

Risk Assessment Tools and the Identification of Individuals at High-Risk of HIV infection in the Delivery of Oral PrEP

Analysis and Recommendations

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**HIV Prevention
Market Manager**

Accelerating Product Introduction
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Oral PrEP Risk Assessment Tools at a Glance

Risk Assessment in the Context of Oral PrEP:

- The World Health Organization recommends oral PrEP for individuals at substantial risk for HIV¹.
- Studies, projects and early implementation efforts have used a variety of **risk assessment tools** to help identify and enroll individuals at substantial risk for HIV infection.
- Accurate identification of individual risk is critical in order to:
 - help ensure that PrEP is offered to those who can benefit the most
 - maximize population-level HIV prevention impact
 - optimize investments

What we know:

- Being at risk is a function of both environment (e.g., living in a community with high underlying HIV incidence) and individual exposure to risk (e.g., having a partner with untreated HIV).
- An individual's perception of their own risk is generally inaccurate and most often underestimated²; repeated conversations about risk can lead to more accurate understanding.
- Those who accurately understand themselves to be at **high risk** are more likely to initiate and effectively use oral PrEP²⁻⁷.
- Those who accurately understand themselves to be at **lower risk** are less likely to use oral PrEP when they don't need it⁵⁻⁷.

What we learned:

- Creating opportunities to build accurate understanding of personal risk is critical for optimizing individual benefit, epidemiological impact and cost-effectiveness.
- Optimizing the delivery of oral PrEP requires identifying those not only at substantial risk for HIV, and also those who are ready to use PrEP correctly.
- People cycle in and out of risk and risk assessment can help determine optimal use of oral PrEP.
- Using tools to screen for eligibility is problematic; no matter how accurate the tool, some high-risk individuals will be missed and not offered PrEP
- Currently, no validated tools exist for key affected groups beyond women, pregnant women and sero-discordant couples.
- Where data are available, e.g. MSM oral PrEP studies, validation of tools can be done and are useful.
- Without available data, validation exercises require investments in large scale validation studies.
- Ensuring that high-risk individuals enroll in PrEP may require a re-framing or movement away from assessing "risk for" HIV in the delivery of oral PrEP, but "vulnerability to" HIV.

What is needed now:

- There is an opportunity now to develop and promote a comprehensive program framework and approach to identifying those at greatest risk for HIV.
- There is potential benefit to moving from assessing "risk for" HIV, to helping people understand their "vulnerability to" HIV. Communication reframing risk to vulnerability may make oral PrEP more appealing to those who could benefit from it the most.
- Continue the development of self-administered risk assessment tools (online or otherwise) to build accurate understanding of individual risk.
- Develop user guides to help programs at scale in the application of risk (or vulnerability) assessment tools for greatest benefit, including modifying tools used at screening for ongoing monitoring.

- Invest in the validation of tools for groups at high-risk for which such tools do not currently exist, where existing data are readily available.

Introduction

The World Health Organization (WHO) recommends oral PrEP for individuals at substantial risk for HIV infectionⁱ as an additional prevention choice within combination HIV prevention.¹ The guidelines further recommend using a multi-faceted approach for identifying those at substantial risk, which is informed by the local epidemiological context, evidence regarding risk factors for acquiring HIV among high-risk individuals and groups in the programmatic setting, and assessment of individual risk.

Accurate identification of individual risk is a critical component of oral PrEP service delivery, both to help ensure that PrEP is offered to those who can benefit the most and to maximize population-level HIV prevention impact by enrolling those at highest risk of infection. Furthermore, oral PrEP is an expensive intervention; thus, in order for the substantial resources involved in rolling-out oral PrEP to have commensurate impact on the epidemic, it will need to be used by those at greatest risk for HIV. Considering the limited resources available for sustained support of HIV prevention broadly, accurate risk identification is critically important for optimizing investments.

However, the process of accurately assessing individual risk in the context of oral PrEP delivery poses significant challenges. Recent evidence highlights that an individual's perception of their own risk is generally inaccurate and most often underestimated. For example, a recent study of oral PrEP implementation in Uganda found that among participants who scored high on a risk assessment tool, only 30% self-identified as being at risk prior to its administration². At the same time, evidence suggests that individuals who self-identify as being at high risk are significantly more likely to initiate and effectively use oral PrEP. From the same Ugandan study, uptake of oral PrEP was only 11% among those screened by providers to be at high risk, versus 39% among those who self-identified as being at risk. Similar findings have been noted in studies across population groups^{3,4}, in particular through oral PrEP open label extension studies with MSM and transgender women, which consistently found higher levels of uptake and adherence among those self-identifying as being at risk^{5,6,7}.

To date, studies, demonstration projects and early implementation efforts have used a variety of risk assessment tools and processes to identify and enroll those at risk. Part of the challenge is that individual risk is driven, at least to some degree, by the underlying risk in the environment, e.g., whether or not there is high underlying HIV prevalence and incidence in the community in which an individual lives. With the aim to understand more about the relative strengths and weaknesses of current tools and approaches being used for risk assessment within oral PrEP studies and implementation, and to

ⁱ The WHO oral PrEP guidelines define substantial risk of HIV infection as HIV incidence of 3 per 100 person-years in the absence of PrEP. HIV incidence greater than 3 per 100 person-years has been identified among some groups of men who have sex with men, transgender women in many settings and heterosexual men and women who have sexual partners with undiagnosed or untreated HIV infection, and among adolescent and young women in sub-Saharan Africa. In locations where the overall incidence is low, there may be individuals at substantial risk.

make recommendations about their use within the context of rollout, this analysis aimed to answer the following questions:

- **What risk assessment tools and processes are used in the delivery of oral PrEP, and how are they used?**
 - What risk assessment tools exist?
 - What are the core elements of risk assessment?
- **How do tools and processes help identify those at substantial risk of HIV infection?**
- **What do implementers need from risk tools to guide oral PrEP delivery moving forward?**
 - What opportunities (for PMM or others) exist to improve the tools and their use?
 - How can tools be used to monitor programs and track individual risk over time?

This analysis represents a discreet activity to inform a larger body of work being conducted by AVAC and partners within the Prevention Market Manager portfolio, focused on understanding who is at high-risk of HIV acquisition, how best to identify and reach them, and how to support them to achieve high-levels of oral PrEP uptake and use.

1. Methodology

The following methods were used in conducting the risk assessment tool analysis.

Collection of existing tools: We invited all PrEP demonstration and implementation projects known to AVAC to share their risk assessment tools. Most of these projects were in sub-Saharan Africa or other low to middle income countries; however, we did identify some tools in use in higher income countries with a programmatic focus on key affected populations. Tool collection was intensified through the convening of implementers (see following paragraph), resulting in 31 tools included in the analysis. A list of the projects contacted and tools assessed is included in Annex A.

Convening implementers to discuss issues of risk assessment: At the IAS conference in Paris, July 2017, we invited a group of implementers, researchers and modelers to discuss issues of risk assessment in the rollout of oral PrEP. We used a discussion guide to facilitate the exploration of the following topics: if and how risk is assessed in their programs; how and what kind of tools have been used in the process of risk assessment; the key strengths and weaknesses of the tools; how tools have been helpful (or not) in identifying high-risk clients; advice and recommendations for tools and risk assessment moving forward; and identifying gaps that exist in the area of risk assessment that work on risk assessment under the PMM project could fill. The discussion guide is included in Annex B.

Tool Mapping and Analysis: We created a data analysis spread sheet and we mapped collected tools across the key elements of the risk assessment, including target population, indicators assessed and perceived strength and weaknesses of the tools in identifying those at substantial risk. A template of the analysis tool is included in Annex C.

Having extracted data from tools, we triangulated information from all the methodological approaches described to address the questions of interest.

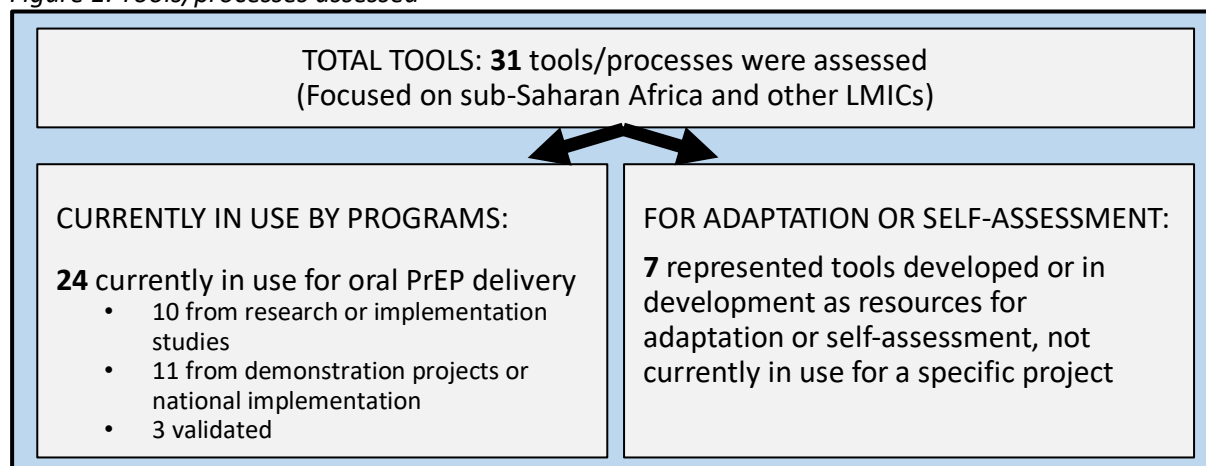
2. Findings

Question #1: What risk assessment tools and processes are used in the delivery of oral PrEP?

Overview of Tools Analyzed

Among the 31 tools analyzed overall, 24 tools were currently in use; 10 of these were from research or implementation studies, 11 were from demonstration projects or national implementation, and 3 were tools validated for use with women, pregnant women and sero-discordant couples in clinical settings. We also analyzed tools developed or under development to serve as resources to be adapted for programmatic use, or for self-assessment.

Figure 1: Tools/processes assessed



The countries represented within the analysis included several from within sub-Saharan Africa (Benin, Kenya, Nigeria, South Africa, Uganda, and Zimbabwe), Brazil, the United States, the Netherlands, the UK, India, New Zealand and Australia. Tools were used in programs targeting at-risk groups in high-risk settings, comprising adolescent girls and young women (AGYW), female sex workers (FSW), men-who-have-sex-with-men (MSM), transgender (TG) persons, sero-discordant couples (SDC) and pregnant women. *Table 1* provides a list of risk tools assessed by project name, population group, and country.

Table 1: Tools/processes assessed by country and population group

Project Name	Target population	Country/ies
Research and Demonstration Projects		
Power	AGYW	Kenya, SA
3Ps	AGYW	SA
HPTN 082	AGYW	SA and Zimbabwe
Caprisa	AGYW	South Africa
MPYA	AGYW	Kenya
SaPPH-IRE	FSW	Zimbabwe
Benin Demonstration Project	FSW	Benin
PSI Zimbabwe (DREAMS)	FSW/AGYW	Zimbabwe
DMSC and Ashodaya	FSW/TGSW	India
NZ PrEP	MSM	New Zealand
Sibanye/Health4Men	MSM	South Africa
PROUD OLE	MSM	UK
Jilinde	MSM/FSW/AGYW	Kenya
LVCT	MSM/FSW/AGYW	Kenya
PrEP Brasil	MSM/TG	Brazil
AmPrEP	MSM/TG	Netherlands
VicPrEP	MSM/TG/ SDC	Australia
Partners Demonstration Project	SCD	Kenya
Nigerian Demonstration Project	SDC	Nigeria
AeGIS	Women	USA
PRiYA	Pregnant women	Kenya
SEARCH	All	Kenya, Uganda
National Implementation		
NASCOP	All	Kenya
South Africa Implementation	FSW/MSM	South Africa

Key risk criteria assessed by target population

The specific risk criteria assessed and questions used to assess them varied widely depending on the target group of the program in which the tool was being used, the country and geographical setting, and whether the tool was used for service delivery with one or multiple population groups. The indicators included were selected based on evidence from research studies or modeling showing association with either HIV incidence or prevalence for these population groups in the programmatic setting. In three cases, tools had been validated for their positive predictive value on HIV incidence (see section on Risk Scoring below).

When grouping criteria assessed in risk tools by the target population, commonalities emerged. Overall, tools used within programs focusing on AGYW focused on participant's age and age of sexual debut, number and ages of partners, condom use with partners and exposure to violence. Tools from within programs focused on MSM or TG persons concentrated more on assessing sexual and behavioral risk, in particular indicators of unprotected anal sex, frequency of STIs, drug and alcohol use, and HIV status of current partner(s). Tools used within programs for sex workers also focused on sexual and behavioral

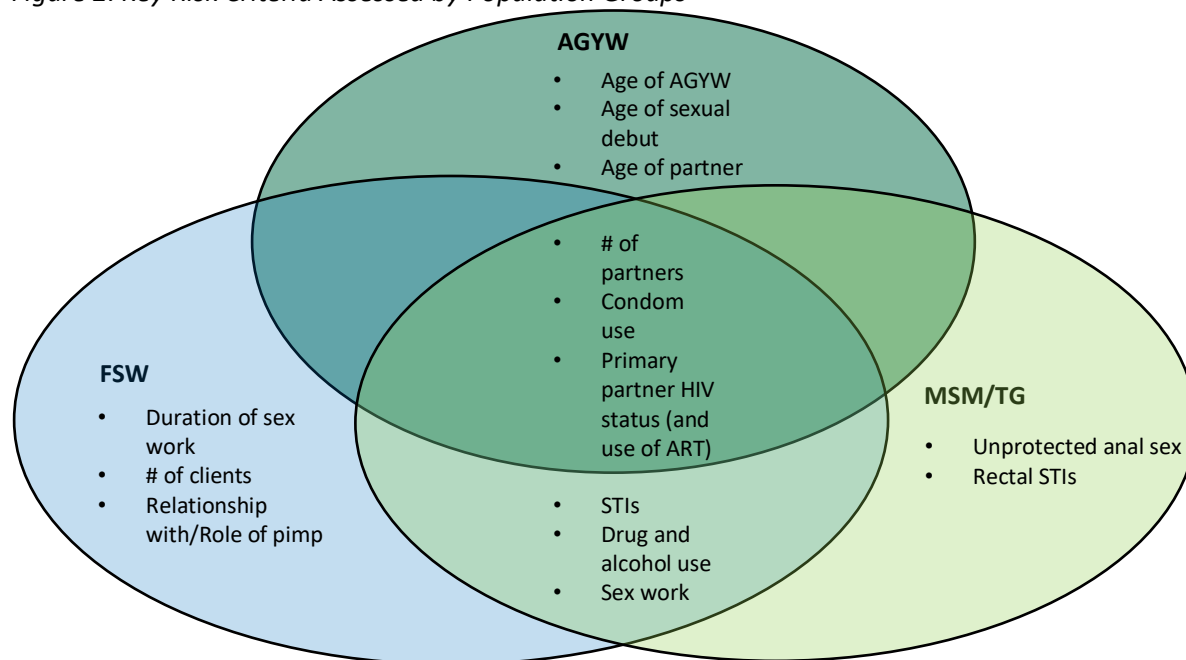
risk, but included questions specific to the duration of and type of sex work and frequency of condom use with clients.

Figure 2 illustrates a summary of individual risk criteria most often assessed according to key population group (AGYW, sex workers, and MSM), also indicating where criteria were generally common across population groups or within more than one subgroup. Summarizing risk criteria in this way is useful for understanding how individual risk has been assessed within groups broadly; however, it is important to note that some tools incorporated additional questions or categories for risk that were quite localized and context specific.

For example, within the India demonstration project with brothel-based sex workers, several questions focused on the client's interaction with their "Babu" or pimp. Questions included those designed to assess a client's exposure to intimate partner violence from her Babu, whether or not she was expected to have sex with him, and if so, the frequency of sex expected, and whether that expectation included having sex without a condom. Such questions reflected a deep understanding of the specific factors likely to influence or increase individual HIV risk within an at-risk population in a given setting.

In oral PrEP programs for sero-discordant couples were somewhat different. The primary criteria used to determine risk for the negative partner, was the positive partner's ART use and viral load status; e.g. if they were not on ART, or they were on ART with unknown or detectable viral load, then the negative partner was considered at high risk and a potential oral PrEP candidate. Other criteria assessed included among SDCs included younger age and condom-less sex.

Figure 2: Key Risk Criteria Assessed by Population Groups



How tools are being used

Figure 3 provides an overview of how tools are currently being used in oral PrEP delivery, and how their use could be expanded (see Question #3 below).

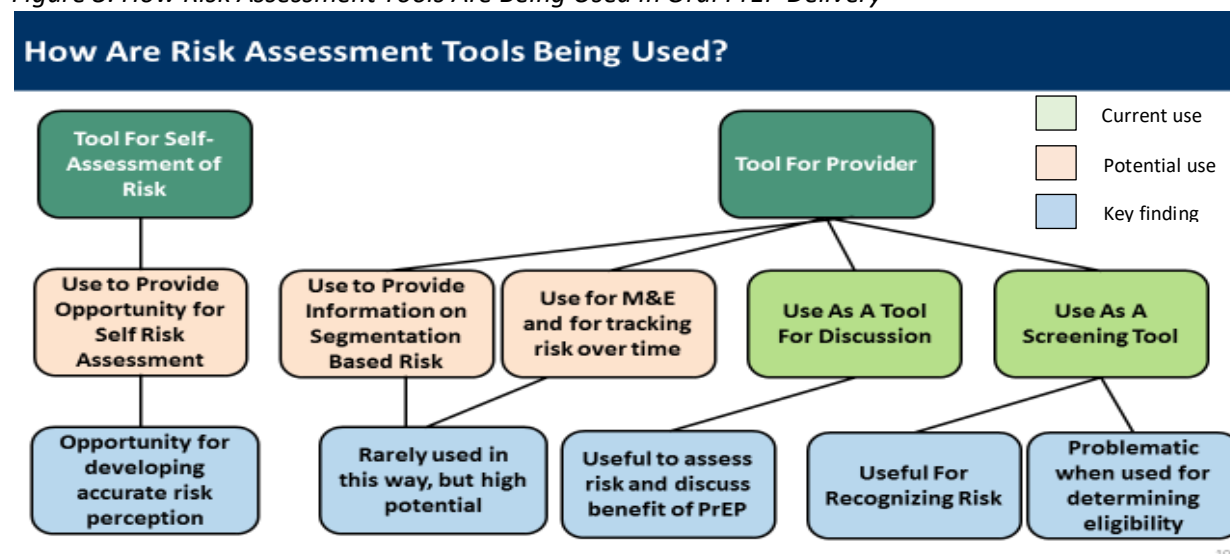
The majority of tools and processes used for assessing individual risk in oral PrEP delivery employ provider-led risk assessments. These risk-assessments are used to both screen eligibility for oral PrEPⁱⁱ, and/or to support the initiation of a conversation about risk and the potential benefits of oral PrEP.

Screening tools determine eligibility for oral PrEP based on risk, either through generating risk scores (e.g. a score of 5 or greater indicates substantial risk and thus eligibility for oral PrEP), or by assessing a set of risk eligibility criteria that a client must meet before they are offered oral PrEP. Among the 24 tools included in this analysis, 14 were used to screen for eligibility, with 6 of these employing risk scoring (see further discussion in the next section).

The key benefit of these types of tools is their definitive quantification of “high-risk”, which guides providers on who should be offered oral PrEP. However, as discussed further below (see section on Risk Scoring), the use of tools to screen people for oral PrEP can be highly problematic. Tools cannot predict individual risk with 100% accuracy. Even with full disclosure from clients assessed, and when tools are validated, some high-risk clients will be missed or misclassified and not offered PrEP.

Ten of the 24 tools in this analysis were used qualitatively, not to determine eligibility for oral PrEP, but to identify risk and initiate a conversation about the potential benefits of oral PrEP. These types of tools were generally used within programs designed around offering PrEP to specific high-risk or target groups. If a client belonged to this group and they desired oral PrEP, they would be offered it (assuming they were clinically determined to be eligible). Responses on these types of risk assessment tools were used to inform clinical discussions, risk reduction messages, and to determine other prevention, health or wrap-around services that might benefit the client. The key benefit of this approach is the opportunity it creates for building risk awareness among clients, without excluding someone from PrEP due to scores or cut offs.

Figure 3: How Risk Assessment Tools Are Being Used in Oral PrEP Delivery



ⁱⁱ There are also clinical eligibility criteria for oral PrEP in most programs settings (e.g. renal and liver function). This analysis was focused on eligibility in terms of the substantial risk criteria only.

Question #2: How do tools and processes help identify those at substantial risk of HIV infection?

Risk scoring

Of the 14 tools used to screen for eligibility, 6 used risk scoring. Risk scoring tools use population-based data and apply it to individuals to estimate their individual risk. The risk scoring approach is appealing, in so far as it offers a clear and objective estimate of risk, which theoretically helps ensure that programs are not squandering limited resources by enrolling large numbers of individuals who do not meet the “substantial risk” threshold. However, as mentioned above, there are important limitations to this approach.

First, only three tools have been scientifically validated for use in risk scoring using data from clinical trials, one for sero-discordant couples,⁸ one for women broadly,⁹ and one for pregnant and postpartum women.¹⁰ Risk scoring tools that have not been validated result in scores that are meaningless in absolute terms. In other words, we don’t know if a score generated from a tool that has not been validated is quantitatively associated with elevated risk for HIV acquisition, let alone whether or not it is associated with a particular level of HIV incidence. Furthermore, tools that have been generated using data from clinical trial participants may not be generalizable to the general population, even for members of the same group for which the tool was developed. For example, a tool that was developed using data from a clinical trial among sero-discordant couples, may not be generalizable to sero-discordant couples more broadly.

Validated tools, on the other hand, provide more assurance that scores are reflective of actual levels of HIV risk. For example, Balkus et al⁹ developed and validated a risk assessment tool to predict HIV acquisition among African women, drawing upon data from three randomized trials of biomedical HIV prevention interventions (VOICE, HPTN 035, and FEM-PrEP). Using standard methods for the development of clinical prediction rules, the risk-scoring tool was created to predict HIV acquisition over the course of one year. Tool performance was assessed through internal and external validations. Scores of >5 were found to be associated with incidence of 5/100 PY, while scores of >3 were associated with incidence of 2 to 4/100 PY. Similar tools have been developed and validated for use with sero-discordant couples,⁸ with scores >5 being associated with HIV incidence of 3/100 PY, and with pregnant women,¹⁰ with scores of >6 being associated with incidence of 7/100 PY.

The obvious strength of these validated tools is that scores are statistically associated with levels of HIV incidence/acquisition risk, and thus can be used theoretically to assess whether or not an individual falls into the category of being at substantial risk of HIV infection. The main limitation of these tools is that they are only valid within the same or very similar populations for whom they were validated. This means that the Balkus tool, for example, is only valid for adult, female, biomedical research participants in sub-Saharan Africa, with limited generalizability to women not enrolled in biomedical prevention studies, or to adolescent women. The predictive value of the tool cannot be applied to other individuals or populations at risk such as MSM, female sex workers, TGW or other men. In theory, tools could be similarly developed and validated for additional populations; however, the data required, i.e. the HIV incidence data within the context of trials that also assessed a variety of risk factors, is not readily available for all populations of interest in all settings. Without available data, validation exercises would require heavy investments in large scale validation studies.

Furthermore, most implementers we engaged with were skeptical about their use to determine PrEP eligibility in actual implementation, as illustrated by the following quotes.

“HPTN 082 [which is using the Balkus tool] looked at decliners and accepters, and it found a median risk score of 7 in both PrEP accepters and non-accepters. Very few were screened out based on the risk score. And the positive predictive value is not great; they don’t work so well in reality.”

“Rigid, quantitative tools [e.g., Balkus] are appealing but can be quite imperfect. Using them not only denies some people PrEP, but makes overall PrEP delivery harder and not necessarily better. The tools are leaky: some who were not offered PrEP will get HIV, denying some PrEP might undermine the program, and doing scoring is cumbersome and clunky in practice.”

There was concern also raised, and anecdotal evidence provided, of individuals who had not scored high enough to be offered PrEP based on risk scoring tools, but were perceived by providers or themselves to be at risk due to factors not captured on tools, or because they had not fully disclosed risky behavior. While problematic inaccuracies of applying population-level or modeling data to individuals was seen to be acceptable for evaluating the impact of programs in terms of enrolling high-risk individuals (see the section Use of Tools for Program Evaluation below), these inaccuracies were NOT perceived as acceptable when used to deny or limit an individual access to oral PrEP. The consensus among those researchers and implementers interviewed was that if an individual desires oral PrEP there is likely a reason, and they should be offered oral PrEP. There was also a concern raised that if people are denied PrEP based on risk scores, and this became known in the service delivery area, that it might serve to turn people off from seeking oral PrEP.

“The more we move into programmatic delivery of PrEP, the less I like using them (risk scores) ...not only because of the accuracy issues, but also because if someone is seeking PrEP, there’s a reason – whether they want to tell us what it is or not.”

“Word of mouth is powerful in terms of getting people in the door. If you start turning people down (due to not scoring high-enough on a risk score) it will do more damage than good.”

Increasing accurate risk perception

As highlighted in the introduction, repeated risk assessments have been shown to increase accurate understanding of personal risk. Feedback from implementers highlighted a number of ways risk assessment tools can be used qualitatively, to promote accurate understanding of personal risk. In turn, accurate understand of personal risk increases uptake and adherence to oral PrEP among those who perceive themselves at high-risk, and decreases the likelihood that lower-risk individuals or the “worried well”ⁱⁱⁱ will opt to enroll on oral PrEP (as it helps them to identify which prevention options are a better fit for them).

As noted by implementers,

“How could risk tools be useful? They are useful for initiating a conversation about PrEP, and identifying all kinds of prevention opportunities, feeling out if PrEP is the right fit, helping them truly understand their level of risk and the right prevention option for them.”

Additionally, one implementer said,

ⁱⁱⁱ The “worried well” in this instance refers to individuals that are concerned about getting HIV and want to be on oral PrEP, but are not actually at substantial risk for HIV infection. It is important to note that implementers with whom we engaged did not see this to be a problem in actual oral PrEP implementation thus far.

“We don’t have great data on younger women, but know they are at really high risk. This is a need. We are limited to finding high-risk women by geography; that is not detailed enough.”

The role of risk assessment within oral PrEP delivery is often understood as identifying those at greatest risk for HIV infection only. While this is a critical component of oral PrEP delivery, it is also true that those at greatest risk may face significant challenges in initiating and adhering to a daily pill for a variety of reasons. As such, optimizing the effectiveness and cost-effectiveness of oral PrEP delivery may require a balance between identifying those who are or are likely to be at substantial risk, and ready to use PrEP effectively.

Question #3: What do implementers need from risk assessment tools to guide oral PrEP delivery moving forward?

Normalize PrEP and re-frame risk

One of the strongest messages that came through from discussions with implementers was the need to normalize the delivery of oral PrEP as a prevention option, in order to promote literacy about and create demand for oral PrEP. While this is a notion not directly tied to risk assessment tools themselves or specific questions or criteria assessed, there was the sentiment that we should not be overly concerned about accurate risk assessment now at the expense of normalizing oral PrEP and creating demand for it in the early days of implementation. There was a strong sense that over-screening may put people off from seeking out PrEP.

In addition, the notion of “risk” and thus “risk assessment” as terminology is potentially problematic, and may act as a barrier to oral PrEP use. Experiential evidence from the field suggests that concerns about significant numbers of the “worried well” accessing and staying on PrEP may be unfounded. Programmatic data have shown uptake in early implementation within South Africa and DREAMS to be slow compared to targets based on estimates of potential need and/or models for achieving epidemiologic impact. Given these data, the message from implementers is that we need to focus on creating literacy about and demand for PrEP now, and worry later about enrolling significant numbers of low-risk individuals on PrEP. It was perceived that even if some lower-risk individuals start on PrEP, only those significantly at risk will stay on PrEP overtime. Therefore, cost implications will not be significant. As one implementer stated,

“We need to normalize and offer PrEP broadly, and then figure out if the right people aren’t coming and how to message for them...It will cost nothing – people might start but they won’t continue.”

Furthermore, it was suggested that the slow uptake of oral PrEP may be, in part, due to the fact that oral PrEP itself has been targeted to high-risk groups which are also often stigmatized. People, particularly young women, may not consider PrEP as viable or appropriate prevention option for them. As one implementer of oral PrEP with adolescent girls and young women put it,

“In the early days of PrEP delivery in Africa we see that AGYW generally self-sort into motivated and able to use PrEP or not, and that it is better to do demand creation that is positive, doesn’t emphasize risk and highlights the benefits of PrEP in terms of empowerment or protection and to build confidence.”

SAY GOODBYE TO 'RISK'

Watch your words. Lose the labels if you want to prevent HIV

By Enid Vázquez
@ENIDVAZQUEZPA

Share:

*Risky business.
Risk taker.
High risk.*

That's not how people want to be seen when it comes to HIV. In the epidemic, the word "risk" is associated with the notion of "doing something wrong."

<http://www.thebodypro.com/content/80435/say-goodbye-to-risk.html>

Communication about Risk

A recent opinion piece underscores this notion of re-framing risk and using different terminology when communicating about what we normally call "risk" and the potential benefits for oral PrEP. In her blog post entitled, "Say Goodbye to Risk," Enid Vasquez suggests that, "In the (HIV) epidemic, the word "risk" is associated with the notion of "doing something wrong." So, using the words "at risk" becomes risky in itself. It runs the risk of turning people off, and away from prevention messages. People may not avail themselves of condoms or PrEP (the HIV prevention pill) if they don't identify with risk. If they don't identify with HIV risk, they don't identify with HIV prevention."

She recommends re-framing the notion of "being at risk for HIV" to one of being "vulnerable to HIV." Being vulnerable to HIV includes things that "happen", as well as active decisions to engage in unsafe sex, such as sexual violence, or unplanned condom-less sex. When asked "how vulnerable are you to HIV", oral PrEP emerges as a viable, and potentially non-stigmatized prevention option, offering protection against this vulnerability. In terms of

risk assessment in this re-framing, rather than assess "risk for" HIV in the delivery of oral PrEP, tools could assess for "vulnerability to" HIV. Many of the questions and criteria would remain the same, but communication with the client about assessment and the process may shift the discussion in important ways to make oral PrEP more appealing to those who can benefit from it.

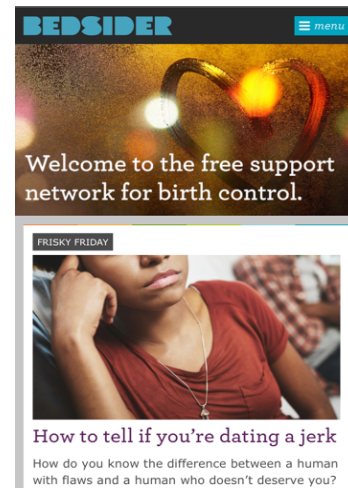
Create more opportunities for self-administered or combined (self and provider-led) risk assessment

This type of re-framing of risk also suggests a need to shift from provider-led screening and risk-assessment only to an approach that is more client-centered and focused on building accurate self-awareness of risk, as discussed above. Tools that promote this type of self-awareness of risk, including an awareness of how underlying levels of HIV prevalence and incidence in a given community creates greater individual risk, could be client-administered and/or a combination of client and provider administered. As one implementer said,

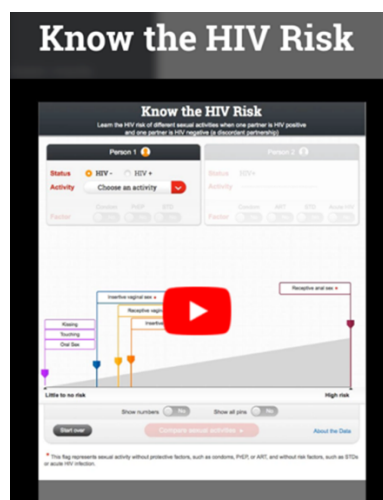
"A better approach (to risk assessment) is to put the tool in the PrEP user's hand, for them to reflect on 'is this (oral PrEP) for me?'...young women really like a tablet based tool. It gives them a chance to reflect on risk without calling it risk, and to think about and explore PrEP as a positive choice to enhance their health."

Several online tools for self-administered risk assessment are under development.

Bedsider Tool: This initiative of the POWER project (<http://www.avac.org/trial/power>) aims to adapt an online application and website designed to support young people to learn about sexual health and make contraceptive choices, to include HIV prevention, including oral PrEP. The Bedsider website (<https://www.bedsider.org/>) provides up-to-date, sex positive, information about contraception and sexual health primarily for a US audience. It includes a page on all available contraceptive methods, and rates them according to the following categories: most effective, party ready, STI prevention, hormone free, easy to hide, and do me now. Adapting this tool to create similar information and categories for HIV prevention methods, including oral PrEP, could help young people assess their own risk or vulnerability to HIV, and learn about their options to make their own decisions about whether or not PrEP is a viable option for them.



Leigh Johnson Tool: This online tool is under development by researchers at the Desmond Tutu Foundation for use at their Masi clinic site. The questions and algorithms built into the tool are based on modeling using data from their research site and clinical trials. As the client goes through the questions posed by the tool, the program helps them identify HIV prevention options, theoretically suited to their needs and risk profile. Due to applying and weighting certain risk criteria based on modeling inputs, recent pilots of the tool have revealed limitations to assessing individual risk. Work is ongoing to improve its performance.



CDC Risk estimator: Developed primarily for use as an educational or literacy tool in the US, this estimator allows individuals to learn about levels of risk associated with different sex acts based on a set of selected criteria, including transmission/acquisition risk when one partner is on oral PrEP. For example, a person can select to learn about the risks of HIV acquisition (if one is HIV-negative) or transmission (if one is HIV-positive). By selecting the category of being HIV-negative, the results will show the risk of acquiring HIV based on certain behaviors and other conditions (e.g. whether partner/s are HIV infected, use of condoms, use of oral PrEP, whether partner is on ARVs etc.). If selecting the category of being HIV-positive, it will show the risk of transmitting HIV, again based on certain conditions, such as use of ART, partner on oral PrEP, use of condoms etc. This estimator could allow an individual to think about his/her own risk, and possibly better understand how s/he might benefit from oral PrEP. The Risk Estimator is currently in beta-testing.

Use of tools for program evaluation

While implementers expressed strong opinions about the limitations of using risk-scoring tools for screening and/or determining eligibility for oral PrEP, there was equally strong interest expressed for exploring how such tools could be adapted and used for oral PrEP program evaluation, in particular for describing the current population of PrEP users in a given setting, and for helping to ensure enrollment of high-risk individuals.

“One possibility is to use risk scores as an evaluation tool, to see if people coming into clinics wanting to enroll on PrEP are the “worried well” or really at risk.”

Recommendations included adapting tools used for intake and screening for ongoing monitoring, and administering these tools among those who accept PrEP (and potentially among those who decline it) to inform a broad behavioral and risk profile over time of those engaging in PrEP programs. This approach would also allow programs to assess who has come to the clinic and enrolled on PrEP, and to evaluate whether those on PrEP in a given program are indeed at high-risk. Using the risk tool to quantify risk among the PrEP patient population to evaluate and measure program success was viewed favorably in contrast to their use to determine individual PrEP eligibility.

If results of these assessments showed high numbers of low-risk clients enrolled on PrEP, these findings could flag implementation changes to help ensure better targeting, and counseling to promote accurate risk-perception and more at-risk clients on PrEP.

Finally, risk assessment conducted regularly with clients on PrEP could help monitor and evaluate changes in individual risk over time, including signs of risk compensation or reductions in risky behavior.

3. Conclusions and Recommendations

The findings from this risk assessment tool analysis point to several overarching conclusions and recommendations.

Conclusion #1: Creating opportunities to build accurate understanding about risk, or as discussed above vulnerability to HIV, in the delivery of oral PrEP is critical for optimizing individual benefit, epidemiological impact and cost-effectiveness; however, risk (or vulnerability) assessment tools are only one part of the process to identify the most at risk.

People have inaccurate and often low perceptions of their own risk. However, accurate risk perception increases with multiple assessments through opportunities to reflect on and self-assess risk. Furthermore, one aspect of accurate risk perception is gaining a better understanding of the local context, in particular using data to describe the underlying HIV prevalence and incidence in individual communities, and using this information to help individuals understand how this context affects their individual risk. People who perceive their own risk as high are more likely to start and use oral PrEP effectively. Risk assessment can be an important tool, but it is only one part of a larger process to identify the most at risk; raising self-awareness of risk may be most critical. Also, as noted below, re-framing risk may promote more accurate understanding through the destigmatizing behaviors or circumstances that puts an individual at risk.

Conclusion #2: Using tools to screen for eligibility is problematic; however, quantitative risk assessments can be useful, particularly for evaluation purposes.

Using tools to screen for eligibility is a process that was created out of necessity within clinical trials; however, such processes may lose relevance in the context of oral PrEP implementation. The most vulnerable may screen out, not because they aren't at risk, but due to discomfort with disclosing why they are at risk, or because what puts them at risk is not included as question on risk assessment forms. Furthermore, most existing tools are not validated, and validating more tools may be impractical given costs and data limitations. However, quantitative risk assessments can be useful to: inform a broad

behavioral profile of those engaged in PrEP programs; evaluate whether those on PrEP in a given program are indeed at high-risk; to inform implementation changes needed to ensure the enrollment of high-risk individuals; and to evaluate changes in risk over time among PrEP users.

Conclusion #3: Ensuring high-risk individuals enroll in PrEP may require a re-framing or movement away from the notion that “PrEP is for those at risk” to a more positive frame promoting wellness and protection against vulnerability to HIV.

Most implementers shared the perception that those who don’t need PrEP won’t use or continue to use it over time, and that low demand may be related to the branding of PrEP as a prevention option for those at high-risk, engaging in “bad” behaviors. People, particularly young women, may not consider PrEP as viable or appropriate prevention option for them when framed in this way. It is possible that when asked “how vulnerable are you to HIV”, oral PrEP may emerge as a viable, and potentially non-stigmatized prevention option, offering protection and promoting wellness against this vulnerability. Therefore, programs might want to focus on tools that assess “vulnerability” to rather than “risk” of HIV. Operational research efforts could help evaluate the potential benefits of re-framing risk in this way.

In light of these conclusions, we provide the following recommendations.

Primary Recommendation: *Create a program framework describing a comprehensive approach to identifying those at greatest risk for HIV*

The conclusions generated from this work confirm that identifying individuals at substantial risk for HIV infection who might benefit from the offer of PrEP requires a comprehensive approach that goes beyond assessing risk at facility point of entry for oral PrEP.

While the process of developing a detailed framework is outside the scope of this analysis, there are four key elements or steps for a comprehensive approach that have emerged from this analysis, for which risk assessment is necessary, and for which risk assessment tools could be useful. These are:

- Building an understanding of risk into the program design
- Generating demand for oral PrEP through increasing accurate risk perception and understanding of the potential benefits or rewards of oral PrEP
- Determining whether oral PrEP is offered through interactive client and provider risk (or vulnerability) assessment
- Using quantitative risk assessment for M&E to ensure the most efficient and cost-effective program investments

1. Building an understanding of risk into the program design

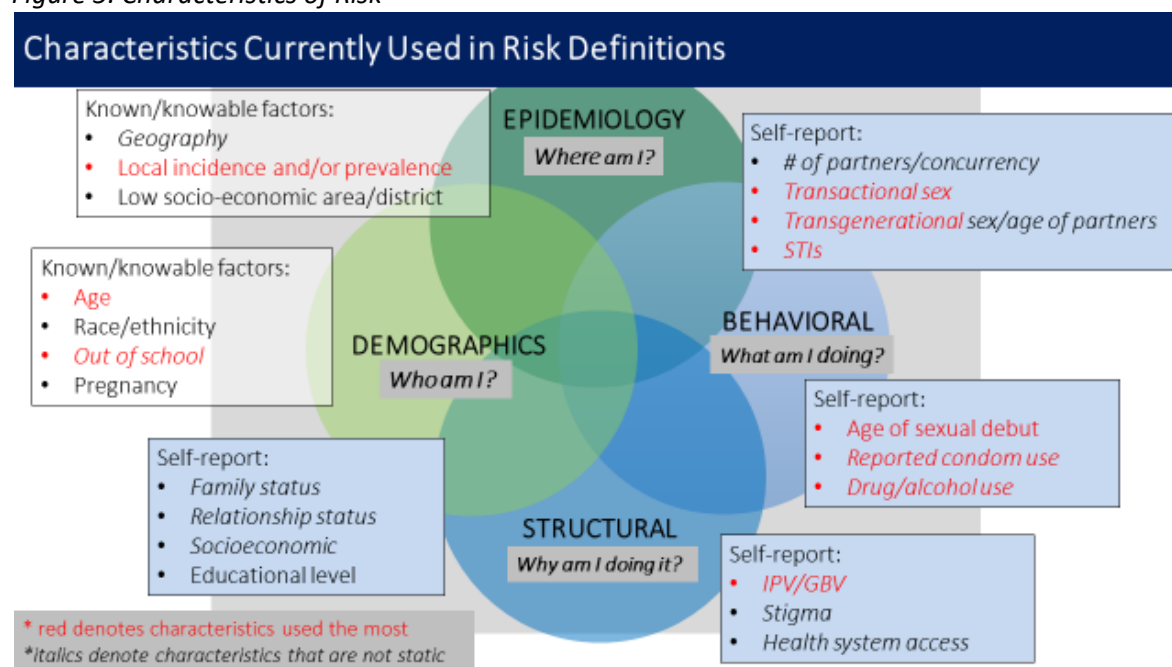
An important aspect of identifying individuals at substantial risk for HIV infection is creating a program from the outset that acknowledges that individual risk is influenced by a multitude of factors, some behaviorally driven, but many contextual, such as the underlying epidemiology in a given setting, an individual’s demographic characteristics, and structural factors including exposure to violence and access to health care.

Many of these factors are known, or knowable (see Figure 5). Programs should be designed to reach and engage with high-risk individuals drawing upon available data and evidence.

Much of this programmatic focus is happening, through demonstration projects and national programs focusing on key population groups known to be at risk for HIV, and being implemented in high-risk settings. However, more can be done to support countries and programs to make evidenced-based decisions about how to focus programs for greatest impact in terms of cost-effective delivery to high-risk individuals. For example, risk assessment decision tools to use at the time of program design can help make decisions about and explore tradeoffs with different kinds of investments both in terms of where and how to deliver PrEP, but also tradeoffs between different HIV prevention investments.

Furthermore, the Institute for Disease Modeling (IDMOD) are currently working with African Health Research Institute to develop tools that will define specific metrics within a given neighborhood or environment that identify and point to spatial (environmental) risk. The concept is to eventually integrate these spatial risk models and with individual risk assessment to more accurately identify those who may most at risk within a given location or community. This effort is working to develop a proof of concept in one area, with the aim to expand it using PHIA data to other locations and countries. Such efforts can help address the “re-framing of risk” (secondary recommendation below) to transition the discussion from “you are high risk because of your behaviors” and towards “you are at risk – at least in part - because of the environment”.

Figure 5: Characteristics of Risk



2. Generating demand for oral PrEP through increasing accurate risk perception and understanding of the potential benefits or rewards of oral PrEP

Risk assessment and risk assessment tools can play a strong role in generating demand for PrEP through promoting accurate risk perception and increasing understanding about oral PrEP. It is important to

note that messaging through the demand creation process for oral PrEP through assessment tools should support the re-framing of “risk” of HIV to “vulnerability” to HIV and assess it so, as discussed in the findings and conclusions sections above.

3. Determining whether oral PrEP is offered through interactive client and provider assessment

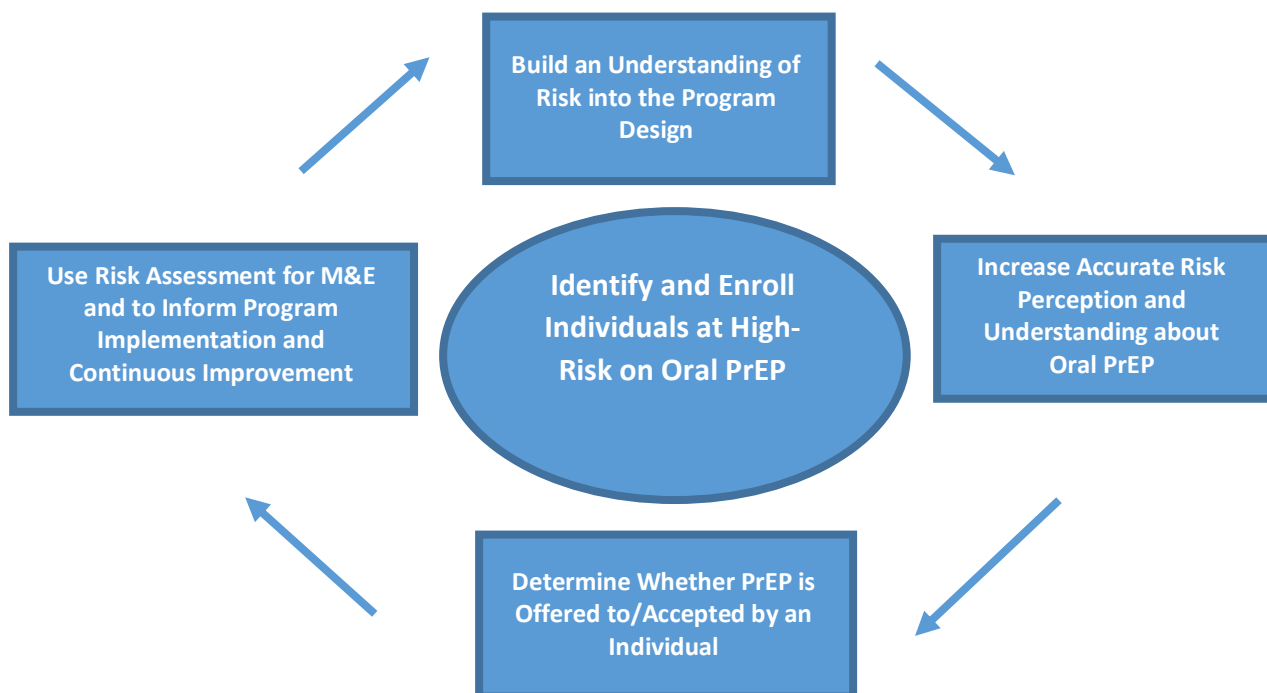
We would not recommend using risk screening or scoring to determine eligibility for PrEP, but qualitatively to foster dialogue between clients and providers, and/or through self-assessment to promote accurate risk perception. This approach can be used to create the opportunity for informed decisions on the part of providers about offering PrEP, and on the part of clients for accepting it (or not). Additionally, it can help providers assess whether a patient may be a high adherer or need additional adherence support.

4. Using quantitative risk assessment for M&E to ensure the most efficient and cost-effective program investments

Quantitative risk assessments for M&E could be used to assess who has come and enrolled on PrEP, to evaluate whether those on oral PrEP in a given program are indeed at high-risk, and to evaluate changes in risk over time among oral PrEP users. The M&E function thus feeds back into #1 to inform implementation changes and program design elements to ensure the enrollment of high-risk individuals. *Figure 6* illustrates a program cycle following these steps, designed to identify and enroll high-risk individuals on oral PrEP.

For example, the Jilinde program in Kenya is piloting an adaptation of risk their assessment tool, expanding it to collect additional data to describe the patient population on oral PrEP, and using this information to feed into program outreach and targeting. This approach could serve as a model to learn from, to potentially expand this practice to other oral PrEP implementation programs and efforts.

Figure 6: Program Cycle of Identifying and Enroll High-Risk Individuals on PrEP



Secondary Recommendation #1: Continue of the ongoing development self-administered risk assessment tools (online or otherwise) geared towards building accurate understanding of risk.

There is great potential for innovative, useful, sex-positive and informative tools to aid individuals in understanding their own risk and the potential benefits of different prevention options, including oral PrEP. While several interesting prototypes are under development to promote self-assessment as described above (Bedsider adaptation, Leigh Johnson tool), ongoing support will need to be made to ensure these come to fruition, and to further study what is needed and impactful from self-assessment tools. Furthermore, the tools under development focus mainly on young people and young women in particular. Additional support may be required to ensure that additional tools are developed that effectively reach the universe of people at substantial risk of HIV infection that might benefit from oral PrEP. Once developed and made available, such tools can be integrated into ongoing oral PrEP implementation, and within the model program described above.

Secondary Recommendation #2: Support the development of user guides for the application of risk (or vulnerability) assessment tools to use within oral PrEP programs at scale.

We recommend investment in the development of tools and a user guide to help programs use risk (or vulnerability) assessment tools in all the ways described above, including for M&E purposes. A user guide could include a standard protocol and package of tools to be used with different settings and populations to the program cycle described above, with the intent to ensure the enrollment of high-risk individuals to initiate and stay on PrEP. The risk (or vulnerability) assessment tools included in the user guides would build on/incorporate the existing, validated tools, or incorporate evidence-based indicators tailored to key affected groups, and adapted to specific risk contexts, working with members of the target community

Secondary Recommendation #3: Consider investing in the validation of additional tools, namely for high risk groups for which validated tools currently do not exist, e.g. MSM, transgender persons, sex workers and injection drug users.

While we do not recommend using risk assessment tools for screening, there are benefits to have accurate tools available to support the monitoring and evaluation of programs. Currently, no validated tools exist for key affected groups beyond women, pregnant women and sero-discordant couples. Data likely exist to replicate efforts similar to how the existing risk tools were developed, from oral PrEP trials with MSM and transgender persons (e.g. iPrEX, PROUD) and female sex workers (SaPPHIRE). Where data exists, this can be done at fairly low-cost, and the outcome of having validated tools worth the investment. If, however, data do not exist, we do not recommend investing in the expense of a large-scale trial with the main or sole purpose to validate a risk tool, especially given the uncertainty around the broader generalizability of validated tools for the general population.

Endnotes

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