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Evaluation of integration models for HIV and family planning services

Submission date
30/09/2015

Recruitment status
No longer recruiting

Registration date
06/10/2015

Overall study status
Completed

Last Edited
22/08/2016

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
The human immunodeficiency virus (HIV) is a growing problem, affecting millions of people worldwide. Many cases of HIV are passed on through sex (sexual transmission), and are easily preventable. In sub-Saharan Africa, low use of contraceptives is thought to play a key role in the transmission of HIV, as well as causing unintended pregnancies and other sexually transmitted infections (STI). In Zambia, improved HIV and family planning services are in short supply and desperately needed. When people are diagnosed with HIV, they are often not followed-up effectively, meaning that they do not have access to treatments which could improve their quality of life. This lack of coordination means that providing new services such as voluntary medical male circumcision (VMMC) to lower male-to-female HIV transmission and long-acting reversible contraception (LARC) to prevent unwanted pregnancy are overlooked. Combining family planning and HIV programs could be an effective way to provide these services to more people. By strengthening links between different programs and providing more referrals to add-on services, HIV prevention could be greatly improved. The aim of this study is to find out whether a combined HIV and family planning service with improved referrals is a cost-effective way of improving add-on service use.

Who can participate?
Sexually active adults who live within the study catchment area in Zambia.

What does the study involve?
Participants are randomly allocated into three groups. Those in the first group (control group) are given the standard care usually provided which includes family planning, HIV testing and counselling and voluntary medical male circumcision. Those in the second group receive the standard package of care with more in-depth counselling, as well as a referral to receive extra services. If participants do not access the add-on services within a week, then they receive a follow up phone call to provide extra encouragement and counselling. Those in the third group receive the same package as group two, except the add-on services that they are referred for are enhanced, and they are given the option of being immediately escorted to the add-on service. Study participants are interviewed at six weeks and six months from the beginning of the study for their opinions on the services provided, as well as to find out how many people took up the add-on services.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Eight health centres in Zambia with family planning and HIV screening facilities.

When is the study starting and how long is it expected to run for?
September 2009 to January 2015

Who is funding the study?
United States Agency for International Development (USA)

Who is the main contact?
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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AID-OAA-A-12-00026

Study information

Scientific Title
Randomized evaluation of HIV and family planning service models

Acronym
REacH

Study objectives
1. Does a provider-initiated referral models increased add-on service uptake compared with an existing vertical service model
2. Are comprehensive provider-initiated referral models more cost-effective, compared with an existing vertical service model

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Population Services International Research Ethics Board, 16/03/2013, ref: 51.2012
2. University of Zambia Biomedical Research Ethics Committee, 12/04/2013, ref: 002-12-12

Study design
Multicentre randomized controlled implementation science research study

Primary study design
Interventional

Secondary study design
Economic evaluation

Study setting(s)
Other

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
HIV/AIDS, STI, family planning and cervical cancer screening services

Interventions
Clients accessing services and voluntarily enrolling were randomized into one of three study arms that offered a different package of services:

1. The standard model of service provision at family planning (FP), HIV testing and counselling (HTC) and voluntary medical male circumcision (VMMC) sites (control)
2. An enhanced client counselling and referral to add-on service arm, with client follow-up
3. An enhanced client add-on service referral and follow-up arm with the addition of an offer of immediate escort to the add-on service

For clients in the two intervention arms, if they did not access the add-on referral services within seven days, they were called and provided additional encouragement and counselling to improve their likelihood of add-on service uptake.

Add-on services consisted of the following:
1. Family planning (FP)
1.1. HIV Testing and Counselling (client/spouse)
1.2. Cervical cancer screening (client)
1.3. VMMC and HTC for (spouses/children)
2. HIV Testing and Counseling (HTC) (client, spouse, children depending on gender)
2.1. HIV care and treatment (for positives) – array of services
2.2. STI care and treatment
2.3. VMMC (for negatives)
2.4. FP
3. Add-on services for Voluntary Male Circumcision (VMMC)
3.1. HIV care and treatment (for positives)
3.2. STI care and treatment
3,.3. HTC (for spouses)
3.4. FP (for spouses)

Study personnel interviewed participants at the study sites at baseline, six weeks, and six months post-enrollment. At the follow-up interviews at six weeks and six months all study participants were asked questions regarding their uptake of an array of add-on services, as well as questions about behaviors and satisfaction with the health services received. Qualitative in-depth interviews conducted among participants and providers from experimental and control sites sought to identify facilitators and barriers to the implementation of enhanced FP and HIV service linkage and integration models. Detailed cost data from entry-point and referral sites, including incremental capital and recurrent costs and valuated provider time related to service provision was collected to conduct a technical efficiency and a cost-effectiveness analysis of the study interventions.

Intervention Type
Behavioural

Primary outcome measure
1. Access to services within 14 days via a client tracking database; client registers at study sites when appearing for add-on service
2. Self-reported uptake of add-on services at six weeks and six months via a structured

behavioural interview, such as “in the last six weeks, which of the following services have you accessed at any health facilities..”
3. Costing and client utilization data were gleaned from partner and facility internal records, while client data were collected using identical baseline, six week and six month interview surveys used at control and experimental sites

Secondary outcome measures
1. Information regarding the structural and individual barriers to service uptake were obtained through in-depth qualitative interviews with a randomly selected sub-set of participants
2. Client satisfaction with services utilized were obtained at six weeks and six month structured behavioural interview
3. Institutional barriers were obtained through in-depth qualitative interviews conducted at the end of recruitment with clinical providers (nurses, counsellors) who participated in the study

Overall study start date
01/09/2012

Completion date
07/01/2015

Eligibility

Key inclusion criteria
1. Presenting at one of the service entry points during the study enrollment period
2. 18 years or older
3. Sexually active, defined as having sex within the past 12 months
4. Plan to reside within the study catchment area for the next 6 months

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
3,963

Key exclusion criteria
1. Unable or unwilling to provide informed consent
2. Unable or unwilling to provide contact information
3. Determined not to be eligible based on the inclusion criteria

Date of first enrolment
17/12/2013

Date of final enrolment
10/11/2014

Locations

Countries of recruitment
Zambia

Study participating centre
Society for Family Health New Start HIV Testing and Counselling Centre
Lusaka
Zambia
10101

Study participating centre
Chawama Public Health Clinice
Lusaka
Zambia
10101

Study participating centre
Kamwala Public Health Clinic
Lusaka
Zambia
10101

Study participating centre
Kapata Public Health Clinic
Chipata
Zambia
90100

Study participating centre
Chipata General Hospital
Chipata
Zambia
90100

Study participating centre
Society for Family Health New Start HIV Testing and Counselling Centre
Chipata
Zambia
90100

Study participating centre
Society for Family Health Voluntary Medical Male Circumcision Centre
Chipata
Zambia
90100

Study participating centre
Young Women's Christian Association
Lusaka
Zambia
10101

Sponsor information

Organisation
Population Services International

Sponsor details
1120 19th Street, NW, Suite 600
Washington, DC
United States of America
20036

Sponsor type
Charity

Website
www.psi.org

ROR
https://ror.org/03zjj0p70

Funder(s)

Funder type

Government

Funder Name
United States Agency for International Development

Alternative Name(s)
U.S. Agency for International Development, Agency for International Development, USAID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Publication and dissemination plan
Intention to publish manuscript(s) reviewing study results

Intention to publish date
30/03/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/08/2016		Yes	No