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Developing an intervention to improve paediatric HIV care in central Mozambique

Submission date
27/06/2019

Recruitment status
No longer recruiting

Registration date
25/07/2019

Overall study status
Completed

Last Edited
10/11/2020

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Infants born to mothers who are infected with the HIV virus are at high risk of becoming infected themselves during pregnancy, labor, or through breastfeeding. Therefore it is important to follow these infants to test them for HIV and ensure that if they are infected that they start treatment, known as anti-retroviral therapy (ART), as soon as possible. The HIV-exposed infant diagnosis (EID) and initiation of HIV-positive infants on anti-retroviral therapy (ART) requires a well-coordinated sequence of visits and tests in a health center, known as the "cascade of care, to ensure that an HIV-exposed infant gets tested and starts treatment. Loss-to-follow-up (LTFU) can occur when a mother does not return for clinic visits in order to have her infant tested or to start treatment. Effective EID is impeded by shortages of healthworkers, difficulty with patient tracking, and long waiting periods. The objective of this research was to design and test an intervention to improve the follow-up of HIV-exposed infants. The project included "formative research", that is research done to understand and identify the problem more clearly, to guide the development of an intervention to improve the pediatric HIV care cascade in central Mozambique. The study was conducted in Manica and Sofala Provinces in central Mozambique where the adult HIV prevalence (i.e. the percentage of the population that is infected with HIV) is higher than the national average. The research focused on 3 large clinics in each province, along the highly populated Beira transport corridor. The aims of the study included to: 1) conduct formative research to identify problems and challenges to providing better care to infants; 2) design an intervention to improve care, 3) implement the intervention, and 4) measure the impact on the intervention to see whether it increased the number and percentage of HIV-exposed infants who were tested for HIV, started on treatment, and who stayed on treatment for at least three months. Initially we did formative research in 2014 over 3 months at six facilities and consisted of 1) mapping the flow of patients in the clinic and collection of health systems data from each step in the clinic sequence of care, 2) measurement of patient waiting times, and 3) interviews with groups of patients and health workers to understand their views and experiences of the care cascade. An intervention was designed based on the information collected to improve enrolment of mother and child in HIV care programs in healthy facilities. The study started 21/12/ 2015 and ended on 20/02/2017. We used a "stepped wedge" design, which means that the intervention was implemented in three steps. It was initiated in two sites (randomly selected from the six), then in two more sites after three months, and finally two more sites after another three months. This design allows a statistical

analysis to show whether the intervention had an impact. The intervention model included the use of community health workers, telephones to contact the mothers, active search for mothers who did not return for scheduled visits, initiation of treatment in the child-at-risk services rather than referring mothers to another part of the clinic, and specific changes to how medical charts were used to support a better patient tracking process. For the data analysis, we used the binomial logistic regression model with mixed effects.

Who can participate?
In the formative research, HIV-positive mothers from peer-support groups already organized at each clinic were invited for interviews. All health workers involved at each step in the care cascade were invited to participate in group discussions. For the intervention itself, all women who came in for postpartum care during the study period at each clinic experienced the intervention, and data were collected on these patients from routine clinic registries to measure impact.

What does the study involve?
In the formative research period, the study include group interviews with mothers and health workers to help develop the intervention. The intervention model that was developed included the use of community health workers, telephones to contact the mothers, active search for mothers who did not return for scheduled visits, initiation of treatment in the child-at-risk services rather than referring mothers to another part of the clinic, and specific changes to how medical charts were used to support a better patient tracking process. The intervention was conducted eventually in all six sites, but initiated in timed steps in two clinics each three months. Women who came for post-partum care during the intervention period would experience that same intervention model across all 6 clinics. Routine data were collected from all six sites for women seeking post-partum from the beginning of the study period. So some of these participants who came for care in a site before it was step into the intervention, would have not experienced the intervention. They acted as the “control” groups to compare to the intervention groups to measure whether the intervention increased the number of infants getting care.

What are the possible benefits and risks of participating?
The risks for mothers and health workers participating in the group discussions were minimal. There could have been some risk of repercussions for health workers if they spoke too negatively about their work environment in front of superiors. For mothers, there could have been some risk of social stigma if they spoke frankly about personal issues and health concerns within the group. Benefits included participating in development of a system that could improve the experience of both mothers and health workers in getting and providing care.

For mothers coming into clinics for postpartum care and experiencing the intervention, there are minimal risks. There is some potential risk in the use of cell phone text messaging or calling for revealing a mother’s HIV-positive status to a partner or family member. Home visits by community health workers could also lead to disclosure. Mothers had to consent to this and could voluntarily choose to not receive calls or texts. Benefits included receiving better care, earlier testing of their infants for HIV, and higher likelihood of starting their infant on treatment that could save their infant’s life.

Where is the study run from?
The study is run from the National Institute of Health - Beira Operational Research Centre, Correia de Brito Street, 350,telephone and fax: +258 23324308, postal address 583, Beira city, Mozambique. There were six clinics involved in the study. These include Munhava, Macurungu, Dondo, Gondola, Primeiro de Maio, and Nhamaonha.

When is the study starting and how long is it expected to run for?
The study started in September 2014 and ended in February 2017.

Who is funding the study?
This study was supported by the United States Government National Academy of Science /National Institutes of Health Partnerships for Enhanced Engagement In Research (PEER) Health, Grant Award Number: AID-OAA-A-11-00012.

Who is the main contact?
The main contact is the principal investigator, Lúcia Da Costa Vieira with email: luciadacostavieira@gmail.com, based on Beira Operational research Centre in Mozambique.

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2000003598

Study information

Scientific Title

Reducing loss-to-follow-up among HIV-exposed infants in Central Mozambique: a randomised controlled trial

Acronym
PEER-LTF-HIV-MOZ

Study objectives
We hypothesize that the proportion of HIV-positive women from maternity clinics at study sites in Manica and Sofala provinces in central Mozambique who enroll their infants in child at-risk clinics and the proportion of infants tested for HIV and enrolled in pediatric HIV care will increase after the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/09/2014, the Mozambique Ministry of Health National Health Bioethics Committee (264, Mpauto, Mozambique; +258426547 or +258821321680; cnbs.mocambique@gmail.com), ref: 278/CNBS/2014.
Approved 23/11/2015, the Mozambique Ministry of Health National Health Bioethics Committee (264, Mpauto, Mozambique; +258426547 or +258821321680; cnbs.mocambique@gmail.com), ref: 336/CNBS/15.

Study design
The study will be a clustered (facility-level) randomized controlled trial, implemented through a stepped wedge design.

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a participant information sheet.

Health condition(s) or problem(s) studied
HIV disease

Interventions
The intervention was developed following the initial formative research phase. The formative research phase includes patient flow mapping, focus group discussions with patients and health workers, and analysis of health facility data as well as health center observations.

Three core components constitute the intervention:
1. System tracking and linkages:
1.1. All HIV-positive women giving birth at maternity clinics counseled and referred to CCR services.
1.2. Caregivers for make home visits, call and send SMS to mothers for all exposed HIV children's and PCR-positive infants identified in CCR
1.3. Counseled and start ART in CCR clinic
1.4. Registries and counseling modified to better track new mothers to CCR enrollment.
2. Optimize counseling approaches and workflow to redirect HIV-exposed infants to CCR when they present to well child and postpartum visits:
2.1. Registries and counseling modified to track HIV-exposed infants and follow-up to enrollment.
3. Integration of FP into PP care and CCR services:
3.1. FP counseling integrated into PP and CCR services and supervised to ensure delivery. These services provided to all mothers in PP and CCR services, not only HIV-positive mothers.
3.2. Physically accompany mothers from CPP to CCR.

We used “Stepped Wedge” design, which means that the intervention was implemented in three steps. It was initiated in two sites (randomly selected from the six), then in two more sites after three months, and finally two more sites after another three months. Duration of the intervention at each site was three months to nine months depending on how each site was stepped in. This design allows a statistical analysis to show whether the intervention had an impact. The intervention model included the use of community health workers, telephones to contact the mothers, active search for mothers who did not return for scheduled visits, initiation of treatment in the child-at-risk services rather than referring mothers to another part of the clinic, and specific changes to how medical charts were used to support a better patient tracking process.

Intervention Type
Other

Primary outcome measure
Data on all outcomes are gathered at 3-month intervals at each of the six clinics, beginning at baseline (3 months before the intervention began):
1. PCR testing rates among HIV-exposed infants presenting to CCR.
2. The proportion of HIV-exposed infants attending 2 or more CCR visits.
3. The proportion of HIV-exposed infants at CCR receiving cotrimoxazole prophylaxis.
4. The proportion of HIV-positive infants identified via PCR at CCR clinics who enrol in care at an HIV treatment clinic within 45 days of positive test results (known as consulta de TARV, or ART).

Secondary outcome measures
Data on all outcomes are gathered at 3-month intervals at each of the six clinics, beginning at baseline (3 months before the intervention began):
1. The proportion of caregivers of infants with positive PCR result who are notified of infant’s positive HIV status.
2. The time interval from CCR visit at which PCR test sample obtained to first ART visit for PCR positive infants.
3. The acceptability of EID oriented intervention to healthcare workers and HIV-positive mothers measured using individual interviews, focus group discussions to the mothers and routine data collections.

Overall study start date
23/10/2012

Completion date
20/02/2017

Eligibility

Key inclusion criteria
Clinics:
1. High patient volume in antenatal care (ANC).
2. High HIV prevalence in ANC.
3. Already implementing Option B+ (HIV test and treat for pregnant mothers).
4. Located along the Beira highway corridor to assure access.

Health workers:
1. Providers of post-partum, child-at-risk, and ART services at each clinic.

Mothers:
1. Active women members of HIV-positive members at each clinic site.
2. HIV-positive Women, age 18-44.
3. Patient at a local clinic.

Participant type(s)
Mixed

Age group
Mixed

Lower age limit
18 Years

Upper age limit
44 Years

Sex
Both

Target number of participants
-A total of up to 25 CCR and postpartum care nurses, counselors and other health center staff from each of the 6 target health units.2. study sites identified an average of about 50 HIV-exposed infants born each month in each maternity.

Key exclusion criteria
N/A

Date of first enrolment
21/12/2015

Date of final enrolment

21/08/2016

Locations

Countries of recruitment
Micronesia, Federated States of

Mozambique

Study participating centre
Munhava health centre
Acordos de Lusaka road
bairro of Munhava
Sofala province
Beira
Mozambique
-

Study participating centre
Macurrungo health centre
Number one road
bairro of Macurungo
Sofala province
Beira
Mozambique
-

Study participating centre
Dondo health centre
Administração road
bairro of Consito
Dondo district
Sofala province
Beira
Mozambique
-

Study participating centre
Primeiro de Maio health centre
Umpulango road
bairro of Centro-Hipico
Manica province
Chimoio

Mozambique
-

Study participating centre
Nhamaonha health centre
Cabeça de Velho road
bairro of Soalpo
Manica province
Chimoio
Mozambique
-

Study participating centre
Gondola distrital hospital
Nacional number 6 road
bairro Josina Machel
Gondola district
Manica province
Chimoio
Mozambique
-

Sponsor information

Organisation
Centro de Investigação Operacional Da Beira

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Sponsor type
Government

Website
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Funder(s)

Funder type
University/education

Funder Name
National Academy of Sciences

Alternative Name(s)
U.S. National Academy of Sciences, NatlAcad of Sciences, United States, National Academy of Sciences, The National Academy of Sciences, The U.S. National Academy of Sciences, NAS

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication of a scientific paper.

Intention to publish date
29/09/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to limitatins imposed by the national Mozambique ethics committee.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		06/03/2020	23/03/2020	No	No
Results article	results	18/03/2020	10/11/2020	Yes	No