

Evaluation Study Design for the Lea Toto Program in Nairobi, Kenya

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Part I – Program Overview

The Lea Toto Program (LTP) is a multi-centre community program in Nairobi that is conducted by the Children of God Relief Institute. The overarching goal of LTP is to improve the quality of life of children (age 0 to 19) living with HIV and to decrease the prevalence of HIV deaths in eight informal settlements in Nairobi: Kibera, Kangemi, Mukuru, Kariobangi, Dandora, Kawangware, Dagoretti, and Zimmerman¹. The objectives of the current phase of the program (to be achieved by 2025) are as follows:

- Raise community awareness of HIV and AIDS amongst people in the informal settlements to reduce stigma towards HIV-infected children and their families.
- Equip HIV-infected youth and adolescents (age 10-18) with life-skills that would help them to manage AIDS and adopt a positive attitude towards their HIV status—all of which are key to their long-term physical and psychological well-being.
- Increase access to HIV testing and antiretroviral treatment (ART).

The 2012 Kenya AIDS Indicator Survey report shows that there is a disproportionate effect of HIV/AIDS on children, especially impoverished children that are living in low-income informal settlements in Nairobi². Despite the efforts of the Government of Kenya to increase access to HIV testing, parents in informal settlements are deterred by the time and financial cost that is associated with bringing their children to the testing facilities. Even if HIV-positive children can determine their HIV statuses, they face many challenges: the high cost of ART, social stigma, and the lack of information about HIV and service availability³. These challenges prevent effective management of AIDS, which in turn can lead to morbidity, depression, and death.

To address the detrimental effect of HIV on impoverished children, LTP established health clinics in eight informal settlements in Nairobi and is currently serving 3,220 children with a holistic care approach⁴. First, the LTP clinics provide services that include free HIV testing, ART, and nutrition services for HIV-positive children in their respective catchment area. Second, the program has a community outreach program that disseminates knowledge about HIV and service availability. Third, LTP conducts life skills-training that educate HIV-positive youths (age 10-19) on HIV management and promote psychological well-being and its sub-characteristics that include self-acceptance and self-reliance. The logic model for the program is included in Appendix A.

The health clinics will require 10 months to become fully operational. Between January to October 2020, health clinics will recruit clinical officers, nutritionists, social workers, and community health volunteers (CHVs). During this period, CHVs will perform weekly door-to-door community outreach and will receive training for conducting life-skills training. Weekly community outreach will be conducted until 2025, with CHVs establishing in-person contact with every household in their assigned communities at least once per year. The health clinics will also be operational throughout the program starting from October 2020. Teenagers in the

¹ Stuer and Greenway, 2017.

² Kagunda, 2018.

³ Ibid.

⁴ Ibid.

program will be separated into 4 age groups and they will participate in weekly life-skills training workshops starting from October 2020 until the end of the program.

Part II – The Evaluation Study Design

The objective of this study is to assess the impact of LTP on two dimensions of *quality of life* – defined as both physical and psychological well-being – of HIV-positive children in eight informal settlements around Nairobi. We will use a concurrent mixed method study to answer two evaluation questions:

- Q1. To what extent did LTP reduce the morbidity rate of HIV-positive children as compared to the standard regime of care?
- Q2. Did the LTP life-skills training increase psychological well-being, which includes sub-characteristics such as self-acceptance, self-efficacy, and relations with others?

The impact of LTP on the physical and psychological well-being of HIV-positive children (Q1 and Q2) will be evaluated using a quantitative two group pre-test post-test randomized experiment. The result of this study will be supplemented by a separate qualitative study (non-experiment with in-depth interviews) that focuses on the potential benefits of life-skills training (Q2). In addition, the qualitative study will be used to perform a process evaluation on the life-skills training workshops.

The study population for the evaluation study is children living with HIV (age 0-19) in impoverished informal settlements around Nairobi, Kenya. For the quantitative component of the study, the sample will be purposively drawn from the study population. In contrast, for the qualitative component of the study, the sample will be drawn from a subset of the study population—HIV-positive children who enrolled in the LTP life skills-training workshops.

A randomized control trial (RCT) will be conducted to evaluate the impact of LTP. The study participants are children who were tested positive for HIV and who expressed interest in joining LTP after being introduced to the program by CHVs. The participants' parents will also provide consent for study participation after receiving information about the purpose and methods of the study from the evaluation team (see the ethical consideration section). The participants will be randomly assigned to the treatment and the control group. In total, there will be 800 children in the study (100 children from each of the 8 informal settlements), with equal numbers in the treatment and control groups. The treatment group will receive LTP services including ART, personalized clinical care, nutritional and psychological counseling, and enrollment in LTP life-skills trainings; the control group will receive the standard of care, including ART and any other traditionally provided services. Individuals from both treatment and control groups will participate in a pre-test to evaluate their levels of physical morbidity using standardized measurements from the Global Burden of Disease, with the results being registered into a database that associates morbidity scores with unique anonymized ID codes. In addition to disease burden, other baseline data (ex: demographics information and other health indicators such as blood pressure and BMI) will be collected before the program and will be used to assess the equivalence of baseline characteristics between the treatment and control groups. There will be two post-test measurements, one at the end of the program in 2025, and one 3 years after the end of the LTP in 2028. The short-run and long-run effects of LTP on physical morbidity will be estimated by comparing baseline measurements to the average difference in disease burden between the treatment and control groups in 2025 and 2028, respectively. The study participants

will also complete a psychological well-being survey (a standard 42-item survey that measures 6 aspects of psychological wellbeing⁵) at baseline and endline (2025 and 2028). The difference in the average item scores between the treatment and control group will be used to estimate the short-run and long-run effects of LTP on psychological well-being.

For the qualitative study, in-depth interviews will be conducted with students who attended at least half of the training workshops and passed a knowledge assessment test. Three students from each of the four age-groups will be selected for in-depth interviews conducted by trained interviewers yearly from 2020 to 2028. If any of the selected students drops out of the study, they will be replaced by another student (of the same gender) from their same class. In-depth interviews will focus on questions related to psychological well-being. In addition, process evaluation questions such as the usefulness of the curriculum and barriers that prevent students from maintaining participation will be asked. For the purpose of triangulation, interviews will be conducted with either a caregiver or the life-skills training instructor of the selected student. These additional interviews will provide external perspectives on the psychological well-being of the students. As well, the LTP instructors will be asked questions related to the fidelity, reach, and dose delivered of the life-skills workshops (see assignment 2). The qualitative data (e.g. in-depth interview notes) will be analyzed such that major themes and patterns will be identified from the text by the evaluation team. Although the qualitative data cannot be used to evaluate the causal impact of the training workshops, they provide information on how the workshops were actually implemented. Furthermore, they may help corroborate our quantitative results and provide suggestive evidence for the long-run benefits of the workshops— especially if the qualitative data shows a trend of improvements in students’ psychological well-being.

The evaluation team will combine the results and insights from the RCT and the qualitative study. In the final evaluation report (a deliverable of this study that will be completed in 2028), the team will present the estimated program effects from RCT as the main results of the study, as this element of the evaluation provides the strongest evidence for LTP’s impact. In addition, the qualitative results will provide additional insights into the potential benefits of life-skills training in that they assist in understanding the “why” of the RCT results. Selected quotes from the in-depth interviews and their analyses will be presented in the evaluation report to paint a more holistic picture on how the program affects HIV-positive children. The process evaluation of the life-skills training will be also presented, including discussion of the implementation of the life-skills training and its potential effect on the program outcomes.

Part III – Threats to Internal and External Validity

Although the RCT eliminates selection bias, the quantitative portion of the evaluation is not without potential pitfalls. One concern is that participants (and their caregivers) who were assigned to the control group might become discouraged because they know of additional services that the treatment group is receiving. This discouragement might lead to undesired behavior such as not taking ART on time and dropping out from the study. In this case, the post-test difference between the two groups will be exaggerated and the program effects will be overestimated. Thus, program staff must take care to describe the program and study in ways that communicate the value of participation to all involved. Spillover is another concern that might occur if children in the skills-training workshops share knowledge with children in the

⁵ <http://sparqtools.org/mobility-measure/psychological-wellbeing-scale/>

control group. This problem will be difficult to detect and avoid and could potentially lead to underestimation of the program's effects.

There are also threats to the external validity of our quantitative study. First, the sample is not randomly drawn from the study population; rather it employs purposive sampling as children were enrolled through the community outreach activity. Thus, the sample is not representative of the entire target population (HIV-positive children in the eight informal settlements). Instead, the sample might represent only a special sub-group of children who have better informed caregivers or have more motivation to seek testing and treatment. For this reason, the results from the quantitative study cannot be generalized back to the entire target population. In addition, the results of the quantitative study cannot be generalized to other informal settlements outside of Nairobi (e.g. rural settlements in other parts of Kenya). Furthermore, the highly context-sensitive nature of the interventions means that impact of program will have to be understood in reference to the specific ways it was undertaken and the specific population that participated. While the use of standardized measures through the Global Burden of Disease metrics will help in communicating the impact of the results beyond the local context, the changes documented by these measures cannot be understood without proper contextualization.

Strictly speaking, internal validity does not exist for the in-depth interviews in our study because they do not establish causal relationships.⁶ Nonetheless, we can assess the soundness and quality of the qualitative study based on its "credibility," or the extent to which the qualitative results are believable from the perspective of the participants.⁷ Although we can increase the credibility of the interviews through triangulation (collecting data from multiple sources including students and their caregivers), the results may suffer from the Hawthorne effect, wherein some students might inflate their reported self-acceptance and self-efficacy to please the interviewer. The quality of the interview data is largely dependent on the skills of the interviewer; thus, each interviewer will participate in a 2-week intensive training session.

The qualitative component of this study is also limited in terms of external validity. This is because the interviewees belong to a specific group that have 1) been tested for HIV and enrolled in LTP, 2) participated in the training workshops, and 3) passed the knowledge assessment test. Thus, the results from the qualitative study cannot be generalized to our study population.

Part IV – The advantages and disadvantages of the study

The quantitative portion of the evaluation study has several advantages. First, the RCT eliminates selection bias and thus establishes the causal relationship between LTP and well-being (physical and psychological). Second, the use of internationally recognized measures of physical health will contribute to the legitimacy of the results outside of the immediate context. Moreover, quantifying the effects of the program will allow for gradations of success (i.e. evaluations can determine not only whether or not targets were met, but also the degree of change relative to targets), providing greater nuance to the understanding of how LTP impacted beneficiaries. Finally, by focusing on changes in health at the individual level, the evaluation may provide greater insight into *how* the program works in addition to indicating *if* it works in tandem with the results of the qualitative study.

⁶ Trochim, 2008.

⁷ Ibid.

However, the quantitative study also has several disadvantages. One example is that the RCT only evaluates the *overall* impact of LTP on physical and psychological health. Thus, the effect of individual program activities cannot be assessed. For this reason, the results cannot be used to decide which program activities should be expanded and which activities should be abandoned. That said, the qualitative portion of this study will provide detailed insights on how children benefit from the life-skills training. Additionally, since the study participants do not represent the target population, the results have limited external validity. Moreover, because the design limits participants to the population interested in taking part in the study after being drawn in by outreach, the benefits of the program may be limited if community engagement is ineffective.

There are several advantages in using in-depth interviews to assess the effects of life-skills training on their participants. First, compared to quantitative measures of psychological well-being (e.g. standardized survey items), in-depth interviews allow us to gain a deeper understanding of life as experienced by the HIV-positive children and therefore allow the evaluation team to assess their psychological well-being in a more holistic way. Second, qualitative information obtained from the interviews can be used to tell engaging stories that are compelling to the donors and the interested public.

In-depth interviews suffer from two disadvantages. First, we cannot establish causal impact from training workshops since we will only collect qualitative information from the treatment group (hence we cannot do randomized or quasi experiment). In particular, we only track students who maintain participation in the training workshops and thus there might be a degree selection bias in the results. Second, the quality of the data is highly dependent on the interviewer and the analysis of data (interview notes and transcripts) will be demanding. In summary, as compared to quantitative methods, it will be more challenging to collect and analyze interview data for the qualitative survey and to derive useful insights about the workshops.

Part V – Staffing, Budget, and Timeline

For the quantitative portion of the study, the health-related data will be collected at baseline and endline by clinicians at the LTP health clinics. A team of 10 staff from the evaluation team will be responsible for overseeing the collection of clinical data, contacting children (and their caregivers) from the treatment and control groups, and arranging appointments for them to come to the LTP clinics (in December of 2020, 2025, and 2028). The psychological well-being surveys will be translated into local languages by a local translator and verified by local LTP staff. A pre-test will be conducted in June 2020 to ensure that the survey items are clear and unambiguous. Modifications to the surveys (based on feedback from the pre-test) will be implemented in July 2020. The psychological well-being paper surveys will be distributed by LTP program staff to children after they have completed their physical checkups at the LTP health clinics. Staff from the evaluation team will be available in the LTP clinics to give instructions and answer any questions that the survey respondents might have. The children will complete the survey at the health clinics and quality assurance checks on the survey data will be conducted by evaluation staff. Data entry, processing and analysis (both health-related and survey data) will be conducted by the evaluation team from January to February of 2020, 2025, and 2028. An estimated budget of USD 100,000 will be allocated to this portion of the study—with \$50,000 going to staff- and labor-related expenditures, \$40,000 going to operational costs (e.g. training evaluation staff, developing and processing transcripts), and \$10,000 going to materials and equipment costs.

For the qualitative component of this study, the evaluation team will outsource the interviewing task to a social research company in Nairobi. The interviewers will go through a two-week training program in March of each year. In total, eight interviewers will be recruited each year, and two interviewers will be assigned to each of the four age-groups. The interviewers will operate in pairs (one interviewer and one transcriber), and each interview team will be responsible for interviewing the three selected students and their caregiver/teacher (six interviews in total). Program staff from the evaluation team will be responsible for selecting the interviewee and identifying his/her caregiver or teacher. Interviews will start in June of each year and will last until the middle of July. The qualitative data, which may consist of interview transcript and notes, will be reviewed by program staff after each interview. Content analysis will be conducted by the evaluation team from August to December of each year. Each interviewer will be paid an hourly wage of 1020 KES (9.60 USD). Assuming each interviewer allots 60 hours to interview 6 persons, the total expenditure will be around 3,192,000 KES (30,000 USD) per year. As mentioned previously, the annual in-depth interviews will be performed from 2020 to 2028.

Part VI – Ethical Considerations

One ethical consideration relevant to this study is the need to obtain informed consent from child participants. We must ensure that children and their caregivers join the research voluntarily after receiving adequate information. The participants are also free to drop-out of the study at any time and should be informed of this option. The evaluation team will seek legal guardian consent before enrolling the children in the study. Children will also be asked for their consent after having the purpose and methods of the study explained in ways that they can understand.

To ensure the study does not cause harm (especially psychological harm) to children, interviewers for the in-depth interviews will be trained by the evaluation staff to cease the interview if they detect emotional distress in the children. If the children choose not to answer some of the questions, they will not be pressured in any way by the interviewers. The integrity and quality of the quantitative and qualitative data will be assessed by the evaluation team on the day that they are recorded, and the data will be labelled with an ID (rather than names of the children) to ensure confidentiality.

The program will promote gender concerns in evaluations of service delivery, workplace standards, and will ensure equitable access to outreach and services in ways that supports women, girls, and boys. Services for children will be aligned with the Government of Kenya's Minimum Service Standards for Quality Improvement of Orphans and Vulnerable Children.

Although the control group in the RCT will not receive the full LTP program, the evaluation team will ensure that they still receive adequate treatment by assisting in their enrollment in the typical care regime (including ART and physical checkups as per standard practice to manage HIV patients).

Finally, the evaluation team will draft a research protocol for the study that contains the purpose of the research, its risks and benefits, and ways in which the privacy and confidentiality of the children will be maintained. The protocol will be submitted to the institutional review board (IRB) for review prior to the start of the evaluation study in 2020 and the study will commence only after it is approved by the IRB.

References

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Appendix A

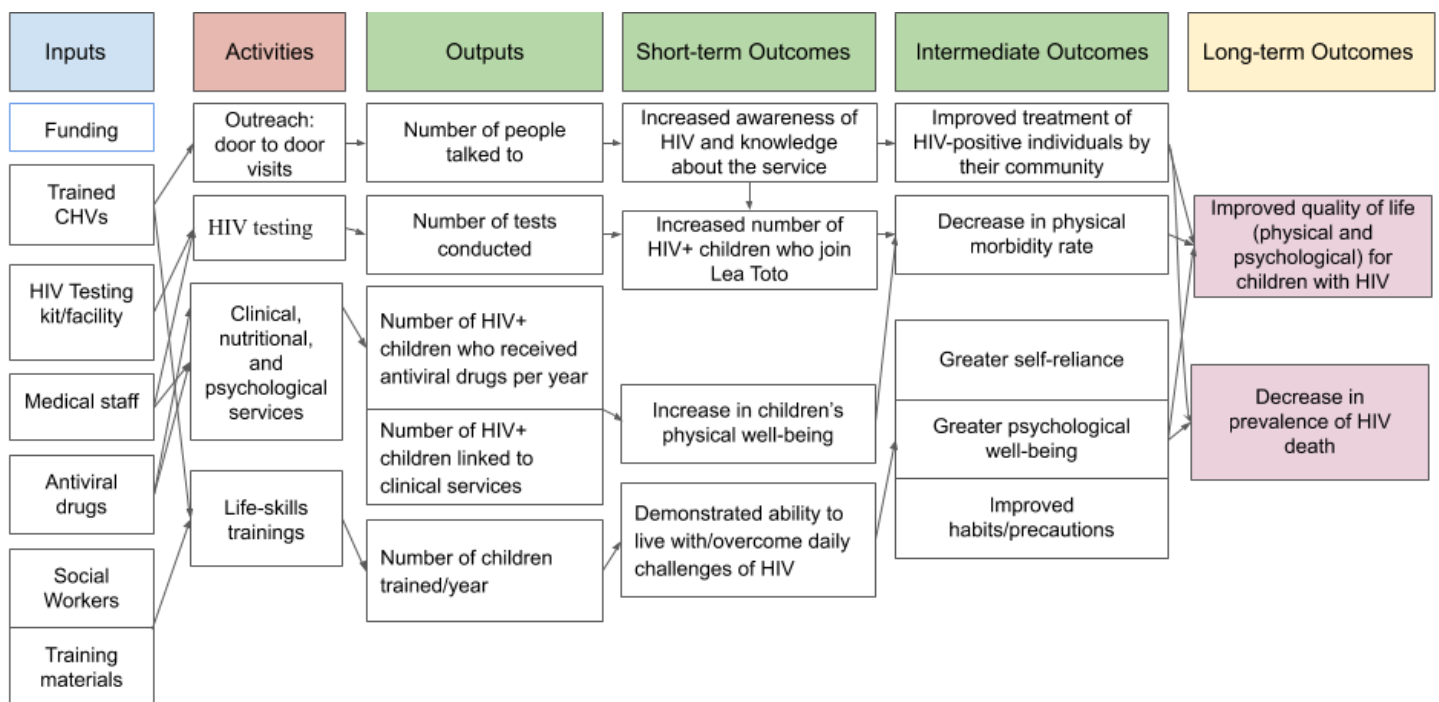


Figure A1: The logic model for the Lea Toto Program.