<u>D</u>iagnostic <u>C</u>ascade <u>E</u>valuation (DiCE) Toolkit

ADAPTATION GUIDE

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Version 1

ABBREVIATIONS

ART	Antiretroviral Therapy
CDC	US Centers for Disease Control and Prevention
CLICQ!	Clinic-Lab Interface Continuous Quality Improvement
CQI	Continuous Quality Improvement
DiCE	Diagnostic Cascade Evaluation Toolkit
DOTS	Directly Observed Treatment-Short course
DR TB	Drug-Resistant TB
HIV	Human Immunodeficiency Virus
MOH	Ministry of Health
mWRD	Molecular WHO-recommended Rapid Diagnostic
NTP	National Tuberculosis Program
OPD	Outpatient Department
PEPFAR	US President's Emergency Plan for AIDS Relief
PII	Personally Identifiable Information
SLMTA	Strengthening Laboratory Management Toward Accreditation
TB	Tuberculosis
TPT	TB Preventative Therapy
WHO	World Health Organization

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I. INTRODUCTION

A. CLINIC-LAB INTERFACE CONTINUOUS QUALITY IMPROVEMENT (CLICQ!) PROGRAM

The process of moving a patient through the cascade of care, from presentation to treatment initiation, often results in patient or specimen loss. The interface between clinics (public or private) and testing laboratories (public or private) is comprised of interconnections that are vulnerable to patient and specimen loss: referred patients may not report for sample collection, samples may be improperly stored, misplaced or undergo transport challenges, laboratories may not conduct adequate testing, laboratories may not report results back to the clinics in a timely fashion and clinics may not record testing results in patient charts. Patient retention is further complicated by the various cascades of care and entry points. For example, persons with presumptive TB may access care through anti-retroviral therapy (ART) clinics, outpatient departments (OPD) or directly observed treatment-short course (DOTS) clinics. There is a need to strengthen the interface between all clinical entry points and laboratory services to ensure patients have access to accurate, timely diagnostic test results, and are linked to appropriate treatment.

The Clinic-Lab Interface Continuous Quality Improvement (CLICQ!) program guides healthcare workers and laboratory staff through review of their clinic-laboratory data and identifies gaps within their patient cascade. Participants walk the patient pathway at their facility, identifying potential opportunities for patient loss at each step of clinical service. They track patients, in aggregate, through the cascade using their on-site registers. Lastly, they attend Learning Sessions to receive training on continuous quality improvement (CQI) practices, data review, and other strengthening activities (e.g., space organization, waste management, completing run charts, etc.).

Site-specific improvement projects are developed, based on insights from the completed exercises, that target prioritized gaps for closure. A metric-based monitoring and evaluation plan is developed for implementation by site clinic and laboratory staff, in parallel with the improvement projects, to track on-site progress. The program aims to build the capacity of national-, subnational and facility-level staff for enhanced data use, and to close/reduce site-specific gaps at any step within the patient pathway, or diagnostic cascade.

B. DiCE TOOLKIT

The Diagnostic Cascade Evaluation (DiCE) Toolkit is an Excel-based companion tool to the CLICQ! program that can also be used as a standalone Toolkit. DiCE provides a standardized framework for comprehensive site assessments to quantify patient and specimen retention across the clinic-lab interface. Additionally, the Toolkit can quantify turnaround times and assess data quality by comparing sources. Healthcare workers utilize the DiCE Toolkit to track patients through the diagnostic cascade using data contained in facility registers. They participate in DiCE baseline assessments to inform improvement project development prior to implementing new practices, policies, or mentorship activities. Progress assessments may be administered over the duration of the program to quantify improvements. At a minimum, one follow-up DiCE assessment is completed at each site at the end of the implementation period to measure program impact.

C. INTENDED AUDIENCE AND USE

This Toolkit is intended for National TB Programs (NTPs), Ministries of Health (MOH), TB, HIV, or other point-of-entry clinics, and/or TB reference or diagnostic laboratories committed to quantifying and closing the gaps within their TB diagnostic cascades of care. The DiCE Toolkit can be customized and implemented at national, subnational, or local levels. Programs are recommended to clearly define their specific goals and objectives prior to use. The DiCE Toolkit can be customized to focus on specific clinical entry points to the cascade (e.g., ART clinics, TB clinics, OPDs) and/or specific patient populations of interest (e.g., drug-resistant TB [DR TB], pediatric and/or HIV-positive TB patients). The predefined scope and customization will guide DiCE Toolkit modification. The DiCE Toolkit is

intended to be adaptable to numerous settings and disease programs. Programs looking to adapt this Toolkit should be prepared for an initial adaptation process of 1–4 weeks. Previous experiences have shown that adapting the DiCE Toolkit to follow similar formatting and appearance of the data sources (e.g., laboratory registers) will facilitate a smoother abstraction process.

D. DiCE TOOLKIT STRUCTURE

The DiCE Toolkit is comprised of several tabs with specific purposes and functions. Some tabs will require data entry during the site assessments while others will be auto populated. Colored tabs are intended to cue the user that data entry from registers will be required. The process includes visits to multiple locations including, at a minimum, the facility where TB screening occurred (HIV Clinic or TB Clinic) and the laboratory responsible for TB diagnostic testing. Aggregate-level data and patient-level data are abstracted in tandem since data sources are the same. It is recommended that personally Identifiable information (PII) such as patient name not be collected within this Toolkit. Below, users can find a brief description of each tab, including illustrative figures.

a. User Guide Tab

The 'User Guide' tab introduces use of the DiCE Toolkit and explains the various tabs in the Excel Toolkit. This tab requires no data entry by the user, however, there are hyperlinks provided to quickly access a tab of interest. Additionally, a dropdown menu is provided ('FILTERING VIEWABLE TABS') where the user may select which tabs are viewable at a given time. This can declutter the available tabs for more efficient use. The user must first activate the dropdown menu by clicking it, which will make the down arrow available to click/ select.

Figure 1. Partial screenshot of the User Guide tab.

b. Assessment Profile Tab

The 'Assessment Profile' tab is intended to document (data entry required) the time, place, and participants involved in the assessment. This includes the main patient entry points (e.g., ART clinic, TB clinic). The user should also select the type of assessment here (entry or follow-up).

| Type of Assessment: | Entry |
| Date of Data Collection: | |

HIV Facility Name		Facility POC Name	
Facility POC Email		Facility POC Number	
Location Address:			

TB Facility Name		Facility POC Name	
Facility POC Email		Facility POC Number	
Location Address:			

Laboratory Name		Facility POC Name	
Facility POC Email		Facility POC Number	
Location Address:			

Name of Collector #1	
Name of Collector #2	
Name of Collector #3	

| Additional Participants: | |

Figure 2. Screenshot of the Assessment Profile tab.

c. Summary and Analysis Tab

The 'Summary and Analysis' tab is intended to highlight the findings from aggregate- and patient-level data entry on the TB cascade steps and demographic information on patients with presumptive TB; all values will be auto-populated (no data entry required from users) from colored data entry tabs (5-7). Analyses will include graphs, calculated percentages, and other values. Key time intervals are also calculated, which are intended to display the time between steps in the diagnostic cascade; this will be

auto-populated from patient-level data entered in tabs 5b-7b. Finally, data entered on TB preventive therapy (TPT) in tab 8a will be summarized here.
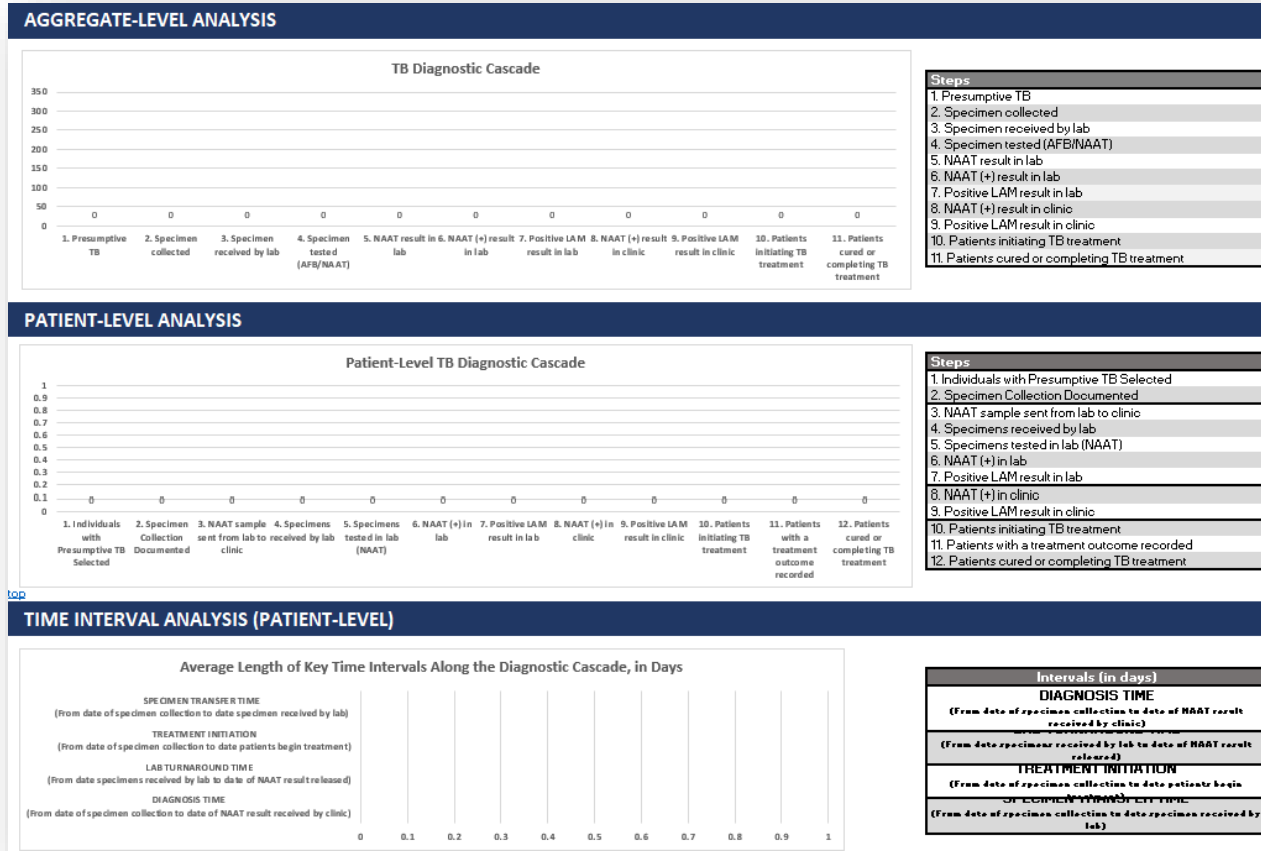

Figure 3. Partial screenshot of the Summary and Analysis tab.

d. Table Summaries Tab

The 'Table Summaries' tab provides disaggregated information, in table format, from the data entered in tabs 5-8. The disaggregated information includes age, sex, type of diagnostic test, etc. This tab is auto populated and requires no data entry from the user.

TB CLINIC PRESUMPTIVE TB REGISTER: AGGREGATE-LEVEL

CATEGORY	Period 1	Period 2	Period 3	TOTAL
Total Presumptive TB	0	0	0	0
Age				
Age (0 - 14)	0	0	0	0
Age (15+)	0	0	0	0
Sex				
Males	0	0	0	0
Females	0	0	0	0
Documented Specimens Collected	0	0	0	0
Smear Activities				
AFB (-)	0	0	0	0
AFB (+)	0	0	0	0
NAAT Activities				
MTB Not Detected	0	0	0	0
MTB Detected, RIF Resistance Not Detected	0	0	0	0
MTB Detected, RIF Resistance Detected	0	0	0	0
MTB Detected, RIF Resistance Indeterminate	0	0	0	0
Error/Incomplete/Invalid	0	0	0	0
TB Lam Activities				
LAM Positive	0	0	0	0
LAM Negative	0	0	0	0
Invalid	0	0	0	0
Known HIV Status				
Positive	0	0	0	0
Negative	0	0	0	0
Unknown HIV Status				
Not Tested	0	0	0	0

Notes:

LAB REGISTER: AGGREGATE-LEVEL
-Diagnosis testing only, excluding referral site samples-

CATEGORY	Period 1	Period 2	Period 3	TOTAL
Total Specimens	0	0	0	0
Sex				
Female	0	0	0	0
Male	0	0	0	0
Age				
Age (0 - 14)	0	0	0	0
Age (15+)	0	0	0	0
Known HIV Status				0
Positive	0	0	0	0
Negative	0	0	0	0
Unknown HIV Status				0
Not Tested	0	0	0	0
Smear Activities				
AFB (-)	0	0	0	0
AFB (+)	0	0	0	0
NAAT Activities				
MTB Not Detected	0	0	0	0
MTB Detected, RIF Resistance Not Detected	0	0	0	0
MTB Detected, RIF Resistance Detected	0	0	0	0
MTB Detected, RIF Resistance Indeterminate	0	0	0	0
Error/Incomplete/Invalid	0	0	0	0
TB LAM Activities				
LAM Positive	0	0	0	0
LAM Negative				0
LAM Invalid				0

Notes: *unable to disaggregate results for "MTB Detected"

TB TREATMENT REGISTER: AGGREGATE-LEVEL

CATEGORY	Period 1	Period 2	Period 3	TOTAL
Total Patients	0	0	0	0
Sex				
Female	0	0	0	0
Male	0	0	0	0
Age				
Age (0 - 14)	0	0	0	0
Age (15+)	0	0	0	0
Type of Patient				
New (N)	0	0	0	0
Relapse (R)	0	0	0	0
Treatment After Failure (TF)	0	0	0	0
Treatment After Loss to Follow-up (TL)	0	0	0	0
Unknown Previous TB Treatment History (THU)	0	0	0	0
Transfer In (TI)	0	0	0	0
AFB				
Not Done (ND)	0	0	0	
AFB (+)	0	0	0	0
AFB (-)	0	0	0	0
NAAT Activities				
MTB Not Detected	0	0	0	0
MTB Detected, RIF Resistance Not Detected	0	0	0	0
MTB Detected, RIF Resistance Detected	0	0	0	0
MTB Detected, RIF Resistance Indeterminate	0	0	0	
Error/Incomplete/Invalid	0	0	0	0
Treatment Outcome				
Cured	0	0	0	0
Treatment Completed	0	0	0	0
Treatment Failed	0	0	0	0
Died	0	0	0	0
Lost to Follow-up	0	0	0	0
Not Evaluated	0	0	0	0
Transferred Out	0	0	0	0

Figure 4. Partial screenshot of the Table Summaries tab.

e. Data Quality Analysis Tab

The 'Data Quality Analysis' tab is intended to compare the concordance of specific elements of patient-level data that appear in multiple sources as a patient progresses through the various stages of care. For example, if a patient is documented as male at one stage and then female at the next, the percent agreement between data sources will be reflected in the provided tables. This will help draw attention to documentation practices in need of strengthening at the facility. This tab is auto populated and requires no data entry from the user.

Figure 5. Partial screenshot of the Data Quality Analysis tab.

f. Aggregate Data Tabs

These tabs are the 'Agg' or aggregate data collection tabs. The tables are built to assist in data abstraction at the aggregate level by counting page totals for each field. Each row will represent sums from one page of a register; sections are provided for each time period. These tabs are designed to follow the formatting of their respective registers from which the data will be abstracted. These tabs all require data entry from the user. There are four aggregate data tabs:

1	PRESUMPTIVE REGISTER – AGG	(Data will originate from the *'Presumptive TB Register'*)
2	LAB REGISTER – AGG	(Data will originate from the *'Laboratory Resister'*)
3	TB TX REGISTER – AGG	(Data will originate from the *'TB Treatment Register'*)
4	TPT REGISTER - AGG	(Data will originate from the *'TPT Register'*)

Figure 6. Partial screenshot of the Presumptive Register-Agg tab. This figure is a representative example for all the '-AGG' tabs.

g. Patient Level Data Tabs

These tabs are the 'PL' or patient-level data entry tabs. The user will select a semi-random sample of presumptive TB patients from the register who were entered in the specified time period. Half the patients should be HIV-positive, and the other half should be HIV-negative. The sampling approach outlined below can be used as a guide. These tabs are designed to follow the formatting of their respective registers from which the data will be abstracted. These tabs all require data entry from the user. There are three patient level data tabs:

1 PRESUMPTIVE REGISTER – PL   (Data will originate from the *'Presumptive TB Register'*)
2 LAB REGISTER – PL   (Data will originate from the *'Laboratory Resister'*)
3 TB TX REGISTER – PL   (Data will originate from the *'TB Treatment Register'*)

While the DiCE Toolkit is not designed to collect PII, assessment teams will temporarily have to use common identifiers (e.g., patient names, sex) to track the patient across data sources (registers). The user will then complete all tab fields (from the various data sources) along the diagnostic pathway.

NOTE: After the patient has been tracked across data sources and the non-PII data entered, any written common identifiers used for tracking will be destroyed

Data entry will be one patient per row; all dates should be entered in format dd-mmm-yy (ex. 30-Mar-19). A place for notes is provided below each section in the event of abnormal findings that do not fit within the DiCE Toolkit parameters.

Sampling Approach for Patient-Level Data Collection

1. Calculate 5% of total individuals with presumptive TB found in the Presumptive TB Register, with a minimum of 6 and a maximum of 20. Select half HIV+ individuals and half HIV- individuals (ex. 400 presumptive TBs = sample of 20; 10 HIV+, 10 HIV-).
2. To ensure random selection, select patients from different pages of the register and different months. Selections should be made independent of data quality or completion.

PRESUMPTIVE TB REGISTER: PATIENT-LEVEL DATA

Instructions:
1. Gather Presumptive TB Registers for data abstraction period.
Sampling:
Sample size will be determined by calculating 5% of total presumptives found in the Presumptive TB Register, with a minimum of 6 and a maximum of 20. Select half HIV+ individuals and half HIV- individuals **randomly**, irrespective of data quality or completion.

Total Patients Captured: 0

TB CLINIC PRESUMPTIVE TB REGISTER: PATIENT-LEVEL

PATIENT	Specimen ID Number	Sex	Age (<15, 15+)	Who Referred the Patient?	Specimen Collection Documented	Date of Specimen Collection*	Date Specimen was Sent to Lab*	Date TB Result Released*	AFB Result	LAM Result	Xpert MTB Result	Xpert RIF Result	Known HIV Status	Unknown HIV Status	Error (with Code)	Invalid or Incomplete Test	Date HIV Result Released*
P1																	
P2																	
P3																	
P4																	
P5																	
P6																	
P7																	
P8																	
P9																	
P10																	

Figure 7. Partial screenshot of the Presumptive Register-PL tab. This figure is a representative example for all '-PL' tabs.

II. KEY STEPS TO ADAPT THE DiCE TOOLKIT

NOTE: Basic knowledge of Excel and formula structure is required to customize the DiCE Toolkit.

A.   IDENTIFY KEY INDICATORS

Depending on the disease program of interest and objectives of the clinic-lab interface assessment, users will identify the key indicators they want to evaluate through DiCE Toolkit use. These indicators will represent measurable steps along a process; steps are often identified by thinking about where along the patient pathway may provide opportunities for patient or specimen loss. By identifying these steps, and the associated data sources and variables, users will be able to identify and quantify step to step gaps in the diagnostic cascade for investigation and remedial action.

DiCE was originally designed to target the TB diagnostic cascade. The 'key indicators' identified for this purpose were:

1. # of patients with presumptive TB
2. # of presumptive TB patients with specimens collected
3. # of presumptive TB patients with specimens collected and received by the lab
4. # of presumptive TB patients with specimens collected, received by the lab, and tested
5. # of tests completed with a molecular WHO-recommended rapid diagnostic (mWRD)
6. # of tests with mWRD (+) results in the lab

7. # of tests with mWRD (+) results, transmitted from the lab to the clinic
8. # of patients initiated on TB treatment

Each of these indicators were collected in disaggregated forms, where possible (e.g., by HIV status, sex, and age). Inclusion of disaggregates will require more time for data abstraction from site registers but may provide a more nuanced understanding to the project team. If gaps are identified among certain populations but not others, project teams should consider the findings when investigating the root causes and designing improvement activities.

B. IDENTIFY EXISTING DATA SOURCES CONTAINING THE KEY INDICATORS

Prior to adapting the DiCE Toolkit, the project team should begin by identifying source documents for each of the key indicators. For this process, copies of relevant patient registers or other documentation identified along the patient pathway of interest should be reviewed by the project team, and their use should be confirmed by persons familiar with documentation practices in facilities. Often, a presumptive or screening register, a lab register, and a treatment register can provide sufficient data and should be used as the data sources, though other sources can be considered. For ease of data collection, data sources with aggregated data (e.g., registers) are preferable over patient specific data sources (e.g., patient files). The data sources identified will need to be collected for abstraction, so project teams should think about minimizing the number of data sources where possible (for example if an indicator is recorded in multiple places, choose the one that may be easier to abstract from, that is already providing other indicator data, or is known to be the most complete).

After the DiCE Toolkit has been fully adapted, a facility walkthrough should be conducted to ensure all data sources are present and being used as expected; this can happen during a field-test of the customized DiCE Toolkit, if practical.

C. CUSTOMIZE AGGREGATE (-AGG) TABS TO RESEMBLE DATA SOURCES

After sources for the key indicators have been identified, the aggregate data tabs in the DiCE Toolkit can be customized to mirror data sources as closely as possible, facilitating easier abstraction. In the base Toolkit, there is one "-AGG" tab and one "-PL" tab per data source identified. The tab names/sheet titles reflect that data source. Some suggested steps to customize are listed below:

a. Update the number and title of the -AGG and -PL tabs.
   Double click tab names to update the names and rename the sheets in the top-colored box to match data sources, if necessary.

   If the number/type of data sources differs dramatically from those in the base DiCE, further customization may be needed than what is described in the subsequent steps. These steps assume users are measuring a diagnostic pathway involving a clinic-lab interface, and that the data sources will likely be similar.
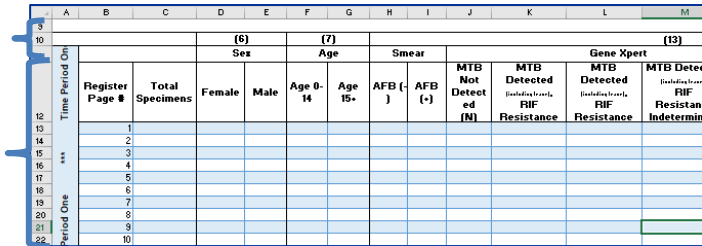
b. Rename columns to match data sources

Within the -AGG tabs, three stacked data tables exist to allow for abstraction from 3 different time periods (ex. 3 months). The column names of these tables should be updated to match the language in the data source so that data abstractors can tell where data should be entered.

Note the data tables on the tabs are formatted as Excel tables. Updating the column titles will automatically update all linked cells, so formulas do not need to be adjusted. For this reason, the column purpose should remain the same (i.e., do not overwrite a column for total specimens with a different data element; the reason for this is that the columns are tied to visuals elsewhere in the Toolkit).

These cells are not linked to anything and can be adjusted to match register headers if helpful.

Formatted as a table; the column names are involved in formulas throughout the Toolkit that will automatically update if the column name is changed.

c. Re-order columns to match registers

To re-order the columns within the Excel tables, highlight the entire column from the header to the title row and drag the column left or right in the table. Data abstraction may be easier if the order of columns matches the data source to be abstracted from.

> Highlight the entire column of the table and drag left or right to re-order columns; merged cells above may need to be adiusted.

d. Add any additional variables to be analyzed

To add an additional column, click into the table where you would like to insert a column, right click and press "Insert", then select "Table columns…". Additional columns can be added to the tables but will not be incorporated into other aspects of the Toolkit. These can be added if needed to the Summary and Analysis or the Table Summaries tabs by entering formulas to refer to the table/cell you wish to reference.

e. Replicate changes for all tables

Each AGG data tab has space for abstraction of three different periods. All changes should be replicated in the three tables, or if period separation if not important for your project, the additional tables may be removed. Additional rows can be added to any of these tables if more space is needed by right clicking and selecting "Insert" then "Table rows".

D. CUSTOMIZE PATIENT LEVEL (-PL) TABS TO RESEMBLE DATA SOURCES

a. Repeat steps a -c from the aggregate tabs section

These steps adjust the tab names. These tabs are also formatted into tables, which helps with formulas throughout the workbook.

These cells are not linked to anything and can be adjusted to match register headers if helpful.

Formatted as a table; the column names are involved in formulas throughout the Toolkit that will automatically update if the column name is changed.


b. Update data validation rules

Most cells in the patient-level tables have data validation rules built in that correspond to the options available to staff who are filling in the data in the facility source documents. To update the choices available in drop downs within the DiCE, follow the steps outlined below.

1. Highlight cells to be edited
2. Select the "Data" tab on the excel ribbon, then select the "Data Validation" button
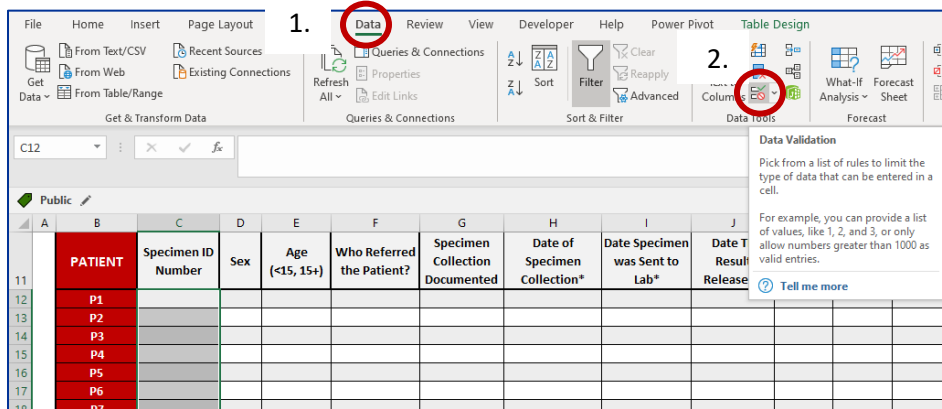
3. Edit the list, separating each option with a comma.
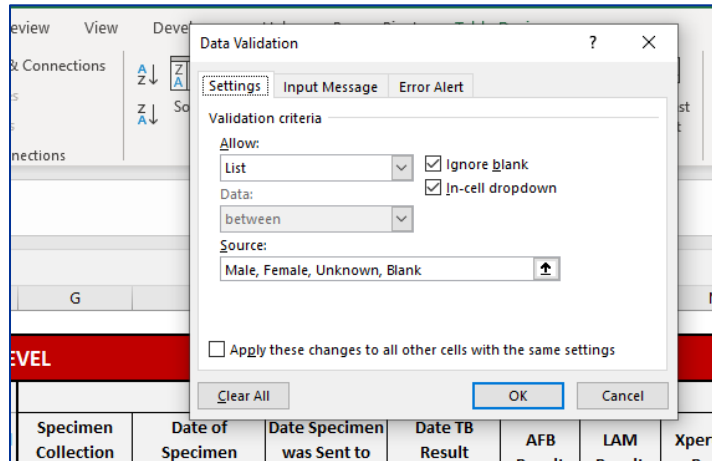

III. QUALITY ASSURANCE – POST CUSTOMIZATION

NOTE: Basic knowledge of Excel and formula structure is required to troubleshoot DiCE.

A. IDENTIFY ERRORS
After customization has been completed, the study team should test DiCE to ensure that all formulas are functional. Begin by entering data into all -PL and -AGG tabs. At least two rows of data should be entered for each period table in each -AGG tab, and at least 2 patients should be entered to each -PL tab. DiCE functionality can be verified by reviewing tabs 2-4 (i.e., 2. Summary and Analysis, 3. Table Summaries, 4. Data Quality Analysis).

B. TROUBLESHOOTING FORMULAS
If formulas in cells do not produce the expected results, they may need to be altered to fit your adapted Toolkit. Formulas lead to named tables within the DiCE; table names can be displayed in the upper left-hand corner of Excel by activating a table (clicking anywhere within the table) and selecting the "Table Design" tab from the ribbon, as shown below:
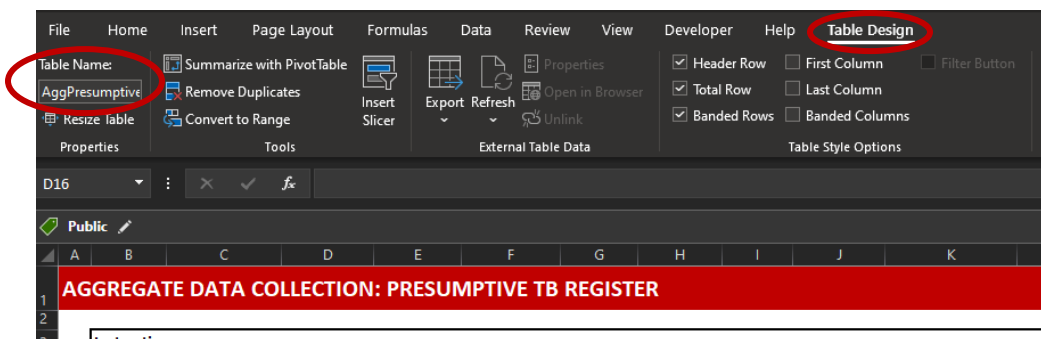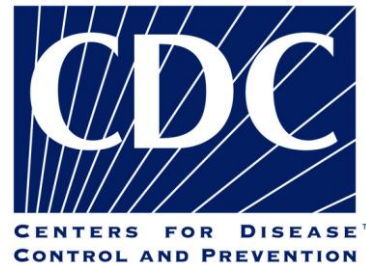
The table names in the base DiCE Toolkit start with either "Agg" or "PL", followed by the data source (Presumptive, Lab, Treatment), and the period (represented by "P1", "P2", etc.). The table names can be changed if appropriate; if table names are updated, formulas will also be updated automatically. Formulas can generally be tracked back to a specific table using these labels. If an incorrect formula is identified, users can overwrite the formula, or adjust the Excel table the formula is referencing to correct the issue.

A. FIELD TEST THE DiCE TOOLKIT

Prior to a broad roll-out of the customized DiCE Toolkit, or its first use in baseline assessments, the Toolkit should be tested in a facility. DiCE assessments are designed to last no more than one day per clinic-lab pair. Field tests should be designed to mimic DiCE assessments. To that end, a walkthrough of the patient pathway should be conducted to understand all the steps and locations where patient and/ or specimen loss could occur. Registers (and any other data sources required for data abstraction) should be requested in advance of the field test to ensure their access and use on-site time efficiently. Presence of registers should be confirmed, and the data abstraction process practiced with the customized Toolkit. If possible, individuals that are projected to serve as DiCE assessors should participate in the field test to gain familiarity and experience with data collection, review, and abstraction processes. Toolkit user experiences and Toolkit function during the field test should then be used to revise and finalize the Toolkit for assessment use.

ACKNOWLEDGEMENTS