TB *Elimination*

TB Genotyping Information Management System (TB-GIMS)

What is TB-GIMS?

The TB Genotyping Information Management System (TB-GIMS) will be a secure web-based system designed to
- Store and manage genotyping data
- Submit and track *Mycobacterium tuberculosis* isolates to and from the contract genotyping labs
- Relay immediate notification of genotyping results and updates
- Link isolate data to patient-level data from surveillance
- Query and export data
- Query selected variables within the current national genotyping database

What are the objectives of TB-GIMS?

- To improve access to and dissemination of genotyping information nationwide
- To serve as a standard database local programs can use to
  - Track *Mycobacterium tuberculosis* complex isolates sent to contract genotyping laboratories
  - Receive and update genotyping information
  - Access nationwide genotyping information
- To provide a way to alert users about potential TB outbreaks in their jurisdictions

Who are the primary users of TB-GIMS?

- TB laboratories that submit isolates for genotyping
- Contract genotyping laboratories in California and Michigan
- TB programs
- CDC

How do I access TB-GIMS?

We anticipate that TB-GIMS will be available in winter 2008. Potential applicants will register online (website will be available soon) to access TB-GIMS. When registering, applicants will be asked to select a level of user access
  - Super User
  - Standard User
  - Restricted-access User
(See table on page 4 for more information on user roles)

Applicants must also select which jurisdiction's data they want to access. The TB-GIMS Administrator for the jurisdiction requested will be prompted electronically to review the application.

The TB-GIMS Administrator will approve or reject the application based on user criteria. If the application is approved, the user will be notified of the decision and will receive further instructions to complete the application process. All approved users are required to complete security training and must agree to the CDC data-use agreement and "rules of behavior."

If the applicant is rejected, and the rejection was based on the level of access requested, the applicant can reapply for a lower level of access.

What can a Super User do?

Super Users will have unrestricted access to TB-GIMS for their approved jurisdiction. They will be able to update, edit, enter, upload, review, search, import and export all TB-GIMS data.

CDC suggests that most jurisdictions should designate two Super Users. It is suggested that the two Super Users be the:
1. Person in the laboratory with primary responsibility for submitting isolates to the genotyping laboratories; and
2. Person from the TB program with the primary responsibility for managing, validating, and analyzing genotype-related activities for their jurisdictions.

What can a Standard User do?

A Standard User has access to genotyping data but cannot edit data in the system. Standard Users can search for genotyping results by case (using patient identifiers) or by specific genotype strains (e.g. spoligotype or MIRU patterns), and can view information and export genotyping and surveillance data.

CDC assumes that most TB-GIMS users will be Standard Users. Program managers and other staff who use genotype data in contact investigations, TB program evaluation, incident response, and other TB control activities are suggested to be Standard Users.

What can a Restricted-access User do?

Restricted-access Users have limited access to data. They will not have access to patient identifiers but will be able to query the database and view aggregated summary data reports. For example, they can search the database to see how many patients in their jurisdiction have an isolate with a particular genotype, but they will not be able to see the patient identifiers.

CDC envisions Restricted-access Users to be researchers and other partners not directly involved with patient-level or programmatic activities.

Who serves as a TB-GIMS Administrator? What is their role?

A TB-GIMS Administrator serves as the authority for reviewing and approving applications for access to TB-GIMS data for their jurisdiction. For some jurisdictions, this may be the state TB Controller. The Administrator will be able to approve the user role (Super User, Standard User, Restricted-access User). The Administrator has the authority to revoke or change a user's access at any time.

The Administrator will NOT be responsible for maintaining a specific list of credentialed users or user activity, nor will they have to manage user names and passwords. TB-GIMS Administrators do not have access to any TB-GIMS data, unless they grant themselves that access and complete the application process. To access data in TB-GIMS, Administrators will have to apply and approve their own access to the system as one of the 3 user roles.

Is there a difference between an Administrator and Super User?

An Administrator may or may not be a Super User. If an Administrator chooses to be a Super User, he or she is responsible for regular maintenance of the TB-GIMS data along with approving user status of applicants for their jurisdiction.

How does TB-GIMS affect laboratories that submit isolates for genotyping?

TB-GIMS will replace the excel spreadsheets that were previously used to submit isolates and receive genotyping results. Laboratories that routinely submit isolates to the contract genotyping laboratory should register for user access for their jurisdiction. Laboratory user roles will be similar to TB program user roles (e.g., Super User, Standard User) and will have laboratory-specific functions such as submitting and tracking isolates to and from the contract genotyping laboratories.

Will big city jurisdictions that receive CDC co-operative agreement funds have their own TB-GIMS Administrator?

This decision requires a mutual agreement between the state TB controller and the big city TB controller. If agreed, a TB-GIMS Administrator for the big city can be designated in addition to the state TB-GIMS Administrator.

It is up to the state and big city jurisdictions to determine who gets access to what kind of information to maintain the data confidentiality, integrity, and quality. CDC officials and public health advisors are available for consultation to help clarify.

Will Regional Training and Medical Consultation Centers (RTMCCs) and other academic institutions be able to access TB-GIMS?

Users who want TB-GIMS data from multiple jurisdictions will need to apply for access to each of the desired jurisdictions. For example, if the Heartland National TB Center wants to view genotyping data for the states in their region, the nurse consultant from the Center would apply to each state in their region for access as a user.

Will TB-GIMS allow for sharing genotyping data across jurisdictions?

TB-GIMS does allow for sharing data across jurisdictions. All users will have access to aggregate cluster distribution reports similar to currently disseminated reports.

If a user would like to access line-listed genotyping data from another jurisdiction, the user must apply to be a Standard User for that jurisdiction. The TB-GIMS Administrator for that jurisdiction may approve or disapprove the request.

How is information protected in TB-GIMS?

CDC is committed to maintaining strict confidentiality and security of the national surveillance information through the National TB Surveillance System (NTSS). TB-GIMS is an extension of NTSS and will be protected in the following ways:

1. Data encryption will be employed when data is transmitted between users and TB-GIMS;

2. Multi-factor authentication will be used upon logon to prevent unauthorized users from gaining access to the system;

3. TB-GIMS will be housed on servers that are protected by reverse proxy firewalls to prevent unauthorized access to the system;

4. TB-GIMS is designed to display data/information based on user roles to ensure users only have access to what they have been authorized by Administrators;

5. All potential users must be authorized by local Administrators.

What are CDC data use agreements and "rules of behavior"?

CDC data use agreements and "rules of behavior" provide general instructions on the appropriate use of IT resources. Rules of Behavior are not to be used in place of existing policy. Rather they are intended to supplement the Health and Human Services (HHS) Information Security Program Policy [http://www.cms.hhs.gov/InformationSecurity]. All TB-GIMS users must sign these agreements electronically to access and view genotype data.

What will happen to previously submitted genotype data?

When TB-GIMS is rolled out, CDC will populate the online database with all of the previously submitted data to date. This linked data will be available to generate the standard reports and query for already existing clusters.

Can data be exported from TB-GIMS? In what format?

Data can be exported from TB-GIMS. The current format for exporting line-listed data is in an Excel spreadsheet, which can be manipulated directly or imported into a statistical package of your choice.

For all other queries and standard reports, PDF format will be used and data can be printed directly from TB-GIMS by using a simple print function at the bottom of each screen.

Dynamic reporting (multi-variable searching) capabilities will be available in future phases of TB-GIMS.

How much will TB-GIMS cost users and public health departments?

TB-GIMS is a web-based application provided by CDC for better dissemination and understanding of genotyping results and reports. It is available to users and health departments free of charge.

Additional Information

For more information on TB-GIMS, please contact tbgenotyping@cdc.gov.

Table 1: TB-GIMS User Roles

	Super User	Standard User	Restricted-access User
Access to GIMS data?	Unrestricted access	Regular access	Limited access
Search Data?	Yes	Yes	Yes
View Data?	Can view aggregated data Can see line-listed data Will have access to patient identifiers	Can view aggregated data Can see line-listed data Will have access to patient identifiers	Can view aggregated data Cannot see line-listed data Will not have access to patient identifiers
Edit Data?	Yes	No	No
Export Data?	Yes Can export line-listed data Can export reports	Yes Can export line-listed data Can export reports	No Cannot export line-listed data Can export reports
Typical Users?	Program epidemiologists, genotype coordinators of a jurisdiction who deal with daily genotype-related activities	Program managers and other staff who use genotype data in contact investigations, TB program evaluation, incident response and other TB control activities	Researchers and other partners not directly involved with patient-level or programmatic activities