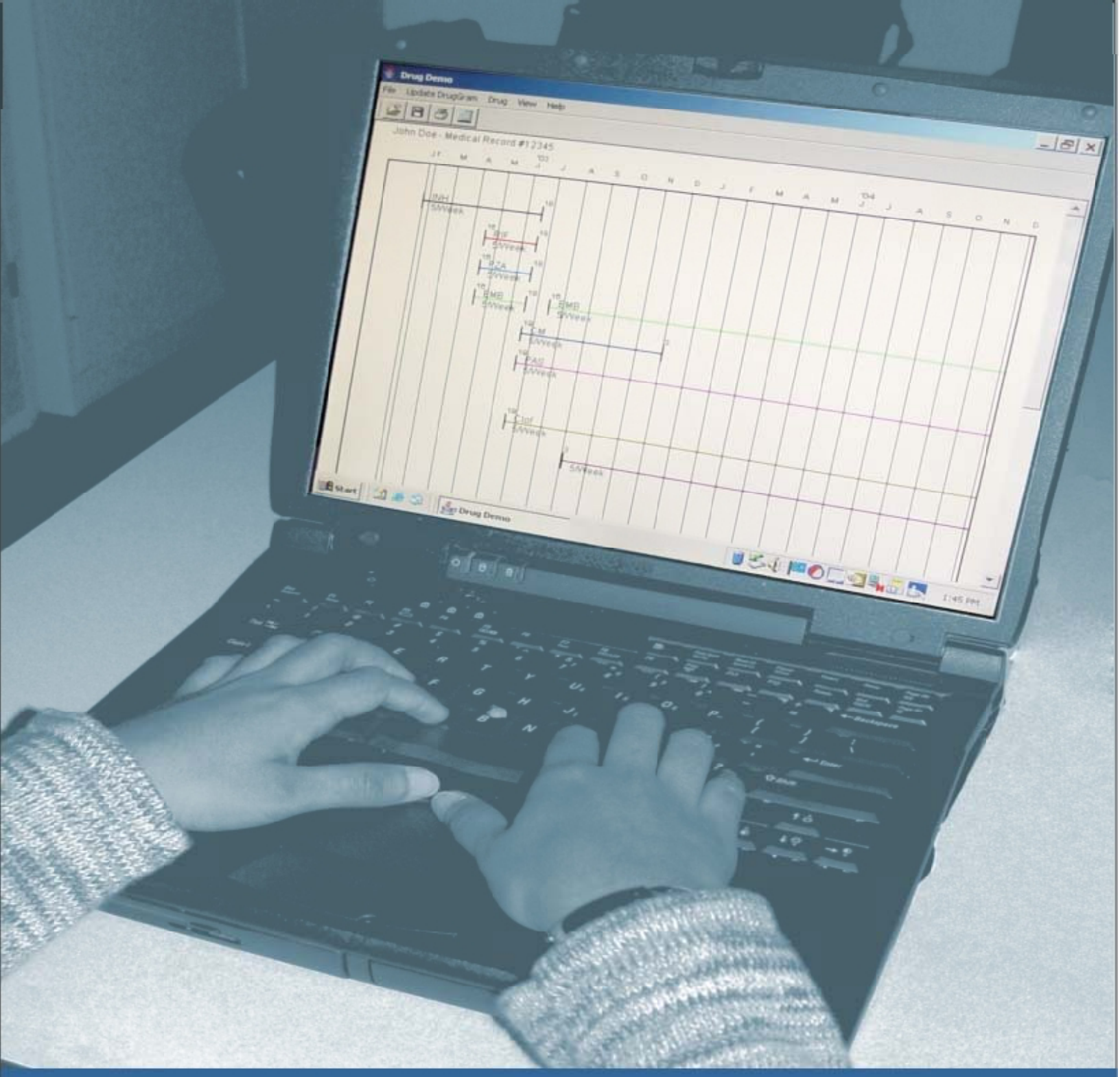

DESIGNING A DRUG-O-GRAM

A Tool for Monitoring and Adjusting TB Therapy

NEW JERSEY MEDICAL SCHOOL
GLOBAL TUBERCULOSIS INSTITUTE

Acknowledgements

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Reynard McDonald, MD
Eileen Napolitano
Alfred Paspe
Lillian Pirog, RN, PNP
Lee B. Reichman, MD, MPH
New Jersey Medical School Global Tuberculosis Institute

Document prepared by: Rajita Bhavaraju and Anita Khilall
Graphic Design: Alfred Paspe
Programming: Michael Recce, PhD and Michael Cody, NJ Institute of Technology

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Designing a Drug-o-Gram: A Program for Initiating Appropriate Tuberculosis Therapy

Management of Anti-Tuberculosis Treatment Regimens

Management of anti-tuberculosis (TB) treatment is a challenging medical responsibility. While the principles of treatment are standardized, many factors can complicate treatment regimen including:

- The duration of treatment
- Interval of time for smear, culture identification, and drug susceptibility results
- Availability of staff to provide directly observed therapy, the preferred treatment strategy

The Centers for Disease Control and Prevention (CDC), American Thoracic Society (ATS), and Infectious Diseases Society of America (IDSA) issued revised TB treatment guidelines in 2002, which state that frequent monitoring of the patient's treatment regimen and response to treatment is critical. Monitoring should include review of the drugs in use, response to therapy, smear and culture status, and adherence. One of the best ways to conduct this monitoring is through the use of a *drug-o-gram*.[1]

Use of the Drug-o-Gram

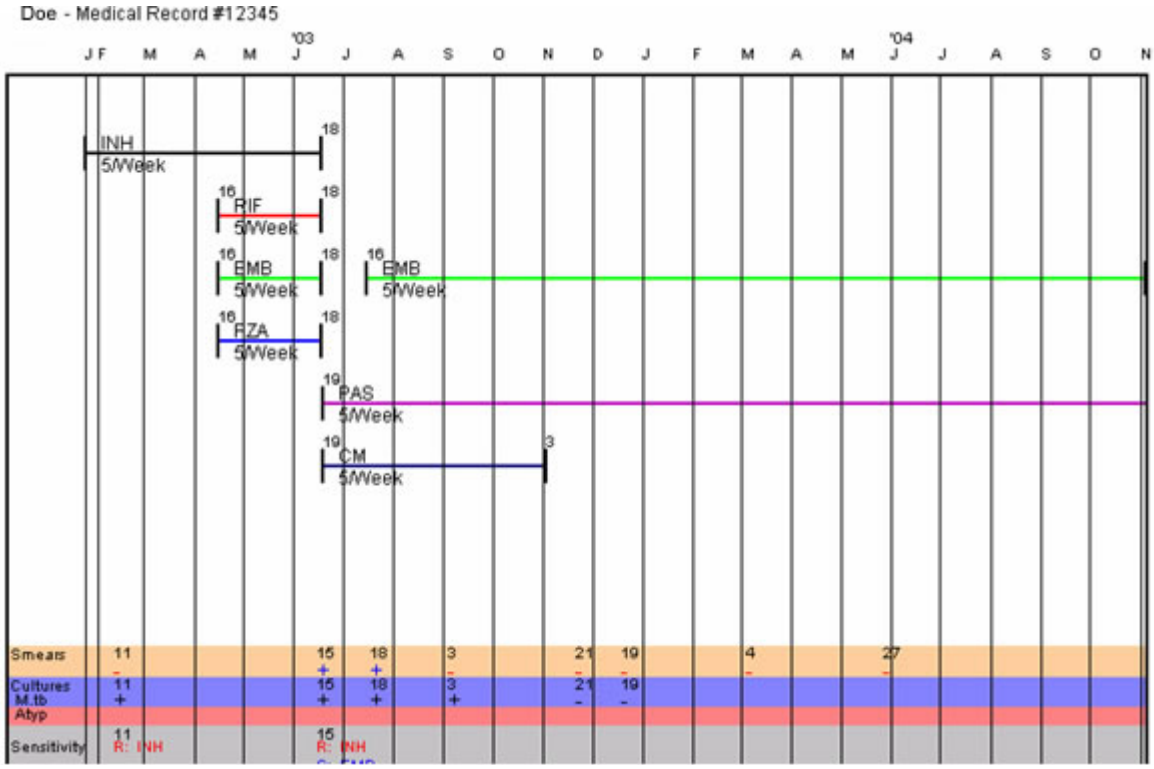
A **drug-o-gram** is a pictorial depiction (see Figure 1) of a patient's treatment which graphically demonstrates the chronological series of events surrounding treatment. It includes important variables such as:

- Drug names and when drugs were started and stopped
- Duration of treatment
- Mode of treatment, i.e., directly observed vs. self-administered
- Smear, culture identification, and drug susceptibility results with dates of specimen collection

This resource can assist in designing a drug-o-gram with the above variables. However, drug-o-grams can also include additional information which can assist in the day-to-day management of patients, such as HIV status, co-existing medical conditions, laboratory results, and dose amounts. Future versions of this resource will provide the ability to include this information.

[1] CDC. Treatment of tuberculosis. *MMWR* 2003; 52(RR-11): 17-18.

Figure 1. Sample Drug-o-Gram



The goal of using a drug-o-gram is to assist the clinician in:

- Monitoring present treatment and clinical progress
- Providing data for cohort analysis
- Teaching or presenting to other clinicians findings from either current or past cases in case discussions, papers, and/or consultations

Most importantly, what is depicted in the drug-o-gram can help in making clinical decisions to prevent the development of drug resistance through inappropriately prescribed regimens.

The accompanying is software for developing a drug-o-gram to accomplish the above goals. Information to create the drug-o-gram is derived from the patient's medical chart. Based on the resulting drug-o-gram, the clinician can take action, if needed, by adjusting the treatment regimen. Use of the resulting drug-o-gram is discussed on pages 11 and 12.

Drug-o-Gram Installation Instructions

Running this program requires Windows 2000/XP and Microsoft Access. If your computer has an older version of Windows, it must also have Microsoft Access. Complete the installation in the order described below.

Java Installation (If you already have Java, please skip the following instructions and go straight to "Drug-o-gram Installation")

1. Go to http://java.com/en/download/index.jsp and follow the steps.
2. When the agreement statement comes up, read and then click on "I accept"
3. Choose "Typical" installation (not "Custom")
4. Click "Next" on each screen as they come up
5. On the last installation screen click "Finish." Java installation is now complete.
6. You may have to restart your computer; if so, the computer will let you know this.

Drug-o-gram Installation

1. After downloading the DrugOGram.zip to your hard drive. Double-click on the file to unzip the contents. (NOTE: Please take note of the directory where the files are extracted)
2. Double click on the "Install" icon
3. Click and drag the "DrugGram" shortcut icon to your desktop.
4. Remove the CD ROM and follow the instructions beginning on page 4 to create a drug-o-gram.

User Instructions

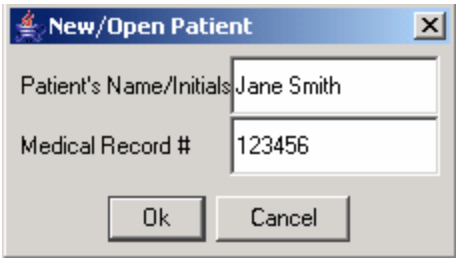
Follow these instructions to create a drug-o-ram.

Entering Patient Information

1. Open the database by double clicking on the "DrugGram" icon on your desktop.

2. When the database opens, you will immediately see the "New/Open Patient" dialog box. Begin by typing the patient's name for the first field. Press Tab to move to the next field or left click with your mouse in the next field and enter the medical record number of the patient. Press Enter or click Ok to continue. A dialog box with the following message "Patient <medical record number – patient name> not found. Create?" will appear. Click Yes or press Enter to proceed to the next step. A sample of the "New/Open Patient" screen is shown in Figure 2.

Figure 2. Load Patient Screen



3. After you click Yes or press Enter, the Patient Information screen will prompt you to enter additional information for the patient. The first two fields will display the Patient's Name and Medical Record Number that were initially entered; verify that this information is correct. Press Tab to move to the next field or left click with your mouse in the next field.

4. The Date of Birth field displays today's date, which you can change in one of two ways.
   (1) Using the same format that is shown (Figure 3), type the correct date of birth or;
   (2) a. Click (the calendar icon) on the right hand side of the field. The "Choose a Date" dialog box will appear (see Figure 4). b. Click ▼ (the down arrow) for the month drop down list and use the right-hand navigation bar to select a month, or click 'Previous' or 'Next' at the bottom of the screen until you see the correct month. c. Click ▼ for the year drop-down list and select a year. Click the date/day of the month and click 'OK.'

Continue entering the required information and press Tab to go to the next field until you reach the last field. Click 'OK' or press 'Enter.' A sample of the 'Patient Information' screen and 'Choose Date' dialog box are shown below.

Figure 3. Patient Information Dialog Box

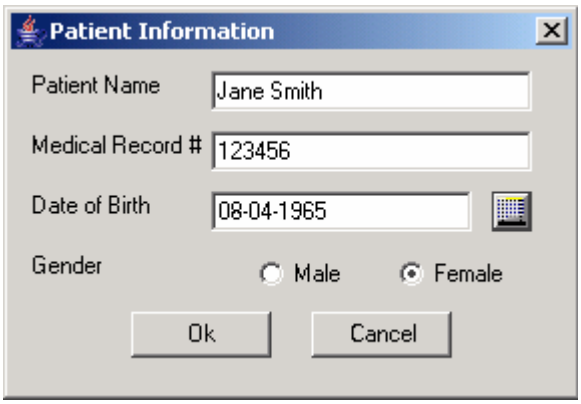
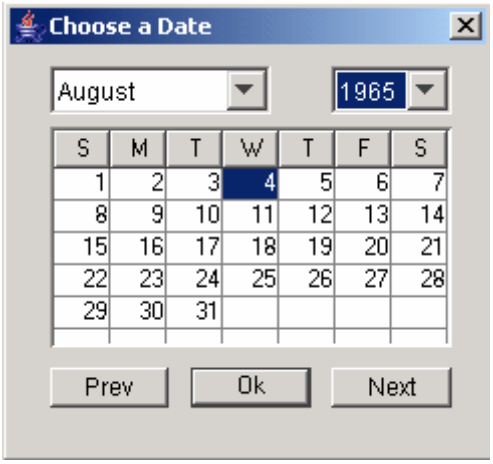


Figure 4. Choose a Date Dialog Box

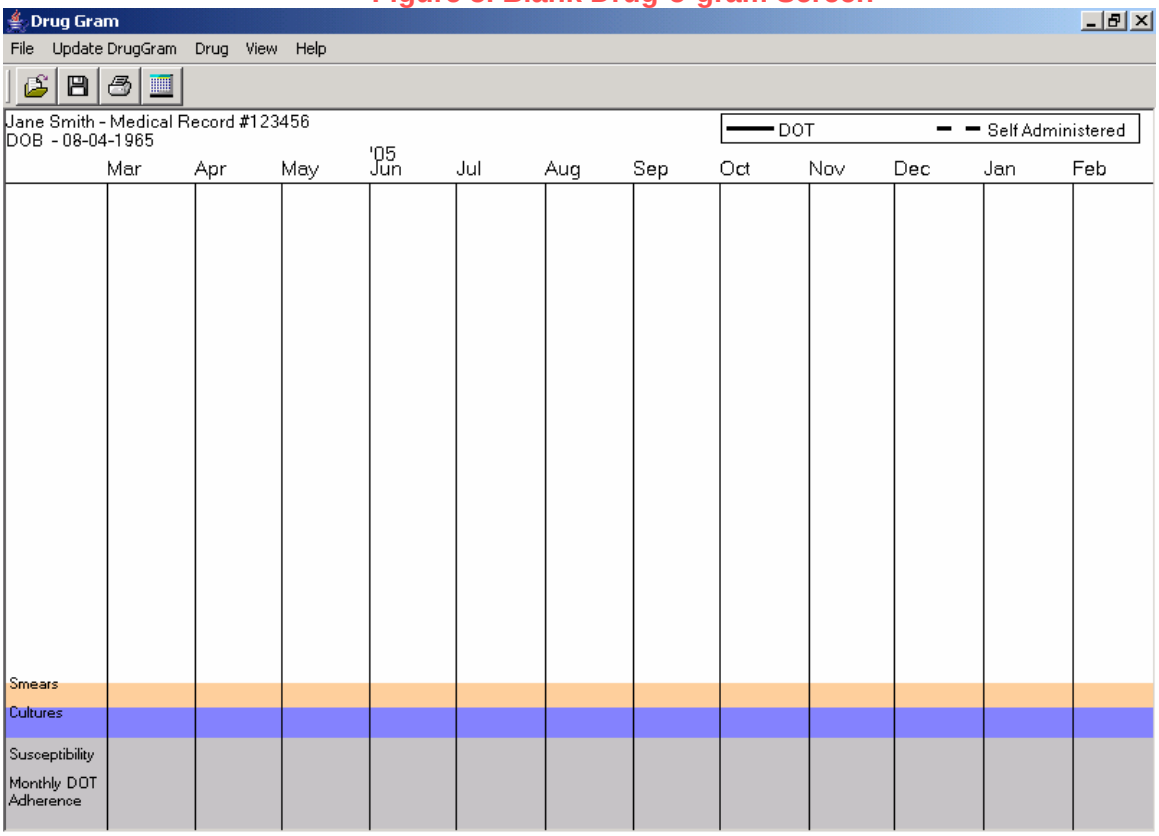


Managing the Program

5. A blank drug-o-gram will be displayed on the screen with a month and year label at the top of each column. The Patient's Name, Medical Record number, and Date of Birth will appear in the upper left-hand corner of the screen. A legend located in the upper right-hand corner of the screen indicates that a solid line represents Directly Observed Therapy (DOT) and a dotted line represents Self-Administered. You will use two types of command bars to operate and manage the drug-o-gram database; menu bar and toolbar. The **menu** bar organizes features of the database into categories: File, Update DrugGram, Drug, View, and Help. Clicking on any of

these categories opens up a list of features for you to choose from. Many of the menu bar options open dialog boxes which allow you to set or change several options related to the feature you choose all at once. The **toolbar** is the command bar with graphical buttons located below the menu bar. Use the toolbar when you want a shortcut to a common feature: Open, Save, Print, and Zoom. A sample of a blank drug-o-gram screen is shown in Figure 5 on page 6.

Figure 5. Blank Drug-o-gram Screen



Entering Treatment Information

6. After you have completed steps 1 – 5, you are now ready to enter treatment information. Click 'Update DrugGram' on the menu bar and select the 'Add Treatment' option. Click ▼ for the Drug drop-down list to select the name of the drug you want to enter. If the name of the drug you want to add does not appear in the drop-down list, follow these steps to add a new drug. Click 'Drug' on the menu bar and select the 'Add Drug' option. Enter the 'Drug Name' and 'Short Name' (if any), then click 'OK'. After you have finished adding the new drug, click on 'Update DrugGram' on the menu bar, select the 'Add Treatment' option, and follow steps 7-9. Samples of the 'Add Treatment' and 'Add Drug' screens are shown below in Figures 6 and 7.

Figure 6. Add Treatment Screen

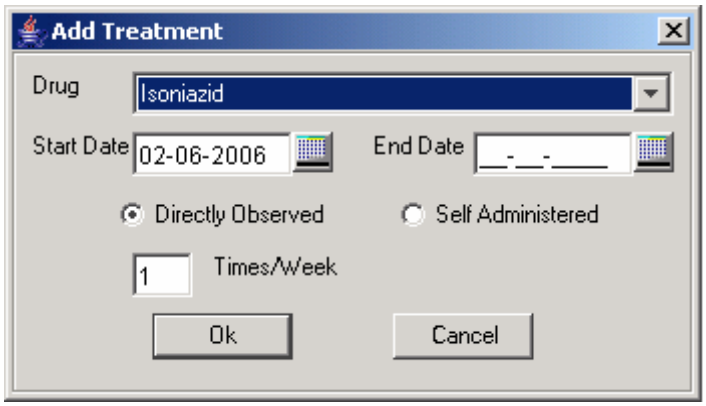


Figure 7. Add Drug Screen

7. Enter the 'Start Date' and 'End Date' for the drug by following the instructions in step 4.

8. If the treatment is ongoing and there is no 'End Date,' leave the field for 'End Date' blank and continue to the next field.

9. Select the method of treatment administration (Directly Observed or Self Administered) and the frequency of the treatment. Click 'OK' and a solid or dotted line will appear on the screen for each drug with a 'Start Date' and 'End Date.' *The solid line represents Directly Observed Therapy and a dotted line represents Self Administered.*

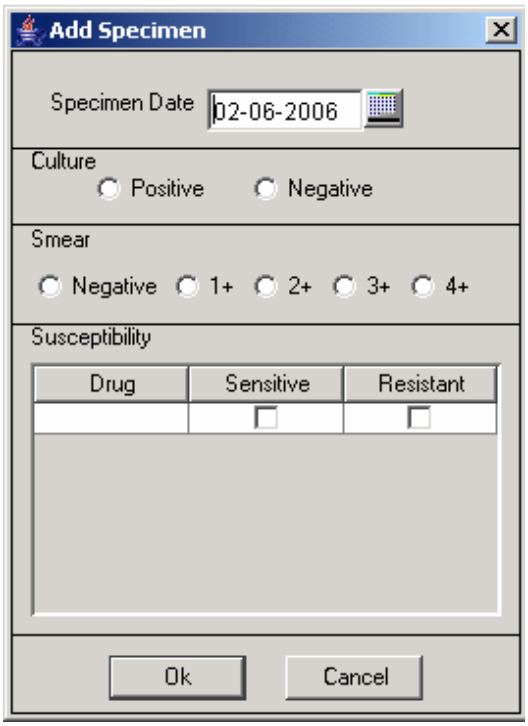
10. Repeat steps 5-9 each time you want to 'Add Treatment' and enter the required information.

Entering Smear, Culture and Susceptibility Results

11. The next type of information that you will need to enter are smear, culture and susceptibility results. To add a smear, culture, or susceptibility result, click on 'Update DrugGram' and select the 'Add Specimen' option from the drop-down list. Enter the date that the specimen was collected and indicate whether the culture result was negative or positive for *Mycobacterium tuberculosis* (*M.tb*). Enter the smear result by clicking on the appropriate option to indicate whether the smear was negative, 1+, 2+, 3+, or 4+ for acid-fast bacilli (AFB). Enter the susceptibility results by clicking on the blank space under the column labeled 'Drug' and click on the check box under the sensitive or resistant columns to indicate whether the patient is sensitive or resistant to the drug. A sample of the 'Add Specimen' screen in Figure 8 on the next page.

Note: Due to limited space on the display screen, please make the following adjustment: For specimens collected on three consecutive days *that yield the same results*, you should choose one date and specimen result to enter for viewing on the drug-o-gram. For specimens collected on three consecutive days which yield different results, all of the results can be entered. However, the information displayed on the screen may be overlapping. For a clearer view of the overlapping results, you can click on View, select the Zoom Range option, and enter the dates for the desired view.

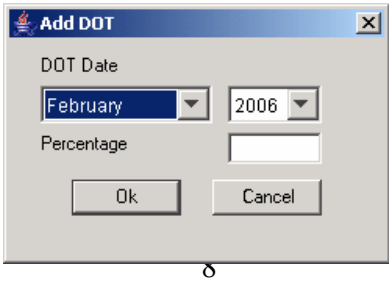
Figure 8. Add Specimen



Entering the DOT Adherence Rate

12. You can also enter DOT adherence rates for each month of a patient's treatment. To enter DOT results, click Update DrugGram and select the Add DOT Result option. Enter the month, year, and percentage corresponding to the DOT adherence for that particular date. A sample of the 'Add DOT' dialog box is shown below in Figure 9.

Figure 9. Add DOT



Saving an Entry

13. To save the drug-o-gram that you have created, click ‘File’ on the menu bar and select the ‘Save’ option or click the floppy disk icon on the toolbar. The database will automatically save the drug-o-gram under the Patient’s Name and Medical Record number that you entered for the patient. Therefore, each time you would like to view or modify the drug-o-gram for a patient, you will have to enter the doctor’s name and medical record number corresponding to that particular patient. Remember to save the drug-o-gram each time a new entry is made or an existing entry is modified.

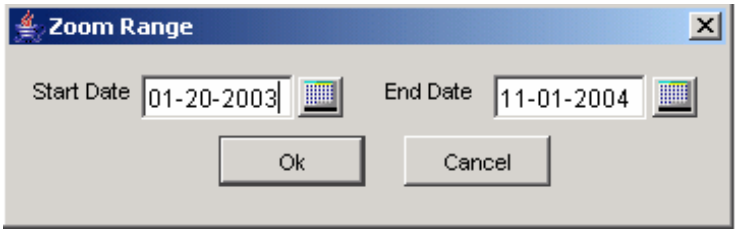
Deleting an Entry

14. To delete a drug, smear result, culture result or sensitivity result, click ‘Update DrugGram’ and select the appropriate option. A deletion dialog box will appear. Click on the check box for the entry that you want to delete and click ‘OK’. To delete a patient record, you will need to open the drug-o-gram created for that patient. Next, click on File and select the Delete Patient option. You will be prompted by a dialog box to confirm whether you want to delete the patient. Click Yes.

Using the Zoom Feature

15. To zoom into a particular range of dates, click on ‘View’ and select ‘Zoom Range.’ Enter the start and end dates for which you would like to view on the screen and click ‘OK’. Click on ‘View’ and select 'Restore’ to return to the previous view. A sample of the “Zoom Range” screen is shown here.

Figure 9. Zoom Range



Exporting the Drug-o-gram

16. If you would like to include the drug-o-gram in a Microsoft PowerPoint® presentation or a Microsoft Word document, you will need to do a screen capture. The ‘PrintScreen’ button your computer keyboard allows you to capture all of the information currently displayed on your computer screen. It is important that your view of the display screen is maximized to ensure that

all of the information on the screen is captured. Once you have selected the view in your drug-o-gram that you want to show on your Power Point slide or in your document, press 'PrintScreen.' Go to the slide in your presentation or place in your document that you want to insert the drug-o-gram, click on Edit and select "Paste." You may format the drug-o-gram as needed by right clicking on the drug-o-gram image with your mouse and select the 'Format Picture' option, which allows you to change the size, layout, etc.

Use of Drug-o-gram Results

Once the drug-o-gram is complete, it can be used to monitor the patient's treatment regimen and guide the clinician in making treatment decisions. Below is a list of results which can be viewed by the clinician to help determine what actions to take. These results can also be teaching points when presenting cases. Note that the following are items to consider but must be looked at in conjunction with the entire clinical picture, radiographic findings, and other laboratory test results not shown on the drug-o-gram.

	Drug-o-gram Result	Clinician Action/Teaching Point[2]
1	After drug resistance is reported, only one drug is added to a failing regimen, based on lack of symptom and chest radiograph improvement.	Never add a single drug to a failing regimen; add at least 2-3 previously unused drugs to which the bacilli are susceptible. One of these drugs may be an injectable agent.
2	Patient is resistant to INH and RIF.	In patients with multidrug resistant organisms with resistance to INH and RIF, the use of 4-6 medications appears to be associated with better results. Patients with MDR-TB require expert consultation
3	Patient has demonstrated resistance to RIF. The clinician has subsequently placed the patient on rifabutin or rifapentine.	Resistance to RIF is associated in nearly all instances with cross-resistance to rifabutin and rifapentine. Addition of a non-rifamycin is necessary.
4	Patient has resistance to an injectable drug. Two additional injectable drugs are then prescribed.	There is universal cross-resistance between amikacin and kanamycin. There is no cross-resistance between streptomycin and other injectable agents. However, simultaneous use of 2 injectable agents is not recommended due the to absence of proof of efficacy and potential amplification of drug toxicity
5	PZA is not used is the initial regimen (8 weeks) with no evidence of previous use or drug resistance.	PZA has the greatest efficacy in the initial phase of treatment along with other anti-TB drugs, especially INH ands RIF. If eliminated from the initial phase of treatment, the continuation phase should be extended by 7 months (9 months of total treatment). Determination of resistance to PZA is technically challenging and, therefore, not done routinely in many labs. If PZA monoresistance is demonstrated, however, it may be because the patient is not infected with *M. tuberculosis* but with *M. bovis*.
6	Patient self-administering drugs for a daily regimen or intermittent regimen (1x, 2x, 3x per week).	A patient must be on directly observed therapy (DOT) for any intermittent regimen to ensure adherence. This is also highly recommended for a daily regimen. However, if not possible with a daily regimen, patient should be educated on importance of adherence and any barriers to adherence should be explored and resolved with patient. Fixed dose combination drugs are strongly suggested when DOT is not prescribed. Consult the health department for assistance with DOT and case management.
7	Patient's smear results are not improving after 8 weeks.	If susceptibility results are not yet available, check patient's adherence, symptom resolution, absorption of drugs, and chest radiograph and/or other radiographic findings for improvement. Two additional drugs may need to be added. If drug susceptibility results are available, make sure the patient is taking at least two drugs to which the bacteria are susceptible.

[2] CDC. Treatment of tuberculosis. MMWR 2003; 52(RR-11): 68-69.

	Drug-o-gram Result	Clinician Action/Teaching Point[2]
8	Patient culture positive after 16 weeks.	If susceptibility results are not yet available, check patient's adherence, symptom resolution, absorption of drugs, and chest radiograph and/or other radiographic findings for improvement. Two additional drugs may need to be added. If drug susceptibility results are available, make sure the patient is taking at least two drugs to which the organisms are susceptible. Also, check culture identification to see if patient has *M. tuberculosis* or a atypical mycobacteria. The latter may require a change in treatment. Patients who are culture positive after 2 months should have the continuation phase of treatment extended for an additional 3 months (total of 9 months of treatment).
9	Periods of time with no treatment.	Ascertain reason(s) for breaks in treatment and try to resolve these reasons. • If patient is non-adherent, use directly observed therapy (DOT)/health department follow-up (e.g., locate patient if lost to follow up, provide incentives/enablers, case management, etc.) • If clinician discontinues medications due to adverse reaction, add each drug one at a time after determining problem drug
10	After drug resistance is reported, continuing use of drugs to which patient is resistant.	There is no efficacy in the continued use of drugs to which TB bacilli are not susceptible. Stop using drugs to which the patient is resistant but make sure patient is on at least 2-3 drugs to which the bacilli are sensitive.
11	Second-line drugs [anything other than isoniazid (INH), rifampin (RIF), rifabutin (RBT), ethambutol (EMB), pyrazinamide (PZA), rifapentine (RPT)] are being administered intermittently.	Second-line drugs must be administered only on a daily basis with the exception of injectable drugs after an initial period (2-3 months usually) of daily therapy.

Conclusion

The teaching points demonstrate essential principles of TB treatment which can be derived by looking at the drug-o-gram. However, this does not substitute for working in conjunction with a clinician experienced in TB treatment, especially in cases involving multi-drug resistance, HIV co-infection, CNS, disseminated, bone and joint TB, and TB in children.

The drug-o-gram provides a way in which the treatment information can be shared with a consulting clinician, especially if consultation is being conducted via telephone or teleconference. The drug-o-gram can be provided electronically or by fax along with available radiographic results and a verbal discussion.[3]

[3] As stated earlier, this version of this program is helpful for formulating a basic drug-o-gram. Future versions will include the ability to enter a larger array of patient information as well as allow for the evaluation of the drug-o-gram results automatically. If you would like to provide feedback on this program, please call the Global TB Institute at (973) 972-0979.

Resources

1. American Thoracic Society, Centers for Disease Control and Prevention, and Infectious Diseases Society of America. Treatment of Tuberculosis. *MMWR* 2003;52 (No. RR-11):1-80.
2. Francis J. Curry National Tuberculosis Center and California Department of Health Services *Drug-Resistant Tuberculosis: A Survival Guide for Clinicians*. 2004:1-276.
3. Partners in Health. *The PIH Guide to the Medical Management of Multidrug-Resistant Tuberculosis*. 2003:1-196.
4. World Health Organization. *Guidelines for the Programmatic Management of Drug-Resistant Tuberculosis*. 2006:1-185.

Feedback Form

Using a scale of 1 to 5 (with 1 being not useful at all and 5 being very useful), please rate how useful you find this program?

1	2	3	4	5
Not useful				Very Useful

Please describe how the drug-o-gram was used?
(Check all that apply)

- ☐ To determine a patient's treatment regimen prior to availability of culture results
- ☐ To determine a patient's treatment regimen after culture results became availability
- ☐ To monitor a patient's response to treatment
- ☐ For use in a case presentation or paper
- ☐ To obtain medical consultation from another physician
- ☐ Other, please specify: _____

Did you experience any of the following difficulties while using this program?
(Check all that apply)

- ☐ Installing/downloading the program
- ☐ Using menu options
- ☐ Using pull down menus
- ☐ Saving/opening a drug-o-gram
- ☐ Deleting drugs, smear, culture, susceptibility/DOT adherence
- ☐ Using the zoom range feature
- ☐ Inserting the drug-o-gram into a Power Point presentation
- ☐ Other, please specify: _____

What did you find most useful?

What did you find least useful?

What would you suggest to improve the drug-o-gram?

Please fax completed form to (973) 972-1064, attn: A. Khilall.