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# Strategies to improve antiretroviral therapy (ART) initiation and early engagement among men in sub-Saharan Africa: A scoping review of interventions in the era of universal treatment

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#### Abstract

**Objectives:** Men in sub-Saharan Africa (SSA) have lower rates of antiretroviral therapy (ART) initiation and higher rates of early default than women. Little is known about effective interventions to improve men's outcomes. We conducted a scoping review of interventions aimed to increase ART initiation and/or early retention among men in SSA since universal treatment policies were implemented.

**Methods:** Three databases, HIV conference databases and grey literature were searched for studies published between January 2016 to May 2021 that reported on initiation and/or early retention among men. Eligibility criteria included: participants in SSA, data collected after universal treatment policies were implemented (2016–2021), quantitative data on ART initiation and/or early retention for males, general male population (not exclusively focused on key populations), intervention study (report outcomes for at least one non-standard service delivery strategy), and written in English.

**Results:** Of the 4351 sources retrieved, 15 (reporting on 16 interventions) met inclusion criteria. Of the 16 interventions, only two (2/16, 13%) exclusively focused on men. Five (5/16, 31%) were randomised control trials (RCT), one (1/16, 6%) was a retrospective cohort study, and 10 (10/16, 63%) did not have comparison groups. Thirteen (13/16, 81%) interventions measured ART initiation and six (6/16, 37%) measured early retention. Outcome definitions and time frames varied greatly, with seven (7/16, 44%) not specifying time frames at all. Five types of interventions were represented: optimising ART services at health facilities, community-based ART services, outreach support (such as reminders and facility escort), counselling and/or peer support, and conditional incentives. Across all intervention types, ART initiation rates ranged from 27% to 97% and early retention from 47% to 95%.

**Conclusions:** Despite years of data of men's suboptimal ART outcomes, there is little high-quality evidence on interventions to increase men's ART initiation or early retention in SSA. Additional randomised or quasi-experimental studies are urgently needed.

#### **KEYWORDS**

care continuum, evidence-based interventions, gender disparities, men, scoping review

### **INTRODUCTION**

Kathryn L. Dovel and Santhi Hariprasad contributed equally to this work. Sustainable Development Goal: Good Health and Wellbeing. Men in sub-Saharan Africa (SSA) experience gender disparities across HIV outcomes compared to women. Men

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living with HIV are at a greater risk of not starting antiretroviral therapy (ART) [1, 2] and greater risk of treatment interruption in the first 8 months after initiation [1, 3]. Improving men's ART initiation and retention is essential to decrease HIV mortality among men and reduce HIV transmission to men's sexual partners [4, 5]. As a result, there is an emerging programmatic focus on men's HIV care [6–8]. Yet, little is known about what types of interventions are effective for this population [9, 10]. It is critical that these resources be focused on proven, scalable interventions to promote ART initiation and early retention.

Recent innovations such as HIV self-testing (HIVST) and same-day ART initiation have reduced barriers to HIV services [11–15]. However, these interventions may simply delay disengagement to a later stage in the treatment cascade, from testing-related barriers to initiation, or from initiation-related barriers to retention. Early retention (largely recognised as the first three to 8 months after initiation) poses a significant challenge due to the frequent facility visits required during this period, and clients' need to develop resiliency strategies and build social support systems around their new HIV status [16-18]. Individuals may still be processing their diagnosis and not yet have disclosed their HIV status or have a support system [19]. Early retention may be particularly difficult for men as they often have fewer tools to navigate these challenges. Historically, men have less exposure to the healthcare system (HIV and non-HIV services) than women [20, 21], healthcare systems are often not 'male friendly', and work demands and related mobility may conflict with regular clinic attendance [22, 23]. Further, most ART counselling curricula are for general populations and do not include tailored messaging for men that is needed to relate to men's unique experiences and foster the internal motivation to engage in care [24–26].

Most research on ART initiation and early retention has focused on either women or the general population [27, 28]. Effective interventions include home- or community-based ART distribution to improve access to care [9, 29-31], intensive, peer-based counselling to help clients navigate intra- and inter-personal barriers to care [32, 33], and same-day ART initiation to streamline initiation [14, 34]. While this evidence is promising, it is not known whether these strategies are effective for men. Further, most of these studies were implemented prior to universal treatment policies, whereby clients are eligible for ART regardless of CD4 count or WHO staging. The majority of clients under universal treatment now feel healthy when being offered ART services and the immediate benefits of ART engagement may not be clear [35, 36]. Therefore, older findings may no longer be relevant under universal treatment policies.

We conducted a scoping review to identify and describe interventions to increase ART initiation and early retention (in the first 8 months after initiation) among men in SSA under universal treatment.

### METHODS

We aimed to answer the following questions through a scoping review of current literature (2016–2021). The primary question was: What recent interventions aim to increase ART initiation and/or early retention among men in SSA under universal treatment? The secondary question was: What gaps in the current evidence base exist across (1) populations represented, (2) methodological approaches used and (3) outcome measurements?

We conducted a scoping review using the original framework of Arksey and O'Malley [37], which was subsequently extended by Levac and colleagues [38]. The review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analysis extension for scoping reviews (PRISMA-ScR) checklist as outlined below [39]. The full protocol is available elsewhere [40].

### Eligibility criteria

We included studies of interventions that: (1) were conducted under universal treatment policies (which started for most countries in SSA in 2016); (2) included quantitative data on ART initiation or re-initiation and/or early retention for males (defined as retention outcomes within the first 8 months after initiation, to be as inclusive as possible); (3) reported findings for the general male population (not exclusively focused on key populations) and had a sample of at least 30 men; (4) had a study site located in SSA; and (5) had a manuscript or abstract available in English. We searched for sources published from 1 January 2016 to the date of our last review of the literature (9 May 2021). For sources where data were collected both pre- and postuniversal treatment, we only included the source if data were disaggregated by pre-/post-universal treatment. We included interventions that specifically focused on men, as well as those for men and women that included sex-disaggregated results or noted there were no statistically significant differences in outcomes by sex. For sources that met all inclusion criteria except for sex-specific outcome data, we contacted authors to request sex-specific data or analyses.

#### Search strategy

We created a search string using Medical Subject Headings (MeSH), keywords, and filters as appropriate (Table 1). This string was used to search the PubMed database and then adapted for use in the Medline, Cochrane Central Register of Controlled Trials, and the CABI Global Health databases. Conference abstracts for the poster and oral presentations from the Conferences on Retroviruses and Opportunistic Infections (CROI) and the International AIDS Society (IAS) were reviewed from 2016 to 2021. We conducted supplemental searches using Google Scholar with similar keywords to identify additional grey literature.

Concept	MeSH	Text keywords	Search strategy (Ovid MEDLINE)
ART	<ul> <li>'Anti-Retroviral Agents'(1)</li> <li>'Anti-Retroviral Agents' [Pharmacological Action]</li> <li>'Antiretroviral Therapy, Highly Active'(1)</li> <li>'Anti-HIV Agents'(1)</li> </ul>	ART Antiretroviral retroviral HAART Retroviral	('Anti-Retroviral Agents'/ or 'Antiretroviral Therapy, Highly Active'/ or 'Anti-HIV Agents'/ or (art or haart or antiretroviral or retroviral). ti,ab,kw)
Initiation or early retention	'Sustained Virologic Response'	Initiat <sup>*</sup> Uptake Retention Retain <sup>*</sup> Linkage 'Viral suppression'	((initiat* or uptake or ((retention or retain*) adj2 (month* or early or care)) or linkage or linked or 'viral suppression' OR 'virological suppression').ti,ab,kw or 'Sustained Virological Response'/)
Sub-Saharan Africa	'Sub-Saharan Africa'	*Saharan Africa	(Angola, Benin, Botswana, Burkina Faso, Burundi, Cabo Verde, Cameroon, Central African Republic, Chad, Comoros, Congo, Democratic Republic of, Congo, Republic of Cote d'Ivoire, Equatorial Guinea, Eritrea, Eswatini (Formerly Known as Swaziland), Ethiopia, Gabon, Gambia, The, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, Sao Tome and Principe, Senegal, Seychelles, Sierra Leone, Somalia, South Africa, South Sudan, Sudan, Tanzania, Togo, Uganda, Zambia, Zimbabwe)
Intervention/facilitators	'Health Services Accessibility' 'Referral and Consultation' 'Continuity of patient care' 'Patient acceptance of health care' 'Study characteristics'	Intervention* Trial Random* Program* project Retrospective prospective Facilitat* Strateg*	((intervention* or trial or random* or program* or project* or retrospective or prospective or facilitat* or strateg*).ti,ab,kw)
Publication year limit			2016:2021.(sa_year)

**TABLE 1** Search strings.

Note: \* 'Wildcard' characters used in literature search.

#### Selection of sources of evidence

We entered results from the search strategy into an Endnote [41] database and removed duplicates. Two reviewers conducted a title and abstract review and removed sources that did not meet study inclusion and exclusion criteria. The full text of the remaining sources was independently reviewed by three reviewers, with any conflicts resolved by KD.

#### Data charting process

We developed a data-charting form (Excel spreadsheet) based on the study objectives. Information included: study and participant characteristics (e.g., country, year of data collection, eligibility criteria), details of intervention and comparison models (e.g., location, frequency and services provided), initiation and early retention outcomes, and any concerns regarding quality (including potential bias in data collection, reporting, or analysis). Data were entered directly into the structured data-charting form independently by two authors. After all data were entered into the data-charting form, lead authors reviewed and refined the form iteratively. Any inconsistencies were reconciled and KD performed spot-checks.

If ART initiation was not reported, a related outcome measure (e.g., linkage to care) was extracted as a proxy. For early retention, a range of time frames (4–9 months) and measure types (e.g., viral load taken, retention in care) were extracted.

#### Synthesis

We categorised interventions into types using Duncombe's framework for differentiating service delivery models [42]. The authors reviewed each intervention and considered how best to categorise it based on: (1) type of services delivered (e.g., counselling or support, direct ART distribution); (2) location of service delivery (e.g., facility, community); (3) provider of health services (e.g., peer, provider); and (4) frequency of health services [42]. We summarised interventions, outcome measures and study designs overall and by intervention type.

Identification

Screening

Eligibility

Included



Intervention type	Definition (examples)	n (%)
Facility-based services	Interventions that primarily focused on changes to protocols or services within facilities.	3 (19%)
Community-based services <sup>a</sup>	ART dispensed outside the health facility	4 (25%)
Outreach <sup>a</sup>	Community-based activities to identify those in need of ART services and/or to promote linkage to a health facility	4 (25%)
Counselling/peer support	Ongoing, intensive counselling to initiaton and/or support early retention by identifying and resolving barriers to care	3 (19%)
Conditional incentives	At least one opportunity to receive monetary/non-monetary incentives conditional on one's engagement in ART services	2 (13%)

<sup>a</sup>Mwango et al. [43] included two interventions in one publication (community-based and outreach intervention types) and was therefore counted twice.

### RESULTS

A total of 5493 data sources were identified. After removal of 1631 duplicates and review of 3862 titles, 210 data sources qualified for full review. Under full review we excluded 195 (Figure 1) for the following reasons: outcomes did not fit criteria (n = 72, 37%); not an intervention study (n = 49, 25%); and data not disaggregated by sex (n = 43, 22%). Overall, 15 data sources met all eligibility criteria; they were published between 2018 and 2021 (no sources from 2016 to 2017). One data source [43] reported on two different interventions that met the eligibility criteria, therefore we included 16 interventions in the data synthesis.

The 16 interventions fit into five overarching types: facility-based services (n = 3) [44–46]; community-based services (n = 4) [43, 47–49]; outreach (n = 4) [43, 50–52]; counselling/peer support (n = 3) [53–55]; and conditional incentives (n = 2) [56, 57] (Table 2).

### Settings and populations of included interventions

All but one (15/16, 94%) of the interventions took place in southern or eastern Africa [43-47, 49-57] (Table 3) with one intervention in western Africa [48]. Almost half (7/16, 44%) of interventions were among rural populations [44, 47-49, 51, 52, 57], a quarter (4/16, 25%) among urban populations [45, 46, 55, 56] and nearly a third (5/16, 31%) included both urban and rural populations. [43, 50, 53, 54]

Only two interventions (13%) focused exclusively on men [56, 57], with most (14/16, 87%) including both men and women [43–54, 56]. The number of men participating in each intervention ranged from 33 to 3010. None of the studies specified sexual orientation or whether participants were cis- or transgender. Most interventions (14/16, 87%) enrolled individuals who were not on ART; while two [44, 56] (13%) enrolled clients who were actively on ART at the time of enrolment and focused only on early retention. Five

		J/.						
Study	Study design	Study year	Country	Setting	Population	Comparison	(C)	Intervention <sup>a</sup>
Facility-based se	rvices							
Ahmed, 2020	Retrospective cohort	2016-2018	Ethiopia	Rural	Men and women	Initiated ART diagnosis	° >7 days after	Same day ART initiation after diagnosis in facility
Rosen, 2019	RCT	2017-2018	South Africa, Kenya	Urban	Men and women	ART initiatio	n within 2 weeks	Clinical algorithm for same-day ART initiation in facilities (excluding individuals with TB symptoms)
Maskew, 2020	RCT	2018	South Africa	Urban	Men and women	ART initiatio	n within 2 weeks	Clinical algorithm for same-day ART initiation in facilities (including individuals with TB symptoms)
Community-bas	ed services							
Labhardt, 2018	RCT	2016-2	017 Lesotho	Rural	Men and v	vomen HI	3HCT and referral to nearest facility	C + Same-day home based initiation with 30-day supply of ART
Katbi, 2019	Non-controlled tri	al 2015	Nigeria	Rural	Men and v who previou decline	vomen N/ usly ed ART	V	Individual and group adherence counselling, home based initiation with 30-day supply of ART, weekly phone calls from physicians
Mwango, 2020	Non-controlled tri	al 2018-21	019 Zambia	Urban, R <sup>ı</sup>	ural Men and v	vomen N/	A	Male-specific community-based (e.g., school, worksite, home) HCT + on-site ART initiation or facility escort and ongoing peer-counselling
Maina, 2019	Non-controlled tri	al 2016	South Africa	n Rural	Farmwork Men aı womer	ers, N/ nd	V	Home and mobile HIV/TB testing $+$ on-site ART initiation
Outreach								
Grasso, 2021	Non-controlled trial	2017	Namibia	Urban, Rural	Men and wom	en N/A	Home-based F	ICT + facility linkage by CHWs
Choi, 2020	Non-controlled trial	2018	South Africa	Rural	Men and wom at local bar	en N/A s	Male CHWs st screening, transportat	ationed outside shebeens (alcohol venues) conducted HIV rapid testing, counselling, and facilitated linkage and/or ion to clinic or district hospital for ART initiation.
Mwango, 2020	Non-controlled trial	2018-2019	Zambia	Urban, Rural	Men and wome	en N/A	Home-based in visit if indi	idex case testing (ICT) services + facility escort. Follow-up home vidual did not initiate ART.
Baisley, 2019	Non-controlled trial	2017	South Africa	Rural	Men and wom	en N/A	Home-based - more week	+ facility linkage, SMS after 2 weeks, and nurse call after two s if not initiated.
Counselling/pee	r support							
MacKellar, 2018	t Non-controlled trial	2014-2017	Tanzania L	Jrban, Rural	Men and women	N/A	Facility escort and appointment in-person visi period.	I treatment navigation, weekly telephone support and ceminder calls, five peer-delivered counselling sessions, and two is for HIV testing of partners and family members over a 90-day
MacKellar, 2021	Non-controlled trial	2015-2018	Eswatini L	Jrban, Rural	Men and women	N/A	Mobile HCT + fa and appointm two in-person 90-day period	cility escort and treatment navigation, weekly telephone support ent reminder calls, five peer-delivered counselling sessions, and visits for HIV testing of partners and family members over a

by male peer nd treatment rtners and family			nic registration,	
At least monthly individual HJV counselling sessions delivered counsellors. Tailored services could include facility escort ar navigation, case-management, and assisted disclosure to pai members over a 6-month period.		<ul> <li>+ 6 conditional monthly incentives of \$4.50 for clinic attendance</li> <li>+ 6 conditional monthly incentives of \$10.00 for clinic attendance</li> </ul>	+ 3 conditional lottery incentives (phone, data, \$100 gift card) for clu ART initiation, and viral suppression at 1, 3 and 6 months	
N/A		o o •	xt C	
den		Standard of car	Motivational te messages	
Urban		Men and women	Men with phones	
uth Africa		Urban	Rural	
2020 50		Tanzania	South Africa	.wc
rolled		018	017-2018	comparison rc
Non-cont trial		RCT 2	RCT 2	listed in the
Malone, 2021	Incentives	Fahey, 2020	Barnabas, 2020	<sup>a</sup> C refers to all activities

(Continued)

TABLE 3

[43, 44, 49, 52] interventions only included newly diagnosed clients and 11 [45–48, 50, 51, 53–57] enrolled both newly diagnosed and re-initiating clients. No intervention disaggregated findings by ART status (initiating v. re-initiating treatment) at the time of enrolment. One intervention [48] targeted individuals who had previously declined ART when offered a lighter-touch intervention (community HIV counselling and testing with facility escort or a USD5 transport incentive).

### Description of study designs

Of the 16 interventions, five (31%) were randomised clinical trials (RCTs) [45–47, 56, 57], one (6%) was a retrospective cohort study [44], and 10 (63%) did not have comparison groups (neither pre-intervention data nor separate control or comparison groups) [43, 48–55]. Study design varied by intervention type: all the facility-based service and conditional incentive interventions were RCTs or retrospective cohort studies, whereas generally the peer support, outreach and community-based services interventions did not have comparison groups.

### ART initiation and early retention measures

Overall, 13/16 (81%) of the interventions measured ART initiation [43, 45–54, 57] and 6/16 (37%) measured early retention. [44–46, 55–57] Across all interventions, ART initiation rates ranged from 27% to 97% and early retention rates from 47% to 95% (Table 4).

Measurement of outcomes varied substantially across interventions. The most frequent measure was ART initiation (9/13, 69%) [45, 46, 49–54, 57], followed by linkage to care (3/13, 23%) [43, 47], and completion of a four-week refill appointment (1/13%, 8%) [48]. The initiation measurement period ranged from same-day to 6 months. Early retention in care was mostly measured by clinic visit attendance (5/6, 84%) [44–46, 55, 56], with one study measuring viral suppression at 6 months (a common proxy for retention). The time period for early retention measures ranged from 5 to 8 months after initiation. Nearly half (7/16, 44%) of the interventions had unspecified time frames [43, 48–51, 55]. Most (13/16, 81%) interventions had verified outcomes and did not rely on self-report [43–46, 48, 49, 51–54, 56, 57].

Overall, the studies examining incentive- and facilitybased interventions had higher quality measures. These all had verified outcomes with specified time frames and included an early retention outcome, unlike the studies examining outreach and community-based services.

#### **Description of interventions**

Facility-based interventions (n = 3) focused exclusively on same-day ART initiation [44–46]. One retrospective cohort

	Partic living	ipants with HIV			Verified (V) v	Initiation-relate	outcomes			Early retention	-related outcon	nes	
Study	Male	Total	ART status	Intervention	self-report (SR) outcomes	Outcome definition	Time frame	Inter- vention	Compar- ison	Outcome definition	Time frame	Inter- vention	Compar- ison
Facility-based se Ahmed, 2020	rvices 468	988	Newly diagnosed,	Same-day ART initiation	>					< 0 days late for clinic visit	6 months	77%	88%
Rosen, 2019	422	1077	Not on ART	Algorithm for same-day initiation (excl. TB symptoms)	>	ART initiation	1 month	85%*	74%	Clinic visit	5-8 months	51%	54%
Maskew, 2020	220	593	Not on ART	Algorithm for same-day initiation (allowing TB symptoms)	>	ART initiation	1 month	<del>*</del> %06	66%	Clinic visit	5-8 months	76%*	63%
Community-bas	ed service	SS											
Labhardt, 2018	47	137	Not on ART	Home-based HCT + ART initiation	SR	Linkage-to-care	3 months	66%*	34%				
Katbi, 2019	239	302	Previously declined ART	Home-based ART initiation with ongoing support	>	ART initiation + 4-week facility visit	Unspecified	58%					
Mwango, 2020	2272	5714	Newly diagnosed	Community-based HCT + ART initiation + ongoing peer support	>	Linkage-to-care	Unspecified	97%					
Maina, 2019	2519	3415	Newly diagnosed	Home- and mobile-based HCT + ART initiation	Λ	ART initiation	Unspecified	92%					
Outreach													
Grasso, 2021	206	510	Not on ART	Home-based HCT + follow- up visits	SR	ART initiation	Unspecified	94%					
Choi, 2019	33	48 <sup>a</sup>	Not on ART	Community-based HCT + facility escort	Λ	ART initiation	Unspecified	45%					
Mwango, 2020	2186	5260	Newly diagnosed	Home-based ICT + facility escort + follow-up visit	Λ	Linkage-to-care	Unspecified	88%					
Baisley, 2019	120 <sup>a</sup>	427	Newly diagnosed	Home-based HCT + SMS + phone follow-up	>	ART initiation	6 months	27% <sup>b</sup>					
Counselling/pee	r support												
MacKellar, 201£	b 310	752	Not on ART	Peer-counselling + case management	Λ	ART initiation	3 months	85%					
MacKellar, 2021	b 438	824	Not on ART	Mobile HCT + peer- counselling + case management	Λ	ART initiation	1 month	96%					

	Partic living	ipants with HIV			Verified (V) v	Initiation-relate	od outcomes			Early retention	-related outcon	les	
Study	Male	Total	ART status	Intervention	self-report (SR) outcomes	Outcome definition	Time frame	Inter- ( vention i	Compar-	Outcome definition	Time frame	Inter- vention	Compar- ison
Malone, 2021	3010	3010	Not on ART	Peer-counselling + case management	SR					Retained in care	Unspecified	95%	
Conditional ince	entives												
Fahey, 2020 <sup>c</sup>	200	330	Initiated or re- initiated ART	Conditional incentives of 4.50 USD (6 total)	2					Retained in care	6 months	88%	84%
			in past 30 days	Conditional incentives of 10.00 USD (6 total)	>					Retained in care	6 months	91%*	84%
Barnabas, 2020	131	131	Not on ART	3 Conditional non-monetary lottery incentives	>	ART initiation	6 months	93%		Viral suppression	6 months	66%	59%
<i>Note:</i> The authors u	sed associa	tted docume	nts (e.g., published stud	y protocols, unpublished reports) rel	evant to these source	e documents if insuf	ficient detail w	as provided in	n the publics	tion itself.			

TABLE 4 (Continued)

Post-universal treatment data only. Calculated by authors.

Findings are for both men and women, article methods or results stated that there were no significant differences in outcomes by sex.  $p \le 0.05$ 

study examined early retention rates among individuals who initiated ART on the same day compared to those who did not, under the same care guidelines [44]. Two RCTs examined the impact of clinical algorithms (i.e., screening tools) to facilitate same-day ART initiation among clinically eligible clients [45, 46].

All community-based ART interventions (n = 4) provided immediate ART initiation and counselling in community, home, and/or work settings [43, 47-49]. Two of these interventions provided ongoing monitoring and counselling to encourage adherence after initiation [43, 48], while two provided a single counselling session at initiation [47, 49]. All outreach interventions (n = 4) offered in-person or phone-based reminders to attend facility [43, 50-52], escorted clients to the facility for initiation (n = 2) [43, 51], or provided transportation to facilities (n = 1) [51].

peer-based support/counselling interventions All (n = 3) included ongoing (ranging from 90 to 180 days) counselling from peers living with HIV, usually at clients' home or other private community-based locations [53-55]. Duration and location were dependent on client preferences and needs. One study was tailored for men, and delivered by male peers living with HIV [55].

Two RCTs assessed the impact of conditional incentives [56, 57]. One intervention [56] offered fixed monetary incentives (USD4.50 or USD10) for each monthly clinic visit to individuals who had initiated or re-initiated ART in the past 30 days; the other [57] offered lottery non-monetary incentives (mobile phone, data, or a USD100 gift card) for clinic registration, ART initiation, and/or viral suppression.

### DISCUSSION

Despite years of evidence of men's suboptimal ART outcomes, research on effective interventions for men in SSA remains scarce. We identified only 16 eligible interventions that included sex-disaggregated data: of these, only two were designed specifically for heterosexual men. The lack of interventions specifically tailored to men may be a concern because men have unique needs that require specific responses [22, 58]. A plethora of interventions specifically target women [24, 59] because they also have unique needs-men are no different. Most interventions did not have a comparison group and had inconsistent outcome measures. We are not the first to bring attention to the lack of evidence for men's interventions. A recent systematic review on long-term ART retention for men in SSA identified only 14 studies with sex-disaggregated data published between 2005 and 2019, with none exclusively targeting heterosexual men [9]. These gaps require urgent attention so that programmatic interventions can be informed by rigorous evidence specific to men in the region (see Figure 2).

All future HIV research should disaggregate findings by sex. Many articles we screened did not include sexdisaggregated results or analyses. The lack of sex-disaggregated outcomes is especially challenging given that men in SSA are

1	Disaggregate study results by sex, and power future studies by sex (and key characteristics within
	each sex, where feasible).
2	Employ rigorous research designs with comparison groups (RCTs and quasi-experimental designs).
	Robust implementation studies can be nested within larger implementation programs in feasible and
	cost-effective ways.
3	Develop and disseminate standard definitions and time frames for ART initiation and early retention
	outcomes so findings can be compared across contexts.
4	Collect data on the early retention (within 8 months of initiation) period and prioritize research on
	interventions that encompass both ART initiation and early retention: a focus on initiation alone is no
	longer sufficient under universal treatment policies.
5	Evaluate a wide range of intervention types (e.g. health system changes, education and counseling,
	rapid multi-month dispensing, interfaces with traditional practitioners, community-based approaches,
	and technology-based approaches.

FIGURE 2 Research priorities for men's early engagement in HIV services.

often underrepresented in HIV studies. WHO highlights the critical importance of sex-disaggregated data [48], which allow health systems to 'identify and respond to gender inequalities in health, and allocate resources accordingly'. Unfortunately, such high-level commitment to sex disaggregation does not necessarily translate into practice. WHO only started reporting disaggregated global health statistics in 2019. High-impact journals in the field often encourage but do not require sexdisaggregated findings [60], and key publications often lack disaggregation [56, 61, 62]. We strongly recommend that journals and funders require sex-disaggregated results where relevant in future publications following the SAGER guidelines [63], as well as the PRISMA-, and CONSORT-Equity extensions [64, 65]. Ideally studies that include both men and women should be powered to identify statistically significant gender differences in HIV outcomes, given that outcomes and barriers to care differ substantially by sex.

Numerous studies had weak study designs and/or methods. Only five [45-47, 56, 57] of the 16 interventions were evaluated using randomised controlled trials and most studies did not have a comparison group. As a result, the majority of the evidence that we found cannot attribute causality to the intervention and conclusions are only suggestive. Increasingly implementation studies are embedded within routine HIV programs. This has extensive benefits in terms of studying intervention scalability and sustainability within real-world settings, instead of within highly-controlled research environments that may not be replicated. However, such studies must employ strong research designs to produce sound results. Experimental and quasi-experimental research methods (such as stepped wedge cluster randomised trials [66, 67] and regression discontinuity designs [68, 69] can be nested pragmatically within large implementation programs. Implementing partners may also contract external evaluation partners to rigorously assess the impact of interventions.

Consistent with prior reviews [70, 71], we find that definitions and timeframes for measuring ART initiation and early retention varied greatly, with nearly half of interventions lacking any timeframe at all. Without standardised, well-defined metrics, outcomes cannot be compared across programs, contexts, and populations. Standard definitions for both ART initiation and early retention in the era of universal treatment should be developed and adopted.

Our study highlights the urgent need for additional research on interventions that improve early retention among men in SSA. Only six interventions measured early retention outcomes, and findings were largely inconclusive. Yet under universal treatment, early retention is emerging as one of the greatest barriers to epidemic control as those who interrupt treatment early are at increased risk of repeat treatment interruptions, long-term disengagement from care, and HIV-related morbidity and mortality [72, 73]. Clients in the period of early retention likely face some of the greatest challenges for ART engagement because this time period often requires navigating status disclosure, developing a lifestyle that facilitates long-term adherence, and attending frequent facility visits (usually monthly) that are time-consuming and may increase risk of unwanted disclosure [20]. Given the unique nature of early ART retention, studies focused on initiation or long-term retention should consider including early retention as a secondary outcome.

Despite these methodological limitations, our review provides some insight into what works for men. Studies with comparison groups provided evidence that same-day facility ART initiation increased men's ART initiation but was inconclusive for early retention [44–46], suggesting that same-day initiation alone does not sufficiently address the barriers that men face during the early retention period [44, 45]. Findings for other intervention types were inconclusive.

To improve men's ART outcomes, a wide variety of interventions should be evaluated. Innovative differentiated models of care during the first months of treatment are likely needed in order to meet the needs of men [22, 74],

such as male-specific counselling and mentorship [22], rapid multi-month dispensing [75], and community-based services [76]. Facility-based interventions such as integrated HIV services with non-HIV care, extended clinic hours, and male-friendly services may improve initiation and early retention outcomes [21]. Only two interventions in our review included any mHealth component [52, 57] though recent literature shows that access to smartphones and other technology is rapidly increasing among individuals in SSA [77] and mHealth may be key for young and mobile male populations who often cannot be reached through other approaches [78, 79]. Finally, none of the interventions included in this review employed community-level strategies to address HIV-related stigma or engagement with traditional health practitioners or religious leaders, groups who are key partners to engaging men in the region [80, 81].

Our study had a number of limitations. A thorough search of grey literature may have yielded more interventions. We only included articles that were published in English. However, we believe that our search strategy was comprehensive in reviewing the published literature on interventions to improving ART initiation and early retention among men in SSA.

#### CONCLUSIONS

Despite clear gaps in men's ART outcomes in SSA, men are largely missing from research on treatment initiation and early retention interventions. There is an urgent need to produce rigorous, sex-disaggregated research on a wide variety of strategies to improve ART initiation and early retention for men under universal treatment policies.

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