Opportunities for increasing utilization of Private Sector delivery of Oral HIV Pre-Exposure Prophylaxis (PrEP) by Men who have Sex with Men (MSM) and Transgender Women (TGW) in Low- and Middle-Income Countries (LMICs):

Application of an Integrated Person-Centered Market Systems Framework.

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58th Master of Public Health/International Course in Health Development

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Application of an Integrated Person-Centered Market Systems Framework.

A thesis submitted in partial fulfilment of the requirement for the degree of

Master of Science in Public Health

by

Ali Asghar

Declaration:
Where other people's work has been used (from either a printed or virtual source, or any other source), this has been carefully acknowledged and referenced in accordance with academic requirements.
The thesis "Opportunities for increasing utilization of Private Sector delivery of Oral HIV Pre-Exposure Prophylaxis (PrEP) by Men who have sex with men (MSM) and Transgender Women (TGW) in Low- and Middle-Income Countries (LMICs): Application of an Integrated Person-Centered Market Systems Framework." is my own work.

Signature: ……

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Abstract

Introduction

In low- and middle-income countries (LMICs) men who have sex with men (MSM) and (TGW) face significant stigma and discrimination which limits their access to Oral HIV Pre-exposure Prophylaxis (PrEP) services. There are substantial gaps in the availability of Oral HIV PrEP services in LMICs for MSM and TGW. This thesis explores opportunities for increasing utilization of private sector delivery of Oral HIV PrEP by MSM and TGW in LMICs.

Method

This paper is a review of existing literature around provision of Oral PrEP services among MSM and TGW in LMICs. Findings summarized in this paper were obtained from available academic databases like VU library, Google Scholar, and PubMed. An adapted version of the Market Systems Framework and Person-centered Healthcare Access Framework was used to explore and map opportunities for private sector delivery of Oral HIV PrEP.

Results

This holistic review of the Oral PrEP service delivery landscape for MSM and TGW in LMICs identified gaps and opportunities in provision of PrEP services at the supply-side, demand-side, policy-level, and supporting functions such as financing, infrastructure, skills, technology, and information. Furthermore, the study was able to highlight differentiated service delivery mechanisms that serve their needs for oral PrEP services in a safe and conducive environment.

Conclusion and Recommendations

Programmes should deploy risk-based, de-medicalized, cost-effective, and differentiated delivery channels with innovative technology for the provision of Oral PrEP services by MSM and TGW in the LMICs environments. Health care providers should undergo capacity building for person-centered quality care to enable provision of interpersonal and gender-affirmative care.

Key Words

“Men who have Sex with Men”, “Transgender Women”, “Oral HIV Pre-exposure Prophylaxis (PrEP)”, “Low- and Middle Income Countries”, “Person-centered”.

Word Count: 9,673

Table of Contents

Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
CBO	Community Based Organization
COVID-19	Coronavirus Disease 2019
DIC	Drop-in Center
FSW	Female Sex Worker
HCW	Healthcare Worker
HIV	Human Immunodeficiency Virus
IDU	Injecting Drug User
KP	Key Population
LMIC	Low- and Middle-income Countries
MSM	Men who have sex with men
MSW	Male Sex Worker
PHAF	Person-centered Healthcare Access Framework
PLHIV	People Living with HIV
PrEP	Pre-exposure Prophylaxis
SDG	Sustainable Development Goal
SRH	Sexual and Reproductive Health
STI	Sexually Transmitted Infection
TGW	Transgender women
UHC	Universal Health Coverage
UNAIDS	The Joint United Nations Programme on HIV and AIDS
WHO	World Health Organization

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1. Background

It has been over forty years since the human immunodeficiency virus (HIV) was first discovered and isolated and within a decade acquired immunodeficiency syndrome (AIDS) was claiming the lives of millions globally. The 90-90-90 targets set by the Joint United Nations Programme on HIV/AIDS (UNAIDS) have guided the progress on the testing and treatment of HIV since 2016. They were defined by the UN General Assembly as the global targets for the year 2020 aiming for 90% of all people living with HIV to know their HIV status, 90% of all people with diagnosed HIV infection to receive sustained antiretroviral therapy (ART), and 90% of all people receiving antiretroviral therapy (ART) to have viral suppression. However, the world missed these targets and by the end of 2020, 84% of people living with HIV knew their HIV status, 87% of people living with HIV (PLHIV) who knew their HIV status were accessing antiretroviral therapy (ART), and 90% of people on treatment were virally suppressed (1). Although huge progress has been achieved but HIV remains a global health crisis. In 2021 there were 38.4 million people living with HIV, 1.5 million people were newly infected with HIV, and 650,000 people died from AIDS-related illnesses globally (2).

Over the past two and a half years, the parallel running pandemics of AIDS and COVID-19, along with other economic and humanitarian crises, have slowed the progress against HIV and placed the global HIV response under great threat. Although the number of new HIV infections fell globally in 2021 but it was the smallest annual reduction since 2016, only 3.6% compared to the drop in 2020. Every day, 4000 people become infected with HIV, which includes 1100 young people aged 15 to 24 years. If the current trends continues, 1.2 million people will be newly infected with HIV in 2025 which is three times more than the 2025 target of 370,000 new infections (3).

Globally, 89% of all new HIV infections are from low- and middle-income countries (LMICs) (1) which is home to 80% of the world's population (4). Although some countries have achieved effective coverage of the testing and treatment services for HIV, but it has been an uneven progress. There has been rapidly growing HIV infections among key populations in LMICs, particularly men who have sex with men (MSM), in countries like Indonesia, Pakistan, and the Philippines (1). There are key populations residing in every region of the world who are particularly vulnerable to HIV infection. Although they account for less than 5% of the world's population, but in 2021 they and their sexual partners made up 70% of new HIV infections. Globally, the burden of new HIV infections has increased in non-African regions. In 2021, key populations and their sexual partners comprised of 94% of the new HIV infections outside of non-African regions (3).

In most parts of the LMICs key populations are marginalized and criminalized based on their sexual orientation, gender identities and expression, and livelihoods. A study conducted by O'Neill Institute for National and Global Health at the Georgetown University showed that the criminalization of key populations negatively impacts their HIV outcomes. They found significantly low levels of HIV status knowledge and viral suppression among people living with HIV in countries where same-sex sexual relationships, sex work and drug use were criminalized as compared to countries without any criminalization laws against these key populations (1). Gay men and other MSM are at 28 times greater risk of contracting HIV than men (15-49 years) in the general population. Similarly, Transgender Women (TGW) are at 14

times greater risk of acquiring HIV as compared to women (15-49 years) in the general population (3).

The World Health Organization (WHO) has recommended to offer Oral Pre-Exposure Prophylaxis (PrEP) as an additional prevention option to MSM and other at-risk population residing in an environment where they face legal and social barriers to accessing health care services (5). It is a promising addition to the HIV combination prevention kit and its efficacy has been proven in multiple clinical trials in different populations across various geographical regions. Although consistent condom use is possible but it has proven difficult to use regularly across all populations since greater agency and support is required to negotiate its use with their sexual partners (1). However, since the decision to use PrEP is with the individual and does not require any negotiation with a partner, it has a huge potential to help decrease HIV infections among key populations world-wide (3). However, in recent years the coverage and utilization of HIV combination prevention among gay men and other MSM was reported low in every region, varying from 27% in Asia and the Pacific to 53% in western and central Africa. Similarly, the coverage and utilization of HIV prevention combination among TGW remained low in all regions, varying from 28% in eastern and southern Africa to 77% in eastern Europe and central Asia, below the 2025 targets (3).

Although it has been a decade since the first evidence of the efficacy of daily oral PrEP, there are substantial gaps in the availability of PrEP services, especially in LMICs. In 2021 despite the COVID-19 pandemic, globally more than 1.6 million people were receiving oral PrEP, yet it remains below the 2025 target of 10 million people receiving it. Achievement of the 2025 targets requires 95% of people at risk of HIV to use combination prevention, but the world is not on track to reach the majority of these targets (3). Majority of the low- and middle-income countries outside sub-Saharan Africa have been unsuccessful in reaching out to the key populations with HIV combination prevention interventions sufficiently and lack the efforts. Achieving the 95-95-95 targets by 2025 will get the global HIV response on the path to end AIDS as a public health threat by 2030 (3).

2. Problem Statement, Justification, and Objectives

In most of the low- and middle-income countries, health care services and other related products are delivered through a mixed healthcare system comprising of public and private sector (6). The private health sector refers to a range of actors (individuals or organizations) that are involved in provision of health care services and are not owned or controlled directly by the government. The nature of the private health sector can be humanitarian or business and comprises of for-profit and not-for-profit organizations. The not-for-profit organizations can further include faith based organizations (FBOs), non-governmental organizations (NGOs), civil society organizations (CSOs), and community-based organizations (CBOs). The private health sector includes formally trained providers (pharmacists, doctors, nurses, and midwives) or informally trained providers (traditional healers, ayurvedic medicine, etc.)(7). The private sector is often considered by governments as a solution to country's problems created due to financial constraints, disease burden, and political and economic instability because private sector is perceived to offer access to better service capacity, better responsiveness, management skills, technology, and innovation (8).

Most of the government in low- and middle-income countries focus their efforts towards the public sector while private sector remains unengaged and on the periphery. Over the last decade considerable attention has been given to the role that the public sector can play towards achieving Universal Health Coverage (UHC). However, equal attention needs to be diverted towards measuring, managing, and engaging the private sector for health systems strengthening and ensuring that health care is accessible by all segments of the population. The private health sector is the key partner in working towards UHC. The time has come for the global community to move forward with an agenda to engage the private health sector strategically to achieve the aim of strengthening the health systems including UHC as well as health-related Sustainable Development Goals (SDGs) (6).

According to WHO's report on the private sector landscape in mixed health systems, health care services are availed mostly through the private sector (for-profit and not-for-profit) in all regions of the world apart from the European region. The region with the highest dependence on the private sector is the WHO Eastern Mediterranean region, 53% of inpatient and 66% of outpatient care happens in the for-profit private sector. Whereas in the WHO European region, 96% of the health care needs are availed through the public sector. In the case of African region, 35% of outpatient care is sought through the for-profit private sector and 17% at shops, faith healers and other informal providers. In total, 26% of health care needs are sought through the private sector, with an additional 10% from informal providers. The largest proportion of health care utilization through the private sector happens in Nigeria (52%) followed by Cameroon, Uganda, and Benin where more than 40% utilization of health care services are availed through the private sector. Given the magnitude of provision of health care services through private sector, its high time to identify effective models of governing and integrating the private sector within health system umbrella (6).

Majority of the population, including the poor segment of the society, receive their health care through the private sector from a variety of for-profit, not-for-profit, formal, or informal

channels(6). Research from other countries have also shown evidence of wide-scale utilization of private sector health care services. They are perceived to be of greater convenience, quality, confidentiality, and enables the service users to form a substantial relationship with the health care provider. Private sector health care facilities are also located in areas of high HIV incidence and are more appropriate for delivery of oral PrEP, especially in urban areas. Private health care sector is reached by those service users who can pay some amount for oral PrEP, which reduces the burden from the public sector resources and allows them to be focused on those who cannot pay for availing these services. This ample size of service users or demand makes a good business case for health care providers in the private sector to deliver oral PrEP as it not only increases their revenue of associated services but also helps the providers to build long-standing relationships with the service users. It also gives them a competitive advantage over other private sector health care providers (9).

Over the past few years, the number of countries implementing Oral PrEP has been increasing via a mix of free and fee-based public and private sector delivery models (10). Despite the disruptions caused by COVID-19 pandemic in 2021, the utilization of oral PrEP has increased with approximately 1.6 million people in at least 86 countries where the users have received Oral PrEP at least one time. Modalities like multi-month dispensing, virtual demand generation, community-based, and on-line service delivery has increased the number of users who initiated PrEP in 21 countries by 157% between April 2020 and March 2021 as compared to the same duration in the previous year. In these 21 countries, most of which are from sub-Saharan Africa, the total number of PrEP users increased from approximately 233,000 in the year before the COVID-19 pandemic to nearly 600,000 in the first year of the pandemic. High scale coverage and utilization of Oral PrEP services have resulted in reducing number of new HIV infections substantially in some high-income countries namely Australia, England, Scotland, and the United States of America, especially among gay and other MSM. However, the coverage and utilization of Oral PrEP services is very low to impact the epidemic on the global scale (3).

The increased utilization of Oral PrEP services has been uneven in various regions of the world. It is mainly concentrated in numerous high-income countries and five low- and middle-income countries in sub-Saharan Africa, namely Kenya, Nigeria, South Africa, Uganda, and Zambia. Racial and socioeconomic inequalities are distorting the awareness and utilization of PrEP services in high-income countries. Achieving wide-scale and effective utilization of PrEP services can be challenging since PrEP is an effective HIV prevention choice therefore enhancing knowledge and awareness among potential PrEP users is essential. This includes efforts to promote its understanding, acceptability, and utilization. Most importantly predictable financing on a wide scale is required to increase the uptake and make it an accessible choice for as many potential users. However, that remains a challenge, especially in LMICs, which is home to many at-risk populations, but the donor funding is limited and extremely rationed. Many prominent bilateral donors have reduced their international assistance for AIDS which has resulted in declined resources for the work against HIV in LMICs and slowed their progress (3).

In Low- and middle-income countries a huge private health care sector thrives across many service domains which includes primary care, hospitals, diagnostics, therapeutic and curative services, and pharmaceutical supply chains. Various international agencies have strategized to engage the private health care sector in achieving and advancing their programmatic objectives (6). Donors have supported various modalities of private sector participation in sexual and reproductive health (SRH) both globally and at the country level for activities in finance, manufacturing, procurement, development, supply chain, service delivery, and capacity building to strengthen public sector stewardship of mixed health systems with the aim to achieve UHC (11).

There is, however, paucity of data and therefore limited understanding of potential opportunities which exist within mixed health care systems of LMICs that can be leveraged by policies and programs to introduce and strengthen supply of Oral PrEP service delivery through private health care sector. Moreover, the demand for Oral PrEP, particularly among hard-to-reach and marginalized key populations such as MSM and TGW is also poorly understood. This thesis will explore opportunities for private sector delivery of Oral Pre-Exposure Prophylaxis (PrEP) for HIV for MSM and TGW in LMICs.

2.1. Study Objectives

Main Objective

To explore opportunities for private sector delivery of oral HIV PrEP among men who have sex with men (MSM) and transgender women (TGW) in low- and middle-income countries (LMICs) and provide recommendations to increase utilization of these services through private sector.

Specific Objectives

1. To explore existing private sector service delivery models of Oral HIV PrEP focused towards MSM and TGW in LMICs.
2. To review and identify existing gaps and opportunities for Oral HIV PrEP services among MSM and TGW through private sector in LMICs.
3. To identify existing evidence-based practices contributing towards increased uptake of private sector Oral HIV PrEP services among MSM and TGW in LMICs.
4. To provide recommendations to policymakers, government bodies, donors, and for-profit and not-for-profit private sector stakeholders for increasing utilization of Oral HIV PrEP among MSM and TGW through private sector in LMICs.

3. Methods

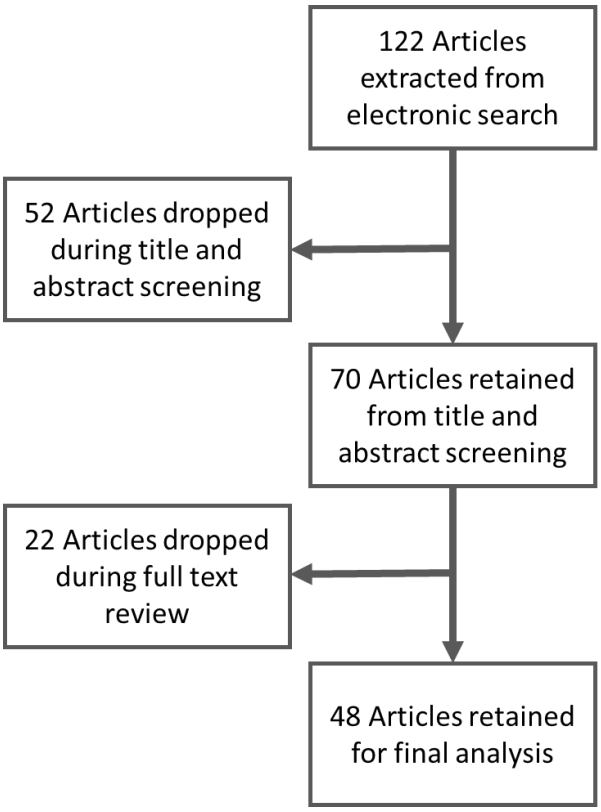
3.1. Search Strategy

The study used a systematic approach to search relevant literature for review. Search strings (Annex 1) were developed by combining key concepts and Boolean Operators to explore library catalogues like VU library and bibliographical databases like Google Scholar and PubMed. Additional literature was searched using Snowballing technique. Grey literature from websites of specialized organizations, PrEP-related organizations (PrEP Watch, PrEP Map), and conferences was also scanned to increase the study's robustness and limit any publication and selection bias.

The review included literature fitting the inclusion criteria of peer-reviewed papers and grey literature published after 2010 in English language with a focus on key concepts defined in the objectives and the framework. Publications that were clinical trials or only focused on populations other than MSM and TGW in LMICs were excluded.

The identified articles were screened by title, abstract and then the full text. The findings were extracted and summarized in a structured table under key concepts of the Integrated Person-centered Market Systems framework.

Flow Chart - Identification of Articles for Final Analysis

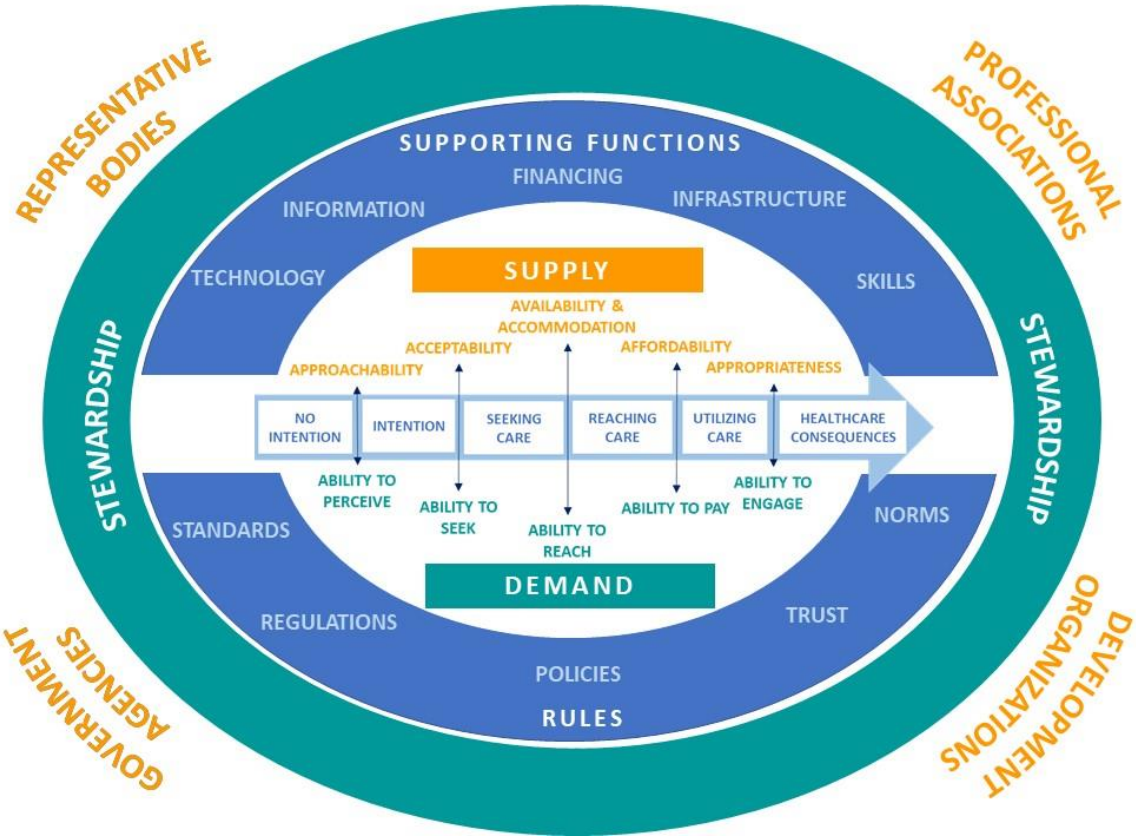


3.2. Conceptual Framework

The study will apply an adapted version of the Market Systems Framework to guide the exploration of the Oral PrEP market and map opportunities for private sector delivery of Oral PrEP among MSM and TGW in LMICs. A market system is defined as a multi-function and multi-player composition which encompasses the 'core function' through which products and services are delivered. The factors that contribute towards the effectiveness of the core function are defined in-terms of the 'supporting functions', which comprises of the required services and resources of the core operation, and 'rules', which refer to the functions that are explicitly related to the formal or informal entities facilitating the decisions in the core function (12).

For the purpose of this study, the core market functions of supply and demand have been further unpacked using the Person-centered Healthcare Access Framework (PHAF) developed by Levesque and colleagues (13). The integration of PHAF in the Market Systems Framework allows for conceptualizing supply and demand as complementary core functions driving consumers through different stages of their healthcare access journey. Integration of the PHAF into market systems, provides a deeper clarification of key concepts underlying the multi-dimensional nature of supply and demand. The core assumption of the framework being that consumers progress to the next stage of this journey when each complementary set of supply and demand side concepts are successfully met. This provides a person-centered lens for understanding the state of the given market based on where consumers are in this journey for that market. **Figure 1** presents a visual overview of the integrated framework for this study, with key concepts defined below.

Figure 1 - Integrated Market Systems & Person-centered Healthcare Access Framework (PHAF)



The Person-centered Healthcare Access Framework is comprehensive and dynamic. It helps in the identification of relevant determinants impacting the access from a multi-level lens which gives a detailed overview of the factors regarding health systems, institutions, organizations, and service providers along with the factors at the individual, household, community, and population perspective (13).

PHAF defines 'core supply function' as consisting of five distinct concepts: Approachability, Acceptability, Availability and Accommodation, Affordability, and Appropriateness of the services.

- **Approachability** refers to the fact that people with the specific health needs can identify existence of those relevant services, are reachable, and the services will have an impact on their health. Key factors underlying approachability of services include transparency, information regarding services, outreach activities and screening.
- **Acceptability** refers to those socio-cultural factors that determines the possibility of accepting those services and judge their appropriateness for seeing care. Key factors underlying acceptability of services includes culture, norms, gender, and professional values.
- **Availability and Accommodation** relates to the fact that health services (either the physical space or health care workforce) are reachable physically and timely both. Key factors underlying availability and accommodation of services include geographic location, accommodation, operating hours, and mechanism of the appointment.
- **Affordability** relates to the economic capability of the people to invest resources and time for using the relevant services. Key factors underlying affordability of services include direct, in-direct, and opportunity costs.
- **Appropriateness** relates to the fact whether the services match the needs of the service user, its timeliness, the quantity of care spent in the assessment of health problems and determining the accurate treatment along with the technical and interpersonal quality of the services. Key factors underlying appropriateness of services include adequacy, coordination, continuity, and observed and perceived technical and interpersonal quality of care.

Similarly, the underlying dimensions of the 'core demand function' for the market identified by PHFA include five key concepts each of which is complimentary and relates to one specific supply concept. These include Ability to Perceive, Ability to Seek, Ability to Reach, Ability to Pay, and Ability to Engage.

- **Ability to perceive** relates to the service user's ability to perceive the health risk and need for care. Key underlying factors include health literacy, health beliefs, trust, and expectations. Complementary supply side concept for ability to perceive is Approachability.
- **Ability to seek healthcare** relates to the concepts of personal autonomy and capacity to make a choice to seek care, knowledge about healthcare choices, and the service user's rights that determine their intention to acquire healthcare. Key underlying factors include personal and social values, culture, gender, and autonomy. Complementary supply side concept for ability to seek is Acceptability.

- **Ability to reach healthcare** relates to the concepts of service user's mobility and availability of transport, occupational flexibility, and knowledge about health services that would enable the service user to reach service providers. Key underlying factors include surrounding environment, transport, mobility, and social support. The complementary supply side concept for ability to reach is Availability and Accommodation.
- **Ability to pay for healthcare** defines the ability to generate financial resources through income, savings, borrowing or loans to pay for healthcare services without any catastrophic expenditure of resources which are required for the basic necessities of the service user. Key underlying factors include income, assets, social capital, and health insurance. Complementary supply side concept for ability to pay is Affordability.
- **Ability to engage** relates to the participation and involvement of the service users in their healthcare decisions and treatment choices. Key underlying factors include empowerment, information, adherence, and care-giver support. Complementary supply side concept for ability to engage is Appropriateness.

The **'**Supporting Functions' of the Market Systems Framework are defined in-terms of Financing, Infrastructure, Skills, Technology, and Information which determine the effectiveness of the core operations.

- **Financing** refers to the financing mechanisms in place for supporting development functions
- **Infrastructure** refers to the basic physical and organizational structures, systems, and facilities needed for the operations
- **Skills** is defined by the correct job-specific knowledge, technical and behavioral competence to do the job right.
- **Technology** refers to the technological applications and solutions aimed at facilitating different market functions, including but not limited to supporting information and market intelligence, skill development, supply and demand, and effective stewardship.
- **Information** which flows through the market system from market stewards to suppliers to consumers (Institutional communication and norms, social and behavior change, demand generation, etc.) and from consumers to suppliers and market stewards (market intelligence).

'Rules' of the Market Systems Framework are defined in terms of Policies, Standards, Regulations, Trust, and Norms as functions that shape decisions in the core.

- **Policies** refer to laws, regulations, procedures, administrative actions, incentives, or voluntary practices of governments and other institutions. In the public health context, policy development also includes the advancement and implementation of public health law, regulations, and voluntary practices that influence system development, organizational change, and individual behavior to promote improvements in health.
- **Standards** refer to explicit statements of expected quality in the performance of a healthcare activity. Standards may take the form of procedures, clinical practice guidelines, treatment protocols, critical paths, algorithms, standard operating procedures, or statements of expected healthcare outcomes among other formats.

- **Regulations** are broadly defined as imposition of rules by the government, backed by use of penalties that are intended specifically to modify economic behavior of individuals and firms in the private sector.
- **Trust** as a sociological construct refers to people's expectations typically for goodwill, advocacy, and competence.
- **Norms** are the perceived informal, mostly unwritten, rules that define acceptable and appropriate actions within a given group or community, thus guiding human behavior**.**

'Stewardship', an implicit, cross-cutting concept within the market systems framework, has been explicitly included as an overarching market function encompassing the overall market system. Stewardship involves the use of policy tools or instruments that, individually and collectively, exert influence on the incentives, capacities, and accountability structures of actors within a given health market system. Stewardship, in this framework, is defined as the careful, and responsible management of various market functions to develop the market for the well-being of the population.

Finally, the Market Systems lens offers an additional advantage of facilitating the mapping of market shaping strategies by using three key market levers (14). These three market levers provide a concise frame for mapping and categorizing a wide variety of market shaping approaches for various market functions. These levers include:

1. **Reduce transaction costs** – Reducing the structural hurdles for market interaction, like simplifying or rationalizing orders.
2. **Increase market information** – Reducing asymmetries of information by generating new data, aligning with existing analysis, or expanding the visibility of data that already exists.
3. **Balance supplier and buyer risks** – Compensating financial risks of suppliers and shifting them towards donors or service users to make market engagement more attractive. This can persuade new suppliers to enter the market or the existing ones to function more actively.

4. Study Results

Mapping findings of the published literature through the lens of the Integrated Person-centered Market Systems framework helped in understanding where private health care sector efforts are being concentrated across the various market functions and where efforts remain underutilized.

4.1. Core Functions

The Core Functions of Supply and Demand from the Market Systems Framework were referenced 48 times in total. Findings on each component of the Core Function are separately shared below.

4.1.1. Supply

Of the total 48 (n=48) articles included, Core Supply function was referred by 34 (n=34) articles defined in terms of Approachability, Acceptability, Availability and Accommodation, Appropriateness, and Affordability.

Approachability

Of the 34 (n=34) articles discussing the Core Supply Function, eight articles (n=8) referenced Approachability of PrEP programmes. Most of these articles focused on a singular PrEP programmer's evaluation and highlighted programmatic activities and methodologies that underscored their respective programmer's Approachability. Broadly, review articles highlighted gaps in PrEP programming that do not address the key barrier of stigma and discrimination faced by the key populations in accessing PrEP services (10) (15). Programmatic evaluation studies used this as the rationale for developing and piloting innovative approaches for providing PrEP services. Claassen and colleagues assessed the impact of using a risk-based criteria, as opposed to the commonly used population-based criteria, for scaling-up provision of PrEP services in Zambia (16). By using a risk-based criteria, they made the programme approachable to anyone facing the risk of HIV, irrespective of identity. By not focusing on key populations in the roll-out, the programme decreased stigmatization faced by individuals from key populations. Furthermore, to enhance programmatic approachability, the remaining articles discussed the impact of other novel approaches: most notably, i) provision of home-based screening and PrEP services, and ii) using community-led participatory approaches whereby PrEP services are regulated and managed by the MSM community themselves for enhancing access (17)(18).

Acceptability

This aspect of the Core Supply Function was discussed by 16 (n=16) articles, out of the 34 (n=34) articles on the overarching function. Key populations, specifically MSM and TG communities, have reported high levels of willingness to use PrEP, however, fear of stigma from healthcare professionals restricts them from accessing services (19)(20)(21). To enhance acceptability, studies emphasized upon housing the provision of PrEP services through community-based approaches (22)(23). Rousseau et al. highlighted the Princess PrEP program

from Thailand which employed a peer approach for increasing PrEP utilization among the transgender community. This approach proved to be effective as it de-medicalizes PrEP service provision for the community by leveraging peers as the contact points who understand the clients' lifestyles (23).

Availability and Accommodation

Under the Core Supply Function, this aspect was discussed the most with 17 (n=17) articles mentioning infrastructural and geographical elements of PrEP programmes. Studies reported using i) community-delivery models including safe spaces for KPs (24), ii) integration of PrEP services into existing HIV treatment clinics to bypass infrastructural issues and cost of setting-up a new facility (25), iii) diversified service delivery points (26), iv) pharmacists as the main provider for PrEP (10), v) outreach services in spaces comfortable for KPs (24), and vi) drop-in centers (DICs) which were highlighted as the preferred service delivery point by the KPs as they can access services in a familiar communal space without stigma and discrimination (18).

Affordability

Direct and indirect costs of obtaining PrEP services have been cited consistently as a key barrier to access to services by MSM and TGW populations. This Core Supply Function was discussed by eight (n=8) articles with almost universal consensus that both public sector and private sector channels should provide PrEP services for free to enable socioeconomically- and socially-marginalized communities' access to PrEP services (15)(27). Sustainable financing of PrEP, specifically in the Asia-Pacific region, through a wide array of stakeholders including donors, pharmaceuticals, and governments was critical for providing free PrEP services (25).

Appropriateness

This aspect of the Core Supply Function was discussed in eight (n=8) articles. The articles highlighted i) the importance of medical considerations for transwomen who are availing or seeking feminine hormone therapy as well (15), ii) priority to use MSM peers for distribution of PrEP through male-only facilities (18), iii) government services were also preferred in certain settings as KP individuals can avail services with greater anonymity, however, poor perceived quality of care and long waiting times are areas of concern (17), and iv) client-centered programming to de-medicalize PrEP services and address the affected community's needs and demands through tailored programme design and communication materials (25).

4.1.2. Demand

Of the total 48 (n=48) articles included, 13 (n=13) articles discussed the Core Function Demand, defined in terms of Ability to Perceive, Ability to Seek, Ability to Reach, Ability to Pay, and Ability to Engage.

Ability to Perceive

Of the total 13 (n=13) articles included, six articles (n=6) referenced this concept under the Core Function Demand. The articles underscored participants' positive perceptions around PrEP services (28) whereby usage of PrEP was associated with "new possibilities in lives",

feelings of empowerment, agency, and safety during sex, as well as greater honesty among partners regarding their HIV statuses (15)(29). Studies across low-, middle-, and high-income countries have found that KP communities with low perceived HIV risk would have a greater non-willingness to use PrEP (17).

Ability to Seek

There were three (n=3) articles discussing the concept of Ability to Seek. The studies highlighted the importance of reducing the geographical distance in the ability of MSM and TGW to access healthcare clinics for Oral PrEP services. Pharmacies were cited as the geographically convenient channel for accessing PrEP (30).

Ability to Reach

Of the 13 (n=13) articles discussing concepts pertaining to the Core Function Demand, only one (*n=1*) article mentioned the concept of Ability to Reach. Mpunga et al. notes leveraging upon community DICs and outreach channels for optimal service delivery of PrEP (18).

Ability to Pay

Four articles (n=4) cited this concept under the Core Function Demand. These articles presented consistent findings whereby the MSM and TGW community members were willing to pay a small fee on a daily or monthly basis. However, economically-marginalized service users often discontinue after the first month or two due to the continued out-of-pocket expense (31)(32).

Ability to Engage

There were two articles (n=2) discussing Ability to Engage. Both of these studies emphasize upon using tailored program design and modalities for MSMs to ensure maximum reach and coverage of PrEP as well as continuation beyond two months (17)(33).

4.2. Supporting Functions

Of the total 48 (n=48) articles included in the final analysis, 36 (n=36) articles discussed the Supporting Functions of the Market Systems Framework, defined in terms of Financing, Infrastructure, Skills, Technology, and Information. These are discussed below.

4.2.1. Financing

Of the 36 (n=36) articles referring to Supporting Functions of the Market Systems Framework, nine (n=9) specifically examined Financing pertaining to varying costs, region and country differences, and insights related to scale-up. Overall, oral PrEP delivery costs varied substantially by scale, duration, and types of clinics (32). Majorly, the types of clinics were determined by the service delivery modality which included community-based, public-private partnerships, specialized STI/HIV clinics, MSM-friendly clinics, hospitals, and pharmacies.

Depending on the specific context of the setting, such as in the Asia-Pacific region, funding support for community-based and public-private partnership service delivery organizations

were primarily financed through pharmaceutical companies, donors, government departments, and international non-profit organizations for a certain period (25). Whereas presence of a resourced private health sector with extensive programs funded nationally and with support from key donors was the norm for South Africa (34). Moreover, the average costs per person in an NGO social franchise clinic in Zimbabwe was 238 USD (183-300 USD across the NGO clinics). Moreover, several articles reported the need for specific funding to deliver services that are tailored to specific sub-populations such as transgender women and men who have sex with men (35)(36).

Other key insights regarding financing scale-up included the need to build on subsidized PrEP options to optimize coverage among those highest at-risk, reaching cost-effectiveness through integration with existing health programs, particularly those of sexual and reproductive health, such as in Kenya (10), and allocating costs in national and ministry budgets (37).

4.2.2. Infrastructure

Of the 36 (n=36) articles related to Supporting Functions, 7 (n=7) specifically referred to Infrastructure. These articles included existing, integration, de-medicalization, task-shifting, and inclusivity for infrastructure development for delivery of oral PrEP.

In certain public-private partnership models, existing health infrastructure were leveraged to build up routine oral PrEP delivery by integrating oral PrEP delivery with active HIV combination prevention activities. In Kenya's Jilinde Project, specifically, apart from public and private health facilities, other sites such as clinic drop-in centers were included which mainly catered to key vulnerable populations (24). Facility-based settings were also deemed feasible in resource-limited settings such as in Democratic Republic of the Congo (DRC) (38).

In addition to delivery in centralized locations such as clinics and hospital settings, community-based, home-based, and pharmacy-based PrEP delivery models targeting specific key populations such as MSM were also seen as a success. In certain contexts, these were also considered strategically cost-effective as they led to task-shifting and de-medicalization of oral PrEP services (10)(23)(39).

One critical area that emerged from the review was the need to ensure health-care sites are inclusive and informed by vulnerable populations' needs and are equipped to provide PrEP to them, particularly transgender women (40)(41).

4.2.3. Skills

Of the 36 (n=36) articles related to Supporting Functions, six (n=6) specifically discussed Skills. These included clinical skills, person-centered skills, and training and capacity building of healthcare providers as well as mobilizers working for oral PrEP delivery.

One of the key elements that emerged was the healthcare providers' clinical gaps in knowledge and practice for oral PrEP which highlighted the need for clinical skills development in PrEP providers which included private providers and hospital staff (37). These

were present even in contexts where national guidelines for oral PrEP had been implemented, showcasing need for training and capacity building amongst hospital staff, nurses, and outpatient providers (42).

Beyond clinical skills, providers' person-centered and interpersonal skills were also another area that could be strengthened especially for vulnerable populations such as MSMs and transgender women. Strategies to alleviate these could be through affirmative training, value clarification and attitudinal transformation, and patient-provider communication (30)(43).

Moreover, task-shifting via enhancing the role of mobilizers in non-profit clinic models could play a significant role in awareness raising, messaging, and serving as ambassadors (33).

4.2.4. Technology

Of the 36 (n=36) articles related to Supporting Functions, eight (n=8) articles were specifically related to Technology. These included digital health models, mobile application models, telemedicine models for oral PrEP, and electronic health records and data systems.

Digital health, mobile application, and telemedicine models are an innovative medium that have been piloted and tested in various country contexts. These models function in an array of ways; to serve as medication reminders, self-reporting, connecting to quality care and healthcare delivery, and to reach those that are in underserved areas (37)(23)(25)(10).

Moreover, other innovations that utilize technology are strengthening service delivery modalities by collecting routine electronic data as well as integrating oral PrEP services with electronic health records to identify at-risk individuals and follow-up maintenance (38)(30).

4.2.5. Information

14 (n=14) articles specifically examined Information regarding clients and provides' individual knowledge and perception, awareness and accuracy, messaging frameworks, and the larger information system.

Individual knowledge and perception amongst potential users and clients indicated low perceptions of risk as well as low knowledge of oral PrEP, however, there was display of high levels of willingness to use among key populations. However, articles also reported that information and willingness amongst transgender women were significantly lower due to an array of factors including preference and focus on gender-affirmative care, use of hormonal therapy, and perceived normative fears and stigmas.

While there was high reported willingness to use oral PrEP once the participants were briefed, the awareness and accurate understanding of oral PrEP was quite limited across settings and populations (31)(37)(44)(45)(46) which can be addressed through community mobilization and health education awareness interventions.

Also, due to limited awareness and accurate understanding, there were many reports of the need to craft careful messaging using frameworks to cascade down information and knowledge to key populations including MSM and transgender women. This messaging needs

to be structured for both the user as well as the healthcare provider (47)(20)(40)(48) including for information education communication and behavior change communication materials .

4.3. Rules

Of the total 48 (n=48) articles included in the final analysis of the study, 16 (n=16) articles discussed the Rules of the Market Systems Framework defined by Standards, Regulations, Policies, Norms and Trust. These are discussed below.

4.3.1. Standards

Of the 16 (n=16) articles referring to Rules of the Market Systems Framework, three (n=3) articles specifically examined Standards regarding provision of Oral PrEP in-terms of risk-based approach, inclusion, sensitizing and educating public and private sector health workforce, and integration of PrEP services with other health services.

A particular strength of the PrEP guidelines developed in Zambia is the inclusion of all persons considered at-risk of HIV and not restricting the provision of PrEP just for the key populations which made the intervention available for everyone. Prior to the risk-based approach, less than 4.000 persons were using PrEP but after the criteria to include everyone considered at-risk of HIV to qualify for PrEP, the number of PrEP users increased six times, 23000 persons started using PrEP just after a year (16).

Standards should be developed for sensitizing and educating health workforce on PrEP in public and private sectors both as well as creating effective linkages for PrEP-related services outside the regular health system (40). Similarly, integrating PrEP services with other health care services like sexual and reproductive health not just increases the efficiency of service delivery but also improves its uptake and adherence which provides opportunities for public health programmes for widening their reach to individuals who could benefit from PrEP and prevent new HIV infections (49).

4.3.2. Regulations

Of the 16 (n=16) articles referring to Rules of the Market Systems Framework, one (n=1) mentioned PrEP regulations. In LMICs, the regulatory approval of Oral PrEP has been slow and a barrier to widespread PrEP scale-up and implementation among MSM (50).

4.3.3. Policies

Of the 16 (n=16) articles referring to Rules, 6 (n=6) articles mentioned the role of PrEP-related policies in low- and middle-income countries in-terms of drug approvals, financing, supply chain, quality assurance, capacity building of health workforce, and delivery channels.

The government's commitment in LMICs plays a major role in developing supportive policies regarding expanding the access to Oral PrEP services (25). The national policies must include standards for the drug approval, supply chain, quality assurance, capacity building, dispensing channels, and sustainable national pharmaceutical budget planning to make PrEP accessible and affordable (15) (40)(25). Countries where stigma and punitive laws are directed towards

key populations like MSM and TGW, a conducive policy environment which supports accessibility and affordability of PrEP could reduce barriers and increase the uptake (37)(25). Policy reports from Kenya, Zambia, Zimbabwe, and South Africa offered nation-wide integrated services for PrEP in strategically selected locations to increase the access (10).

4.3.4. Norms

Of the 16 (n=16) articles referring to Rules, 11 (n=11) articles mentioned the role norms play in-terms of self and social stigma, and stigma associated with PrEP use.

Perceived and enacted self and social stigmas impact the intention to use PrEP and its adherence (37). Self and social stigmas are barriers to PrEP uptake and adherence among MSM and TGW (40). PrEP awareness and willingness to use is low among TGW who are part of a transgender community which indicates a need to address specific barriers within TGW communities (41). Stigma also plays a role when it comes to health care workers (HCWs) and prescribing PrEP. Overall, the HCWs showed a high level of understanding about PrEP and were favorable about its benefits for the users at high risk of HIV, but some HCWs showed hesitancy to prescribe it due to concerns about risk compensation, stigma, and low adherence (51).

In a study conducted by Mpunga et al., married MSM indicated that they would like PrEP use to be concealed from their spouses or parents, so they don't suspect anything (18). Concerns were also raised that PrEP usage could be interpreted as a sign of engaging in sexual risk behavior for HIV, potentially causing suspicion in love relationships or by family and friends and being labeled as HIV-positive or promiscuous (52)(45). It is essential for community-level interventions to engage sex partners, opinion leaders and the general population about their role in HIV prevention. If PrEP users come to be perceived by the community as ''high risk'' or ''promiscuous'', it could greatly impact its uptake (15).

To normalize HIV prevention, it is important to disseminate non-stigmatizing and clear messages widely to dispel myths, reduce stigma, and avoid confusion in understanding between ART and PrEP (48)(15). Interventions that augment self-efficacy, empowerment, individualized adherence support, and social cohesion are effective and mutually reinforcing (15). Opportunities to reduce PrEP stigma and discrimination should be explored, for instance, using different branding and packaging for PrEP versus ARVs along with expanding advocacy efforts to increase PrEP access where MSM and TGW are stigmatized (16).

4.3.5. Trust

Of the 16 (n=16) articles referring to Rules of the Market Systems Framework, 7 (n=7) articles mentioned Trust in-terms of health services, pharmacies, and control over one's sexual health.

A systematic review regarding barriers to the uptake of PrEP among transgender populations showed concerns regarding the drug's interactions with hormone treatment and their distrust in health services (44) which calls for interventions targeted towards improving the capacity of HIV preventive services (42).

MSM showed their lack of trust in buying PrEP sold through pharmacies, especially at a high price. They belief that pharmacies may distribute fake PrEP which undermines trust in quality and potency along with their anticipated fear and shame that pharmacists might consider PrEP buyers to be HIV positive, promiscuous or MSM (45)(52).

PrEP use in some studies raised hope as participants quoted increased control over their sexual health and hope in avoiding infection, especially among men involved in sex work or in known sero-discordant relationships (53). Male and female sex workers in Kenya cited PrEP as a potential "expression of self-love and self-care" synonymous to "making a choice to live" (53). Key populations are important advocates for PrEP, therefore, empowering them with the correct knowledge will strengthen community trust, mitigate against rumors, increase acceptance, uptake, and adherence (15).

4.4. Stewardship

A review of several case studies in LMIC settings that have exhibited the effectiveness of building multi-sector partnerships between public health sectors, academic institutions, international organizations and MSM CBOs. Utilizing multi-sector partnerships may be particularly critical in LMIC settings where fear of discrimination, anti-gay legislation and health-care related stigma in public sector health services prevent many MSM from seeking sexual health care. MSM CBOs have greater local buy-in and trust among MSM communities but may not have the resources to provide sexual health services. Collaboration between public health, academic, non-profit sector, and community-based organizations in LMICs have been fruitful in expanding prevention and testing services for HIV and other STIs, even where they are criminalized (50).

5. Discussion

To understand the service delivery landscape around oral PrEP services for MSM and TGW in LMICs, this study conceptualized and operationalized the Integrated Person-centered Market Systems framework. This is the first study, to the best of my knowledge, that synthesized healthcare markets' macro elements with individual-level elements pertaining to healthcare accessibility. This holistic framework was deployed to qualify the existing literature on Oral PrEP programming and key populations' perceptions around Oral PrEP services.

The Integrated Person-centered Market Systems Framework proved useful to understand where prior research studies and interventions have been focused on across the market functions. As aforementioned, 48 articles were included in the final analysis with 34 articles referring to the Core Supply Function, 14 referring to the Core Demand Function, 36 referring to the Supporting Functions, 16 discussing Rules, and 1 referring to Stewardship. While this framework supported the mapping of Private Health Sector delivery for oral PrEP across these market functions, it also revealed trends in terms of which market functions are most prominently featured in reviews and research studies. This study found that across the framework, Availability and Accommodation (*n=17),* Acceptability (*n=16),* Information (*n=14),* Ability to Reach (*n=13),* Ability to Perceive (*n=13),* and Norms (*n=11)* were the most referenced market functions in the articles included in the review, suggesting that efforts have been largely concentrated on these market functions. This can also be due to items within these functions often being considered as barriers for oral PrEP use and continued maintenance among key populations which is why programming thus far has been largely focused on alleviating and understanding the underpinnings behind these.

Existing literature on the Core Supply Function of the Integrated Person-centered Market Systems Framework highlights gaps and unique approaches in the current PrEP programming landscape. One of the major shortcomings noted consistently among systematic reviews as well as independent programmatic evaluation report was the high rates of discontinuation of Oral PrEP services. This is largely due to the limited understanding of programmes on key population communities' perceptions and lifestyles and their difficulty to access Oral PrEP services. WHO proposes using Differentiated Service Delivery approaches to tailor PrEP programming to the respective community's needs and context(54). This is consistent with the recommendations shared in the articles reviewed in this study as well of using community-based delivery models backed by client-centered programming for sensitive and effective Oral PrEP service delivery.

The literature on the Core Demand Function of the Integrated Person-centered Market Systems Framework captures the MSM and TGW communities' perceptions around oral PrEP services. Participants across studies reported an overwhelmingly positive attitude and high willingness to use oral PrEP services with varying degrees of HIV risk perceptions. However, favorable beliefs have not resulted in high utilization of PrEP services. Linking with the gaps noted above in programming, participants shared their preferences for how they would like to avail PrEP services such as in MSM-friendly or HIV and other STIs specialized clinics or via

pharmacies, and the specific barriers that alienate them from accessing and continuing using PrEP services.

Literature on the Supporting Functions of the Integrated Person-centered Market Systems Framework, defined in terms of Financing, Infrastructure, Skills, Technology, and Information, reveal opportunities and barriers for the private health sector to leverage uptake and continued use of oral PrEP amongst key populations such as MSM and TGW. Under this function, information was the most reported result arena among the studies reviewed. Specifically, regarding Information, results suggest a potential avenue for strong health awareness and education interventions. Reported willingness to use was high across populations and settings, however, there were variations across risk perceptions, knowledge, awareness, and accuracy of oral PrEP. This signifies an opportunity for leveraging this gap to build knowledge and awareness through health education, counselling, and messaging and advocacy campaigns. Another key area that emerged is regarding the specific needs of transgender women, who alongside, the need for HIV prevention and treatment also require gender-affirmative and person-centered care. Moreover, there is also a need to focus on reducing perceived and enacted stigma by developing community norms of acceptance for use of oral PrEP for HIV prevention.

Showcasing consistency with findings from other studies, this study found that subsidized and cost-effective oral PrEP options can drastically improve coverage for at-risk populations in LMICs (55)(56). Moreover, in 2016, UNAIDS also suggested allocating 25% of costing efforts and funds towards HIV prevention(57). From specific examples of South Africa and other countries in Africa, there are various strategies that can be employed to achieve this which include integrating a well-resourced private sector with national funded programs for treatment and prevention or utilizing funding for Oral PrEP by strategic and cost-effective endeavors such as prioritizing geographic and key populations most at-risk and incorporating PrEP delivery with other healthcare services such as sexual and reproductive health like in Kenya. By ensuring there are enough products available at reasonable rates, donors can help LMICs to stabilize their health supply chains and lessen their vulnerability to supply shortages(11). Donors can also assist by integrating and enhancing current private sector service delivery channels that focus on equity, this would expand access for all income groups and help the countries in achieving universal health coverage(11).

Alongside conventional service delivery, several articles reported the growing importance of technology and digital health for oral PrEP. These include mobile health clinics which are able to delivery acceptable and integrated oral PrEP services that are focused on MSM and TGW at easy-to-access locations which leads to high potential for PrEP uptake, as well as telemedicine and health apps which have the benefit of discretion, no long waiting time at clinics, and personalized and informed decision-making and care for oral PrEP which leads to greater perceived personal agency among key populations, particularly, MSM. This is a particular area where the private health sector, specifically for-profit organizations, can play a major role for sourcing and seeding grants for innovative models that utilize technology due to their increased investments for social enterprise projects particularly in the case of resource constrained and LMIC settings (58)(59)(60) .

Efforts to increase the private sector's involvement in health care services goes back at-least 25 years (8). When it comes to private health care sector, most of the government's in LMICs face common obstacles which include weak legal and regulatory frameworks, low profitability of sexual and reproductive health commodities and services, poor understanding, and limited capacity to engage with the private health care sector (11). Those countries which have well-established regulation of the private health care sector and good regulatory capacity, they can use a range of regulatory and financial means to manage mixed delivery of health services in the public interest. In the absence of regulations and limited regulatory capacity, the private health care sector will not necessarily operate in a way that is aligned with the health goals and objectives of the country (8). Governments are the stewards of their health systems; steps should be taken to ensure the management and regulatory controls of the private health care sector. Achieving the Sustainable Development Goals (SDGs) demand a new approach to development which is based on cooperation and collaboration between government, CSOs, for-profit, not-for-profit, and other actors to achieve these goals. This translates into an urgency to better manage the private sector and mixed health systems to ensure that all public and private providers contribute effectively to the goal of universal health coverage (8).

The Private Health Sector plays a prominent role in LMICs in sensitive contexts of immunization service delivery, child health and nutrition, and sexual and reproductive health, particularly for Family Planning (61). In the context of HIV prevention and Oral PrEP services, the landscape changes due to the stigma around HIV and the affected communities. Hence, CBOs play a vital role in ensuring their communities' access to HIV prevention mechanisms and Oral PrEP services. Private health care sector has struggled to effectively serve the vulnerable and at-risk populations such as MSMs and transgender women, due to a limited understanding of these communities' lifestyles, cultures, and social realities. Consequently, PrEP programmes do not hit the mark with the communities demanding for PrEP services. To facilitate the private health care sector in bridging gaps in service delivery, this study will share recommendations for increasing utilization of Oral PrEP services among MSM and TGW communities in LMICs.

6. Limitations

There are limitations to the extent of comprehensiveness of this literature review. The articles identified for final analysis were concentrated on some specific components of the Integrated Person-centered Market Systems Framework and other concepts were not as clearly articulated in the context of Oral PrEP and market systems. Much of the evidence for Oral PrEP in LMICs setting might not have been reported yet in the peer-reviewed literature since PrEP is a relatively new intervention and evidence for its implementation to increase the uptake among MSM and TGW in various settings is still developing. Also, there was no liberty to assess and compare the quality of the articles due to limited availability of relevant literature. The search excluded clinical trials and studies which were solely focused on KPs other than MSM and TGs in LMICs.

7. Conclusion and Recommendations

Communities vulnerable to HIV, such as MSM and TGW, face significant stigma and discrimination resulting in social marginalization. Specially in LMICs, where certain behaviors and expressions are criminalized as well, it restricts these communities from accessing essential oral PrEP services and information. To support programme development for working with the MSM and TGW communities, the study applied an adaption of the Integrated Person-centered Market Systems framework. This holistic review of the Oral PrEP service delivery landscape for MSM and TGW in LMICs facilitated the identification of gaps and opportunities in provision of PrEP services at the supply-side, the demand-side, the policy-level, and supporting elements such as financing, infrastructure, skills, technology, and information. Furthermore, the study was able to highlight differentiated service delivery mechanisms that serve these communities' needs for oral PrEP services in a safe and conducive environment. Future research on Oral PrEP service delivery can apply this framework for assessing PrEP programmes for their "person-centeredness" and explore the applicability of the framework in developing and evaluating "person-centered" programmes.

The Integrated Person-centered Market Systems Framework is a holistic framework that can be applied to review and assess PrEP programming in a particular context. The findings of this literature review are consolidated into recommendations for increasing the utilization of oral PrEP programming and service delivery for MSM and TGW in LMICs. Based on the study's findings, below are the recommendations for improving aspects under the Core Functions, Supporting Functions, and Rules.

7.1. Core Functions

Potential stakeholders for these specific recommendations under Core Functions can be program planners and implementers, program managers, health directors and health managers, Ministry of Health actors, Population and Welfare department heads, and District Health Teams.

1. To deploy the Risk-based Criteria for delivering PrEP services as it increases accessibility of services for all vulnerable populations while minimizing the identity-based stigma that restricts key populations' access, in roll-outs deployed under the Population-based Criteria.
2. To increase MSM's utilization of PrEP services, programmes need to de-medicalize PrEP services by using "MSM-led" programming and service delivery. Programmes and service delivery points accomodated within the MSM-led community programming addresses several major barriers that are currently restricting and demotivating the MSM community from accessing PrEP services.
3. Aligned with the WHO's recommendation (54), differentiated modes of service delivery should be adopted for providing PrEP services. Programs must consider departures from using healthcare facilities to provide PrEP services by using Pharmacies and community drop-in centers as service delivery points to increase the social comfort and ease of access among MSM and Transgender Women.

7.2. Supporting Functions

Potential stakeholders for these specific recommendations under Supporting Functions can be program planners and implementers, program managers, health directors, health managers, for-profit organizations, community-based organizations, not-for-profit and non-governmental organizations, Ministry of Health, Ministry of Women, Gender, and Youth, Population and Welfare department heads, and District Health Teams.

1. To increase the awareness among key populations such as MSMs and transgender women and information regarding oral PrEP, strong messaging campaigns using structured frameworks adopting a gain-frame approach, health awareness and education interventions, and comprehensive counselling is required to disseminate accurate and needs-specific oral PrEP information that also state the difference between ART and PrEP that caters to potential users, at-risk population groups, and health providers.
2. Demand creation should take place at the community-level through mobilizers, peers, and health educators through community awareness and education sessions that focus on addressing risk perceptions, perceived value, benefits, and perceived and enacted stigmas and norms for oral PrEP.
3. To ensure continued uptake of oral Prep, utilizing cost-effective strategies both programmatically and individually that account for the prevailing health system and establish appropriate service delivery channels, and referrals and linkages to existing health channels in the health system for oral PrEP delivery options at clinics, hospitals, and health centers for MSM and Transgender Women populations.
4. Service delivery points and modalities of oral PrEP in the healthcare systems of various contexts need to be integrated within larger holistic healthcare that incorporates HIV prevention and treatment within the ambit of sexual and reproductive health rights and services.
5. To ensure uptake among populations, particularly for vulnerable and at-risk populations such as MSM and transgender women, healthcare providers should undergo capacity building and training for person-centered quality care to enable provision of interpersonal and counselling skills, clinical knowledge and practice, and gender-affirmative care.
6. To aid oral PrEP uptake, leveraging technology to develop innovative digital applications for medication reminders, self-reporting, and connecting with service delivery points is recommended for use and maintenance among MSM and Transgender Women populations.

7.3. Rules

Potential stakeholders for these specific recommendations under Rules can be donors, advocates, lobbyists, policymakers, Ministry of Health, Ministry of Women, Gender, and Youth, Population and Welfare department heads, Drug Regulatory Authorities, Drug

Administrative and Control departments, Pharmaceutical Control Bureaus, and Education and Training Quality Assurance entities.

1. Aligned with WHO's recommendations, advocacy for national policies to ensure drug approval and establishment of supply chains for ensuring PrEP access as well as legislative and regulatory frameworks that enable the prescription and provision of oral PrEP services at pharmacies is highly recommended for ease of accessibility and uptake among MSM and Transgender Women.
2. Development of guidelines, curriculums, and training for service provision of oral PrEP is also another key recommendation from this study as often, healthcare providers report feeling unequipped to provide oral PrEP services and are not able to adequately counsel and provide services to those that would benefit from Oral PrEP. Focusing on these policy provisions with guidelines, curriculum, and trainings would support providers' capacity building for oral PrEP service delivery to MSM and Transgender Women.

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Appendix 1 – Search Strings

No.	Concept	String
1	Private Sector	“private sector” OR “private health sector” OR “private health care” OR “private provider” OR “pharmacy” OR “for-profit sector” OR “non-profit sector” OR “not-for-profit”
2	Delivery	“delivery” OR “service delivery” OR “health service delivery” OR “health services”
3	Increasing	“increasing” OR “expanding” OR “expanded” OR “widening” OR “widened” OR “improving” OR “increased”
4	Utilization	“utilization” OR “utilizing” OR “use” or “avail” OR “availing”
5	PrEP	“PrEP” OR “Pre-exposure prophylaxis”
6	HIV	“HIV” OR “human immune-deficiency virus”
7	MSM	“msm” OR “men who have sex with men” OR “gay” OR “bisexual” OR “homosexual” OR “same-sex men”
8	TGW	“tgw” OR “tg” OR “transgender” OR “transgender women” OR “trans-women” OR “transgender male to female” OR “transgender MTF” OR “transgender M2F”
9	LMICs	“LMICs” OR “low income countries” OR “middle income countries” OR “developing countries” OR “limited resource countries” OR “developing nation” OR “underdeveloped nation” OR “emergent nation” OR “less developed countries”
10	Market Systems	“market systems” OR “health market” OR “health systems” OR “market systems for health”
11	Supporting Functions	“supporting functions” OR “information” OR “technology” OR “infrastructure” OR “financing” OR “skills” OR “financing for supply” OR “financing for demand”
12	Rules	“rules” OR “policies” OR “standards” OR “regulations” OR “trust” OR “norms”
13	Supply	“supply” OR “approachability” OR “acceptability” OR “availability” OR “accommodation” OR “affordability” OR “appropriateness”
14	Demand	“demand” OR “need” OR “ability to perceive” OR “ability to seek” OR “ability to reach” OR “ability to pay” OR “ability to engage”
15	Stewardship	“stewardship” OR “strategic stewardship” OR “technical stewardship”