

## **Use of Presumption Criteria in the Assessment of HIV transmission in view of prevention-based clinical trials in social settlements**

*Background:* In preparation of clinical trials of Tenofovir for the prevention of HIV near female sex workers, a study with the title “Formative Research in Support of Phase 2 Extended Safety and Effectiveness Trials of Tenofovir for HIV prevention—Site Preparation Assessment” was funded by the Bill and Melinda Gates Foundation, sponsored and supervised by Family Health International and conducted by IRESO (Institute for Research and Behavioral Studies) from July 2003 to March 2004 in Douala (Cameroon). The objectives of the said study were to identify HIV transmission areas in Douala; assess the intensity of transmission across the respective areas; assess the desirability or eligibility of sectors/areas of transmission for the clinical trials and provide recommendations for the recruitment of clinical trial participants.

*Methods:* A combined approach included a **reference experts’ workshop**; a subsequent validating participant observation of the areas; and in-depth investigative interviews near key informants of the areas.

The experts workshop was aimed at updating the procedure for characterizing, classifying and mapping of HIV transmission areas on the one hand; then on the other hand, at identifying and mapping the high transmission areas (HTAs) of HIV in Douala.

Participant observation was conducted in order to check the accuracy of the breakdown of Douala into high, moderate and low transmission areas/sectors as proposed by the experts’ workshop and provide an insight of transmission interactions and stigma and risk phenomena vis-à-vis HIV. Investigators used observation and dialogue techniques likening them to natural actors of the sectors while observing the transmission panorama and dialoguing with key-informant, about the said. They were also drafting physical maps on geographic and streetwise profile and HIV transmission related sites.

The in-depth interviews of local key-informants targeted the profiling of local community, exploring the drives and factors explaining the HIV risk interactions in the transmission sites and their periodic variations.

Sampling included review of data for the entire city at the expert meeting. For each of the 6 HTA/MTAs proposed by the meeting, field investigations recruited the 4 sectors at the extreme corners for in-depth description and sectors lying within their interval for rapid assessment. For each of the selected sector enumeration of transmission sites was done on a selected main street, where a selected important middle site was exhaustively assessed. Sex Workers, their clients, petit traders/transporters, gatekeepers and other key groups were evenly sampled across the sites for interviews.

*Results:* Posterior to defining key mapping concepts like area, sector, sites and socio-professional groups at risk, a map of the city was produced partitioning Douala into 15 geo-demographic areas.

Two types of criteria for the characterizing of an area against the presence and intensity of HIV transmission were listed and categorized by experts during the reference workshop.

They included two (2) epidemiologic certainty criteria (prevalence and incidence of the infection/disease) in the one hand. In the other hand, there were presumption criteria such as nine (9) economic conditions and factors and fourteen (14) cultural and social variable. For operational purposes the said criteria were ranked into major and minor criteria that could help discriminate between levels of transmission. Thus, the resulting list of criteria for rating the level of transmission included:

(Major) 1. *Presence of a clustering or concentration of many entertainment sites;* 2. *Presence of at risk socio-professional activities or actors;* 3. *Presence of lack of intimacy in household's life/demographic density* ; 4. *High prevalence/frequency of Sexually Transmitted Infections/ AIDS/Tuberculosis;* and (Minor) 5. *The rest of criteria listed as transmission factors in the general record.*

Characterizing a transmission area or sector can be done by performing a direct, a documentary or an indirect observation of the said settings that underline the presence or absence of the respective criteria. The criteria can be further partitioned into factors to which finer scores can be applied.

The proposed procedure for classifying areas or sectors according to the intensity of transmission relies on the identification of maximal and minimal values or modalities of the respective criteria. Once such rating borders are available, three (3) equal intervals are demarked within the field between them. The referred three-fold partition does systematically apply to the major criteria. While some of the factors derived from such general categories would need a finer partition that may result in four or more modalities. Therefore provision was made for a rapid assessment procedure using the general criteria and a systematic assessment using an in-depth description of the criteria by respective derived factors including application of more accurate scores of intensity.

During the experts' workshop, *rapid assessment allowed to classify four (4) areas as HT As Bépanda/Bassa, New-Bell, Deïdo and Nylon, two (2) futher as moderate transmission area, (Akwa/Bali and Bonabéri) and the remaining nine (9) as low transmission areas. The scale used integrated three levels of prevalence ( $\geq 10\%$ ;  $[5 \text{ à } 10\%]$ ;  $< 5\%$ ) and three levels of the presence of presumption criteria as well ( $nMf \geq 2$ ;  $nMf = 1 + mf$ ;  $nMf = 0 \pm mf$ )  $\leq$ .*

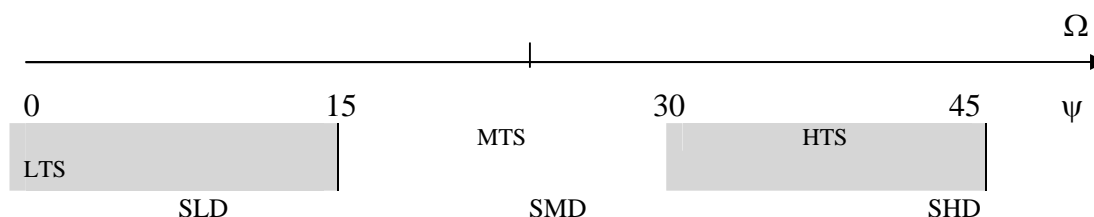
Because of programmatic constrains it was not possible to validate the above classification of areas against a systematic assessment of the intensity of transmission.

Via participant observation in association with in-depth interviews of key-informants all above 6 areas were confirmed to be important transmission settings, but no systematic relevant discrimination of levels of transmission could be achieved. Systematic assessment of presence of transmission and its intensity using major presumption criteria was done in 20 sectors across the 6 areas. A set of 5 criteria including numeric eligibility; sedentary status, social accessibility, use of condoms and intensity of sexual intercourses were used in ranking the respective 20 sectors against the feasibility or desirability of the proposed clinical trials with Tenofovir.

Then (15) factors coded A to J (transmission) and B' to F', derived from major presumption criteria were measured. Scores recorded by the respective sectors against the different factors were aggregated and positioned on gradients of levels/intensity of transmission and of desirability of the sectors for the recruitment and compliance of expected participants of the trials (see figure 1 below:)

$\Omega$  (omega) and  $\psi$  (Psy), being respectively the indexes of transmission of HIV in a given sector (S) and of desirability of the said sector for clinical trials

If  $35 \leq \Omega$  and  $\psi \leq 50$  then S is a HTS and a SHD ; if  $20 \leq \Omega$  and  $\psi < 35$  then S is a MTS and a SMD<sup>1</sup>; if  $\Omega$  et  $\psi < 20$  then S is a SLT a SLD



**Figure 1 :** *Ranking of Areas/sectors in the city of Douala by level/intensity of transmission of HIV and by level of desirability for recruiting Clinical Trial Subjects.*

The integration of transmission and desirability gradients demarked 5 HTS of high desirability, 1 HTS of moderate desirability, 6 MTS of high desirability and 7 MTS of moderate desirability.

**Conclusions:** In the face of insufficiency of epidemiologic standard indicators, presumption criteria can be used, as they proved consistent to certainty criteria when applied comparatively where applicable. Depending on the users needs and constrains an expert meeting, field mapping by rapid or systematic assessment or a combining of some or all the three can be used according to the targeted level of accuracy. Ranking areas against HIV transmission intensity needs a systematic and time consuming approach. Application of a rapid assessment method is a mere palliative thereto. A sector-based approach appears more practical. The level of accuracy increases when investigations move from general criteria based measures to measures based on factors of the said criteria. Although technically demanding, the use of context specific scales of intensity of transmission and feasibility of community-based trial promises high relevancy. Concrete recommendations about circumstances of the recruitment of trial participants, patterns of interaction with the community and strategies to increase compliance against behavioral and social interferences are induced by the approach described in this abstract.

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HTS= High Transmission Sector for HIV; MTS= Moderate Transmission Sector...; LTS: Low etc.  
SHD= Sector of High Desirability for recruiting clinical trial participants; SMD: Sector of moderate...; SLD: Sector of low...