

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

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**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 IRESCO (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 to provide an insight of both transmission interactions and stigma/risk phenomena vis-à-vis HIV and proposed trials. Investigators used observation and dialogue techniques likening them to natural actors of the sectors while observing the transmission patterns and dialoguing with key informant, about the said. They also drafted maps of the geography, streets profile and HIV transmission related sites.

In-depth interviews of local key informants were to profile of local community, exploring drivers and factors of the HIV risk interactions within transmission sites and period/cvariations thereof.

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 sectors enumeration of transmission sites was done on a sample main street, where a selected important middle site was exhaustively assessed. Sex Workers, their clients, petty traders/transporters, gatekeepers and other key groups were evenly sampled across the sectors 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 infecton/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 variables.

Operationally 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 enter-

tainment sites; 2. Presence of at risk socio-professional activities or actors; 3. Presence of lack of intimacy in households 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 transmission areas and sectors was done by a direct, documentary an indirect observation of the said settings, underlining 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/modalities of the respective criteria. Once such rating borders are available, three (3) equal intervals are demarcated 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 HTAs (A, B, Nw, D) and Ny, two (2) further as moderate transmission areas (A5 and B5) and the remaining nine (9) as low transmission areas. The scale used integrated three levels of prevalence (< 10%, 15 à 45%) and three levels of the presence of presumption criteria as well (nMI=2; nMI=1+; nMI=0+nt) =

Because of programmatic constraints 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 relevant systematic discrimination of levels of transmission could be achieved. Systematic assessment of presence of transmission and its intensity using major or 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 intercourse were used in ranking the respective 20 sectors against the feasibility or desirability of the proposed clinical trials with Tenofovir.

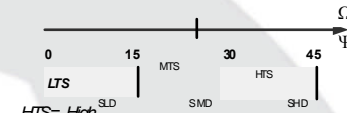
The n (15) factors coded A to J (transmission) and B' to F' (desirability), derived from major presumption criteria were measured. Scores recorded by the respective sectors against the different factors were aggregated and positioned on a gradient of levels/intensity of transmission and a gradient of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

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

If  $35 < \Omega$  and  $\Psi \leq 50$  then S is a HTS and a S-HD;

If  $20 < \Omega$  and  $\Psi \leq 35$  then S is a MTS and a S-MD;

If  $\Omega$  and  $\Psi < 20$  then S is a SLT or a S-LD



HTS= High Transmission Sector for HIV; MTS= Moderate Transmission Sector...; LTS= Low etc. S-HD= Sector of High Desirability for recruiting clinical trial participants; S-MD: Sector of moderate...; S-LD: Sector of low...

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 demarcated 5 HTS of high desirability, 1 HTS of moderate desirability, 6 MTS of high desirability, 7 MTS of moderate desirability and 1 LTS.

**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 users needs and constrains an expert meeting, field mapping by either 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 therefore. A sector-based approach appears more practical. The level of accuracy increases when investigations move from measures based on general criteria to measures based on factors of the said criteria. Although technically demanding, the use of context specific scales of intensity of transmission and of 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 for increasing compliance against behavioral and social interferences are induced by the approach described in this poster.

