MONITORING OF HIV DRUG RESISTANCE USING WHO EARLY WARNING INDICATORS (EWIs) IN SOUTHERN HIGHLANDS ZONE. A STUDY CONDUCTED BY THE HJF MEDICAL RESEARCH INTERNATIONAL TANZANIA

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1. Executive Summary:

Population-based HIV Drug resistance (HIVDR) monitoring is important for determining the quality of ART response and HIVDR emergence. Since HIVDR testing is not routinely available in resource-limited settings (RLS), the World Health Organization (WHO), as part of its global strategy for the prevention and assessment of HIVDR, recommends that ART program factors such as prescribing/dispensing practices, patient retention in care, continuity in drug supply and patient adherence be monitored to optimize the quality of patient care and to sustain the site performance of national ART program in resource limited settings (RLS) (Bennett et al., 2009).

In order to limit emerging HIVDR and support the performance of treatment and prevention programs in RLS, the WHO developed a global strategy for the assessment and prevention of HIVDR. One key component of this strategy is monitoring the quality of care in ART programs using "Early Warning Indicators" (EWI) of HIVDR. In line with this strategy, we conducted a survey of HIVDR EWI in care and treatment clinics (CTC) supported by the Walter Reed Program/HJFMRI in the Southern Highlands, in order to identify programmatic and patient risk factors that enhance HIVDR emergence within these CTCs and provide informed corrective measures for evidence-based decision-making.

The purpose of the evaluation was to monitor the quality of services that are provided at CTC facilities in southern Tanzania with the aim of identifying gaps that exist in the provision of ART services and propose ways to improve uptake of care and treatment services at the CTC clinics. Additionally, monitoring of EWIs is an important strategy for alerting clinicians on facility level factors that need increased support to reduce the potential for failure and the emergence of preventable HIVDR. Early and ongoing EWI monitoring can help to alert clinic and district managers to address problem areas and may reduce the need for more costly laboratory assessments to evaluate HIVDR emergence. EWI results form the basis of recommendations for quick action either at the site, region or national level. Recommendations include increased training and resources for specific aspects of care, provision of targeted support for adherence, or reduction of barriers to continuous access to ARVs. Additional assessments, including operational research to clarify the source of problems and the support required to address them, may also be recommended from this evaluation.

This evaluation intended to answer four of the five WHO-established EWI:

1. What are the rates of on-time pill pickup at each CTC?
2. What are the rates of retention in care after 12 months of ART at each CTC that is evaluated?
3. Does the health facility have issues of discontinuity in drug supply at the pharmacy?
4. What is the quality of the dispensing practices at each CTC?

Retrospective data for 2013 and 2015 was abstracted from ART client records from April 2016 to September 2018. The WHO RESNET tool was used to analyze the collected data.

Findings of evaluations from 2013 data indicated that 90% of the ART clinics in the Southern Highlands zone of Tanzania are performing relatively well in terms of the dispensing practices (EWI 4). However, ART facilities were not performing well in terms of all the other EWIs, i.e. less than 80% performance, suggesting there was a high chance of emergence of HIV drug resistance among people living with HIV (PLHIV) initiated on ART in the zone. Limitations of the evaluation were related to data quality and the retrospective nature of data collection. There was some data that could not be retrieved because it was poorly documented or was missing altogether. The study concluded that it is important to carry out yearly EWIs analysis at health facilities providing ART with the aim of monitoring performance and improving on the generated results.

2. Project Background:

The evaluation was carried out in 50 health facilities selected from HJFMRI-T supported facilities that provide HIV/AIDS care and treatment services in the southern highlands of Tanzania. The facilities were from the regions of Mbeya, Ruvuma, Rukwa, Katavi and Songwe regions.

Study data collection took place from April 2016 and ended in September 2018. Data analysis and dissemination in-country occurred 2019-2020. Before the study commenced, IRB approval was received from the Mbeya and National Review boards in Tanzania. The total cost of the evaluation was$261,340.20. The general objective of this project is to determine HIVDR EWIs in the Southern Highlands' CTCs in order to evaluate the quality of ART services uptake with an aim of helping to minimize the emergence of preventable HIVDR.

The specific objectives of the project will be based on four EWIs. The evaluation aimed to:

1. Determine the rate of on-time pill pickup at each CTC.
2. Determine the rate of retention in care after 12 months of ART at each CTC.
3. Determine discontinuity in drug supply at the pharmacy of each CTC.
4. Determine the dispensing practices at the CTC.

3. Evaluation Design, Methods, and Limitations

3.1 Evaluation Type & Design:

The EWI study was a process evaluation that sought to determine whether the key areas of provision of care and treatment of HIV/AIDS were being implemented as intended. This included looking at (1) patient on-time pill pick up practices; (2) retention on ART for 12 months; (3) pharmacy stock-outs and (4) ARV dispensing practices. The fifth indicator of viral load suppression at 12 months was not evaluated as it was not a routine test of care in 2013.

This study was a retrospective, cross-sectional review of clinical data from 50 CTC sites in the Southern Highlands in support of EWI_1 EWI_4. EWI_2 and EWI_3 were addressed via one-year longitudinal data collection. The selected sites included health centers, district hospitals, regional referral hospitals and one zonal referral hospital. Private health facilities were not included in the study. Data was abstracted from ART registers and pharmacy records of each site. In terms of data interpretation, programmatic related indicators were EWI_2, EWI_3 and EWI_4, while patient related indicator was EWI_1.

Two to three nurses from each facility selected for the study received training on nationally validated data abstraction techniques using facility-held care and treatment patient cards (CTC2). Study staff verified the

data in completed tools. They also administered structured questionnaires to facility healthcare providers to collect information on programmatic factors such as facility maturity (number of months providing ART services), average hours clinics are open per day, average time patients spend in the clinic (defined as total time spent at the clinic, cumulatively in all departments, while waiting for and receiving services), and other characteristics in order to understand facility-level determinants of EWI performance. Client data was uploaded into WHO HIVResNet excel-based tool for analysis.

Data about medical and laboratory services provided to CTC clients were used to analyze all EWIs except for the ARVs stock-outs. Percentage of ART clinics that met the desirable, fair, and poor target criteria of each indicator were monitored. No informed consent was required as data used in this study was secondary de-identified data from the CTC database and client files. Pharmacy stockouts were calculated for each CTC site as the percentage of months in the reporting year in which there were no stock-out days of the ARV drug.

Data review included analysis of variables that included dates of key events (birth, clinic visit and death) and ARV regimens prescribed. Each clinic's performance was categorized according to its ability to meet the desired target for each EWI (desirable, fair, or poor for retention, LTFU, and on-time pill pick-up; and desirable or poor for ARVs dispensing practices and ARVs stock-outs). Where data were not available for a clinic or if a clinic did not report data on ARVs stock-outs, it was excluded from analysis.

The findings of the study provided indications on whether there were opportunities for HIVDR development among the program clients. EWI and HIVDR surveillance would be used as a proxy to determine effectiveness of care and treatment services in mitigating HIVDR.

3.2 Sampling strategy:

The sample size for the study was calculated based on the number of patients receiving ART during the previous year at the care and treatment clinic (CTC) as guided by WHO. The table below shows how to obtain the sample size by annual number of eligible patients at each facility as per the WHO-binomial sampling method.

Annual number of eligible patients at the site	**Number to be sampled at the site (Sample size)**
1-75	All
76-110	75
111-199	100
200-250	110
251-299	120
300-350	130
351-400	135
401-450	140

451-550	145
551-700	155
701-850	160
851-1600	175
1601-2150	180
2151-4340	200
4341-5670	210
5671-10000	215
>10000	Consult WHO

The sample sizes in the table above are the minimum sample sizes required to achieve a 95% confidence interval of ±7%. If greater numbers can be abstracted, a more precise estimate will be obtained.

Separate sample size calculations were done for each group of eligible patients (those initiating ART and those on ART) at the site. The sample size for EWIs based on patients initiating ART was lower than those for EWIs based on patients on ART.

3.3 The definition and criteria for evaluation of each EWI:

1. On-time pill pick-up:

On time pill pick up is considered a pharmacy adherence measure. It requires patients to pick up pills on time i.e. on or before the date on which the previous prescriptions would run out if taken according to directions. This indicator is used for monitoring adherence. Monitoring of this indicator is feasible using existing pharmacy and patient medical records.

The definition of this indicator is the proportion of patients aged 18 years and above who pick up ART no more than 2 days late at the first pick-up after the baseline pick-up.

Numerator: Number of patients picking up their ART **on time** at the first drug pick up after baseline pick up date.

Denominator: Number of patients who picked up ARV drugs on or after the designated EWI sample start date.

NB: On time as it relates to pill pick up is defined as a patient picking up their ART within 2 days of their previous prescription running out if taken according to schedule.

Targets: Poor performance (red) <80%; Fair performance (Amber) 80-90%; Desirable performance (Green) >90%.

Data elements abstracted for each eligible patient:

- A patient identifier: This is the NACP (National AIDS Control Programme) number. This is a unique identifier, for example: 12-07-0100-123456 where: 12 is the region (Mbeya), 07 is the district (Mbeya), 0100 is the facility name and 123456 is the patient number.
- The date of the first ARV drug pick-up (‘baseline pick-up’);

- The dates of the two consecutive ARV drug pick-ups after the 'baseline pick-up' ('pick-up 1' and 'pick-up 2');
- The ART regimen, including number of days, or pill number/volume and strength (mg) and pills/day or dose/day dispensed at 'baseline pick-up' and the subsequent ARV drug pick-up ('pick-up 1');
- The date of transfer out after 'baseline pick-up' (if applicable);
- The date of death after 'baseline pick-up' (if applicable);
- The date of ART stop after 'baseline pick-up' (that is, a recorded decision by the patient or physician that ARV should be stopped, if applicable).

Data analysis - exclusion factors:

Information is abstracted on consecutive eligible patients, including those with missing data. The following patients were excluded from the final EWI analysis:

1. Patients who transferred out between baseline pick-up date and baseline pick-up run-out date.
2. Patients who died between baseline pick-up date and baseline pick-up run-out date.
3. Patients who stopped ART, without a restart, between baseline pick-up date and baseline pick-up run-out date.
4. Patients for whom any of the following crucial information is missing: Patient ID; Date of baseline ART pick-up; Number of days of ARVs picked up at baseline ART pick-up; Date of first ARV drug pick-up after baseline; Number of days of ARVs picked up at first ARV drug pick-up after baseline.

2. Retention on ART at 12 months (Percentage of adults known to be alive and on treatment 12 months after initiation of ART):

There is a close relationship between poor retention at an ART site and lost to follow up (LTFU) resulting in HIV drug resistance and poor health outcomes. Therefore, monitoring a random fraction of patients retained on ART is important in understanding the proportion of individuals potentially dying or experiencing treatment interruptions. Unplanned treatment interruptions >48 hours for patients receiving NNRTI-based regimens in observational studies have been reported to predict virological rebound and development of HIVDR in both low and high income countries (Parienti et al., 2004).

Numerator: Number of adults and children known to be alive and on ART 12 months after initiating ART.

Denominator: Total number of children and adults who initiated ART who were expected to achieve 12 months outcomes within the reporting period. The denominator excludes patients who transferred to another site. This indicator includes children.

Targets: Poor performance: (Red) <75%; Fair performance: (Amber) 75-85%; Desirable Performance: (Green) >85%.

Data elements abstracted for each eligible patient:

- A patient identifier (NACP number).
- The date of ART initiation at the site (either as an ART prescription or ARV drug pick-up)
- The '12-month date' (i.e. one year after the date of ART initiation)
- The '15-month date' (i.e. 15 months after the date of ART initiation)

- The date of the last clinical consultation attended on or before the '12-month date'
- The date of the last scheduled or expected clinical consultation missed on or before the '12-month date' (if applicable)
- The date of the first clinical consultation attended between the ‘12-month date’ and the ‘15-month date’ (if any)
- The date of the last ARV drug pick-up on or before the '12-month date'
- The ART regimen picked up at the last drug pick-up on or before the '12-month date' including number of days (or strength and pill number/volume dispensed)
- The date of the first drug pick-up between the ’12-month date’ and the ‘15-month date’ (if any)
- The date of transfer out on or before the ‘15-month date’ (if applicable);
- The date of death on or before the ‘15-month date’ (if applicable);

Data analysis exclusion factors: Information is abstracted on consecutive eligible patients, including those with missing data. The following patients are excluded from final EWI analysis:

1. Patients who transferred out prior to 12-month date
2. Patients for whom any of the following crucial information is missing.

    • Patient ID

    • ART initiation date

This EWI allows for classification based on either clinical or pharmacy information. One of the following combinations of information is required:

• 'date of last clinical consultation attended', 'last ART regimen prescribed' and 'number of days of ART prescribed at the last clinical consultation attended'; or

• 'date of last ARV drug pick-up', 'ARV drugs picked-up at last ARV drug pick-up', and number of days of ARV drugs picked-up at the last drug pick-up'.

3. Pharmacy Stock outs:

Monitoring whether sites have a continuous supply of all routinely dispensed ARVs is important considering that data linking stock outs on ART within pharmacies to factors which can predict development of HIVDR such as treatment interruptions of >48 hours.

The definition of this indicator is percentage of months in a designated year in which there were no ARV drug stock outs.

Numerator: Number of months in the designated year in which there were no stock out days of any ARV drug routinely used at the site.

Denominator: 12 months.

Targets: Poor performance (Red) <100%; Desirable Performance (Green) 100%.

Data elements abstracted: Months in which there was a stock-out of any ARV drug routinely used at the site.

Data analysis:

- For each ARV drug or fixed-dose combination (FDC), either the month(s) in which there was a stock-out, or confirmation that there was no stock-out during the year, must be recorded.

4. ARV dispensing Practices: percentage of adults (or children) picking up a mono or dual regimen.

This indicator is cross-sectional and is intended to assess pharmacy dispensing practices for populations on ART after any period of time on ART (including patients receiving 2nd line ART). This indicator provides needed data for all patients on ART.

Numerator: Number of patients who picked up from the pharmacy a regimen consisting of one or two ARVs. This excludes HIV exposed infants taking ARV for purposes of prophylaxis.

Denominator: Number of patients picking up ART on or after the designated EWI sample start date.

Target: As this indicator is strongly associated with HIVDR and there is no medical reason to prescribe a mono or dual drug regimen, poor performance (red) is defined as >0% and desirable performance (green) is defined as 0%.

Data elements abstracted for each eligible patient:

- A patient identifier; (NACP Number).
- The date of ART initiation at the site (either as an ART prescription or an ARV drug pick-up).
- The ART regimen initially prescribed (or ARV drugs initially picked up).

Data analysis exclusion factors: Information is abstracted on consecutive eligible patients, including those with missing data. The following patients are excluded from final EWI analysis:

- Patients for whom any of the following crucial information is missing:
  - Patient ID
  - ART initiation date
  - Initial ART regimen

3.4 Data collection methods and rationale:

The data was abstracted from patient records and pharmacy ledgers at each of the health facilities that were selected for the study. For facilities with paper-based systems, data was abstracted from the patient files and entered into data collection tools, while for facilities with electronic records, data was exported directly into the WHO RESNET tool. The data was collected as per the specific EWI indicators captured under the evaluation plan in 5.1 above.

3.5 Data handling and analysis plan:

All the data generated from the study was reviewed for completeness at the data abstraction and entry steps. Paper-based and electronic data were both abstracted and stored in locked study cabinets and password protected computers respectively. All data that was collected was coded and did not have personal identifiers. No identifiable information was collected for analysis purposes. Representatives from PEPFAR and other appropriate reviewing bodies listed on the protocol had access to anonymized data and material from this evaluation. Supervisors at site designated staff who were further trained by HJFMRI to complete data validation on-site. Anonymized data was reviewed centrally by HJFMRI staff for accuracy in entry and secondary verification.

To ensure data quality, prior to data collection on each site, heads of CTCs and their respective data collection agents were trained on the definition and utility of HIVDR EWIs, as well as on the methodology

for data abstraction and recording. This helped to ensure data reliability in terms of QA, which included ensuring all data was appropriately recorded from the ART registers, minimal errors in the process of data collection, and the validation of collected data by the supervisory team. Data abstractors were formally trained to abstract data at each site. Data was abstracted into a secure database and quality checks were performed regularly by the study data manager. Data was checked for completeness and consistency.

Two main data abstraction sources were used in the study i.e. the paper-based medical records and the electronic medical records. For facilities with paper-based records in place, abstractors were trained on how to abstract the data at each site and enter it into the WHO RESNET data analysis tool. Where the electronic medical records were in place, the RESNET tool was used to import and analyze the data directly. The RESNET tool was used to analyze the data automatically once all the required data was entered.

Data analysis involved review of key events such as birth, clinic visit, viral load tests, and death; ARV regimens prescribed, and VL tests performed and VL test results. Patient and service data were analyzed and EWI results were presented in aggregated average format with 95% confidence interval (CI). Tests of EWI performance trends over time were also performed. Clinic's performance was categorized according to its ability to meet the desired target for each EWI (desirable, fair, or poor for VL testing coverage, VL suppression, retention, LTFU, and on-time pill pick-up; and desirable or poor for ARVs dispensing practices and ARVs stock-outs). Where data was not available for a clinic or if a clinic did not report data on ARVs stock-outs, it was excluded from analysis. Proportion of clinics classified by performance was presented.

3.6 Limitations of the design and analytic methods:

A major limitation of the study was the design that involved collection of retrospective data. As a result, there were some data sets that were difficult to retrieve as they were either not available or had been captured erroneously in the patient files. Additionally, some of the facility pharmacy records were poor making it difficult to determine if and when there were stock outs at those facilities.

3.7 Summary of stakeholder engagement:

The study was carried out in collaboration with Regional Medical Officers of each of the five regions of implementation. Additionally, healthcare workers working at CTCs were trained on how to carry out data abstraction at the sites where they work. The intention was to help them acquire the skills for doing evaluation of their site's performance on their own as a way of quality assurance. On the research side, there were coinvestigators from the National AIDS Control Program (NACP) Tanzania. These represented the government and HIVDR Technical Working Group on the study to ensure the study results were used to inform the country approach to HIVDR.

3.8 Ethical Considerations:

The study was approved by the Mbeya Medical Research and Ethics Committee (MMREC) and the National Institute of Medical Research (NIMR) IRBS on the 25th of February 2016 and 7th December 2015 respectively, and the Walter Reed Army Institute of Research Human Subjects Protections Branch on 7th June 2016. The study was given a Non-Human Subjects Research determination. Annual renewal of approvals was done thereafter. The protocol did not involve contact with clients as it involved data abstraction and hence there was no informed consent involved. All staff that were involved in the study were trained on data abstraction procedures and briefed on the importance of maintaining confidentiality for all the data they handled. All protected health information was maintained within the subjects' medical records. No identifiable patient information was collected.

3.9 Deviations and adjustments from the approved SOW/Protocol:

There were no deviations from the study procedures. All study procedures were carried out as indicated in the protocol.

4. Findings and conclusions:

4.1 Key Findings for program improvement in relation to evaluation questions:

The EWIs score card developed by WHO (Table 1) was used for scoring the performance of the health facilities.

Table 1: Score card HIVDR EWIs targets (summary)

Early Warning Indicator	Status	Target
1. On-time Pill Pick-up		• Red <80%; Amber 80–90%; Green >90%
2. Retention in care		• Red <75% retained after 12 months ART • Amber 75–85% retained after 12 months ART • Green >85% retained after 12 months ART
3. Pharmacy stock-outs		• Red <100% of a 12 month period with no stock-outs; Green 100% of a 12 month period with no stock-outs
4. Dispensing practices		• Red >0% dispensing of mono or dual therapy • Green 0% dispensing of mono or dual therapy

NB: *Red (poor performance, below desired level)**,** Amber (fair performance, not yet at desired level but progressing towards desired level)**,** Green (excellent performance, achieving desired level) and Grey (data not available)*

The key findings for the study included the following:

1. **EWI-1 On-time Pill Pick up:** None of the facilities that were sampled met excellent performance (>90%) as per the WHO target. For all the facilities, drugs were picked later than was expected.
2. **EWI-2 Retention on ART Treatment:** Only five out of 50 facilities had an excellent performance of >85% as per the WHO target. This showed that retention on ART was a key challenge in the southern highlands.
3. **EWI-3 Pharmacy ARV stock-outs:** Only two facilities out of the study facilities met an excellent performance (100%) of no stock-outs. All other facilities reported challenges of having an ARV stock-out at any given time.
4. **EWI-4 Pharmacy Dispensing practices:** In terms of ART dispensing practices, for the 44 facilities where the data was abstracted successfully, it was seen that >97% of the facilities had excellent dispensing practices.

4.2 Conclusions:

Overall, the study findings of the 2013 data indicate that 90% of the ART clinics in the Southern Highlands zone of Tanzania are performing relatively well in terms of the dispensing practices (EWI 4). However, the report also shows that the ART facilities were not performing well in terms of other EWIs, suggesting there is a high chance of emergence of HIV drug resistance among people living with HIV (PLHIV) initiated on ART in the southern highlands zone of Tanzania.

4.3 Recommendations:

There is need for continuous monitoring of HIVDR to ensure there is improved performance at the CTCs to ensure that the HIV/AIDS patients receive optimal care. These findings support the case for targeted and focused interventions to improve the quality of services provided at the ART clinics.

Due to the high risk of emergence of HIV drug resistance as far back as 2013 demonstrated by the EWIs, there is a need for HIVDR surveillance in the Southern Highlands to determine the extent of both transmitted and acquired HIV drug resistance to evaluate the appropriateness of current empirical first and second line HIV therapy, and to determine the need for third line therapy. Drug resistance surveillance will also help determine the need for baseline drug resistance testing prior to commencing therapy and targeted drug resistance testing in individuals failing therapy.

5. Dissemination plan:

The data generated from this study was shared with the Tanzania National HIVDR Technical Working Group so that the country is aware of the situation of EWIs in southern Tanzania. The data was incorporated into a report on the status of HIV Drug Resistance in Tanzania. Additionally, the generated data has been shared in presentations in local conferences in Tanzania and is being prepared for publication in peer reviewed journals. The findings of the specific health facilities has been shared with the heads of those facilities to ensure the information is used to improve facility performance.

6. References

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7. Appendices:

a. **Approved Evaluation SOW/Protocol:** {Attached}

b. **Data collection instruments/tools:** {Attached}
c. **Abridged bios of the evaluation team:** {Attached}
d. **Conflict of interest statement**
e. **Evaluation costs**
f. **Project Results Framework**

7d. **Conflict of interest statement**: The evaluation staff certify that they have no affiliations with or involvement in any organization or entity with any financial interest or non-financial interest in the protocol discussed in this report.

7e. **Evaluation cost:** $261,340.20

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7f**. Project results framework or logical framework**

	INDICATOR	**DEFINITION** How is it calculated?	**BASELINE** What was the original value?	**TARGET** What is the target value?	**DATA SOURCE** How will it be measured?	**FREQUENCY** How often will it be measured?	**RESPONSIBLE** Who will measure it is done?	**REPORTING** Where will it be reported?
Goal	On-time drug pick-up	**Numerator:** Number of patients picking up their ART **on time**. **Denominator:** Number of patients who picked up ARV drugs on or after the designated EWI sample start date.	Unknown	>90%	Patient files and CTC2 database	Annual	Study staff	Study reports
	Patient retention on care after one-year of ART	**Numerator:** Number of adults and children known to be alive and on ART 12 months after initiating ART. **Denominator:** Total number of children and adults who initiated ART who were expected to achieve 12 months outcomes within the reporting period.	Unknown	>85%.	Patient files and CTC2 database	Annual	Study staff	Study reports
	ARV drug supply continuity	**Numerator:** Number of months in the designated year in which there were no stock out days of any ARV drug routinely used at the site.	Unknown	100%	Pharmacy records	Annual	Study staff	Study reports

		Denominator:12 months.						
	ART dispensing practices	**Numerator:** Number of patients who picked up from the pharmacy a regimen consisting of one or two ARVs. This excludes HIV exposed infants taking ARV for purposes of prophylaxis. **Denominator:** Number of patients picking up ART on or after the designated EWI sample start date.	Unknown	0%	Client and Pharmacy records	Annual	Study staff	Study reports
Outcomes	Improved patient treatment outcomes	Summary of all EWIs performance.	Unknown	Relevant improved scores as per the targets	Client records, pharmacy records and CTC2 database.	Annual	Facility Staff	Health facility CTC reports
Outputs	Improved EWIs indicators' performance as per specific targets	Summary of all EWIs performance.	Unknown	Relevant improved scores as per the targets	Client records, pharmacy records and CTC2 database.	Annual	Facility Staff	Health facility CTC reports