South Africa - Adherence Guideline Impact Evaluation - Effectiveness of Fast-track Treatment Initiation Counselling 2015-2018

South Africa National Department of Health, National Health Laboratory Service, Johannesburg, South Africa, World Bank, Boston University School of Public Health

Report generated on: September 19, 2019

Overview

Identification

ID NUMBER
ZAF_2015-2018_SAGIE_v01_M

Version

VERSION DESCRIPTION
Version 2.1: Edited, anonymized dataset excluding individual patient viral load and CD4 count test results. Dataset extracted from routine data systems for public distribution.

NOTES
Data harvested from multiple routine data systems were combined, cleaned and quality-checked to produce this final version.

Overview

ABSTRACT
The dataset contains core data on HIV patients who were eligible for fast-track treatment initiation counselling (FTIC) in the Adherence Guidelines evaluation of the South Africa Department of Health and The World Bank. This evaluation's purpose was to assess the effectiveness of five interventions recommended by the Adherence Guidelines by looking at short-term and final outcome results. This data set includes data from the fast-track treatment initiation counselling intervention. The objective was to determine if fast-track treatment initiation counselling improved treatment initiation one month after eligibility, and viral suppression during patient follow-up. There were 12 intervention clinics and 12 control clinics providing the prevailing standard of care. The patients were enrolled from routine data bases into the evaluation without patient contact. The patient-level data include the enrolment clinic, intervention arm, age group, and whether the patient had a diagnosis of tuberculosis at cohort enrolment. The datafile also provides the short-term and final outcome data for the evaluation of FTIC effectiveness. The datafile supports an academic publication on the evaluation.

KIND OF DATA
Clinical data [cli]

UNITS OF ANALYSIS
HIV Patient

Scope

NOTES
The Scope the survey includes the following:

- Characteristics of patients initiating HIV treatment,

- HIV treatment initiation rates,

- Viral suppression rates during HIV treatment,

- Retention in HIV care rates

Coverage

GEOGRAPHIC COVERAGE

Provinces of Gauteng, KwaZulu Natal, Limpopo and North West

UNIVERSE

HIV cases eligible to initiate antiretroviral treatment based on South African clinical guidelines

Producers and Sponsors

PRIMARY INVESTIGATOR(S)

Name	Affiliation
South Africa National Department of Health	
National Health Laboratory Service, Johannesburg, South Africa	
World Bank	
Boston University School of Public Health	

OTHER PRODUCER(S)

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David Wilson	World Bank	

FUNDING

Name	Abbreviation	Role
World Bank		Funding for data collection, cleaning and analysis components
Government of South Africa		Funding for implementation of the adherence interventions
National Institutes of Health Fogarty International Center		Funding data analyst time

Metadata Production

METADATA PRODUCED BY

Name	Abbreviation	Affiliation	Role
Development Economics Data Group	DECDG	The World Bank	Documentation of the DDI

DATE OF METADATA PRODUCTION
2019-09-10

DDI DOCUMENT VERSION
Version 01 (September 2019)

DDI DOCUMENT ID
DDI_ZAF_2015-2018_SAGIE_v01_M

Sampling

Sampling Procedure

The sample size was 730 patients, slightly higher than the target sample size of 720 to allow for missing data. The RapIT study of rapid ART initiation conducted in Gauteng Province PHC clinics, found that about 60% of ART-eligible patients initiated under standard care within 30 days. Conservatively assuming 60% initiation without the intervention and 75% with the intervention, about 30 subjects in each of the 24 clusters were required to detect a difference of 15%. Sample sizes were determined using PASS software for cluster-randomised designs. Each sample size was determined to measure the short-term outcome and calculations assumed a site-clustered design with the clinic as the cluster and 24 clusters evenly split between intervention and control groups. We assumed power of 80% and an alpha of 0.05. Sample sizes accounted for the cluster-randomised design by assuming a coefficient of variation of 0.1.

Patients eligible for inclusion were aged 18 years or above and patients who were not resident in the facility's catchment area, were recorded as having an intention to transfer care to a different facility within 12 months, or were pregnant and eligible for prevention of mother to child transmission were excluded. The specific inclusion criteria for the Fast-track Treatment Initiation Counseling cohort followed the December 2014 national guidelines for HIV care and ART and July 2016 National Adherence Guidelines for Chronic Disease (HIV, tuberculosis and non-communicable diseases). In order to identify eligible patients to enrol, information recorded on their electronic medical record were consulted. At intervention sites, lists were reviewed against clinic records, registers and other documentation for each intervention to identify eligible patients. At control sites, we reviewed lists against clinic records to confirm eligibility. If the patient file was found and eligibility for a cohort was confirmed then patients were enrolled sequentially until the required sample size was reached for the cohort. Due to delays in electronic data capturing data was not complete. To account for this at some sites, individuals receiving each intervention were identified directly from registers for that intervention.

Clinic files were then reviewed to confirm eligibility and patients were enrolled until the required sample size was achieved. For each patient enrolled, regardless of the method used to identify them, patient files were reviewed and information was extracted using an electronic case report form to confirm patients met all eligibility criteria for the cohort.

Response Rate

Two subjects (0.2% of total sample size) do not have outcomes as they were not found in the data base providing viral load results, and the patient files were not able to be located during follow-up data collection.

Questionnaires

Overview

The Case Report Form was composed of multiple modules, each containing specific data fields. The modules covered identifiers and eligibility (including whether the patient had treatment initiation counselling, how often and of what type, and whether a treatment adherence plan had been developed for the patient), as well as demographics and clinical data.

Data Collection

Data Collection Dates

Start	End	Cycle
2015-01-01	2015-12-31	Pre-intervention data on patients at intervention and control sites
2016-01-08	2016-12-07	Enrollment period - Fast-track treatment initiation counseling
2012-12	2018-06	Follow up data collection 12-18 months after eligibility

Data Collection Mode

Other [oth]

Data Collection Notes

We included data on subjects eligible for FTIC between 08 Jan 2016 and 07 December 2016 (enrollment period). Follow-up data were included for a minimum of 12 months after eligibility of a patient and up to 18 months after eligibility. We also used pre-intervention data on patients at intervention and control sites from Jan 1, 2015 through Dec 31, 2015 who met the inclusion criteria, in order to compare differences in outcomes between arms during the intervention period adjusted for differences prior to the intervention period.

Routine data from primary health care clinics in South Africa were extracted into a Case Report Form (CRF) by trained staff. For each of the participating provinces we hired a data collection team consisting of a provincial coordinator and two data support officers. These staff ran the day-to-day implementation of research activities including meeting with site staff and sub-national Department of Health members as well as the implementing partners in each province. The team completed all data collection activities and monitored progress with the implementation of interventions at the site.

Refresher training occurred during follow up to ensure the SOPs were followed. The CRF was piloted and continuous quality checks were implemented on the evaluation database, as per detailed SOP. Study staff travelled to each of the evaluation clinics on a routine basis to obtain electronic data sets, capture paper records and registers on electronic case report forms on dedicated tablets, and review data quality.

Questionnaires

The Case Report Form was composed of multiple modules, each containing specific data fields. The modules covered identifiers and eligibility (including whether the patient had treatment initiation counselling, how often and of what type, and whether a treatment adherence plan had been developed for the patient), as well as demographics and clinical data.

Data Collectors

Name	Abbreviation	Affiliation
Health Economics and Epidemiology Research Office	HE2RO	University of the Witwatersrand

Supervision

In order to ensure study protocols were followed, data collection teams were supervised by a team of three people in the Johannesburg office: a local team leader, a data manager and a research project manager. Their responsibilities included training and oversight, supervision of data collection, meeting with NDOH and local DoH leaders and implementing partners as needed, developing standard operating procedures and oversight of all site level activities. Supervision was implemented through weekly conference calls with all staff members. In terms of communication with sites from the Johannesburg office, the research project manager in collaboration with the local team lead were in contact with all sites on a nearly daily basis to set priorities and troubleshoot stumbling blocks. WhatsApp® groups were utilized as a way for each provincial team to address issues more immediately. A shared calendar was also used to ensure that the management team knew the

expected location of the Provincial teams. This could also be monitored through GPS location and tracking included on the tablets used for data collection. Progress was also monitored through regular completion of an electronic status report.

Data Processing

Data Editing

The HE2RO Johannesburg office study team oversaw the development and management of the database. As needed data was converted to SAS and STATA for cleaning and data analysis. The study team reviewed data files on a monthly basis and returned queries to provincial staff for response. All databases were password protected with access restricted to the members of the study team. A fully de-identified data set will be made available through one or more open access portals when the study is closed.

Other Processing

The team entered all data not captured electronically at the facility onto electronic case report forms on tablets on site, so that we did not need to use paper forms. Once patient data was captured on the tablet, the information was immediately sent to a highly secure cloud server and wiped from the tablet. The data were then downloaded onto secure, protected drives at the local office and at Boston University. All electronic data files were stored on secure, protected drives at the local office and at Boston University, with access limited to relevant study staff.

Data Appraisal

No content available

File Description

Variable List

JIAS_ENHANCE_FTIC_Data_4Sept19_deidentified_stata11

Content	Evaluation of adherence guidelines - FTIC short and long-term outcomes
Cases	730
Variable(s)	10
Structure	Type: Keys: ()
Version	
Producer	
Missing Data	

Variables

ID	NAME	LABEL	TYPE	FORMAT	QUESTION
V1	unique_id	Unique (deidentified) ID	discrete	character	
V2	cohort	Cohort	discrete	numeric	
V3	facility	Facility by province	discrete	numeric	
V4	intervention	Intervention/control status	discrete	numeric	
V5	gender	Gender	discrete	numeric	
V6	agecat	Age category	discrete	numeric	
V7	tbdiagnosis	TB diagnosis at baseline	discrete	numeric	
V8	st_outcome_ftic	Short term outcome (ART initiation within 30 days)	discrete	numeric	
V9	finaloutcome_6mos	Retention outcome at 6 months	discrete	numeric	
V10	finaloutcome_12mos	Retention outcome at 12 months	discrete	numeric	

Unique (deidentified) ID (unique_id)
File: JIAS_ENHANCE_FTIC_Data_4Sept19_deidentified_stata11

Overview

Type: Discrete
Format: character
Width: 5

Valid cases: 730
Invalid: 0

Cohort (cohort)
File: JIAS_ENHANCE_FTIC_Data_4Sept19_deidentified_stata11

Overview

Type: Discrete
Format: numeric
Width: 1
Decimals: 0
Range: 1-1

Valid cases: 730
Invalid: 0
Minimum: 1
Maximum: 1

Facility by province (facility)
File: JIAS_ENHANCE_FTIC_Data_4Sept19_deidentified_stata11

Overview

Type: Discrete
Format: numeric
Width: 2
Decimals: 0
Range: 1-24

Valid cases: 730
Invalid: 0
Minimum: 1
Maximum: 24

Intervention/control status (intervention)
File: JIAS_ENHANCE_FTIC_Data_4Sept19_deidentified_stata11

Overview

Type: Discrete
Format: numeric
Width: 1
Decimals: 0
Range: 0-1

Valid cases: 730
Invalid: 0
Minimum: 0
Maximum: 1

Gender (gender)
File: JIAS_ENHANCE_FTIC_Data_4Sept19_deidentified_stata11

Overview

Type: Discrete
Format: numeric
Width: 10
Decimals: 0
Range: 1-2147483627

Valid cases: 730
Invalid: 0
Minimum: 1
Maximum: 2

Age category (agecat)
File: JIAS_ENHANCE_FTIC_Data_4Sept19_deidentified_stata11

Overview

Type: Discrete
Format: numeric
Width: 1
Decimals: 0
Range: 1-4

Valid cases: 730
Invalid: 0
Minimum: 1
Maximum: 4

TB diagnosis at baseline (tbdiagnosis)
File: JIAS_ENHANCE_FTIC_Data_4Sept19_deidentified_stata11

Overview

Type: Discrete
Format: numeric
Width: 10
Decimals: 0
Range: 0-2147483627

Valid cases: 729
Invalid: 1
Minimum: 0
Maximum: 0

Short term outcome (ART initiation within 30 days) (st_outcome_ftic)
File: JIAS_ENHANCE_FTIC_Data_4Sept19_deidentified_stata11

Overview

Type: Discrete
Format: numeric
Width: 1
Decimals: 0
Range: 1-2

Valid cases: 728
Invalid: 2
Minimum: 1
Maximum: 2

Retention outcome at 6 months (finaloutcome_6mos)
File: JIAS_ENHANCE_FTIC_Data_4Sept19_deidentified_stata11

Overview

Type: Discrete
Format: numeric
Width: 1
Decimals: 0
Range: 1-5

Valid cases: 727
Invalid: 3
Minimum: 1
Maximum: 4

Retention outcome at 12 months (finaloutcome_12mos)
File: JIAS_ENHANCE_FTIC_Data_4Sept19_deidentified_stata11

Overview

Type: Discrete
Format: numeric
Width: 1
Decimals: 0
Range: 1-5

Valid cases: 727
Invalid: 3
Minimum: 1
Maximum: 4

Documentation

Reports

ENHANCE Data Collection Case Report Form (CRF)

Title	ENHANCE Data Collection Case Report Form (CRF)
Date	2016-03-23
Country	South Africa
Language	English
Description	The purpose of this document is to outline the information that will be extracted from patient files and clinic registers for the EHNAHCE study.
Filename	ENHANCE_CRF_22Mar16.pdf

Technical documents

Codebook: Evaluation of Adherence Guidelines - FTIC Short and Long-Term Outcomes

Title	Codebook: Evaluation of Adherence Guidelines - FTIC Short and Long-Term Outcomes
Language	English
Filename	JIAS_FTIC_Codebook_4Sept2019_v2.xlsx