might not otherwise undergo testing. The substantial proportion of clients
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24 with ‘unknown’ test results is expected, and may reflect the voluntary nature of HIV testing in VMMC,
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26 as well as the frequency of HIV test kit stockouts (e.g., Ethiopia and Namibia experienced intermittent
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28 stockouts in 2017).
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35 The fact that few circumcisions were performed by device methods throughout 2015-2017
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37 reflects in part the relatively short period that device-based circumcision has been available, as well as
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39 the rigorous country-level vetting process which new devices undergo when being introduced in a new
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41 country,⁴⁰ prior to nationwide rollout. It may also reflect current preferences of clients and programs.
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43 As of publication, all countries implementing PEPFAR-supported VMMC except Ethiopia and Namibia
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45 have begun the evaluation process for at least one device, although scale-up of device-based service
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47 delivery can take time even after evaluation is completed and policy is in place. Although devices offer
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49 several advantages over surgical circumcision, they require more intense post-market safety monitoring
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51 tailored to their mechanisms of action, until more VMMCs have been done using these methods. Most
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PEPFAR circumcisions through 2017

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4 recently, uptake of the most commonly-used device has also been negatively impacted by the WHO
5 advice and PEPFAR policy related to tetanus vaccination prior to device placement,⁴¹ driving the
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7 decline noted from 2015-2017.
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12 Although the follow-up rate of 84% in 2017 is not precisely comparable to rates in 2015 and
13 2016 because of the inclusion of device followup, the low proportion of the program represented by
14 device MCs makes the apparent increase likely to constitute a true trend. Followup is also likely to be
15 underestimated, because all clients without a reported followup visit were treated in calculations as not
16 following up, rather than missing data. This is encouraging, but more remains to be done in countries
17 with low follow-up rates. There is evidence that adverse events (AEs) are actually more common among
18 males who do not return for follow-up than among those who do.⁴² While VMMC is extremely safe,⁴³
19 achieving high follow-up rates to allow early AE diagnosis and intervention is crucial for program
20 safety.
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34 The findings in this paper are subject to several limitations. These data reflect results supported
35 by PEPFAR, rather than country totals. Additionally, cross-tabulations between disaggregations are not
36 reported, and therefore it is not possible to determine associations between age range, result of HIV test
37 offer and procedure technique, or control for measured potential confounders. For reasons discussed
38 above, VMMC clients are not representative of the general male population of their countries; they are
39 younger, less likely to be HIV-positive, and possibly at lower behavioral risk; findings here are not
40 intended to be generalized outside the client population. Data entry errors such as those discussed above
41 for follow-up, and variations in reporting practice, are possible. Category definitions combine some
42 disparate groups (e.g. “unknown” test results include men who were not tested at VMMC sites for any
43 reason, whether preference, test kit shortage, or documentation of recent outside testing.) Finally, though
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PEPFAR circumcisions through 2017

we believe client characteristics are representative of those of all VMMC clients, PEPFAR's focus on the areas of each country with highest absolute HIV burden⁴⁴ could mean that clients of other VMMC programs in other areas (which may have lower HIV incidence and prevalence, or simply be less densely populated) differ demographically, in unknown ways.

The global VMMC program's achievements to date have demonstrated the feasibility of rapid scale-up of circumcision coverage, but program strategy will need to continue evolving to maximize impact, achieve revised targets, maintain safety, and meet broader UNAIDS and PEPFAR objectives of integrating services into existing health care systems. Though current achievements have totalled the majority of the initial global target, this target was recently revised under the new UNAIDS Fast Track framework to include 27 million additional circumcisions by the end of 2020 beyond those conducted through 2015,⁴⁵ to reach 90% coverage among 10-29-year-olds.⁴⁶ Reaching these VMMC targets is a key component of the Fast Track strategy: the overall impact projection for achievement of Fast Track goals – 28 million HIV infections averted by 2030 – depends in part on achieving and maintaining this coverage. Among these, attracting the PEPFAR priority subpopulation of clients in the 15-29 years age range, and ideally other high-risk clients who will benefit most from VMMC, will yield the fastest impact on HIV incidence but may require new demand creation approaches and service delivery models. Finally, the updated 2016 WHO/UNAIDS framework for VMMC⁴⁷ calls for circumcision programs to shift from largely stand-alone service delivery toward greater integration within a broad platform of adolescent and adult male reproductive health. Strategies that reached “early adopters” predisposed to uptake VMMC rapidly may differ from those needed to reach the remaining uncircumcised men, and to do so within this integrated platform. To achieve the ambitious goals in this framework, substantial

1 PEPFAR circumcisions through 2017
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4 engagement and increased resource commitments from stakeholders other than PEPFAR, including
5 national ministries of health, will be needed.
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22 **COMPETING INTERESTS:** Authors declare no competing interests.
23
24

25 **DISCLAIMER:** The findings and conclusions in this report are those of the authors and do not
26 necessarily represent the official position of the funding agencies, the Centers for Disease Control and
27 Prevention, the US Agency for International Development, or the United States Government.
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33 **CONTRIBUTORSHIP:** Stephanie M. Davis drafted and finalized the manuscript.
34

35 Jonas Hines, Melissa Habel, Jonathan M. Grund, Renee Ridzon, Jonathan Davitte, Anne Thomas,
36 Valerian Kiggundu, Caroline Cooney, and Naomi Bock revised the manuscript.
37

38 Brittney Baack and Paran Pordell revised the data and manuscript.
39

40 Carlos Toledo conceived of the paper, obtained the data, and revised the manuscript.
41

42 Irum Zaidi oversaw all data collection.
43
44
45

46 **DATA SHARING:** As described in this article, the dataset underlying the tables and results is
47 publically available at <https://data.pepfar.net/quarterlyData/>.
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1 PEPFAR circumcisions through 2017
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4 **ETHICAL STATEMENT:** Use of this routinely collected, aggregate-only program data was reviewed
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6 and approved by CDC Human Subjects Protection.
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10 **RESEARCH REPORTING CHECKLISTS:** Because this manuscript is based on routinely collected
11
12 program data and does not examine associations between risk factors and outcomes, none of the
13
14 standard checklists are entirely applicable, including per EquatorWizard. At the editors' request, the
15
16 STROBE checklist has been filled and included with resubmission.
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PEPFAR circumcisions through 2017

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Figure Legend

Figure 1: Cumulative Number of PEPFAR-supported Voluntary Medical Male Circumcisions by Country, 2007-2017

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PEPFAR circumcisions through 2017

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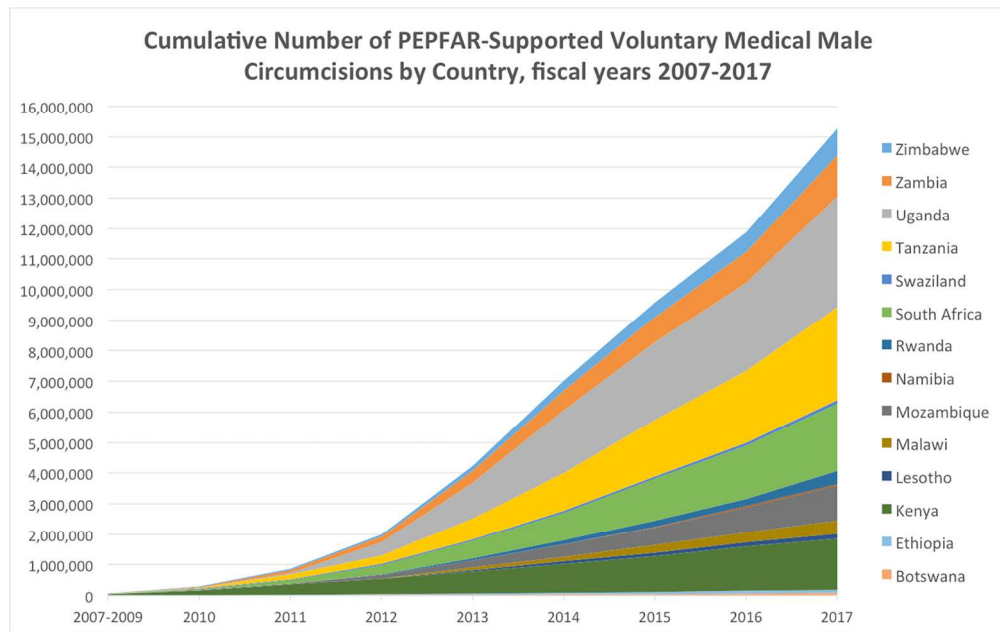


Figure 1: Cumulative Number of PEPFAR-supported Voluntary Medical Male Circumcisions by Country, fiscal years 2007-2017

152x95mm (300 x 300 DPI)

view only

STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract – pg 1 (page numbers are for clean version) (b) Provide in the abstract an informative and balanced summary of what was done and what was found – pg 2
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported – pg 4-6
Objectives	3	State specific objectives, including any prespecified hypotheses – pg 5
Methods		
Study design	4	Present key elements of study design early in the paper – pg 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection – pp 4-6
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants – pg 5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable – pg 7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group – pg 7
Bias	9	Describe any efforts to address potential sources of bias – pg 18 (this is a limitation of the way program data is collected)
Study size	10	Explain how the study size was arrived at – pg 5 (all clients – program data)
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why – pg 7-10
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding – pg 6-8, 18 (b) Describe any methods used to examine subgroups and interactions - N/A (no subgroups, no interactions) (c) Explain how missing data were addressed – pg 6, 10 (d) If applicable, describe analytical methods taking account of sampling strategy (N/A) (e) Describe any sensitivity analyses (N/A)
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed - pg 10 provides total numbers, but there are no exclusion stages for program data like those described above (b) Give reasons for non-participation at each stage - N/A (c) Consider use of a flow diagram - N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders – pg 12 (b) Indicate number of participants with missing data for each variable of interest – pg 11
Outcome data	15*	Report numbers of outcome events or summary measures – pg 12

1			
2	Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included – pg 12 (confidence intervals are not applicable because the data represents a census of the client population rather than a sample, and is not being extrapolated to any larger population), 17
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8			(b) Report category boundaries when continuous variables were categorized – pg 7
9			
10			(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period – N/A
11	Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses – N/A
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14	Discussion		
15	Key results	18	Summarise key results with reference to study objectives – pp13-18
16	Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias – pp 18-19
17			
18	Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence – pp 13-18
19			
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21			
22	Generalisability	21	Discuss the generalisability (external validity) of the study results – pg 19
23			
24	Other information		
25	Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based – pg 20
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*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

**Progress in Voluntary Medical Male Circumcision for HIV
Prevention
Supported by the United States President's Emergency Plan
for AIDS Relief through 2017:
Longitudinal and Recent Cross-sectional Program Data**

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7 **Progress in Voluntary Medical Male Circumcision for HIV Prevention**
8 **Supported by the United States President's Emergency Plan for AIDS Relief through 2017:**
9 **Longitudinal and Recent Cross-sectional Program Data**

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ABSTRACT:

OBJECTIVE This article provides an overview and interpretation of the performance of PEPFAR's male circumcision program, which has supported the majority of voluntary medical male circumcisions performed for HIV prevention, from its 2007 inception through 2017, and client characteristics in 2017.

DESIGN Longitudinal collection of routine program data and disaggregations.

SETTING 14 countries in sub-Saharan Africa with low baseline male circumcision coverage, high HIV prevalence, and PEPFAR-supported voluntary medical male circumcision programs.

PARTICIPANTS Clients of PEPFAR-supported voluntary medical male circumcision programs directed at males aged 10 years and above.

MAIN OUTCOME MEASURES Numbers of circumcisions performed and disaggregations by age band, result of HIV test offer, procedure technique, and follow-up visit attendance.

RESULTS PEPFAR supported a total of 15,269,720 circumcisions in 14 countries in southern and eastern Africa. In 2017, 45% of clients were under 15 years of age, 8% had unknown HIV status, 1% of those tested were HIV+, and 84% returned for a follow-up visit within 14 days of circumcision.

CONCLUSIONS Over 15 million VMMCs have been supported by PEPFAR since 2007. VMMC continues to attract primarily young clients. The nontrivial proportion of clients not testing for HIV is expected, and may be reassuring that testing is not being presented as mandatory for access to circumcision, or in some cases reflect test kit stockouts or recent testing elsewhere. While VMMC is extremely safe, achieving the highest possible follow-up rates for early diagnosis and intervention on complications is crucial, and programs continue to work to raise follow-up rates. The VMMC program has achieved rapid scale-up but continues to face challenges, and new approaches may be needed to achieve the new UNAIDS goal of 27 million additional circumcisions through 2020.

STRENGTHS AND LIMITATIONS OF THIS STUDY:

- The large dataset covers eleven years of program data on over 15 million men.
- PEPFAR-supported clients constitute a large majority of all voluntary medical male circumcision clients, making client characteristics reported here likely to be representative of the program as a whole.
- The multicountry nature of the data allows determination of client characteristics common across settings.
- The routine reporting system is aggregate only, and collected data does not support analyses of associations between client characteristics.
- Data are not complete for all client characteristics (disaggregations) in all countries.

INTRODUCTION:

Male circumcision, the removal of the foreskin, reduces a man's risk of acquiring HIV through heterosexual exposure by approximately 60 percent.^{1,2,3} Since its adoption as a recommended HIV prevention strategy by the World Health Organization (WHO) and Joint United Nations Programme on HIV/AIDS (UNAIDS) in 2007,⁴ voluntary medical male circumcision (VMMC) has become a core component of the global HIV prevention portfolio through support by national and global programs, such as the United States President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis and Malaria.⁵ The WHO/UNAIDS's guiding document for VMMC from 2012-2016 recommended scale-up of VMMC in 14 countries in southern and eastern Africa with high HIV prevalence, low circumcision coverage and primarily heterosexual HIV transmission,⁶ with an initial goal of circumcising 20 million men to achieve 80% coverage among males aged 15-49 years in these countries by 2016. As a one-time biomedical intervention conferring lifelong partial protection from HIV, and the only prevention method specifically targeted at HIV-negative heterosexual men, VMMC complements other behavioral and clinical prevention interventions such as condom promotion, reduction in number of sex partners, pre-exposure prophylaxis, and treatment-as-prevention.

VMMC services were launched progressively by ministries of health in each of the recommended 14 countries between 2007 and 2011, primarily with PEPFAR support. PEPFAR-supported VMMCs are surgical or procedural interventions often lasting 5-15 minutes,⁷ provided by physicians or nurses under local anesthesia. They are offered with the WHO-recommended minimum package⁸ of accompanying services, including the offer of HIV testing and linkage to care and treatment for HIV-positive individuals, HIV risk-reduction education, condom provision, and sexually transmitted infection (STI) screening and treatment or referral. Over the lifetime of the program, several additional key innovations with potential to impact the volume and client demographics of the program have also been incorporated. These include the introduction of WHO-prequalified circumcision devices as

1 alternatives to conventional surgery; the introduction of WHO “Models for Optimizing Volume and
2 Efficiency”;⁹ the identification of the 15-29 year age group as the focal demographic for rapidly
3
4 reducing population-level HIV incidence through VMMC;¹⁰ enhancement of safety measures based on
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6 accumulating data, particularly for adolescents based on their unique surgical safety requirements;
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9 introduction of policies on tetanus vaccination prior to VMMC;¹¹ and increased emphasis on linking
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11 clients testing HIV-positive to care and treatment,¹² to support WHO/UNAIDS treatment scale-up
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13 goals.¹³
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18 All PEPFAR-supported VMMC programs report on key program outcomes, including the total
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20 VMMCs performed in each country and select disaggregations for all clients: client age range, result of
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22 HIV test offer, circumcision technique (device or surgical), and adherence to routine post-operative
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24 follow-up. These indicators provide an overview of the accomplishments and key current attributes of
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26 the PEPFAR VMMC program. This article presents all PEPFAR-supported VMMCs performed since
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28 program inception in 2007, compares key disaggregations from U.S. fiscal year 2017 with those from
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30 2015 and 2016, and discusses future challenges and directions for the program. The primary objective
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32 of this paper is to describe PEPFAR’s VMMC program, and identify in which aspects the program is
33
34 performing well and in which gaps and challenges remain and should be prioritized. Making key
35
36 demographic data on VMMC clients available may also support refining projections around impact.
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38 Client characteristics described here are expected to be reasonably representative of the global VMMC
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40 clientele to date because PEPFAR supports the majority of VMMCs conducted globally (approximately
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42 82% through 2016)¹⁴, and because VMMC donors operate under the common WHO minimum package
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44 service structure.
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51 **METHODS:**

52 Data reported by PEPFAR-supported VMMC programs are drawn initially from site-level client
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54 registers and records, and reported by the implementing partners at the site level to PEPFAR in each
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1 host country. Data are then cleaned in-country; and then reported to PEPFAR's central coordinating
2 body, the Office of the Global AIDS Coordinator. Implementing partners also report to their host
3 country governments, following procedures agreed upon in-country; this may occur independently or
4 may use the same data stream. Data are currently reported to PEPFAR on a quarterly basis, and then
5 grouped by U.S. Government fiscal year, which runs October 1st through September 30th, rather than by
6 calendar year. These numerical data are now available online¹⁵ and were used here to calculate
7 percentages where relevant. Monitoring trends across years is possible, but prior to 2015, fewer VMMC
8 disaggregations were collected.

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21 The disaggregations reported for VMMCs performed, and definitions where needed, are listed in
22 table 1. Their rationales and context are summarized below. Not all sites are able to collect and report
23 circumcision data by each disaggregate for all clients. Therefore, percentages presented here for each
24 disaggregate are calculated only among clients for whom data on that disaggregate were reported.

Table 1: Disaggregations and Categories for PEPFAR-supported VMMC program reporting on VMMCs performed, 2016

Disaggregation	Client Categories
Age	<ul style="list-style-type: none"> - < 61 days (early infant male circumcision) - 2 months-<10 years (not funded by PEPFAR due to safety concerns) - 10-14 years (this and younger categories are collapsed here as '<15') - 15-19 years - 20-24 years - 25-29 years - 30-49 years - 50+ years
Result of HIV test offer at VMMC site	<ul style="list-style-type: none"> - HIV+ - HIV - - Unknown: includes clients with undocumented or indeterminate status and those not tested at the VMMC site for any reason
Technique	<ul style="list-style-type: none"> - Surgical - Device-based
Follow-up visit attendance	<ul style="list-style-type: none"> - Returned for at least one post-operative follow-up visit within 14 days of surgery - Did not return within 14 days

- 1) Client age range: Age ranges represent those selected for PEPFAR routine reporting to support fine analysis of client age patterns. PEPFAR's prioritization of, or "age pivot" to, the 15-29 year age range began in fiscal year 2016. Ages below 15 years constitute the largest combined proportion of VMMCs performed, but will have delayed impact on the HIV epidemic due to the delay until sexual debut and other risk behaviors. These age ranges are collapsed together in this report.
- 2) Result of HIV test offer at VMMC site: Under PEPFAR¹⁶, UNAIDS¹⁷ and WHO¹⁸ guidance active in 2016, HIV testing at the VMMC site should be encouraged but is not required for access to VMMC, and clinically eligible clients who do test may proceed with VMMC regardless of their results. As a disaggregation within the cohort of clients receiving VMMC, this reporting does not include men who were tested at VMMC sites but then decided against VMMC after receiving a positive HIV test result. This may not be unusual, as men testing

1 positive are counseled that circumcision will not affect the course of their HIV infection and
2 may choose not to proceed.
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6 3) Circumcision technique used: Circumcision devices offer an alternative to surgery, and
7 advantages include faster procedures and potentially avoiding the injection of anesthesia and
8 incision of living tissue. Initially, PEPFAR-supported circumcision was exclusively surgical,
9 using one of three WHO-recommended techniques: forceps-guided, dorsal slit, and sleeve
10 resection.¹⁹ With WHO prequalification of the PrePex device in 2013²⁰ and ShangRing in
11 2015,²¹ some ministries of health have introduced device-based services as additional options
12 for clients. Both PrePex and ShangRing devices remain on the penis for seven days and are
13 removed by a provider during a follow-up visit. Anatomic and age-based eligibility criteria
14 vary between devices and can be stricter than surgical eligibility criteria, restricting the pool
15 of eligible clients.²² Numbers of circumcisions performed using a device therefore reflect
16 national policies and eligibility for, as well as availability and client uptake of, these
17 alternative methods. They also reflect the impact of tetanus mitigation policies as discussed
18 below.
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36 4) Follow-up visit attendance: PEPFAR-supported programs follow fixed schedules for routine
37 postoperative follow-up set by national ministries of health to ensure client safety. These
38 often include a return visit at days two and seven after surgery, or day seven after device
39 placement (for device removal). In 2015 and 2016, the PEPFAR follow-up indicator was
40 only reported among surgical cases, which therefore constituted the denominator for
41 determining follow-up percentage; in 2017 it was calculated among all circumcisions.
42 Followup was only reported on if it took place, so that clients who did not follow up cannot
43 be distinguished from those whose followup status is unknown.
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1 Comparison data on country-specific total annual VMMC volume (including both PEPFAR-
2 supported and non-PEPFAR supported procedures) is drawn from the most recent WHO VMMC
3 Progress Brief, covering 2007-2016.¹⁴ Data on PEPFAR's 2017 country-level VMMC targets is drawn
4 from annual PEPFAR Budget and Target reports.²³

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11 *Patient and public involvement:* Because this manuscript reports program data rather than
12 research data, no research question or study design was formulated for data collection. Data collected
13 instead consists of indicators designed to monitor program achievements. VMMC clients were
14 beneficiaries choosing to uptake a public health interventions, not research participants. However,
15 satisfied VMMC clients are sometimes involved in recruiting peers for VMMC. Results are publically
16 available online as referenced above.

26 RESULTS:

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29 From PEPFAR fiscal year 2007 through 2017, a total of 15,269,720 PEPFAR-supported
30 VMMCs were performed in 14 countries in southern and eastern Africa. From 2010 through 2014,
31 annual VMMC numbers approximately doubled annually, reaching 2,794,808 in 2014. In 2015,
32 2,573,273 VMMCs were performed, followed in 2016 by 2,290,200; these represented the third- and
33 fourth-highest annual totals. The year 2017 saw an increase to 3,665,866, the highest annual total to
34 date. Over half (54%) of PEPFAR-supported circumcisions performed since the program's inception
35 were performed in 2015-2017 (Figure 1, Table 2). In 2016, the latest year for which WHO national-
36 level data is available, PEPFAR-supported VMMCs constituted 80% of all VMMCs reported by WHO,
37 and 55% or more of reported VMMCs in each individual country except Rwanda.¹⁴ VMMCs conducted
38 in 2017 achieved 92% (3,664,531/3,665,866) of PEPFAR targets for that year, with nine countries
39 reaching 90% or more of their targets.

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2 Twelve countries provided >85% data completeness across all disaggregations in 2017 for which
3 completeness was calculable. By disaggregate, 3,278,130 clients had age data (387,736 missing =
4 12%); 3,309,077 had result of HIV test offer (including unknown status; 356,789 missing = 11%);
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6 3,282,987 had technique data (382,879 missing = 12%); of whom 2,736,851 had a reported follow-up
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8 within 14 days. Because programs only reported the number of clients who received follow-up in 2017,
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10 and did not separately report the number which did not, we are unable to assess completeness for this
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12 disaggregate (but see table 2 footnote). Where data completeness for a given disaggregate in a country
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14 (sum of all VMMC's across categories for that disaggregate, divided by total VMMC's performed) was
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16 less than the 85% threshold we selected for this analysis, values are bolded (Table 3).
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23 In 2017, 48% of VMMC clients were within the 15-29 years age range, to which PEPFAR
24 shifted focus that year, a relatively stable proportion from 46% in 2016 and 48% in 2015. There was
25
26 wide variation among countries, ranging from 25% in Botswana to 68% in Rwanda. In contrast, 45% of
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28 PEPFAR VMMC clients were within the 10-14 years range, representing a stable increase, along with
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30 46% in 2016, from 42% in 2015. Eight countries experienced an increase in the proportion of clients in
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32 the 10-14 year age range from 2016 to 2017. This shift was largest in Rwanda (5% to 28%), Botswana
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34 (45% to 66%), and Namibia (12% to 34%), all relatively small programs. However other programs, like
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36 South Africa, did successfully achieve the reverse (43% in 2017, from 51% in 2016). Countries which
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38 had previously shifted in 2016 toward younger clientele included several large programs which also
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40 showed decreases in overall achievements in that year, such as Tanzania, South Africa and Zambia,
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42 though in the first two cases this trend reversed in 2017.
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PEPFAR circumcisions through 2017

Table 2: Annual PEPFAR-funded VMMCs performed by country, 2007-2017, and PEPFAR 2017 VMMC targets*

Country	2007-2009	2010	2011	2012	2013	2014	2015	2016	2017	2017 PEPFAR Target	Total
Botswana	5,180	534	0	8,590	12,464	13,893	7,712	24,201	22,645	20,911	95,219
Ethiopia	0	3,110	8,236	12,445	16,393	11,831	11,307	14,335	13,782	17,184	91,439
Kenya	45,657	112,574	182,788	158,278	214,851	229,390	233,813	264,490	227,272	240,010	1,669,113
Lesotho	0	0	199	6,971	36,418	39,175	28,909	31,709	25,445	40,573	168,826
Malawi	0	0	778	13,314	67,384	68,334	90,820	82,381	99,435	109,348	422,446
Mozambique	0	4,009	18,946	79,002	129,581	160,660	187,186	241,793	315,239	427,536	1,136,416
Namibia	117	1,229	5,379	6,121	0**	785	9,927	15,116	27,736	34,746	66,410
Rwanda	0	896	3,922	17,639	36,441	74,803	65,048	50,204	175,902	95,936	424,855
South Africa	18,100	14,956	72,004	170,849	294,977	327,473	472,047	355,917	460,668	428,486	2,186,991
Swaziland	3,802	19,728	13,399	14,456	9,708	11,934	12,156	16,003	15,071	18,616	116,257
Tanzania	262	21,581	117,351	151,915	381,394	554,673	615,089	519,437	696,572	696,449	3,058,274
Uganda	0	9,052	57,132	352,039	742,978	906,615	466,650	330,343	753,198	1,011,964	3,618,007
Zambia	0	21,236	63,444	103,517	199,372	239,464	216,394	185,028	323,180	271,260	1,351,635
Zimbabwe	0	9,811	30,608	36,765	88,114	155,778	156,215	159,243	227,299	252,847	863,833
Total	73,118	218,716	574,186	1,131,900	2,230,075	2,794,808	2,573,273	2,290,200	3,383,444	3,665,866	15,269,720

PEPFAR circumcisions through 2017

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* Fiscal years

** PEPFAR support for VMMC in Namibia was paused for strategic planning in 2013.

PEPFAR circumcisions through 2017

Table 3: Numbers and Characteristics of PEPFAR-funded Voluntary Medical Male Circumcisions, Fiscal Year 2017 (Oct. 1, 2016-Sept 30, 2017) by country and 2015-2016 totals

Country	VMMCs	Client Age Range in Years (%)*						Result of HIV test offer at VMMC site (%)		Technique: Device Method Used (%) (vs. Surgical)	Follow-up Visit Attendance **(%)
		<15	15-19	20-24	25-29	30-49	50+	HIV+ among tested clients	Unknown status*		
Botswana	22,645	66	10	9	7	7	1	0	18	0	72
Ethiopia	13,782	47	26	14	6	7	0	0	32	0	96
Kenya	227,272	60	23	9	5	3	0	0	2	1	80
Lesotho	25,445	56	18	8	6	10	1	2	50	0	90
Malawi	99,435	42	28	15	8	6	0	1	0	0	89
Mozambique	315,239	45	30	13	6	5	1	2	6	0	81
Namibia	27,736	34	21	15	13	16	1	1	44	0	99
Rwanda	175,902	28	48	15	6	4	0	0	0	53	100
South Africa	460,668	43	22	12	10	11	1	2	20	0	59
Swaziland	15,071	54	29	10	3	3	1	3	1	0	99
Tanzania	696,572	46	26	15	6	6	1	0	13	0	92
Uganda	753,198	46	26	13	8	6	1	1	3	0	86
Zambia	323,180	38	27	16	10	9	0	0	4	0	94
Zimbabwe	227,299	47	25	13	8	7	0	0	0	5	***
Total in 2017	3,383,444	45	27	13	8	7	1	1	8	3	84
Total in 2016	2,290,141	46	27	12	7	7	1	1	9	4	78
Total in 2015	2,573,238	42	28	13	7	8	1	1	7	5	72

Bolded entries indicate <85% data completeness.

* Includes clients with undocumented or indeterminate status and those not tested at the VMMC site for any reason

** Percent of clients who returned for at least one post-operative follow-up visit within 14 days of surgery or device placement

*** Followup rate in Zimbabwe unknown for 2017. Facilities representing 46% of all Zimbabwe circumcisions did not report followup data, due to delays in adoption of the new follow-up reporting method.

PEPFAR circumcisions through 2017

Overall, 8% of clients had “unknown” HIV status in 2017, as compared to 9% in 2016 and 7% in 2015, with individual country values ranging from 0% in Rwanda and Zimbabwe to 50% in Lesotho; other countries with high “unknown” rates were Ethiopia at 32% and Namibia at 44%. Among clients tested for HIV, 1% were positive, essentially unchanged from 2015-2016, with individual country positivity varying between 0% in Zimbabwe, Tanzania, Mozambique and Ethiopia, and 5% in Malawi.

Device-based circumcision techniques constituted a small percentage of circumcisions in all countries in 2017, accounting for 3% of VMMCs across countries (down from 5% in 2015 and 4% in 2016), ranging between 0% in many countries and 53% in Rwanda. Botswana and Zimbabwe showed substantial respective drops from 28% to 0% and 27% to 5%.

Post-procedure follow-up rates among all clients were 84% overall (excluding Zimbabwe), higher than the 72% in 2015 and 78% in 2016. These rates ranged between 59% in South Africa and 100% in Rwanda, falling at or above 75% in 11 countries.

DISCUSSION:

VMMC has undergone a scale-up of historic proportions within global health, comparable to the scale-up of HIV treatment.²⁴ This manuscript demonstrates that overall program volume is high and increasing, but there is progress to be made in increasing volume further to pursue Fast Track targets, attracting older clients with higher HIV risk and, in some places, raising postoperative follow-up rates to ensure complications are managed promptly.

PEPFAR circumcisions through 2017

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5 With respect to program volume, over 15 million PEPFAR-supported VMMC were performed
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7 between 2007 when support began and 2017, making VMMC a major prevention intervention for
8
9 achieving the PEPFAR goal of an AIDS-free generation through epidemic control in sub-Saharan
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11 Africa.²⁵ PEPFAR had committed in 2015 to supporting at least 13 million VMMCs through 2017,²⁶
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13 and exceeded that target. Models estimate that global VMMCs conducted through 2016 alone will avert
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15 500,000 infections by the end of 2030.¹⁴ Scale-up has been enabled not only by dedicated resources,
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17 totaling over \$1.5 billion through 2017 from PEPFAR alone, but also through leadership from ministries
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19 of health, rapid expansion of surgical skills and responsibilities to non-physician health cadres, and
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21 public outreach campaigns. It has provided millions of men with lifelong partial protection from HIV
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23 and some STIs, and connected them with additional HIV and other health services through testing, STI
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25 screening, and referrals for other health conditions. Infections averted in men through VMMC also help
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27 prevent new HIV infections among women and girls,^{27,28,29} and male circumcision is also associated
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29 with lower prevalence of a range of STIs in women.²⁹
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35 In light of the high proportion of global VMMCs supported, PEPFAR client data is also expected
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37 to provide a reasonably representative view of the global VMMC clientele to date. References to
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39 achievements and characteristics below refer to the PEPFAR program except where otherwise stated.
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43 All VMMC implementing countries continue to scale up VMMC. However, in 2015 and 2016
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45 there were substantial declines in PEPFAR VMMC achievements in Uganda (the largest contributor to
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47 VMMC results); these were mirrored by declines in total VMMCs achieved in Uganda.¹⁴ Service
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49 delivery and policy were impacted by the identification of tetanus as a risk among VMMC clients in the
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51 Ugandan setting, due to limited historical tetanus immunization coverage.^{30,31,32} WHO issued global
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53 recommendations that additional visits for tetanus vaccination be performed prior to circumcision using
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PEPFAR circumcisions through 2017

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4 device-based VMMC methods associated with increased risk of tetanus,³³ and the Uganda National
5 VMMC Program ultimately required an additional visit for tetanus vaccination prior to VMMC. Similar
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7 policies may have also impacted performance in other countries with significant device contributions
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9 (not shown) like Botswana and Rwanda. Additionally, a PEPFAR policy issued in late 2014
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11 discontinued the use of the forceps-guided surgical technique in young adolescents to avoid the
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13 associated risk for injury to the immature glans, causing some country programs to decrease VMMC
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15 provision to this age range until they could retrain their VMMC workforces in a more appropriate
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17 method. In 2016, Tanzania, South Africa and Zambia also experienced declines (Uganda had not
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19 previously reported age data), though these were accompanied by *increases* in client proportions in the
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21 10-14 age group, and were followed in 2017 by increases in overall performance and shifts toward older
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23 clientele. These 2016 declines may thus be due to strategic shifts in program geography and funding.
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25 Total program performance then increased substantially in 2017, with nine countries showing increases
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27 over 2016, including these largest programs. We attribute this recovery to resolution of the challenges
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29 described above, combined with increases in available resources.
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38 Country-level PEPFAR VMMC targets are set each year for the following year, based on
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40 previous years' achievements, available resources, overall ministry of health targets, and remaining
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42 unmet need to achieve saturation. In 2017, overall performance was well-matched to targets (92%),
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44 with variations including some countries with marked overperformance (Rwanda and Zambia) and
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46 others with high absolute performance but even more ambitious targets (e.g. Uganda, with the highest
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48 national PEPFAR VMMC performance ever reported). In addition to the policy factors discussed above,
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50 reasons for variation in performance against targets can include implementing partner capacity and
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PEPFAR circumcisions through 2017

ambition (partners may choose to surpass their targets once achieved, if funding remains) and unexpected external factors such as civil unrest and health care strikes.

VMMC client populations in 2017 were young, with males in the 10-14 years age range representing 45% of all PEPFAR VMMCs (virtually all VMMCs in clients <15 years are in the 10-14 year range), as compared to 12% of the combined male general population of the 14 implementing countries.³⁴ This represents a change from the program's historical client age distribution; from 2010 through 2013, clients in the 10-14 years age range characterized no more than one third of all clients in any year.³⁵ The 2015 distribution (42% of clients were aged <15 years) served as the baseline prior to implementation of the "age pivot"; yet the actual age balance shifted further toward the younger range in 2016 (46%), with only slight recovery in 2017, despite this focus. In some countries, the shift toward younger ages may partially reflect the maturation of the VMMC program: 'exhaustion' of older age ranges and replacement with younger males. Additional potential barriers which may apply disproportionately to older males include reluctance to abstain from sex for the 6-week healing period, perception of low risk due to having established partners, the opportunity cost of lost wages during recovery, and fear of creating perceptions in a stable partner that they intend to seek other sexual partners.^{36,37} Age ranges 30 years and above represented a small (8% in 2017) percentage of VMMC clientele, despite being a sexually active group at risk for HIV, possibly for similar reasons. However, some countries and individual partners did successfully make modest shifts toward older clientele, and identification and broader adoption of their best practices are called for.

VMMC clients also have low HIV positivity compared to the general population, 1% among all clients in 2015, 2016 and 2017, as compared to 5.5% (95% confidence interval 4.9-6.0%) prevalence among males aged 15-49 years in the southern and eastern Africa region in 2016.³⁸ The young age of

PEPFAR circumcisions through 2017

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4 the client population is almost certainly the major underlying factor; pre-adolescents and early
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6 adolescents have less exposure to sex and consequently less HIV risk and lower HIV prevalence than
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8 older age groups. Because HIV test results are not disaggregated by age group, this effect cannot be
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10 controlled for in PEPFAR VMMC reporting data. Lower HIV prevalence among VMMC clients could
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12 also reflect self-selection of men with health-protecting behaviors into the pool of VMMC clients and/or
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14 the effects of messaging promoting VMMC for HIV prevention, leading to the self-exclusion of men
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16 who know they are HIV-positive (including any who learn they are HIV-positive at the VMMC site and
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18 consequently opt out of VMMC). Despite this low prevalence, it should be noted that men in sub-
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20 Saharan Africa have lower HIV testing uptake than women³⁹ and the VMMC program provides an
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22 opportunity to reach men who might not otherwise undergo testing. The substantial proportion of clients
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24 with ‘unknown’ test results is expected, and may reflect the voluntary nature of HIV testing in VMMC,
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26 as well as the frequency of HIV test kit stockouts (e.g., Ethiopia and Namibia experienced intermittent
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28 stockouts in 2017).
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35 The fact that few circumcisions were performed by device methods throughout 2015-2017
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37 reflects in part the relatively short period that device-based circumcision has been available, as well as
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39 the rigorous country-level vetting process which new devices undergo when being introduced in a new
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41 country,⁴⁰ prior to nationwide rollout. It may also reflect current preferences of clients and programs.
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43 As of publication, all countries implementing PEPFAR-supported VMMC except Ethiopia and Namibia
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45 have begun the evaluation process for at least one device, although scale-up of device-based service
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47 delivery can take time even after evaluation is completed and policy is in place. Although devices offer
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49 several advantages over surgical circumcision, they require more intense post-market safety monitoring
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51 tailored to their mechanisms of action, until more VMMCs have been done using these methods. Most
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PEPFAR circumcisions through 2017

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4 recently, uptake of the most commonly-used device has also been negatively impacted by the WHO
5 advice and PEPFAR policy related to tetanus vaccination prior to device placement,⁴¹ driving the
6 decline noted from 2015-2017.
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12 Although the follow-up rate of 84% in 2017 is not precisely comparable to rates in 2015 and
13 2016 because of the inclusion of device followup, the low proportion of the program represented by
14 device MCs makes the apparent increase likely to constitute a true trend. Followup is also likely to be
15 underestimated, because all clients without a reported followup visit were treated in calculations as not
16 following up, rather than missing data. This is encouraging, but more remains to be done in countries
17 with low follow-up rates. There is evidence that adverse events (AEs) are actually more common among
18 males who do not return for follow-up than among those who do.⁴² While VMMC is extremely safe,⁴³
19 achieving high follow-up rates to allow early AE diagnosis and intervention is crucial for program
20 safety.
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34 The findings in this paper are subject to several limitations. These data reflect results supported
35 by PEPFAR, rather than country totals. Additionally, cross-tabulations between disaggregations are not
36 reported, and therefore it is not possible to determine associations between age range, result of HIV test
37 offer and procedure technique, or control for measured potential confounders. For reasons discussed
38 above, VMMC clients are not representative of the general male population of their countries; they are
39 younger, less likely to be HIV-positive, and possibly at lower behavioral risk; findings here are not
40 intended to be generalized outside the client population. Data entry errors such as those discussed above
41 for follow-up, and variations in reporting practice, are possible. Category definitions combine some
42 disparate groups (e.g. “unknown” test results include men who were not tested at VMMC sites for any
43 reason, whether preference, test kit shortage, or documentation of recent outside testing.) Finally, though
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PEPFAR circumcisions through 2017

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4 we believe client characteristics are representative of those of all VMMC clients, PEPFAR's focus on
5 the areas of each country with highest absolute HIV burden⁴⁴ could mean that clients of other VMMC
6 programs in other areas (which may have lower HIV incidence and prevalence, or simply be less
7 densely populated) differ demographically, in unknown ways.
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14 The global VMMC program's achievements to date have demonstrated the feasibility of rapid
15 scale-up of circumcision coverage, but program strategy will need to continue evolving for several
16 reasons. Though current achievements have totaled the majority of the initial global target, this target
17 was recently revised under the new UNAIDS Fast Track framework to include 27 million additional
18 circumcisions by the end of 2020,⁴⁵ a necessary component of achieving the Fast Track strategy's
19 projected impact. Among these, attracting the PEPFAR priority subpopulation of clients in the 15-29
20 years age range, and ideally other high-risk clients who will benefit most from VMMC, may require new
21 demand creation approaches and service delivery models. Finally, the updated 2016 WHO/UNAIDS
22 framework for VMMC⁴⁶ calls for circumcision programs to shift from largely stand-alone service
23 delivery toward greater integration within a broad platform of adolescent and adult male reproductive
24 health. Strategies that reached "early adopters" may differ from those needed to reach the remaining
25 uncircumcised men, and to do so within this integrated platform. To achieve the ambitious goals in this
26 framework, substantial engagement and increased resource commitments from stakeholders other than
27 PEPFAR, including national ministries of health, will be needed.
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1 PEPFAR circumcisions through 2017
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24 **CONTRIBUTORSHIP:** Stephanie M. Davis drafted and finalized the manuscript.
25

26 Jonas Hines, Melissa Habel, Jonathan M. Grund, Renee Ridzon, Jonathan Davitte, Anne Thomas,
27 Valerian Kiggundu, Caroline Cooney, and Naomi Bock revised the manuscript.
28

29 Brittney Baack and Paran Pordell revised the data and manuscript.
30

31 Carlos Toledo conceived of the paper, obtained the data, and revised the manuscript.
32

33 Irum Zaidi oversaw all data collection.
34
35
36

37 **DATA SHARING:** As described in this article, the dataset underlying the tables and results is
38 publically available at <https://data.pepfar.net/quarterlyData/> .
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46 **ETHICAL STATEMENT:** Use of this routinely collected, aggregate-only program data was reviewed
47 and approved by CDC Human Subjects Protection.
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51 **RESEARCH REPORTING CHECKLISTS:** Because this manuscript is based on routinely collected
52 program data and does not examine associations between risk factors and outcomes, none of the
53
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1 PEPFAR circumcisions through 2017
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4 standard checklists are entirely applicable, including per EquatorWizard. At the editors' request, the
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6 STROBE checklist has been filled and included with resubmission.
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PEPFAR circumcisions through 2017

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Figure Legend

Figure 1: Cumulative Number of PEPFAR-supported Voluntary Medical Male Circumcisions by Country, 2007-2017

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PEPFAR circumcisions through 2017

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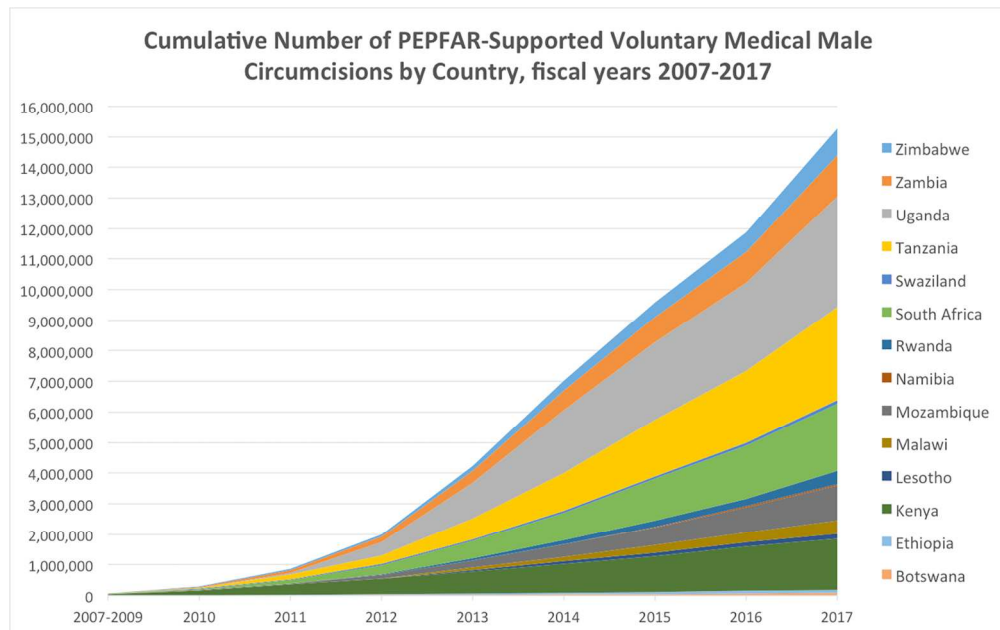


Figure 1: Cumulative Number of PEPFAR-supported Voluntary Medical Male Circumcisions by Country, fiscal years 2007-2017

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STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract – pg 1 (page numbers are for clean version) (b) Provide in the abstract an informative and balanced summary of what was done and what was found – pg 2
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported – pg 4-6
Objectives	3	State specific objectives, including any prespecified hypotheses – pg 5
Methods		
Study design	4	Present key elements of study design early in the paper – pg 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection – pp 4-6
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants – pg 5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable – pg 7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group – pg 7
Bias	9	Describe any efforts to address potential sources of bias – pg 18 (this is a limitation of the way program data is collected)
Study size	10	Explain how the study size was arrived at – pg 5 (all clients – program data)
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why – pg 7-10
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding – pg 6-8, 18 (b) Describe any methods used to examine subgroups and interactions - N/A (no subgroups, no interactions) (c) Explain how missing data were addressed – pg 6, 10 (d) If applicable, describe analytical methods taking account of sampling strategy (N/A) (e) Describe any sensitivity analyses (N/A)
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed - pg 10 provides total numbers, but there are no exclusion stages for program data like those described above (b) Give reasons for non-participation at each stage - N/A (c) Consider use of a flow diagram - N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders – pg 12 (b) Indicate number of participants with missing data for each variable of interest – pg 11
Outcome data	15*	Report numbers of outcome events or summary measures – pg 12

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2	Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included – pg 12 (confidence intervals are not applicable because the data represents a census of the client population rather than a sample, and is not being extrapolated to any larger population), 17
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8			(b) Report category boundaries when continuous variables were categorized – pg 7
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10			(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period – N/A
11	Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses – N/A
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13			
14	Discussion		
15	Key results	18	Summarise key results with reference to study objectives – pp13-18
16	Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias – pp 18-19
17			
18	Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence – pp 13-18
19			
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22	Generalisability	21	Discuss the generalisability (external validity) of the study results – pg 19
23			
24	Other information		
25	Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based – pg 20
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*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.