# Development and implementation of a patient-centered peer support intervention to promote the detection, reporting and management of ADR among PLHIV in Uganda

Investigators and Collaborators: Ronald Kiguba, Helen B. Ndagije, Victoria Nambasa, Cordelia Katureebe, Henry Zakumumpa, Stella Nanyonga, Jacquellyn Nambi Ssanyu, Phil Tregunno, Kendal Harrison, Corinne S Merle, Marie-eve Raguenaud, Freddy Eric Kitutu

#### Overview of Presentation

- Introduction and study objectives
- Mobile data transmission technologies
- Peer Support Intervention
- Study design and population
- Study variables
- Quantitative results
- Implementation Challenges & Opportunities

#### Introduction and Study Objectives

#### Introduction

- Spontaneous reporting of adverse reactions - backbone of pharmacovigilance (PV) globally
- Patient engagement is low:
   <12% of PV reports in</li>
   Uganda's database.
- Peer support plus mobile technologies - empower patients to report & improves ADR management through linkage to care.
- Med Safety/Unstructured Supplementary Service Data

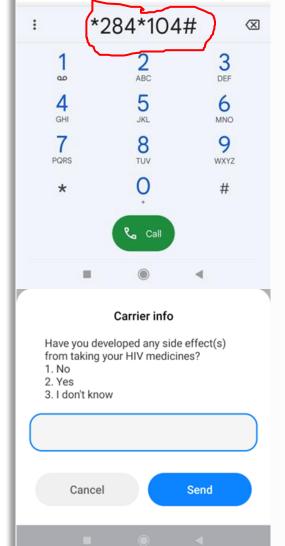
#### Hypothesis

- Peer support plus mobile data transmission technologies for promoting the detection, reporting and management of ADRs in PLHIV is feasible and acceptable.
- Peer support plus mobile data transmission technologies will significantly increase the number of PV reports submitted to the national database by PLHIV during 4months of follow-up when compared with the number of reports from PLHIV who do not receive peer support.

# Specific Objectives

- 1.Develop a peer support plus mobile data transmission technologies intervention
- 2.Explore barriers & facilitators to peer support plus mobile technologies
- 3.Describe the patterns of ADR-reporting by PLHIV
- 4.Estimate effect of peer support plus mobile data transmission technologies on the rate of ADR-reporting by PLHIV

# Unstructured Supplementary Service Data (USSD)



**Toll-free Unstructured Supplementary Service Data** 

Available for both low-tech non-smartphones and high-tech smartphones

No Internet connection is needed

#### **Med Safety Mobile Application**



**Launched in Uganda in February 2020** 

Available only for smartphones

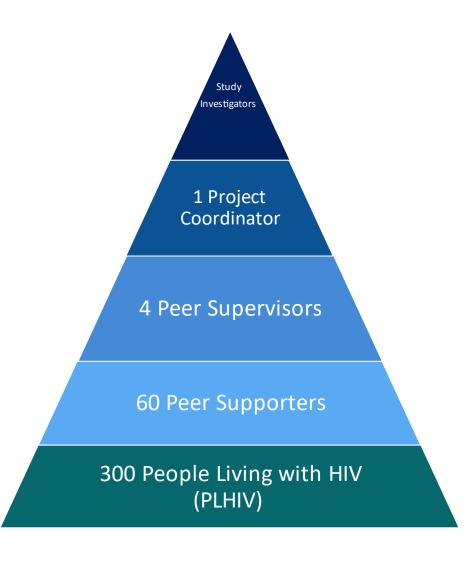
Internet is required to transmit reports

Promotes two-way communication

#### Peer Support Intervention..1

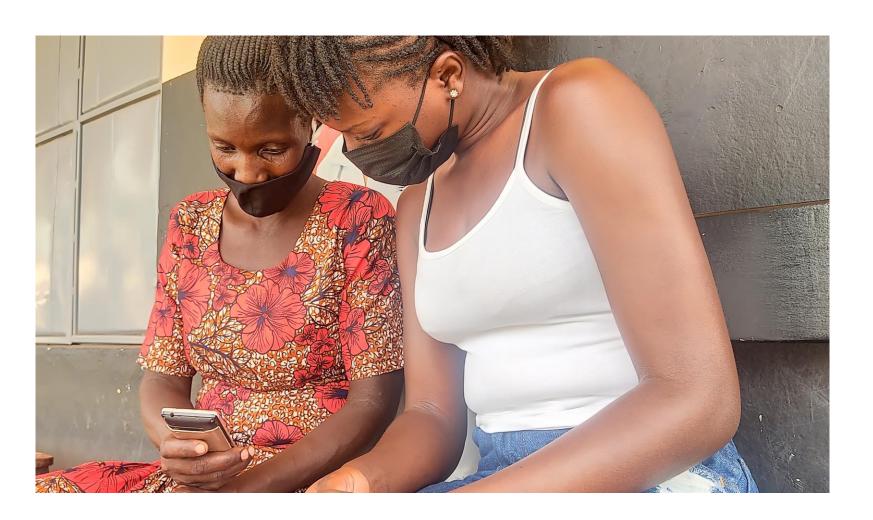
- Leverages mobile technologies (Med Safety, USSD) in addition to traditional methods (paper, online, voice call)
- Layers of supervision
  - · Per region: 1 peer supervisor, 15 peer supporters, 75 Mentored PLHIV
  - Four regions: 4 peer supervisor, 60 peer supporters, 300 Mentored PLHIV
- PLHIV in the intervention arm will be assigned to peer supporters to guide their ART care for 4-months
- Peer supporters will constitute a mixed group of lay people, namely; i) expert clients who are PLHIV with more
  experience in the use of ART and, ii) recognized community health workers
- · Peer supporters will guide the mentored PLHIV to report ADRs to the National Pharmacovigilance Centre
- PLHIV will be matched with the respective peer supporters of similar age, gender and proximity of residence
- · Non-random matching of PLHIV to peer supporters: to promote easier and faster bonding of the peer-relationships

#### Peer Support Intervention..2



- Principal investigator(PI) overseesimplementation
- PI reports to the study investigator team every 2 months
- Pl attends the monthly Study Coordinator-Peer Supervisor(s) meetings/calls
- Coordinates monthly meetings with 4 Peer Supervisors
- Provide support supervision & counselling to motivate the Peer Supervisors, Peer Supporters and PLHIV
- Updates the PI weekly on the progress of implementation
- 1 Peer Supervisor from each of the 4 regions of Uganda
- Peer Supervisor doubles as a Peer Supporter
- Overseas 14 other Peer Supporters in the same region
- 2 Phone calls per month to each Peer Supporter
- 15 Peer Supporters from each of the 4 regions of Uganda
- 5 PLHIV assigned to 1 Peer Supporter for 4-months
- 1 daily face-to-face or phone call interaction with 1 PLHIV
- 5 interactions with 5 PLHIV each week
- 1 weekly face-to-face or phone call interaction with the assigned Peer Supporter for up to 4-months
- Guided to report ADRs to NPC using Med Safety, USSD and traditional methods (paper, online,toll-free voice call)

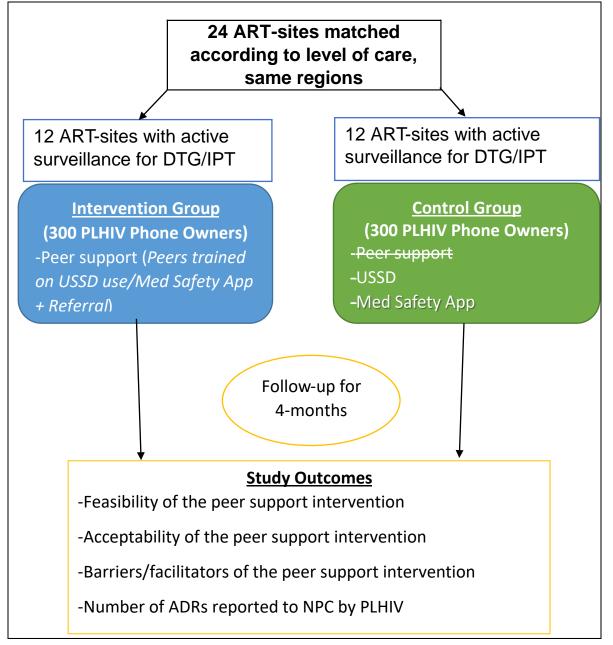
## Peer Support Intervention..3





Humanizing healthcare model for peer support

#### Study Design: Quasi-experimental study



#### Eligibility criteria

#### Inclusion criteria: Selection of study units occurred at three levels:

- First, eligible PLHIV should i) be aged > 15 years, ii) receive ART at the selected study sites, iii) own
  a mobile phone (smartphone, basic feature phone) and, iv) provide written/thumb-printed informed
  consent. Child consent can be given by emancipated minors aged 15 to 17 years in Uganda
- Second, eligible peer supporters (expert clients, CHWs) were those that were recognized and seconded by the study sites or collaborating patient safety groups. These peer supporters we those that are attached to the study sites and have already received institutional training in their role as expert clients/CHWs; they should own mobile phones.
- Third, study health facilities will be selected and enrolled as follows; in each of the four geographical regions, blocks of three health facilities each with an ART-site, including at least a tertiary, secondary and primary health facility will be created based on the catchment of each tertiary facility. From the created blocks of three health facilities in each region, two blocks will be selected by simple random sampling to participate in the study as the intervention and comparison health facilities, respectively.

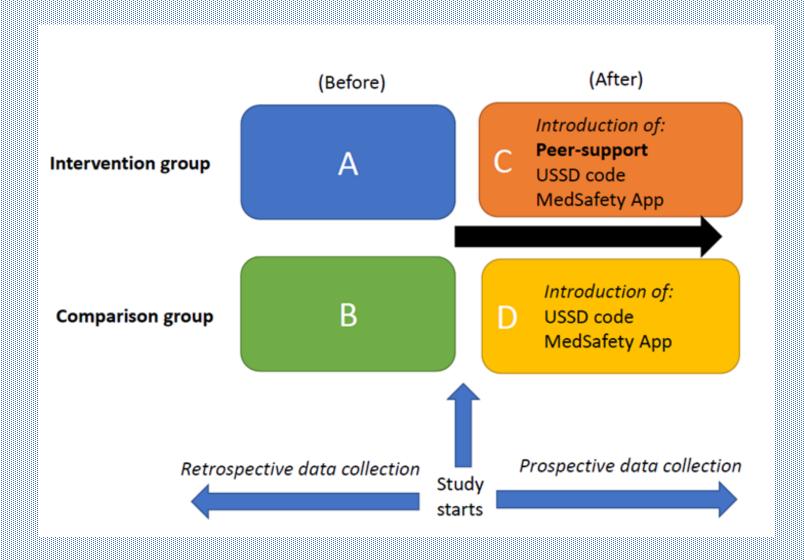
#### Study variables

#### Primary outcomes:

 Feasibility of the peer support intervention - attrition rate recorded as the number of study participants who remain in the study until the end of follow-up at 4 months

 Number of suspected ADR reports submitted to NPC by PLHIV as measured by questionnaire and data abstracted from the national pharmacovigilance database at baseline and 4 months

## Data Collection and Analysis



# No. of Pharmacovigilance Reports submitted

Study Arm	USSD	Med Safety App
Intervention	4,125	183
Control	360	18
Total	4,486	201

# Rate of Reporting by PLHIV

Variable	Completed (n1)	Expected (n2)	Completion rate (%)	Attrition rate (%)
Peer Supporters	58	62	94	6
Clients (Intervention)	250	305	82	18
Clients (Control)	254	300	85	15
Weekly reports	4,159	4,960	84	16
Linkage to care for adverse drug reaction management	544			

#### Implementation Challenges and Opportunities

#### Challenges

- Installation and demonstration of the Med Safety App
  - ✓ Incompatible phones
  - ✓ Poor or no internet connectivity
  - ✓ No space for new apps
  - √ Faulty phones
- Delayed completion of participant enrolment

#### Opportunities

- Clients prefer peer supporters to healthcare workers
- USSD platform is preferred because its easier to use
- Increased rollout of digital pharmacovigilance
- Increased patient engagement in pharmacovigilance
- Reporting rate increased from 6 reports/month to 39 reports/month to the national regulatory agency over 8 months prior to and 8 months after the peer support intervention

# Acknowledgements











Thank You!

Questions??