Oral PrEP Risk Assessment Tools at a Glance

Background
In light of the World Health Organization’s recommendation to make oral PrEP available for individuals at substantial risk for HIV, many countries are mobilizing to offer and expand access to oral PrEP. Accurate identification of individuals at substantial risk is a critical component of any PrEP program in order to:

• help ensure that PrEP is offered to those who can benefit from it the most
• maximize population-level HIV prevention impact
• optimize scarce investments

Being at risk is a function of both the 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). Many individuals have an inaccurate understanding of their own risk, and often underestimate it. Accurate risk perception is an important step in effective PrEP service delivery: those who accurately understand themselves to be at high risk are more likely to initiate and effectively use oral PrEP; those who accurately understand themselves to be at lower risk are less likely to use oral PrEP when they don’t need it.

Analysis Overview
To date, demonstration studies and early implementation efforts have used a variety of risk assessment tools and processes to identify and enroll those at greatest risk. To understand more about the relative strengths and weaknesses of current tools and approaches being used to help guide implementation, we conducted an analysis of risk assessment tools (www.prepwatch.org/risk_tool_analysis) to answer the following questions:

• What risk assessment tools are used in the delivery of oral PrEP and how are they used?
• How well do tools help identify those at substantial risk of HIV infection?
• How best can implementers use these tools to assess risk in oral PrEP delivery moving forward?

What we learned:
Purpose of Risk Tools: Risk assessment tools are used in two ways. Many tools are designed to screen a client for eligibility by generating risk scores (e.g. a score of 5 or greater indicates substantial risk and thus eligibility for oral PrEP) or through identifying criteria that a client must meet before the offer of oral PrEP.

While risk scoring tools have appeal in that they provide a clear indication of who should be offered PrEP, they can be highly problematic for a number of reasons. Many clients will not feel comfortable disclosing the behaviors or experiences that put them at increased risk, and even the best tools cannot predict risk with 100% accuracy. Most of these tools are not validated; therefore, their ability to predict true risk is unknown. Validation is a process that uses data from clinical trials to rigorously assesses a tool’s capacity to predict – in this case – the likelihood of HIV acquisition based on reporting a specific set of risk factors. Only three risk assessment tools have been validated for use in oral PrEP delivery: one for use among women of reproductive age (http://www.prepwatch.org/balkus),
one for use among pregnant women ([http://www.prepwatch.org/pintye](http://www.prepwatch.org/pintye)) and another for use among sero-discordant couples ([http://www.prepwatch.org/kahle](http://www.prepwatch.org/kahle)). However, even validated tools lose their capacity to accurately predict HIV risk when adapted in any way, or even when used without adaptation outside of the populations or contexts within which the tools were studied. Furthermore, use of validated tools in not immune from limitations related to self-report as described above. When using tools with risk scores or other cut-off criteria to determine eligibility for oral PrEP, whether these tools are validated or not, it is inevitable that some high-risk clients will be missed or misclassified and not offered PrEP.

**Tools can, however, be highly effective in helping providers and clients initiate a conversation about risk and the potential benefits of oral PrEP, as long as scores or criteria assessed are not used to define a cut-off for the offer of PrEP.** Responses to questions within these tools help clients understand their own risk, inform clinical discussions and risk reduction messages, and provide guidance to providers on which prevention services should be offered to the client - including oral PrEP when indicated. This approach creates the opportunity for building risk awareness among clients, does not exclude potential users from PrEP based on externally derived scores or cut offs, and shifts the locus of informed decision-making from provider to the individual.

*Figure 1: How Risk Tools Are Used*

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**Risk factors:** We also looked at whether programs look at the same risk factors. *Figure 2* summarizes risk criteria most often assessed within different population groups (AGYW, sex workers, and MSM). We found that risk assessments are generally focused differently by population group, based on what is known to be the strongest predictor or risk within that group through epidemiological studies. *Figure 2* summarizes the most important risk factors to assess within each group, including some factors that should be assessed regardless of group. Oral PrEP programs for sero-discordant couples (SDC) are not included in the figure as this population has different indicators of risk for the negative partner, including the positive partner’s ART use and viral load status, and as condom use.
Guidance for programs and providers:
The primary role for a risk assessment tool is to assist potential PrEP users to build an accurate understanding of their own risk, and guide providers to share information about and potentially offer oral PrEP to clients who could benefit from it. Risk tools when used in this way can help guide a decision on initiation, as well as encourage continued use when risk is ongoing.

While using risk scoring to determine eligibility for PrEP can be problematic as described above, such tools can be used effectively for data collection within oral PrEP implementation to help describe and understand a facility’s or program’s oral PrEP client population over time. Estimating the average level risk among the client population on oral PrEP can serve a valuable M&E function to help programs determine whether or not they are reaching those at greatest risk. Using quantitative tools in this way can also help programs understand if and how the risk levels of their clients are changing over time. This information can inform program outreach, in particular the need to modify efforts to reach higher-risk individuals and how to support their clients use of PrEP over time.

While we posit that provider led tools can be a useful way to promote greater understanding of risk among clients, there is also a need for more widely available tools that allow for innovative, sex-positive ways to promote self-assessments of risk and that aid individuals in understanding their own risk and the potential benefits of different prevention options, including for oral PrEP. Some online tools are undergoing research and development, but they are not yet in the public domain. This is a critical underdeveloped area of oral PrEP service delivery.

Implementer experience:
“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 think about and explore PrEP as a positive choice to enhance their health.”