

# Quick Start Guide

## Running the model with User Defined Strategy

The Flexible Diagnostics (FlexDx) TB Model is a flexible, simple, transmission modeling tool that allows users without modeling expertise to generate evidence to aid decision-making for implementation of tuberculosis (TB) diagnostics under local conditions. Using a simple web-based interface, FlexDx incorporates local estimates of TB incidence, MDR-TB, HIV, and costs into a combined decision analysis-transmission modeling framework to generate five-year projections of epidemiological impact and cost-effectiveness of nine diagnostic strategies in reducing TB transmission and mortality.

Users can run the FlexDx TB Model by defining their own diagnostic strategy as an algorithm for new and previously treated patients with and without HIV infection. Running the model for a User Defined Strategy will use global pre-loaded values from WHO estimates and other sources for the model parameters. FlexDx will return projected estimates for key epidemiologic indicators based on implementing the User Defined Strategy for diagnostic testing compared to 8 other diagnostic strategies. Users can also run the FlexDx TB Model with pre-set values at the country level, taken from WHO estimates and other sources, that provide some additional functionality (including exploration of uncertainty) than the model with a User Defined Strategy. For users who have values other than the standard country values, we offer a User Input model (with slightly less functionality) in which users can input their own values using the country baseline values as a foundation. See the *Quick Start Guides for Running the model with User Input Values* and *Country Pre-set Values* for more information.

### Using the FlexDx TB Web Interface

**Flex<sup>D</sup>X: Xpert Scale-Up**  
A user-friendly, open source transmission model of TB

Help us improve this model; click [here](#) to take our survey

**Click here to go to the User Defined Strategy webpage and define your own diagnostic strategy or algorithm** → **User Defined Strategy** | About | Help

### Model Inputs

(Optional) Select a country:  Adjust inputs manually

☒ Single Strategy [Click for List]

- ☒ 1. Xpert for smear-positive
- ☐ 2. Xpert for HIV+
- ☐ 3. Xpert for previously treated
- ☐ 4. Xpert for sm-neg HIV+ or prev tx
- ☐ 5. Xpert for all HIV+ or prev tx
- ☐ 6. Xpert for smear-negative
- ☐ 7. Xpert for all
- ☐ 8. Xpert for all, same-day
- ☐ All Strategies

**Epidemiological Scenario**

Target TB incidence, per 100,000:

Target MDR-TB prevalence among new cases, %:

Target adult HIV prevalence, %:

**Costs (please include ALL costs, including labor, infrastructure, supplies, etc.)**

Treatment of one patient with first-line drugs, \$:

#### Brief Description of Diagnostic Strategies

**Baseline(Smear)**  
Sputum smear microscopy for each diagnostic attempt, with liquid-media TB culture only to evaluate smear-positive cases with a history of previous TB treatment for drug resistance.

**Xpert for smear-positive**  
Sputum smear for all patients, plus Xpert MTB/RIF for smear-positive patients only (i.e., for rapid DST), with a positive test for rifampin resistance triggering treatment for MDR-TB.

**Xpert for HIV+**  
Xpert MTB/RIF for HIV-infected patients only, with a positive test for rifampin resistance triggering treatment for MDR-TB. This strategy is conceived as a "best-case" scenario for HIV targeted TB testing: if individuals unaware of their HIV status are not tested with Xpert, this strategy will overestimate effectiveness, and if those unaware of their status are tested, it will underestimate costs.

**Xpert for previously treated**  
Xpert MTB/RIF used to diagnose TB in any previously treated individual with symptoms regardless of smear status, with a positive test for rifampin resistance triggering treatment for MDR-TB.

## Using the User Defined Strategy Web Interface

The User Defined Strategy allows users to define their own diagnostic testing strategy algorithm from a separate webpage interface than running the FlexDx TB Model with Country Pre-set Values or User Input Values. The model parameters that are contained on the FlexDx TB Web Interface are pre-populated with global TB estimates from WHO and other sources when running the model for a User Defined Strategy. Thus, users may define their own diagnostic strategy, but the model will return results based upon implementing the User Defined Strategy in the context of the global TB burden.

**FlexDx: Xpert Scale-Up**  
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Click here to return to the main FlexDx webpage

Help us improve this model; click here to take our survey

Click here for Help Files or more information about the model's creators

**1. Read instructions for running FlexDx with a User Defined Strategy**

**Instructions**

**Instructions:**

This is a tool designed to allow users to specify custom algorithms for diagnosis and treatment of TB. To use this tool, follow these steps:

1. Open the "TB Diagnosis Section" by clicking on the arrow.
2. Enter a diagnostic algorithm for each of the four different types of patients shown. The default algorithm is sputum smear only.
3. Open the "Drug Susceptibility Testing" by clicking on the arrow.
4. Enter a treatment algorithm for patients with each of the test results shown.
5. Click "run" to see results.

Please note that, while we have provided some standard tests (described in the upper right-hand box), it is also possible to define tests of your own using the boxes on the lower right. To do this we have provided three user defined diagnostic tests and one DST test; enter the characteristics of each user-defined test and click "Save Test" to add that test to the possible options for TB diagnosis or DST.

**TB Diagnosis Section**

**Drug Susceptibility Testing**

Click to collapse instructions window

Click to expand TB Diagnosis Section and Drug Susceptibility Testing windows

**Diagnostic Test Descriptions**

We have pre-populated this tool with certain standard tests; in this section we describe their model inputs.

<b>Smear</b>
Sensitivity Sm-: 50%, Sensitivity Sm+: 50%, Specificity: 99%
<b>GeneXpert (GXP)</b>
Sensitivity Sm-: 70%, Sensitivity Sm+: 100%, Specificity: 99%
<b>Chest X-Ray (CXR)</b>
Sensitivity Sm-: 95%, Sensitivity Sm+: 100%, Specificity: 99%
<b>Culture</b>
Sensitivity Sm-: 85%, Sensitivity Sm+: 100%, Specificity: 99%
<b>Urine LAM (LAM)</b>
Sensitivity Sm-: 50%, Sensitivity Sm+: 50%, Specificity: 99%
<i>HIV+ only</i>

**User Defined Tests**

This feature allows you to build custom tests within the framework of this model

Please click on a test to alter the details

**User Test 1**

Scroll to view diagnostic strategy descriptions

After reading the instructions for defining your own strategy, users may view the TB Diagnosis Section to view the diagnostic tests available. See next page for more information.

## TB Diagnosis Section

For more information on these tests, users may view the Diagnostic Test Descriptions on the right. The User Defined Strategy also has the option to include up to 3 tests defined by the user if a test of interest is not included in the TB Diagnosis Section.

**Instructions** ^

**Instructions:**

This is a tool designed to allow users to specify custom algorithms for diagnosis and treatment of TB. To use this tool, follow these steps:

1. Open the "TB Diagnosis Section" by clicking on the arrow.
2. Enter a diagnostic algorithm for each of the four different types of patients shown. The default algorithm is sputum smear only.
3. Open the "Drug Susceptibility Testing" by clicking on the arrow.
4. Enter a treatment algorithm for patients with each of the test results shown.

**1. Define a testing strategy for each Patient Type**

**3. Enter % of patients that will be empirically treated if tests 1 and 2 are negative for each Patient Type**

TB patients = people with active TB  
Non-TB patients = people with TB symptoms but without true TB

**TB Diagnosis Section** ^

Please specify whether DST will be performed as a results of a positive test in the DST section below.

Patient Type	Test1	Test2	% treated if all tests neg.	
HIV-, New	Smear	None	TB patients: 0.0	Non-TB patients: 0.0
HIV+, New	Smear	None	TB patients: 0.0	Non-TB patients: 0.0
HIV-, Prev. Treated	Smear	None	TB patients: 0.0	Non-TB patients: 0.0
HIV+, Prev. Treated	Smear	None	TB patients: 0.0	Non-TB patients: 0.0

**Please note...**  
\* - If Chest X-Ray (CXR) is chosen for Test1, Test2 is executed if the CXR result was positive; all other options will execute Test2 if and only if Test1 is negative.

**Drug Susceptibility Testing** v

**2. Select Diagnostic test options for Test 1 and Test 2, or create a user defined test**

**Click Test drop down box to select test**  
Test 1 = Diagnostic Test  
Test 2 = Confirmatory or DST Option that will be performed as a result of a positive result for Test 1

**Test options for HIV+ patient types also include the option of LAM as a diagnostic test**

**Reset To Defaults**

**Model** **About** **Help** **Create a User Defined Test in this window**

**Diagnostic Test Descriptions** v

**User Defined Tests**

This feature allows you to build custom tests within the framework of this model

Please click on a test to alter the details

**User Test 1** ^

(Optional) Name: Enter name for User Defined Test

Sensitivity: (%) Enter test Sensitivity for Smear+ and Smear- patients

Smear-  Smear+

Specificity: (%) Enter Specificity for both Smear+ and Smear- patients

Both

Cost per Test, including labor, transport, etc: Enter per test Cost

Percent of patients lost between test & treatment: Enter % of patients lost to follow-up due to time required between time of testing and time of treatment initiation

**Clear Test** **Save Test**

**User Test 2** v

**User Test 3** v

**User Defined DST** v

**Click here to clear User Defined Test characteristics**

**Click here to save User Defined Test to use in User Defined Strategy**

**TB Diagnosis Section** ^

Please specify whether DST will be performed as a results of a positive test in the DST section below.

Patient Type	Test1	Test2	% treated if all tests neg.	
HIV-, New	Smear	None	TB patients: 0.0	Non-TB patients: 0.0
HIV+, New	Smear	None	TB patients: 0.0	Non-TB patients: 0.0
HIV-, Prev. Treated	Smear	None	TB patients: 0.0	Non-TB patients: 0.0
HIV+, Prev. Treated	Smear	None	TB patients: 0.0	Non-TB patients: 0.0

**\* - If Chest X-Ray (CXR) is chosen for Test1, Test2 is executed if the CXR result was positive; all other options will execute Test2 if and only if Test1 is negative.**

**Click to clear selections and return to default settings**

## Drug Susceptibility Testing (DST) Section

In this section, users can specify whether or not a DST will be performed based on results from the TB Diagnosis Section. The base model assumes, if a test from the TB Diagnosis Section has a positive result:

- All people diagnosed with TB by GXP or by culture will be treated as MDR-TB if the rifampin result is positive
- All people diagnosed with TB by GXP or by culture without rifampin resistance will be treated with 1st-line drugs
- All people diagnosed with TB by smear, LAM, or user-based tests will be treated with 1st-line drugs

If users would like to add an additional test to any of these results to diagnose or confirm drug susceptibility, you can enter that drug susceptibility test (DST) in this section as Test 1 or Test 2. If users enter a test in the DST section, then the model will assume that treatment is offered based on the results of this confirmatory DST for rifampin resistance. Users also have the option to define an additional DST if a test of interest is not included in the DST Section.

**1. Define a testing strategy for each Patient Type**

**2. Select DST Test from drop down box**  
 Test 1 = Drug Susceptibility Test (DST)  
 Test 2 = Confirmatory DST

**3. Enter a name for your User Defined Strategy**

**4. Click here to RUN the model using your User Defined Strategy**

**Create a User Defined Test in this window**

**Click here to clear User Defined Test characteristics**

**Click here to save User Defined Test to use in User Defined Strategy**

**User Defined Tests**  
 This feature allows you to build custom tests to the framework of this model.  
 Please click on a test to alter the details

**User Test 1**  
**User Test 2**  
**User Test 3**

**User Defined DST**  
 (Optional) Name: Enter name for User Defined Test  
 Sensitivity for RIF: Enter test Sensitivity for Rifampin resistance  
 Specificity for RIF: Enter test Specificity for Rifampin resistance  
 Cost of DST: Enter per test Cost  
 Clear Test Save Test

Patient Type	Test1	Test2
HIV-, New	None	None
HIV+, New	None	None
HIV-, Prev. Treated	None	None
HIV+, Prev. Treated	None	None

Name your Strategy: User Defined

Go!

On the next page, we will go through an example of running the FlexDx TB Model with a User Defined Strategy and the accompanying results output.

In this example, we defined a strategy where all patient types will first be tested with Smear and second by GXP. Those people without HIV that test negative by Smear and GXP will be considered to be Non-TB Patient who have TB symptoms but not true TB regardless of history of TB. Those people with HIV that test positive by Smear and GXP will be considered to be TB patients with active TB and will have a second GXP performed to confirm their drug-resistance status prior to initiating TB treatment.

Instructions ▾

**TB Diagnosis Section ^**

Please specify whether DST will be performed as a results of a positive test in the DST section below.

Patient Type	Test1	Test2	% treated if all tests neg.
HIV-, New	Smear ▾	GXP ▾	TB patients: 10.0 Non-TB patients: 5.0
HIV+, New	Smear ▾	GXP ▾	TB patients: 10.0 Non-TB patients: 5.0
HIV-, Prev. Treated	Smear ▾	GXP ▾	TB patients: 10.0 Non-TB patients: 5.0
HIV+, Prev. Treated	Smear ▾	GXP ▾	TB patients: 10.0 Non-TB patients: 5.0

\* - If Chest X-Ray (CXR) is chosen for Test1, Test2 is executed if the CXR result was positive; all other options will execute Test2 if and only if Test1 is negative.

Reset To Defaults

1. Select TB Diagnostic Tests for each Patient Type

**Drug Susceptibility Testing^**

The base model assumes that all people diagnosed with TB by GXP or culture will be treated as MDR-TB if the rifampin result is positive (and with first-line drugs if TB is diagnosed without rifampin resistance), and it assumes that all people diagnosed with TB by smear, LAM, or user-based tests will be treated with first-line drugs. If you would like to add an additional test to any of these results to diagnose or confirm drug susceptibility, please enter that drug susceptibility test (DST) below. The model will then assume that treatment is offered on the basis of the results of this confirmatory DST for rifampin resistance.

2. Select DST options for each Patient Type

Patient Type	Test1	Test2
HIV-, New	None ▾	None ▾
HIV+, New	None ▾	GXP ▾
HIV-, Prev. Treated	None ▾	None ▾
HIV+, Prev. Treated	None ▾	GXP ▾

Name your Strategy: User Defined

Go

3. Enter a name for your User Defined Strategy

4. RUN the model using your User Defined Strategy

**Diagnostic Test Descriptions ^**

We have pre-populated this tool with certain standard tests; in this section we describe their model inputs.

**Smear**  
 Sensitivity Sm-: 50%, Sensitivity Sm+: 50%, Specificity: 99%

**GeneXpert (GXP)**  
 Sensitivity Sm-: 70%, Sensitivity Sm+: 100%, Specificity: 99%

**Chest X-Ray (CXR)**  
 Sensitivity Sm-: 95%, Sensitivity Sm+: 100%, Specificity: 99%

**Culture**  
 Sensitivity Sm-: 85%, Sensitivity Sm+: 100%, Specificity: 99%

**Urine LAM (LAM)**  
 Sensitivity Sm-: 50%, Sensitivity Sm+: 50%, Specificity: 99%  
*HIV+ only*

**User Defined Tests**

This feature allows you to build custom tests within the framework of this model

Please click on a test to alter the details

User Test 1 ▾

User Test 2 ▾

User Test 3 ▾

User Defined DST ▾

On the next page, we will go through the results output from running the FlexDx TB Model with a User Defined Strategy.



## Output for each Single Strategy assessed by the FlexDx TB Model

The results using User Input values are displayed below for all strategies. Note that this is the output returned when the model is run for a single strategy as well. The estimates displayed reflect projections that are expected in Year 5 of the strategy's implementation.

Click to return to the FlexDx main webpage [Back to Inputs](#)

**Model options:**

TB Incidence: 250 per 100,000 Adult HIV prevalence: 0.83% Percent of new TB that is MDR: 0.037000000000000005%

- Treatment of one patient with first-line drugs: \$500
- Treatment of one patient with retreatment ("category 2") regimen: \$1000
- Treatment of one patient with second-line (MDR) drugs: \$5000
- One outpatient visit (e.g., for TB diagnosis): \$10
- Full sputum smear evaluation (e.g., collection & evaluation of 2 smears): \$2
- Single Xpert MTB/RIF test: \$15
- Single Xpert, including extra costs to make results available on same day: \$15

**Epidemiological Scenario and Cost parameter values used to generate the model's results are displayed here.**

**\*If the values for any of the parameters are not appropriate for your setting, users can click 'Back to Inputs' to return to the model inputs page and adjust the values as necessary and run the model with User Inputs but not with a User Defined Strategy.**

Click to view the different single strategy results Tabs

1. Xpert for smear-positive 2. Xpert for HIV+ 3. Xpert for previously treated 4. Xpert for sm-neg HIV+ or prev tx

5. Xpert for all HIV+ or prev tx 6. Xpert for smear-negative 7. Xpert for all 8. User Defined Interactive Incidence/Cost

Click to view all strategies and summary results Tabs

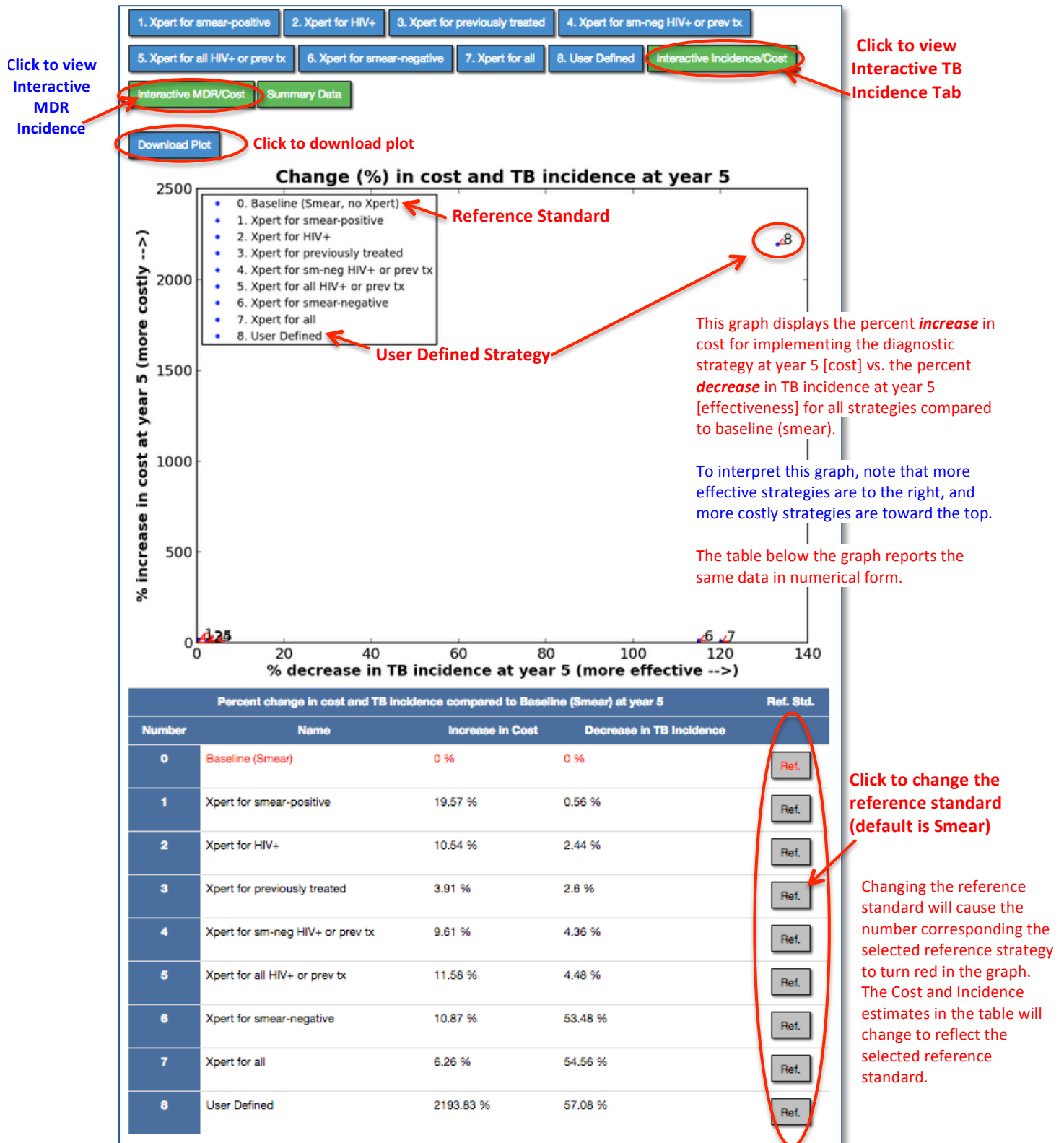
Click to view User Defined Strategy compared to baseline results

Baseline (Smear)		8. User Defined	
Description	Value	Description	Value
<b>TB Incidence</b>		<b>TB Incidence</b>	
New:	229 per 100,000	New:	75.6 per 100,000
Retreatment:	21 per 100,000	Retreatment:	31.7 per 100,000
Total:	250 per 100,000	Total:	107.3 per 100,000
	Baseline Reference		57.1% decrease
<b>Drug-Resistance</b>		<b>Drug-Resistance</b>	
INH New:	11.8%	INH New:	12.3%
INH Retreatment:	16.9%	INH Retreatment:	14.2%
MDR New:	3.7%	MDR New:	4.92%
MDR Retreatment:	15.19%	MDR Retreatment:	11.82%
Total MDR:	11.67 per 100,000	Total MDR:	7.46 per 100,000
	Baseline Reference		36.1% decrease
<b>Additional Outputs/Indicators</b>		<b>Additional Outputs/Indicators</b>	
TB/HIV:	12.5%	TB/HIV:	25.4%
HIV Prevalence:	0.8%	HIV Prevalence:	0.9%
TB Duration:	1.61 years	TB Duration:	1.09 years
TB Mortality:	51.4 per 100,000	TB Mortality:	13.8 per 100,000
	Baseline Reference		73.2% decrease
<b>Costs</b>		<b>Costs</b>	
In Year 1:	\$95027	In Year 1:	\$2085566
	Baseline Reference		2094.7% increase
In Year 5:	\$95027	In Year 5:	\$2179760
	Baseline Reference		2193.8% increase

**\*See the full FlexDx TB Model User's Manual for a more detailed description of the output.**

## Interactive Incidence/Cost and MDR/Cost Tabs

The FlexDx TB Model will generate an interactive graph and summary table Tab for TB Incidence and MDR Incidence that allow the user to change the reference standard. The results for overall TB Incidence are shown below, but the corresponding results for MDR Incidence can be seen by clicking the Interactive MDR/Cost Tab.



## Summary Tab

The Summary Data Tab provides the user with a summary of the FlexDx TB Model results for TB and MDR Incidence, Mortality, Year 1 Cost, and Year 5 Cost projections.

1. Xpert for smear-positive 2. Xpert for HIV+ 3. Xpert for previously treated 4. Xpert for sm-neg HIV+ or prev tx

5. Xpert for all HIV+ or prev tx 6. Xpert for smear-negative 7. Xpert for all 8. User Defined Interactive Incidence/Cost

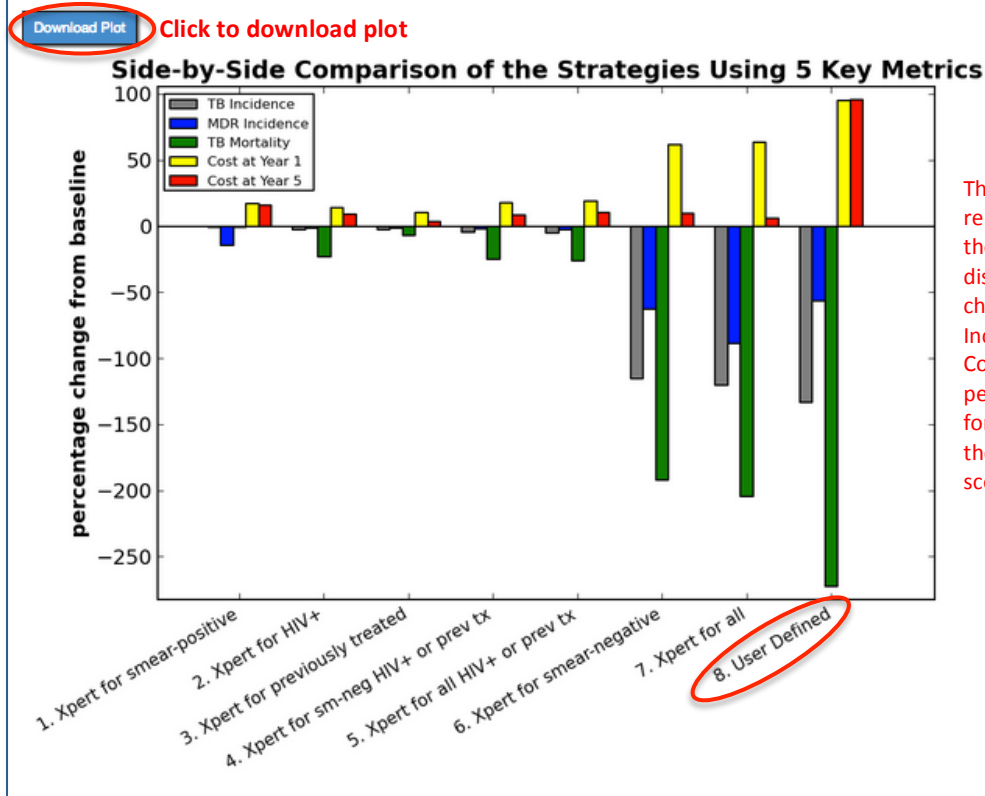
Interactive MDR/Cost **Summary Data** Click to view Summary Data Tab

Name	Chg in total inc.	Chg in MDR inc.	Chg in TB mort.	Cost Chg Yr1	Cost Chg Yr5
1 Xpert for smear-positive	0.6%	12.5%	0.4%	21.3%	19.6%
2 Xpert for HIV+	2.4%	0.9%	18.7%	16.8%	10.5%
3 Xpert for previously treated	2.6%	1.5%	6.4%	12.1%	3.9%
4 Xpert for sm-neg HIV+ or prev tx	4.4%	1.7%	20%	21.8%	9.6%
5 Xpert for all HIV+ or prev tx	4.5%	2.4%	20.6%	24.2%	11.6%
6 Xpert for smear-negative	53.5%	38.6%	65.8%	164.4%	10.9%
7 Xpert for all	54.6%	47%	67.1%	175.5%	6.3%
8 User Defined	57.1%	36.1%	73.2%	2094.7%	2193.8%

All values indicate percentage change from baseline scenario (smear)  
Green values represent reductions, red values represent increases

This table displays the projected changes in TB Incidence, MDR Incidence, TB Mortality, Year 1 Costs, and Year 5 Costs as a percent decrease (green) or increase (red) for All Strategies compared to the Baseline (smear) diagnostic scenario.

To extract the data in this table, users may take a screen shot of the table or manually extract and copy the data into a program of their choice. The next version of FlexDx will offer the option to download the table.



This graph provides a visual representation of the data in the summary table above, displaying the projected changes in TB Incidence, MDR Incidence, TB Mortality, Year 1 Costs, and Year 5 Costs as a percent decrease or increase for All Strategies compared to the Baseline (smear) diagnostic scenario.

## Limitations of the FlexDx TB Model

As with any modeling analysis, the FlexDx TB Model and the user generated results from the model have important limitations. Thus, while FlexDx can be a very useful tool to provide access to “first-pass” estimates in epidemiological settings (e.g., sub-district level data) that will never be captured by more detailed and closely-calibrated TB transmission models, it does not eliminate the necessity for more detailed models.

For more information or to access the help files for the FlexDx Model, users can click on the ‘About’ and ‘Help’ buttons on the model input page. See the full ***FlexDx TB Model User’s Manual*** for more details on using the model.