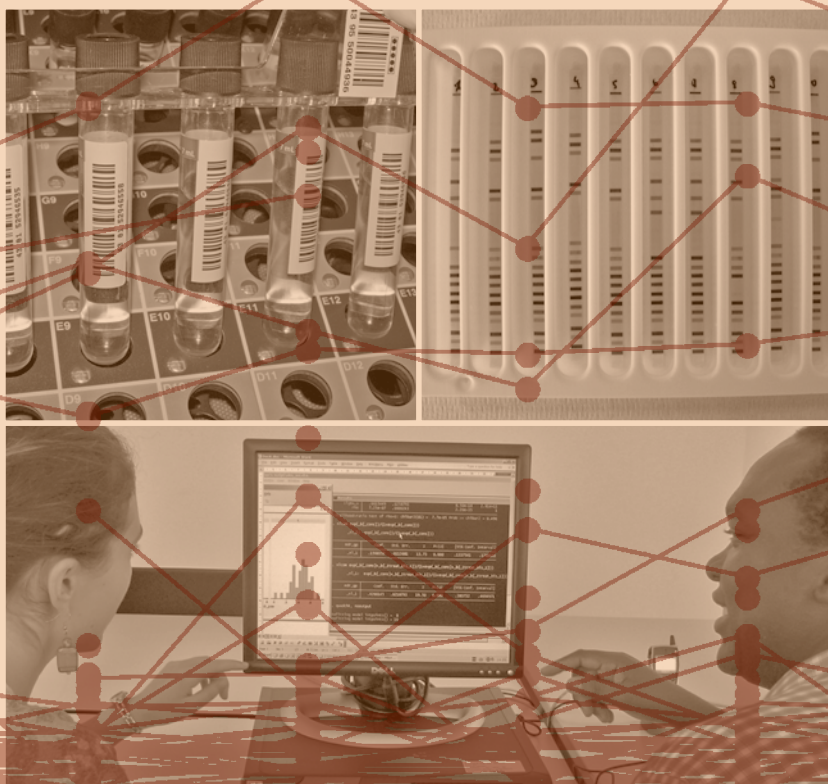


Guidelines for surveillance of drug resistance in tuberculosis

FOURTH EDITION



World Health
Organization

Guidelines for surveillance of drug resistance in tuberculosis

FOURTH EDITION



**World Health
Organization**

WHO Library Cataloguing-in-Publication Data:

Guidelines for surveillance of drug resistance in tuberculosis – 4th ed.
WHO/HTM/TB/2009.422

1. Antitubercular agents – pharmacology. 2. Tuberculosis, Multidrug-resistant – epidemiology. 3. Drug resistance. 4. Epidemiologic surveillance – methods. 5. Guidelines. I. World Health Organization.

ISBN 978 92 4 159867 5

(NLM classification: WF 360)

© World Health Organization 2009

All rights reserved. Publications of the World Health Organization can be obtained from WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel.: +41 22 791 3264; fax: +41 22 791 4857; e-mail: bookorders@who.int). Requests for permission to reproduce or translate WHO publications – whether for sale or for noncommercial distribution – should be addressed to WHO Press, at the above address (fax: +41 22 791 4806; e-mail: permissions@who.int).

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

Cover: Photographs (top left and right) courtesy of Paolo Miotto, San Raffaele Scientific Institute, Milan, Italy; (bottom) WHO. Points and lines depict survey and routine surveillance data provided to the Global Project on Anti-Tuberculosis Drug Resistance Surveillance.

Designed by minimum graphics
Printed in France

Contents

Acknowledgments	vii
Introduction	ix
Part I. Principles of anti-tuberculosis drug resistance surveillance in the Global Project	1
1. Mechanisms of surveillance that produce data representative of a geographically-defined population	3
1.1 Surveillance systems based on routine drug susceptibility testing	4
1.2 Periodic surveys	5
1.3 Sentinel surveillance systems	6
1.4 Regimen surveys	7
2. Standardized stratification of results by patient categories	8
2.1 Patient treatment history classifications	8
2.2 Age groups, sex, HIV status, and other patient biographical and clinical factors	10
3. Quality-assured laboratory methods for determining resistance to first- and second-line drugs	13
3.1 WHO-recommended methods of drug susceptibility testing	13
3.2 Consensus on critical concentrations for first- and second-line drug susceptibility testing	15
3.3 Selection of drugs to be tested for susceptibility	17
3.4 Quality assurance of drug susceptibility testing	18
3.4.1 Internal quality control	18
3.4.2 External quality assessment and the role of the Supranational Reference Laboratory Network (SRLN)	19
4. Ethical considerations	21

Part II. Conducting a survey	23
5. Survey planning	25
5.1 Setting specific objectives	25
5.2 Development of a protocol and time schedule	26
5.3 Minimum required facilities for a survey area	26
5.4 Sampling of cases	27
5.4.1 Defining the sampling frame	28
5.4.2 Sample size	29
5.4.3 Sampling strategies	30
5.5 Formation of a national coordination team	32
5.6 Budgeting	33
5.7 Training	33
5.8 Laboratory preparedness	34
5.9 Pilot study	35
6. Survey logistics	36
6.1 Inclusion and exclusion criteria	36
6.2 Patient intake	36
6.2.1 Clinical information form	37
6.3 Sputum collection, processing and transport	38
6.4 Central reference laboratory processes	39
6.4.1 Decontamination	39
6.4.2 Cultures	39
6.4.3 Identification	40
6.4.4 Internal quality assurance at the survey laboratory	41
6.4.5 Susceptibility testing, including rechecking	41
7. Survey data management and analysis	43
7.1 Data management	43
7.2 Data analysis	44
7.2.1 Imputation of missing values	46
7.2.2 Sampling design effects on standard errors	47
7.2.3 Other considerations for data analysis	48
7.3 Interpretation of results	49
References	51

Annexes	55
Annex 1a First-line anti-tuberculosis drug resistance results	57
Annex 1b Second-line anti-tuberculosis drug resistance results	59
Annex 1c Multidrug resistance stratified by age groups and sex	60
Annex 1d Multidrug resistance stratified by patient HIV status	61
Annex 2 Supranational reference laboratory list	62
Annex 3a Example of a proficiency testing results form (first-line drugs)	65
Annex 3b Example of a proficiency testing results form (second-line drugs)	66
Annex 4a Example of a proficiency testing analysis sheet (first-line drugs)	67
Annex 4b Example of a proficiency testing analysis sheet (second-line drugs)	68
Annex 5a Example of a rechecking analysis sheet (first-line drugs)	69
Annex 5b Example of a rechecking analysis sheet (second-line drugs)	70
Annex 6 Drug resistance survey protocol checklist	71
Annex 7 Weighted cluster sampling	74
Annex 8 Survey budget template	76
Annex 9 Example of a clinical information form	77
Annex 10 Safe shipment of infectious material	79
Annex 11 Sample size for rechecking TB strains	80

预览已结束，完整报告链接和二维码如下：

https://www.yunbaogao.cn/report/index/report?reportId=5_29212

