Use of Routine Data in Evaluation:
Technical Brief

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Impact of a Systems Engineering Intervention on PMTCT Service Delivery in Côte d'Ivoire, Kenya, Mozambique: A Cluster Randomized Trial

This document is part of a series that describes how routine data were used in research and evaluations of health programs and projects. Data for Impact (D4I) has compiled these examples from its own work and the work of others found through a literature review—and consultation with the original authors—to compare ways routine data can be appropriate for evaluations and to shed light on its benefits and shortcomings for evaluation.

A companion guidance document compiling these lessons is available at the D4I website. This suite of materials may be useful for others contemplating using available and routine data in their own work.

The report outlines results of a study to identify and then rectify barriers to implementing programs aimed to prevent mother-to-child transmission of HIV (PMTCT). Access the full report here.

Program Description

Sub-Saharan Africa accounts for more than two thirds of the HIV infections globally and, despite scaling up prevention of mother-to-child transmission (PMTCT) interventions, this type of transmission continues to increase (the Joint United Nations Programme on HIV/AIDS [UNAIDS], 2016). In Côte d'Ivoire, Kenya, and Mozambique, a package of tools was implemented to improve the first three steps in the PMTCT cascade: HIV testing and coverage during antenatal care consultations, antiretroviral (ARV) coverage among HIV-positive pregnant women, and screening infants exposed to HIV. This intervention—made up of a package of system engineering tools—was called the Systems Analysis and Improvement Approach (SAIA) study intervention.

SAIA was a five-step iterative package of systems analysis and improvement tools that required the active participation of staff at the health facilities. The first two steps helped facility staff understand barriers to PMTCT service delivery in their health facility, using system engineering and decision support tools such as the PMTCT Cascade Analysis Tool (PCAT). In step 3, staff developed and implemented a micro-intervention to prevent the bottlenecks in the cascade; and, in step 4, they updated the PCAT and assessed the impact of the micro-interventions. Lastly, in step 5, staff either modified the current micro-intervention or implemented a new one. This iterative cycle was then repeated throughout the duration of the intervention (see https://www.healthallianceinternational.org/project/saia/ for detailed information about the tools).

Prior to SAIA's implementation, staff at each facility participated in a four-day workshop that introduced them to the intervention's purpose and the components of SAIA. Thereafter, follow-up visits were conducted systematically throughout the nine-month study implementation period (February–November 2014).

To assess the effectiveness of the tools, the study used a pragmatic two-arm longitudinal cluster-randomized trial. The study randomized health facilities to either an intervention group that received SAIA or a control group that did not receive SAIA. It was stratified by country and volume of the first antenatal care visit.

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Rationale for the Use of Routine Data

The advantage to the study for using routine data from facility registries were that these data were readily available and, secondly, the data could easily and inexpensively be compared to data generated from future real-world interventions. The outcome data were collected from monthly data from the antenatal care, PMTCT, maternity, and postpartum registries at health facilities in the countries of interest, with the exception of data from two health facilities in Kenya where there was unanticipated violence nearby. Data from those two facilities were extracted from the national health information system.

Evaluation Questions

The routine data were used to answer the following questions:

1. **Impact of intervention on HIV testing coverage**: Do micro-interventions developed using a package of system engineering tools increase the percentage of pregnant women tested for HIV during their first antenatal care consultation in the intervention group compared to the comparison group?

2. **Impact of intervention on ARV coverage**: Do micro-interventions developed using a package of system engineering tools increase the percentage of HIV-positive pregnant women receiving ARVs in the intervention group compared to the comparison group?

3. **Impact of intervention on HIV-exposed infants screening coverage**: Do micro-interventions developed using a package of system engineering tools increase the percentage of HIV-exposed infants screened for HIV with polymerase chain reaction (PCR) test by 6-8 weeks of age in the intervention group compared to the comparison group?

Data Description and Data Management

Data were collected from 36 randomized health facilities in Kenya, Côte d'Ivoire, and Mozambique. In each country, a total of six intervention and six control facilities were selected. The data were accessed directly from the facility registries except, as noted, for two facilities in Kenya. Starting in spring of 2014, study staff extracted data from the national health information system (NHIS) for these two facilities. The data were collected retrospectively from January to December 2013 and prospectively from 2014 until March 2015 on a monthly basis. Any of the monthly outcome data collected that exceeded 100 percent were capped at 100 percent.

A team of two collected the data from the facility registries in each country. The data collectors used a standardized form to record the information from the registries. Each standardized form listed the following:

- The number of first antenatal care visits
- The number of pregnant women tested for HIV during the first antenatal care visit
- The number of HIV-positive pregnant women receiving ARV
- The location where the data were collected (antenatal care, pharmacy, or other)
- The number of HIV-positive pregnant women newly identified in first antenatal care visit
- The number of HIV-positive pregnant women newly identified in subsequent visits
- The number of HIV-positive pregnant women previously identified
- The total number of HIV-positive pregnant women identified
- The number of infants less than six weeks of age receiving a PCR test for HIV.

The data collectors also noted which registry contained information on each indicator.

Thereafter, the in-country database managers double-entered the data on the forms into Microsoft Excel and noted any missing or implausible values. Any discrepancies between the first and second data entry were resolved and sent to the study headquarters, where further data checks were conducted. Program data provided information on the types and number of micro-interventions implemented at the intervention health facilities.

Assessment of Usability and Quality of Data

Two trained data abstractors collected the data from facility registries to maximize accuracy and to compare the data collected. Any differences in the data collected between the two abstractors were reviewed on-site until they reached consensus. A similar approach was used when data was entered by database managers. The data were double-entered into Microsoft Excel and discrepancies were resolved. In addition, missing and implausible values were noted and corrected before sending to

the study headquarters. At headquarters, the assigned team member checked the available data for outliers, missing values, or implausible values each month and followed up with the database manager as needed.

Contextual events affected the data collection efforts and HIV services delivery during the study period which affected the usability of the data collected. For example, in 2014, there was a nationwide shortage of HIV test kits in Kenya. The national election in Mozambique that same year reduced the delivery of health services across sectors. Although data were collected during these periods, they were not included in the analysis because the events did not occur during the defined pre-intervention (January 2013–January 2014) or post-intervention (January–March 2015) periods.

Data Analysis Methods Used

An "intent to treat" approach was used to determine the impact of the micro-interventions between the pre-intervention and post-intervention periods. For each outcome, two-sided t-tests were used to determine if the mean during these two periods differed between the study arms. In addition, one pre-specified sub-group analysis was conducted and stratified by country. Due to the randomized nature of the study, the analysis did not adjust for covariates. The analysis also did not account for clustering because the unit of randomization and the unit of analysis were at the cluster level.

Limitations in Using Routine Data for Evaluation

The study was constrained to the variables available in the facility registers and Kenya's national health information system. As a result, the denominator to calculate the screening coverage of HIV-exposed infants was extrapolated. The routine facility records were not collected primarily for research purposes. Secondly, this study used data from three different countries with various levels of data quality or training on data collection. For example, in Côte d'Ivoire, the antenatal care registry was updated in mid-2013 and this could have impacted the data quality across the study arms. It also should be noted that the study had a small sample size, which could have affected the statistical significance of the results.

Routine data reporting systems do not take into account secular events that can impact the availability and quality of data, thus there is a a need to build resilient systems that can deal with these interruptions. For example, violence in Kenya affected data collection from two facilities but the team was able to obtain an alternate data source.

Another major limitation was the lack of unique patient identifiers, which mean that as a result, only cross-sectional analyses could be conducted. Although missing data and double-counting of data are common problems of using routine data, this study did not encounter this issue. There was no missing data, in part because the study used data aggregated on a monthly basis. Additionally, there was no reason to think that double-counting was common, but there was no way to independently verify this.

What Worked Well?

Routine data use requires collaboration with in-country colleagues to maximize access to health facility data and we were fortunate to have collaborators in each country to facilitate access. The collaboration between in-country and Seattle-based study staff was excellent. Staff at the health facilities were trained in quality improvement and data abstraction skills that are applicable to other quality improvement and research activities. This ensured that there were minimal issues with the logistics of obtaining and conducting quality checks.

Conclusion

The study used routine data to show that micro-interventions could substantially increase the coverage of the first three aspects of the PMTCT cascade. Substantial increases were seen in antiretroviral coverage and screening of HIV-exposed infants at the intervention facilities compared to control facilities. Moreover, the evaluation questions were best answered with routine data because this was a pragmatic trial designed to generate results that could be directly applied to other health facilities without their having to significantly alter their data collection. The benefit of using routine data was that the results could be directly comparable to future real-world interventions since health systems across the world collect many of the same indicators.

References

UNAIDS. (2016). *Prevention Gap Report*. Geneva. Retrieved from https://www.unaids.org/en/resources/campaigns/prevention-gap

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