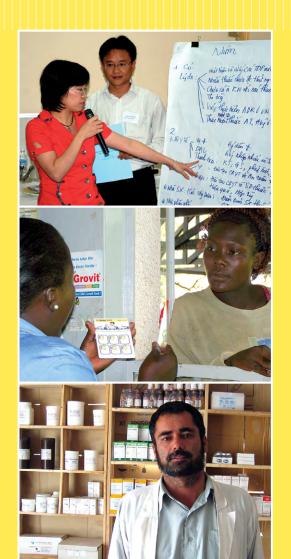




# Managing Access to Medicines and Health Technologies





Copyright © 2012 Management Sciences for Health, Inc. All rights reserved.

Teachers, trainers, and facilitators may make printouts or photocopies of chapters from this book for noncommercial use, for students or participants in a training program, without prior permission, provided that Management Sciences for Health (MSH) is acknowledged. Use of the whole book requires prior written permission from the publisher. Any translation, adaptation, or commercial use of any part of this book in any form or medium requires the prior written permission of the publisher. A permission request form is provided on the MSH website: http://www.msh.org/resource-center/ebookstore/copyright.cfm.

Management Sciences for Health Attn: Managing Drug Supply 4301 North Fairfax Drive, Suite 400 Arlington, VA 22203 USA Tel.: +1-703-524-6575 Fax: +1-703-524-7898 E-mail: mds@msh.org Website: www.mds-online.org

#### Acknowledgments

The development of MDS-3: Managing Access to Medicines and Health Technologies was largely supported through the Strategies for Enhancing Access to Medicines grant from the Bill & Melinda Gates Foundation. The opinions expressed herein are those of the authors and do not necessarily reflect the views of the Gates Foundation.

#### **Recommended Citation**

Management Sciences for Health. 2012. MDS-3: Managing Access to Medicines and Health Technologies. Arlington, VA: Management Sciences for Health.

Technical Writer Reference Reviewer and Editor Karen Frenchu

Martha Embrey Illustrators

Managing Editor Eustace Githonga

Marian Ryan Uto Hogerzeil

Tony Namate

Edna Jamandre Cover Photo Credits

(from top to bottom)

Copyeditor (from top to bottom)

Laura Glassman Michael Paydos (Tanzania)

Martha Embrey (Kenya)

Proofreaders David Lee (Vietnam)

Karen Weller-Watson Saul Kidde (Uganda)

Robin O. Surratt Mark Morris (Afghanistan)

## **Contributors by Chapter**

This list shows the technical contributors to each chapter and their professional affiliations and locations at the time of their contribution—not necessarily their current affiliation and location. Contributors are listed alphabetically, not in relation to the proportion of material they contributed. Many chapters retain a substantial proportion of text from the first two editions of this book. Authors from earlier editions are indicated by an asterisk. Authors who contributed to both the current and previous editions are indicated with a dagger.

#### 1. Toward Sustainable Access to Medicines

Martha Embrey, MSH, USA

- \*Graham Dukes, Euro Health Group, Norway
- \*Jonathan D. Quick, MSH, USA

#### 2. Historical and Institutional Perspectives

†Graham Dukes, University of Oslo, Norway Helena Walkowiak, MSH, USA

\*Ronald W. O'Connor, MSH, USA

#### 3. Intellectual Property and Access to Medicines

Sisule Musungu, South Centre, Switzerland

#### 4. National Medicine Policy

†Graham Dukes, University of Oslo, Norway

\*Pascale Brudon, World Health Organization (WHO), Switzerland

#### 5. Traditional and Complementary Medicine Policy

Torkel Faulkenberg, Karolinska Institutet, Sweden

#### 6. Pharmaceutical Legislation and Regulation

Enrique Fefer, Consultant, USA

- \*Graham Dukes, Euro Health Group, Norway
- \*Marcelo Vernengo, Universidad de Belgrano, Argentina
- \*Robert L. Watt

#### 7. Pharmaceutical Production Policy

Martha Embrey, MSH, USA

- \*John Holley, Integral Development Associates, USA
- \*Paul J. N. Lamberts, Deventer Hospital Pharmacy, The Netherlands
- \*Ronald W. O'Connor, MSH, USA
- \*Robert L. Watt

#### 8. Pharmaceutical Supply Strategies

Malcolm Clark, MSH, Australia

- \*Jonathan D. Quick, MSH, USA
- \*James R. Rankin, MSH, USA
- \*Germán Velásquez, WHO, Switzerland

#### 9. Pharmaceutical Pricing Policy

David Henry, University of Newcastle, Australia Andrew Searles, University of Newcastle, Australia

#### 10. Economics for Pharmaceutical Management

†David Henry, University of Newcastle, Australia

- \*Kara Hanson, Harvard School of Public Health, USA
- \*Jonathan D. Quick, MSH, USA
- \*Germán Velásquez, WHO, Switzerland

#### 11. Pharmaceutical Financing Strategies

Martha Embrey, MSH, USA

- \*William Newbrander, MSH, USA
- \*Jonathan D. Quick, MSH, USA
- \*Catriona Waddington, Overseas Development Administration, UK

## ${\bf 12.\,Pharmaceutical\,Benefits\,in\,Insurance\,Programs}$

John Chalker, MSH, UK

#### 13. Revolving Drug Funds and User Fees

Martha Embrey, MSH, USA

- \*Margaret Hume, MSH, USA
- \*Jennie I. Litvack, World Bank, USA
- \*Jonathan D. Quick, MSH, USA

#### 14. Global and Donor Financing

Logan Brenzel, World Bank, USA

- \*Enrique Fefer, Pan American Health Organization, USA
- \*Margaret Hume, MSH, USA
- \*Irene Klinger, Pan American Health Organization, USA

#### 15. Pharmaceutical Donations

Malcolm Clark, MSH, Australia Martha Embrey, MSH, USA

\*Christel Albert

\*Hans Hogerzeil, WHO, Switzerland

#### 16. Managing Medicine Selection

Christopher Olson, MSH, USA

\*Hans Hogerzeil, WHO, Switzerland

#### 17. Treatment Guidelines and Formulary Manuals

Christopher Olson, MSH, USA

\*Chris Forshaw, WHO, Malawi

\*Hans Hogerzeil, WHO, Switzerland

#### 18. Managing Procurement

Andrew Barraclough, MSH, Thailand Malcolm Clark, MSH, Australia

\*David Lee, MSH, USA

\*Jonathan D. Quick, MSH, USA

#### 19. Quality Assurance for Pharmaceuticals

Thomas Layloff, MSH, USA

\*David Lee, MSH, USA

\*Jonathan D. Quick, MSH, USA

#### 20. Quantifying Pharmaceutical Requirements

Laila Akhlaghi, MSH, USA

\*Christopher Olson, MSH, USA

\*James R. Rankin, MSH, USA

#### 21. Managing the Tender Process

Malcolm Clark, MSH, Australia

Ned Heltzer, MSH, USA

James Rankin, MSH, USA

\*Johan van Haperen, Danida, Denmark

#### 22. Managing Distribution

Malcolm Clark, MSH, Australia

\*Anthony Battersby, Feilden Battersby Health Systems Analysts, UK

\*James Bates, MSH, USA

\*Andrew Garnett, Feilden Battersby Health Systems Analysts, UK

#### 23. Inventory Management

Vimal Dias, MSH, Sri Lanka

\*Jonathan D. Quick, MSH, USA

\*James R. Rankin, MSH, USA

#### 24. Importation and Port Clearing

†Hilary Vaughan, Crown Agents, UK

\*Vimal Dias, MSH, Sri Lanka

\*John Ellery, Greenshields Cowie, UK

#### 25. Transport Management

Gabriel Daniel, MSH, USA

\*Anthony Battersby, Feilden Battersby Health Systems Analysts, UK

\*Andrew Garnett, Feilden Battersby Health Systems Analysts, UK

#### 26. Kit System Management

Henk den Besten, IDA Solutions, The Netherlands \*Miguel de Clerck, Médecins sans Frontières,

Switzerland

\*Jean-Pierre de Lamalle, Médecins sans Frontières, Switzerland

\*Myriam Henkens, Médecins sans Frontières, Switzerland

\*Hans Hogerzeil, WHO, Switzerland

\*Ignacio J. Packer, Médecins sans Frontières, Switzerland

#### 27. Managing for Rational Medicine Use

John Chalker, MSH, UK

\*Richard O. Laing, MSH, USA

\*Budiono Santoso, Gadjah Mada University, Indonesia

#### 28. Investigating Medicine Use

Lloyd Matowe, MSH, USA

\*Dennis Ross-Degnan, Harvard University, USA

#### 29. Promoting Rational Prescribing

John Chalker, MSH, UK

\*Richard O. Laing, MSH, USA

\*David Ofori-Adjei, University of Ghana Medical School, Ghana

\*Christopher Olson, MSH, USA

\*Budiono Santoso, Gadjah Mada University, Indonesia

#### 30. Ensuring Good Dispensing Practices

†Paul Spivey, Consultant, UK

#### 31. Community-Based Participation and Initiatives

Jane Briggs, MSH, Guatemala

\*Aida Girma, United Nations Children's Fund (UNICEF), USA

#### 32. Drug Seller Initiatives

Malcolm Clark, MSH, USA Ned Heltzer, MSH, USA Keith Johnson, MSH, USA Robert Staley, MSH, USA

# 33. Encouraging Appropriate Medicine Use by Consumers

Consumers

Keith Johnson, MSH, USA

\*Daphne A. Fresle, WHO, Switzerland

#### 34. Medicine and Therapeutics Information

Keith Johnson, MSH, USA

\*O. M. J. Kasilo, University of Zimbabwe Medical School, Zimbabwe

#### 35. Pharmacovigilance

Christopher Olson, MSH, USA

#### 36. Pharmaceutical Supply Systems Assessment

Martha Embrey, MSH, USA

\*James R. Rankin, MSH, USA

#### 37. Managing Pharmaceutical Programs

Sylvia Vriesendorp, MSH, USA

\*Jonathan D. Quick, MSH, USA

#### 38. Planning for Pharmaceutical Management

Malcolm Clark, MSH, Australia

\*James Bates, MSH, USA

\*A. Frederick Hartman

\*Jonathan D. Quick, MSH, USA

#### 39. Contracting for Pharmaceuticals and Services

Raj Gonsalkorale, Consultant, Australia

\*Elvira Beracochea, MSH, USA

\*Vimal Dias, MSH, Sri Lanka

\*Sherita Gregoire, Goodwill, Dominica

\*Jonathan D. Quick, MSH, USA

# **40.** Analyzing and Controlling Pharmaceutical Expenditures

†James Rankin, MSH, USA

\*Peter Graaff, WHO, Malawi

\*Vimal Dias, MSH, Sri Lanka

\*Jonathan D. Quick, MSH, USA

#### 41. Financial Planning and Management

David J. Walsh, Consultant, UK

\*David H. Collins, MSH, USA

#### 42. Planning and Building Storage Facilities

†Andrew Garnett, Consultant, UK

\*Jan F. Dik, Euro Health Group, Denmark

\*Therese Edera-Piech, Design Development, Kenya

#### 43. Security Management

Gabriel Daniel, MSH, USA

\*Jonathan D. Quick, MSH, USA

#### 44. Medical Stores Management

†Vimal Dias, MSH, Sri Lanka

\*Anthony Battersby, Feilden Battersby Health Systems Analysts, UK

- \*Andrew Garnett, Feilden Battersby Health Systems Analysts, UK
- \*Jean-Pierre Sallet, MSH, South Africa
- \*John C. Turnbull

#### 45. Hospital Pharmacy Management

†Christopher Olson, MSH, USA

\*Anthony Savelli, MSH, USA

#### 46. Pharmaceutical Management for Health Facilities

Jean-Pierre Sallet, MSH, South Africa

\*Richard O. Laing, MSH, USA

\*Hanif S. Nazerali

#### 47. Laboratory Services and Medical Supplies

Catherine Mundy, MSH, USA

\*Hans Hogerzeil, WHO, Switzerland

\*Kirsten Myhr, University of Trondheim, Norway

#### 48. Monitoring and Evaluation

Maria Miralles, MSH, USA

\*Agnes B. Guyon, UNICEF, USA

\*Jonathan D. Quick, MSH, USA

#### 49. Pharmaceutical Management Information Systems

Julie Frye, MSH, USA

\*David R. Wilson, MSH, USA

#### 50. Computers in Pharmaceutical Management

†Julie Frye, MSH, USA

\*Wilbert Bannenberg

\*Paul Krystall, Data Dynamics, USA

\*Jonathan D. Quick, MSH, USA

\*James R. Rankin, MSH, USA

\*Jean-Pierre Sallet, MSH, South Africa

# 51. Human Resources Management and Capacity Development

Ummuro Adano, MSH, USA

Mary O'Neil, MSH, USA

\*Carl F. Browne, Ministry of Health and the

Environment, St. Vincent and the Grenadines

\*John Fox, Intermedia, USA

#### 52. Designing and Implementing Training Programs

Ross Holland, MSH, USA

\*Sam Muziki, WHO, Switzerland

\*A. Frederick Hartman

## **Reviewers**

Reviewers provided feedback on one or more chapters. Reviewers' professional affiliations and locations are from the time of their review—not necessarily their current affiliation and location. Their input does not necessarily reflect the views of their employers.

Frances Aboagye-Nyame	MSH, USA	Rama Lakshminarayanan	World Bank, USA
Syed Rizwanuddin Ahmad	USA	David Lee	MSH, USA
Samvel Azatyan,	WHO, Switzerland	Evan Lee	MSH, France
Guitelle Baghdadi-Sabeti	WHO, Switzerland	Andrew Marsden	MSH, France
Andrew Barraclough	MSH, Thailand	Lloyd Matowe	MSH, USA
Hare Ram Bhattarai	MSH, Nepal	Thomas Moore	MSH, USA
Tina Brock	MSH, USA	Gail Naimoli	MSH, USA
Malcolm Bryant	MSH, USA	Bannet Ndyanabangi	MSH, USA
Robert Burn	MSH, USA	William Newbrander	MSH, USA
Edelisa Carandang	WHO, Switzerland	Christopher Olson	MSH, USA
Peter Carrasco	WHO, Switzerland	Patricia Paredes,	MSH, USA
John Chalker	MSH, UK	Alain Prat	WHO, Switzerland
Malcolm Clark	MSH, Australia	Jonathan Quick	MSH, USA
Peter Cross	MSH, USA	James Rankin	MSH, USA
Gabriel Daniel	MSH, USA	Steve Reed	MSH, USA
Vimal Dias	MSH, Sri Lanka	Andreas Seiter	World Bank, USA
Alex Dodoo	University of Ghana	John Sheptor	MSH, USA
	Medical School, Ghana	Rima Shretta	MSH, USA
Alison Ellis	MSH, USA	Anthony So	Duke University, USA
Marthe Everard	WHO, Switzerland	Robert Staley	MSH, USA
Julie Frye	MSH, USA	Helen Tata	WHO, Switzerland
Michael Gabra	MSH, USA	Linda Tawfik	MSH, USA
Louis Garrison	University of Washington	Dat Tran	MSH, USA
	School of Pharmacy, USA	Anita Wagner	Harvard University, USA
Natalie Gaul	MSH, USA	Helena Walkowiak	MSH, USA
Nigel Gericke	Consultant, South Africa	Hella Witt	MSH, USA
Raj Gonsalkorale	Consultant, Australia	Andre Zagorski	MSH, USA
Ned Heltzer	MSH, USA	Xiaorui Zhang	WHO, Switzerland
Suzanne Hill	WHO, Switzerland	<u> </u>	
Hans Hogerzeil	WHO, Switzerland		
Kathleen Holloway	WHO, Switzerland		
Keith Johnson	MSH, USA		
Mohan Joshi	MSH, USA		
Charles Kagoma,	MSH, Tanzania		
Grace Kahenya	MSH, Zambia		
Richard Laing	WHO, Switzerland		

# **Contents**

#### Preface

How to Use MDS-3

#### Part I Policy and Economic Issues

#### Policy and Legal Framework

- 1 Toward Sustainable Access to Medicines
- 2 Historical and Institutional Perspectives
- 3 Intellectual Property and Access to Medicines
- 4 National Medicine Policy
- 5 Traditional and Complementary Medicine Policy
- 6 Pharmaceutical Legislation and Regulation
- 7 Pharmaceutical Production Policy
- 8 Pharmaceutical Supply Strategies

#### Financing and Sustainability

- 9 Pharmaceutical Pricing Policy
- 10 Economics for Pharmaceutical Management
- 11 Pharmaceutical Financing Strategies
- 12 Pharmaceutical Benefits in Insurance Programs
- 13 Revolving Drug Funds and User Fees
- 14 Global and Donor Financing
- 15 Pharmaceutical Donations

#### Part II Pharmaceutical Management

#### Selection

- 16 Managing Medicine Selection
- 17 Treatment Guidelines and Formulary Manuals

#### Procurement

- 18 Managing Procurement
- 19 Quality Assurance for Pharmaceuticals
- 20 Quantifying Pharmaceutical Requirements
- 21 Managing the Tender Process

#### Distribution

- 22 Managing Distribution
- 23 Inventory Management
- 24 Importation and Port Clearing
- 25 Transport Management
- 26 Kit System Management

#### Use

- 27 Managing for Rational Medicine Use
- 28 Investigating Medicine Use
- 29 Promoting Rational Prescribing
- 30 Ensuring Good Dispensing Practices
- 31 Community-Based Participation and Initiatives
- 32 Drug Seller Initiatives
- 33 Encouraging Appropriate Medicine Use by Consumers
- 34 Medicine and Therapeutics Information
- 35 Pharmacovigilance

#### Part III Management Support Systems

#### Planning and Administration

- 36 Pharmaceutical Supply Systems Assessment
- 37 Managing Pharmaceutical Programs
- 38 Planning for Pharmaceutical Management
- 39 Contracting for Pharmaceuticals and Services
- 40 Analyzing and Controlling Pharmaceutical Expenditures
- 41 Financial Planning and Management
- 42 Planning and Building Storage Facilities

#### Organization and Management

- 43 Security Management
- 44 Medical Stores Management
- 45 Hospital Pharmacy Management
- 46 Pharmaceutical Management for Health Facilities
- 47 Laboratory Services and Medical Supplies

#### Information Management

- 48 Monitoring and Evaluation
- 49 Pharmaceutical Management Information Systems
- 50 Computers in Pharmaceutical Management

#### Human Resources Management

- 51 Human Resources Management and Capacity Development
- 52 Designing and Implementing Training Programs

#### Index

# **Preface**

It is my great pleasure to present MDS-3: Managing Access to Medicines and Health Technologies. In the thirty years since the original publication of Managing Drug Supply, the world has experienced remarkable changes as the global health context has evolved. Think, for example, about the profound impact that HIV/AIDS alone has had. Advances in science and medicine, donor funding for vast global health initiatives, the advent of innovative information technologies, and a greater focus on building strong health systems have fundamentally affected our work. What has not changed over the years is MSH's commitment to identifying problems in access to and use of medicines and designing and implementing relevant, effective responses. We hope that MDS-3 will be a valuable tool in the effort to ensure universal access to quality medicines and health technologies and their appropriate use.

The new and updated information in *MDS-3* reflects the dramatic changes in the public health landscape. Nearly 100 experts from a wide range of disciplines and virtually every corner of the world have contributed to this third edition. In addition to new country studies, references, and extensive revisions, *MDS-3* offers new chapters on areas such as pharmaceutical benefits in insurance programs, pricing, intellectual property, drug seller initiatives, and traditional and complementary medicine. The revisions and new chapters echo the wide variety of issues that are important to health practitioners and policy makers today. Even the book's new title depicts the need to broaden our focus from medicines to include *health technologies*, such as test kits and laboratory supplies, and to embrace the concept of *access*. Too often people assume that if medicines and technologies are available, positive health outcomes will naturally result. Access, however, encompasses not only product availability, but also the need to provide medicines and pharmaceutical services that are safe, efficacious, cost-effective, and high quality. Equally important are affordability and acceptability, including cultural and personal preferences.

We hope that *MDS-3* will be used widely by those with an interest in improving access to medicines and health technologies. To make the book accessible to as many users as possible, we are making the content available in several formats. The easiest way to access *MDS-3* is online at http://www.mds-online.org. The entire book can be searched online, and individual chapters can be downloaded. *MDS-3* is also available directly from MSH on flash drive or CD-ROM for those without reliable Internet access or who prefer these media. We are working on an arrangement to make print copies available as well.

As users of *MDS-3*, you are vital to ensuring that it remains a valuable and dynamic resource. Your suggestions for enriching and updating the information and improving its presentation are greatly welcome. We will update individual chapters as needed to provide new material in a timely manner. Please send suggestions to us at mds@msh.org.

We acknowledge with great appreciation all the authors, reviewers, and others whose efforts are reflected in *MDS-3*. Any contribution that *MDS-3* makes is a direct result of their knowledge, experience, and deep dedication—and of the hard work of those around the world who each day strive to help their countries and their programs realize the full health impact of ensuring access to medicines and health technologies for all.

**Jonathan D. Quick, MD, MPH**President and Chief Executive Officer
Management Sciences for Health
February 2012

## How to Use MDS-3

*MDS-3: Managing Access to Medicines and Health Technologies* may seem intimidating, but you do not need to read it from cover to cover. To ease accessibility, we have organized its content to present a sequential overview of major topics and then within each section to provide more detailed explanations of fundamental concepts, definitions of basic terms, and practical ideas for designing and implementing effective changes in pharmaceutical management systems.

The following features make the material accessible to readers looking for information in specific areas.

Overview chapters. Starting with Part II, Pharmaceutical Management, overview chapters introduce each element in the pharmaceutical management framework: selection (Chapter 16), procurement (Chapter 18), distribution (Chapter 22), use (Chapter 27), and management (Chapter 37). These overview chapters provide background information that lays the foundation for more detailed discussions of specific topics in the the chapters that follow them.

**Chapter summaries.** Each chapter begins with a summary of its contents. Readers who are interested in a brief overview of an area or of all aspects of managing access to medicines can read the relevant summaries.

**Country studies.** Reports of experiences in various countries illustrate points in the text. Although conditions in some countries may have changed since these country studies were written, they provide useful examples of the ways in which the pharmaceutical management process can operate, and in some cases, how it should not operate.

**Boxes.** Boxes are used to make information, such as the steps of a process, easy to locate and use. In addition, some boxes contain general experiences or descriptions of relevant initiatives or resources.

**Glossaries.** Glossaries are included for the chapters on intellectual property (Chapter 3), insurance (Chapter 12), selection (Chapter 16), procurement (Chapter 18), distribution (Chapter 22), use (Chapter 27), management (Chapter 37), analyzing expenditures (Chapter 40), financial management (Chapter 41), storage facilities (Chapter 42), and computers (Chapter 51).

**References and further readings.** Each chapter contains a list of references cited in the text or that relate to topics the chapter covers. Particularly useful references are indicated by a star.

**Chapter annexes.** Annexes provide sources of additional information and samples of pharmaceutical management forms currently in use in various parts of the world.