



## Improving Access to Essential Medicines for Mental, Neurological, and Substance Use Disorders in Sub-Saharan Africa: Workshop Summary

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Diane E. Pankevich, Sheena M. Posey Norris, Theresa M. Wizemann, and Bruce M. Altevogt, Rapporteurs; Forum on Neuroscience and Nervous System Disorders; Board on Health Sciences Policy; Board on Global Health; Institute of Medicine

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**IMPROVING ACCESS TO  
ESSENTIAL MEDICINES FOR  
MENTAL, NEUROLOGICAL,  
AND SUBSTANCE USE  
DISORDERS IN  
SUB-SAHARAN AFRICA**

**WORKSHOP SUMMARY**

Forum on Neuroscience and  
Nervous System Disorders

Board on Health Sciences Policy

Board on Global Health

Diana E. Pankevich, Sheena M. Posey Norris,  
Theresa M. Wizemann, and Bruce M. Altevogt,  
*Rapporteurs*

**INSTITUTE OF MEDICINE**  
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The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The serpent adopted as a logotype by the Institute of Medicine is a relief carving from ancient Greece, now held by the Staatliche Museen in Berlin.

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Willing is not enough; we must do.”*  
—Goethe



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**DIANA E. PANKEVICH**, Program Officer  
**SHEENA M. POSEY NORRIS**, Research Associate  
**RACHEL J. KIRKLAND**, Senior Program Assistant (*until April 2014*)

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## Reviewers

This workshop summary has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published workshop summary as sound as possible and to ensure that the workshop summary meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the process. We wish to thank the following individuals for their review of this workshop summary:

**Albert Akpalu**, Korle Bu Teaching Hospital

**François Bompert**, Sanofi

**Marcelo Cruz**, Padre Carollo Hospital

**Hans Hogerzeil**, Groningen University

**Prashant Yadav**, University of Michigan

Although the reviewers listed above have provided many constructive comments and suggestions, they did not see the final draft of the workshop summary before its release. The review of this workshop summary was overseen by **Brian Strom**, Rutgers, The State University of New Jersey. Appointed by the Institute of Medicine, he was responsible for making certain that an independent examination of this workshop summary was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this workshop summary rests entirely with the rapporteurs and the institution.



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# 1

## Introduction and Overview<sup>1</sup>

Approximately one-third of the developing world's population does not have regular access to essential medicines. The World Health Organization (WHO) defines essential medicines as “those that satisfy the priority health care needs of the population and are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and community can afford. Essential medicines are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness.”<sup>2</sup>

In 2011 the Grand Challenges in Global Mental Health initiative identified priorities that have the potential to make a significant impact on the lives of people with mental, neurological, and substance use (MNS)<sup>3</sup> disorders (Collins et al., 2011). Reduction of the cost and improvement of the supply of effective medicines was highlighted as one of the top five challenges. For low- and middle-income countries, improving access to appropriate essential medicines can be a tremendous

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<sup>1</sup>The planning committee's role was limited to planning the workshop, and the workshop summary has been prepared by the workshop rapporteurs as a factual summary of what occurred at the workshop. Statements, recommendations, and opinions expressed are those of individual presenters and participants, and are not necessarily endorsed or verified by the Institute of Medicine, and they should not be construed as reflecting any group consensus.

<sup>2</sup>See [http://www.who.int/medicines/services/essmedicines\\_def/en](http://www.who.int/medicines/services/essmedicines_def/en).

<sup>3</sup>The phrase “MNS disorders” is used throughout this summary to refer broadly to the wide range of mental, neurological, and substance use disorders. This terminology, first adopted by the participants at the 2009 Institute of Medicine (IOM) workshop on reducing the treatment gap for MNS disorders in sub-Saharan Africa (IOM, 2009a), and subsequently used for the 2012 IOM workshop on strengthening human resources (IOM, 2012), has been retained for the current workshop.



challenge and a critical barrier to scaling up quality care for MNS disorders. Reduction of cost and improvement of the supply of effective medicines has the potential to significantly impact the lives of patients with these disorders.

## ORIGINS OF THE WORKSHOP

Recognizing the importance of quality of care for MNS disorders and the limitations of most sub-Saharan Africa (SSA) countries in treating such conditions, the Institute of Medicine (IOM) Forum on Neuroscience and Nervous System Disorders and the Forum on Health and Nutrition of the Uganda National Academy of Sciences convened a joint workshop in 2009 in Kampala, Uganda, to address these issues (IOM, 2009a). The purpose of this meeting was to assess the current state of quality of care for MNS disorders and to elucidate, identify, and prioritize areas that might benefit from improvements that could build on the preexisting or easily obtainable infrastructure. Among the opportunities discussed to decrease the treatment gap and improve the quality of care were:

- increasing the number of health care providers with expertise in MNS disorders; and
- improving access to medicines to treat MNS disorders.

As a result of the discussions from the 2009 workshop, the IOM Neuroscience Forum convened two more workshops focused on these specific opportunities. The first took place in Kampala, Uganda, in 2012, bringing together key stakeholders to discuss candidate core competencies that providers might need to help ensure the effective delivery of services (IOM, 2013d).<sup>4</sup> The workshop focused on four MNS disorders that account for the greatest burden in low- and middle-income countries: depression, psychosis, epilepsy, and alcohol use. Individual workshop participants discussed a series of candidate core competencies for non-specialized and specialized providers. Competencies were related to three specific areas: screening/identification, formal diagnosis/referral, and treatment/care. It was noted by many workshop participants that the

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<sup>4</sup>See <http://www.iom.edu/reports/2013/Strengthening-Human-Resources-Through-Development-of-Candidate-Core-Competencies-for-Mental-Neurological-and-Substance-Use-Disorders-in-Sub-Saharan-Africa.aspx>.

candidate core competencies might apply beyond the four disorders discussed to all MNS disorders. Participants were invited to consider the future needs of MNS health care providers, discuss potential mechanisms for task-shifting and task-sharing, explore potential methods for acquiring and maintaining core competencies, and consider tangible next steps for dissemination of the identified candidate core competencies and performance requirements and for adaption based on specific country needs.

Given the importance of access to appropriate essential medicines to help decrease the treatment gap of MNS disorders in SSA, the IOM Neuroscience Forum convened a third workshop on January 13-14, 2014, in Addis Ababa, Ethiopia. The goal of the workshop was to bring together key stakeholders to discuss opportunities for achieving long-term affordable access to medicines for MNS disorders. His Excellency Amir Aman, State Minister of Health at the Federal Ministry of Health (FMOH) in Ethiopia, welcomed participants to the workshop. He stated that having the workshop in Ethiopia was important as the country continues to make strides in reducing the treatment gap for MNS disorders. The development in 2011 of the Ethiopian National Mental Health Strategy was a critical milestone in the country's journey toward increasing quality, effective, and accessible MNS care for all, he said (FMOH, 2011). In the past 5 years, there has been a significant increase in the number of psychotropic medicines on the FMOH's Essential List of Drugs, and the demand for and supplies of these medicines has increased as well.

Tedla Giorgis, advisor to the Ethiopian FMOH, charged participants to consider the opportunities for improving access to essential medicines (see Box 1-1, Statement of Task). Giorgis called on participants to consider frameworks and strategies for increasing access to quality medicines for MNS disorders in SSA by learning from successful activities in other countries and for different diseases.

**BOX 1-1**  
**Statement of Task**

- Identify critical barriers that impact the procurement of essential medicines for mental, neurological, and substance use (MNS) disorders.

- Explore challenges and opportunities for improving access to essential medicines in four critical areas: demand, selection, supply chains, and financing and pricing.
- Examine successful activities that increase access to essential medicines both within sub-Saharan Africa (SSA) and in other developing countries.
  - Identify critical components of these models that might be features in SSA programs focused on MNS disorders.
- Consider the role of governments, nongovernmental organizations, and private groups in procurement of essential medicines for MNS disorders.
  - Examine current funding and payment practices at each level.
  - Explore the impact of prescription practices on determining priority setting for acquiring essential medicines.
- Identify the key components of a distribution framework that may serve as a demonstration project focused on increasing access for three essential medicines.

## **ORGANIZATION OF THE WORKSHOP AND REPORT**

In addition to several overview presentations, the workshop was organized around a series of focused discussions on challenge areas identified by the workshop planning committee: insufficient demand, inappropriate selection, ineffective supply chains, and high pricing and poor financing. In the first session, experts presented their individual definition of each challenge area and their perspectives on barriers and opportunities for improving access to medicines across the challenge area (see Box 1-2).

### **BOX 1-2 Defining the Challenges**

#### **Insufficient Demand**

Demand for medications to treat mental, neurological, and substance use (MNS) disorders in sub-Saharan Africa (SSA) is driven by several, often inter-related, factors. Factors that influence help-seeking for MNS disorders, their recognition and adequacy of treatment, and the dynamics of supply are important in any consideration of how to improve demand. (Oye Guerje)

**Inappropriate Selection**

Selection of essential medicines for MNS disorders poses several specific challenges: (1) the effectiveness of many medicines for MNS disorders cannot easily be established, as treatment effects are difficult to assess; (2) the cost-effectiveness of most MNS treatments is not very well established, especially for newly developed medicines, which are often costly; and (3) many psychiatrists prefer to use a range of different medicines in the same therapeutic category in order to adapt to individual treatment response and patient preferences. Contrary to short-term treatments, long-term medications are a challenge to the supply system and pose a real threat of catastrophic health expenditure to the patient. A rights-based approach, focusing on a small range of proven cost-effective medicines, is the best guarantee for equitable access to medical treatment of MNS disorders. (Hans Hogerzeil)

**Ineffective Supply Chains**

Improved access to medicines for MNS disorders requires a well-functioning supply chain that delivers these medicines to the end population affordably, reliably, robustly, and in an equitable manner. Numerous challenges exist in the supply chains for MNS medicines, including (1) low levels of current use, often due to lack of provider and patient awareness, leading many supply chain actors to believe the true demand is low; (2) MNS medicines are currently only offered in selected secondary and tertiary health facilities requiring long travel time for patients without a guarantee of access; and (3) carrying out procurement, storage, and distribution of the product from point of production to point of consumption is challenging while maintaining high quality, product integrity, and minimizing diversion or misuse. (Prashant Yadav)

**High Pricing and Poor Financing**

Relatively little is known about the price, availability, and affordability of medicines to treat mental health conditions in SSA countries. Where there are data, medicine availability is poor especially in the public sector, forcing patients to purchase in the private sector where prices are unaffordable. (Margaret Ewen)

Appropriate provision of essential medicines is being held back by a lack of affordability as well as by a lack of service access. Although most essential medicines for MNS disorders are inherently cheap (at the point of production), a combination of import tariffs, sales taxes, mark-ups, and other charges raises the

cost to end-users by a considerable—and for the poor, an unmanageable—degree. In populations with low or nonexistent health insurance/financial protection, out-of-pocket spending on medicines for MNS disorders and other costs of care represents a critical barrier to access as well as a potential source of impoverishment. (Dan Chisholm)

NOTE: The above statements are the perspective of the individual speakers. These statements were presented to stimulate discussion and do not reflect group consensus.

In the next session, individual speakers presented examples of programs addressing access to medicines to facilitate exploration of best practices and lessons learned from other acquisition and distribution models (see Appendix A). The examples were selected for inclusion by the workshop planning committee and serve to explore various efforts across the globe focused on improving access in low- and middle-income countries. The program examples are meant to provide potential ideas and solutions for each of the challenge areas and are not comprehensive nor a complete examination of literature or information available but the perspective of the individual speakers. The examples included two country-level programs, the Ghana National Health Insurance Scheme (NHIS) and the Accredited Drug Dispensing Outlet (ADDO) program in Tanzania; efforts to increase access to treatments for an infectious disease, multidrug-resistant tuberculosis (MDR-TB); and programs for two noncommunicable diseases, Novo Nordisk's program aimed at treating diabetes and Sanofi's Access to Medicines program focusing on schizophrenia. Following the overview and example presentations, individual participants engaged in focused discussions to further explore opportunities to improve access to essential medicines for MNS disorders. The workshop closed with overviews and a broader discussion.

The following report summarizes the presentations and discussions by the expert panelists and individual participants. The report is divided according to the four challenge areas: insufficient demand (Chapter 2), inappropriate selection (Chapter 3), ineffective supply chains (Chapter 4), and high pricing and poor finance (Chapter 5). Included in each of these chapters are lessons learned from the examples presented and tables of barriers and potential opportunities that were raised during

discussions with individual workshop participants. Lastly, practical considerations for moving forward are summarized in Chapter 6.

During the focused discussions, individual participants engaged in active dialogues on the constraints, barriers, and opportunities related to demand, selection, supply chains, and pricing and financing. In some cases, participants expressed varying opinions about whether a particular opportunity could be useful and included in the list. It is important to note that the workshop was not designed or conducted as a consensus process and the barriers and opportunities described in this report are not a formal consensus product of the workshop. Rather, they are a compilation of all comments by workshop participants and should be attributed to the rapporteurs of this summary as informed by the workshop.

Throughout the workshop, many participants employed the phrase “mental health” in reference to health care systems and essential medicines. Many of the same participants commented that their use of the term “mental health” as it related to the workshop discussions was meant to be inclusive of all MNS disorders.

### **BARRIERS TO ACCESS TO ESSENTIAL MEDICINES FOR MNS DISORDERS**

Sub-Saharan Africa has one of the largest treatment gaps for MNS disorders. Atalay Alem, professor of psychiatry at Addis Ababa University, said that on average, two-thirds of those with MNS disorders do not receive treatment and access to appropriate essential medicines for these disorders remains a challenge. Alem noted that globally, the median percentage of government health budget expenditures dedicated to MNS disorders is slightly less than 3 percent, and country income level does not fully account for the lower levels of funding for MNS disorders (WHO, 2011a). In addition, compared to all other WHO regions, Africa has the lowest number of outpatient facilities with the ability to treat MNS disorders, rates of admission to mental hospitals, and human resources (WHO, 2011a). Alem noted that, even if essential medicines for MNS disorders are available in a country, the absence of trained health care providers to diagnose and treat patients presents a challenge. Furthermore, several countries have restrictions on who can prescribe MNS medicines based on the provider type. This can affect the demand for access to essential medicines for MNS disorders. Alem

closed by emphasizing several key areas for focus to improve access to essential medicines for patients in SSA: poor and/or interrupted supply, low funding, and a lack of adequate human resources.

### **A HEALTH SYSTEM FRAMEWORK FOR ACCESS TO MEDICINES**

Hans Hogerzeil, professor of global health at Groningen University in the Netherlands and former director of essential medicines and pharmaceutical policies at WHO, opened by noting that access to essential medicines can be considered from the perspective that access is one of the elements of the fundamental right to health, which includes accessibility, availability, acceptability, and quality (Hogerzeil, 2006). From a health system perspective, access is an overall attribute of a strong health care system that is necessary to achieve health outcome goals, along with coverage, quality, and safety. The six building blocks of a health system as defined by WHO are (1) service delivery; (2) health workforce; (3) health information; (4) essential medical products, vaccines, and technologies; (5) health financing; and (6) leadership and governance (WHO, 2007). Hogerzeil noted that with regards to the fourth building block, WHO states that “a well-functioning health system ensures equitable access to essential medical products, vaccines and technologies of assured quality, safety, efficacy and cost-effectiveness, and their scientifically sound and cost-effective use” (WHO, 2007, p. vi). In association with achieving the health system strengthening targets of the United Nations Millennium Development Goals (MDGs), WHO formulated an access framework that highlights four key elements that must be in place to ensure medicines are accessible: rational selection, affordable prices, sustainable financing, and reliable health and supply systems (WHO, 2004a,b).

Challenges specific for low- and middle-income countries include inappropriate selection of medicines, interrupted supply chains, high pricing, and inadequate financing of medicines (Bigdeli et al., 2013a). Overall, Hogerzeil indicated, there tends to be a fragmented vertical approach—one that focuses on a single disease and is donor driven—to access to medicines and a disconnect in the health system between medical products and the other system building blocks. The interaction among the building blocks is what leads to a functional health system,

with people at the center of the system (Alliance HPSR and WHO, 2009).

Using the work of Bigdeli and colleagues, Hogerzeil jump-started the conversation about improving access by describing potential barriers that might exist at various levels within health care systems (Bigdeli et al., 2013b; Hanson et al., 2003). Bigdeli and colleagues assessed barriers at each level of the health care system: individuals, households, and community; health service delivery; the health sector as a whole; country public policies cutting across sectors; and international and regional factors (see Table 1-1). Hogerzeil noted that existing access to medicines frameworks only address part of the system. For example, the Strategies for Enhancing Access to Medicines (SEAM)<sup>5</sup> program focuses on health service delivery while the WHO access framework addresses barriers mainly at the pharmaceutical and health sector levels (WHO, 2004a,b).

**TABLE 1-1** A Multilayer Health System View of Barriers to Access to Medicines

Level of the Health System	Barriers to Access to Medicines
I. Individual, household, and community	<ul style="list-style-type: none"> <li>• Physical barriers (geographical location, opening hours, etc.)</li> <li>• Perceived quality of medicines and health services</li> <li>• Inadequate health-seeking behavior and demand for medicines</li> <li>• Inadequate use of medicines</li> <li>• Social and cultural barriers (stigma related to poverty, ethnicity, gender, etc.)</li> </ul>
II. Health service delivery	<ul style="list-style-type: none"> <li>• Low quality of health services, including staff capacity and motivation, infrastructure, etc.</li> <li>• Competition between public and private health service delivery</li> <li>• Low level of funding for service delivery</li> <li>• Weak supply of medicines, low availability</li> <li>• Inadequate prescription and dispensing</li> <li>• Low-quality/substandard medicines</li> <li>• High medicine prices</li> </ul>

<sup>5</sup>Considered at the World Health Organization Management Sciences for Health consultative meeting in Ferney-Voltaire, France, in 2000, see <http://projects.msh.org/seam/5.0.htm>.



Level of the Health System	Barriers to Access to Medicines
III. Health sector	<ul style="list-style-type: none"> <li>• Weak governance of the health sector affecting all building blocks:               <ul style="list-style-type: none"> <li>○ Absence of stewardship over a pluralistic health system, including private and informal health sector</li> <li>○ Absence of partnership with civil society or civil society participation in governance</li> <li>○ Weak human resources planning and capacity development</li> <li>○ Weak health information system and capacity for monitoring and evaluation</li> <li>○ Low level of funding for health, inefficiency in the use of funds, low coverage of pre-payment and social protection schemes, overreliance on donor funding</li> </ul> </li> <li>• Weak governance of the pharmaceutical sector affecting all functions: registration, selection, procurement, distribution, licensing of pharmaceutical establishments, inspection, control of medicines promotion, etc.</li> </ul>
IV. Public policies cutting across sectors	<ul style="list-style-type: none"> <li>• Low public accountability and transparency</li> <li>• Low priority attached to social sectors</li> <li>• High burden of government bureaucracy</li> <li>• Conflict between trade and economic goals for pharmaceutical markets and public health goals</li> </ul>
V. International and regional levels	<ul style="list-style-type: none"> <li>• International donors agenda, including for medicines</li> <li>• Weak regional development and economic cooperation mechanisms</li> <li>• Unethical use of patents and intellectual property rights</li> <li>• Research and development not targeting disease burden in low- and middle-income countries</li> </ul>

SOURCE: Hogerzeil presentation, January 13, 2014, adapted from Bigdeli et al. (2013b).

Hogerzeil described Bigdeli's proposed conceptual framework for access to medicines from a health system perspective. This framework

includes three key paradigm shifts: (1) adopting a holistic view on the demand-side constraints, including vulnerabilities of individuals, households, and communities; (2) considering the multiple dynamic relationships among all building blocks of the health system at the service delivery level; and (3) considering multilayer leadership and governance (Bigdeli et al., 2013a).

In addition to the framework, Bigdeli and colleagues conducted a priority-setting exercise that included consultation with global stakeholders and literature review (Bigdeli et al., 2013a; Rashidian et al., 2013; Zaidi et al., 2013). The process yielded 18 high-priority policy research questions, of which Hogerzeil listed the top 3 questions:

1. In risk protection schemes, which innovations and policies improve equitable access to and appropriate use of medicines, sustainability of the scheme, and financial impact on beneficiaries?
2. How do policies and other interventions in private markets impact access to and appropriate use of medicines?
3. How can stakeholders use the information available in the system in a transparent way toward improving access to and use of medicines?

In summary, access to medicines can be classified in many ways. These classifications have become increasingly complex, but present a solid basis for action. Policies and interventions can use any entry point, but Hogerzeil said that a wider picture should be kept in mind, taking a more comprehensive, systems approach.

### **OPPORTUNITIES FOR IMPROVING ACCESS TO ESSENTIAL MEDICINES FOR MNS DISORDERS<sup>6</sup>**

Throughout the workshop, individual participants discussed a number of potential opportunities to improve access to essential medicines for MNS disorders related to the four challenge areas: demand, selection, supply chains, and pricing and financing. These

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<sup>6</sup>The following list highlights recurring topics and is provided here as part of the factual summary of the workshop. Items on this list should not be construed as reflecting any consensus of the workshop participants or any endorsement by the Institute of Medicine or the Forum on Neuroscience and Nervous System Disorders.

opportunities listed below, as identified by individual participants, are expanded upon in succeeding chapters.

#### *Cross-Cutting Opportunities*

- **Commitment and support:** Several participants noted that commitment and support from key stakeholders in government, industry, academia, nongovernmental organizations (NGOs), and patients could help raise MNS disorders as a priority focus in health care. Many participants noted that identifying high-profile champions to help advance support for improved care could be beneficial. In particular, several participants suggested that such champions might be able to break down stigmas associated with MNS disorders.
- **Partnerships:** Throughout the workshop many participants noted that improving access to essential medicines might benefit from strong partnerships across all levels of the health care system, organizations, and disease areas. Critical partnerships highlighted by various participants included WHO; ministries of health, finance, and trade; the World Bank; professional organizations; pharmaceutical companies; employers; and NGOs.
- **Data:** Several participants noted a need for epidemiological and surveillance data on the prevalence of MNS disorders within countries to have a better understanding of the demand for access to essential medicines. In addition, a few participants noted that market and supply chain analyses may help stakeholders to identify barriers within the system. Several participants noted that it may be helpful to consider lessons learned from other disease areas (e.g., HIV/AIDS) regarding data collection and analysis of multiple factors influencing access and how these may inform efforts for MNS disorders.
- **Training:** The need for trained human resources, from distributors to providers, was noted by many participants. Several participants suggested that implementing the WHO Mental Health Gap Action Programme (mhGAP) intervention guide would be helpful. In addition, a few participants noted that training prescribers and local dispensary personnel to comply with regulations regarding the quality of medicines is also important.

*Challenge Area Opportunities*

- **Insufficient demand:** Several participants noted that low demand can be linked to the combination of low perceived need for MNS-specific medical care and inadequate training and education of health care providers and managers about MNS disorders. Implementation of the mhGAP intervention guide and training modules was suggested by several participants as a potential mechanism to address this barrier and increase demand for essential medicines by health care providers. Participants also discussed the impact of policies that limit prescribing practices. Many participants suggested an outcome of increasing the ability of all levels of providers to prescribe medications might be greater access to prescribers and increased demand.
- **Inappropriate selection:** A large number of participants suggested the use of developing coherent and comprehensive national strategies for the treatment and care of MNS disorders. Such a strategy could be based on mhGAP and assist in the development of evidence-based national medicine lists and treatment guidelines. A few participants noted that selection of essential medicines at a national level, and adherence to WHO guidelines, might reduce inconsistencies in the selection and procurement of medicines for MNS disorders. Several participants stressed the importance of training and continuing education about MNS treatment guidelines to include key individuals and organizations involved with selection and procurement of essential medicines.
- **Ineffective supply chains:** Many participants suggested that effective supply chains could result in better forecasting of need and reduced stock-outs or overstocking of medicines. Although challenges may be country specific, several participants noted that some common barriers include the lack of data on supply and demand, long procurement lead times, and multiple and/or unnecessary steps in the supply chain that all compound and lead to fluctuations in the availability of medicines. To address these barriers, several participants suggested development of an information network systems approach to improve availability of data. Increased training and allocation of human resources to supply chains was emphasized by several participants as an important mechanism for determining the needs of health care

systems. Many participants noted that the distribution process could be streamlined through reduction in the number of steps between central warehouses and patient distribution centers, improved transportation, and increased funds for national medicine supply agencies.

- **High pricing/poor financing:** Several participants noted that a lack of data and market analysis makes it difficult to understand pricing and financing practices and develop evidence-based policies for procuring essential medicines. Many participants suggested that increased resource allocation by governments, NGOs, and manufacturers might increase demand and, subsequently, drive down prices. A few participants noted that markets in SSA might be unattractive to manufacturers, but that increasing competition and lowering of barriers for entry might lead to decreased prices. Many participants suggested that inclusion of MNS medicines on country-specific essential medicines lists and health insurance schemes might increase coverage for these medicines, lower prices for patients, and prevent catastrophic expenditure because of long-term treatment.

## 2

### **Challenge: Insufficient Demand**

#### **Opportunities to Address Insufficient Demand as Identified by Individual Participants**

- Implementation of the World Health Organization Mental Health Gap Action Programme (mhGAP) intervention guide and training modules to increase detection, diagnosis, and treatment.
- Development of national task forces composed of government officials and key stakeholders to advocate for and develop training and education plans for mental, neurological, and substance use (MNS) disorders.
- Integration of patient- and family-oriented training into existing community-based programs to develop an informed population about MNS disorders and treatment outcomes.
- Reduction or removal of policy limitations on which levels of health care providers can prescribe medications and which medications they can prescribe, leading to an increased number of available prescribing providers.

NOTE: The items in this list were addressed by individual participants and were identified and summarized for this report by the rapporteurs. This list is not meant to reflect a consensus among workshop participants. For additional attribution information, please refer to the table at the end of this chapter.

Increasing patient and provider demand for appropriate essential medicines for MNS disorders is a critical first step to improving access, noted Oye Gureje, professor in the department of psychiatry at the University of Ibadan in Nigeria. If patients do not seek out treatments and health care providers do not properly diagnose and prescribe appropriate medicines, the result is a health system with low demand and continued patient suffering. Gureje noted there are associated challenges related to low demand, including perceived quality of care; acceptability of seeking care (i.e., negative attitudes toward those with MNS disorders); cost of care and affordability of medicines; and overall awareness of the need for care by patients, families, and health care providers.

### **THE CONTEXT OF MNS CARE IN SSA**

As previously noted, SSA has one of the largest treatment gaps for MNS disorders. Gureje gave the example that in many SSA countries, as little as 5 to 10 percent of epilepsy patients receive any form of treatment (Chin, 2012; WHO, 2012). He added that among the few who do receive treatment for MNS disorders, there is often a delay in accessing treatment (Wang et al., 2007). Challenges associated with services, continuity of care, treatment, and medication costs can lead to non-adherence—withdrawal from formal treatment—resulting in reduced demand for MNS medications, Gureje said.

#### **Challenges to Seeking and Receiving Treatment for MNS Disorders**

##### *Perceived Quality of Care*

Having access to properly trained health care providers is important for patients with MNS disorders to be diagnosed and properly treated, said Gureje. However, in SSA countries, human resources for treating these disorders are scarce (WHO, 2011a). For example, there is less than 1 psychiatrist per 100,000 population in SSA, compared to about 10 per 100,000 in Europe. In many SSA countries, the ratio is 1 psychiatrist to more than 1 million people (WHO, 2011a). Several countries have only one psychiatrist, Gureje said, and some do not have any (WHO, 2011).

There are roughly 20,000 mental health workers across all SSA countries, with a staff-to-population ratio of about 1 mental health worker for 40,000 people, or 2.5 mental health workers or full-time equivalents (FTEs)<sup>1</sup> per 100,000 population (WHO, 2011a). WHO estimates the minimum number of health workers across all specialties required in order to deliver on the health-related commitments of the Millennium Development Goals<sup>2</sup> (MDGs) is 2.5 health workers per 1,000 population, indicating that current levels are 100 times below what is needed to fulfill the MDGs. Given these limited numbers, Gureje noted that when patients do receive care it is usually in a primary or general health care setting from providers who may not be adequately trained to recognize, diagnosis, and treat MNS disorders (Gureje et al., 1995a,b).

A large portion of medical school programs in SSA only provide 2 to 4 weeks of psychiatric training, at most. Gureje went on to explain that many physicians have little to no training in the treatment of common MNS disorders such as depression or anxiety. Non-specialized, non-prescribing providers, such as community health officers, may only have 15 hours of instruction over a 2-year general training program and likely will not see a clinical case during training. A WHO survey found that few countries had a majority of providers receiving in-service training on MNS disorders within a 5-year period (WHO, 2011a). In addition, provider knowledge about prescribing medications for MNS disorders can be limited, Gureje said. Guidelines or manuals about the management and treatment of MNS disorders are only available in about 25 percent of SSA countries and can often be unclear about treatment recommendations (WHO, 2011a). Gureje noted that many times treatments are either inappropriate or inadequate (e.g., suboptimal dose) when patients are seen by primary care health providers.

Several participants noted that increasing the number of providers might not be sufficient to address the issues of quality of care. They stressed the importance of increasing capabilities of providers around identification, diagnosis and treatment of MNS disorders. Providers in urban and rural settings that might be targeted for increased training included psychologists, medical doctors, nurses, and community health care workers. Many participants noted that the development of core

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<sup>1</sup>Full-time equivalent is the number of working hours corresponding to one full-time employee during a fixed year.

<sup>2</sup>See <http://www.un.org/millenniumgoals>.



competencies, such as those discussed in the previous IOM workshop,<sup>3</sup> might be a robust mechanism for improving patient outcomes through improved provider knowledge.

### *Acceptability of Care*

Even when services are available, patients may not seek access to care because of poor knowledge about and persistent stigma associated with MNS disorders, noted Gureje. A study of 2,040 people in Nigeria found that more than 40 percent believe that some MNS disorders are due to supernatural causes and 30 percent believe in faith or spiritual treatments rather than medical treatments (Gureje et al., 2005).

During the open discussion, a few participants pointed out that the negative attitude of the public toward individuals with MNS disorders and associated stigma can discourage individuals and their families and relatives from seeking out treatment. For example, 78 percent of Nigerians said they would be upset working with someone with an MNS disorder and 83 percent would be ashamed if people knew they had an MNS disorder (Gureje et al., 2005). This means, Gureje said, that immediate family members might discourage a relative to seek treatment because of the perceived shame associated with MNS disorders. Several participants suggested that the first step to changing individual and community behavior is to educate the public that MNS disorders are medical conditions.

Many participants discussed the roles of local and international champions in helping to raise awareness and push for quality medications. A participant pointed out the parallels with epilepsy in the United States, where there is limited patient and public awareness and a lack of training of primary care providers in recognition and treatment (IOM, 2012). In this case, public service announcements were key to increasing awareness and reducing stigma. Ismet Samji, director of Portfolio Expansion at GlaxoSmithKline, suggested taking lessons from the successful awareness campaigns in the field of oncology. She noted that nearly everyone knows someone who has cancer and many governments rally behind oncology; a similar approach could be used for MNS disorders. A participant suggested that another effective approach to raising political awareness and garnering support from leadership and

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<sup>3</sup>See <http://www.iom.edu/reports/2013/Strengthening-Human-Resources-Through-Development-of-Candidate-Core-Competencies-for-Mental-Neurological-and-Substance-Use-Disorders-in-Sub-Saharan-Africa.aspx>.

ministers might be to refine the message and focus on a few specific disorders rather than on MNS disorders broadly. Many participants emphasized that there is a need to demonstrate to politicians and private employers the economic impact of lost work days due to MNS disorders. One participant suggested that this might bolster both financial and service commitments toward treatment and care of patients with MNS disorders.

Finally, several participants suggested focusing first on demonstrating that training can be provided to develop the clinical capacity to diagnose and treat patients and that quality medicines can be accessible at affordable prices for these few disorders, and in time, efforts can be expanded to a much wider range of conditions.

#### *Cost and Affordability of Treatment*

The cost of care for MNS disorders directly influences the demand for medicines, said Gureje. Given the lack of universal health insurance coverage in most SSA countries, patients must pay out-of-pocket for health care expenses, even though 70 percent live below the poverty line in some countries (World Bank, 2014). The cost of care not only includes the fees for services and medicines, said Gureje, but also transportation costs to see a health care provider. For illustration purposes, Gureje noted that in Nigeria, risperidone, an antidepressant, costs 6,000 naira (~37 USD) for a 1-month supply and carbamazepine, an antiepileptic, about 10,000 naira (~62 USD), while the minimum wage in public service is 9,000 naira (~55 USD) per month. The affordability of health services and treatment is an important consideration when patients consider seeking out care, said Gureje.

### **Low Demand Perpetuates Low Access**

Challenges associated with the perceived quality, acceptability, and affordability of care for MNS disorders can lead to reduced demand for medicines. This lack of demand is directly correlated with the availability of essential medicines. Overall procurement of MNS medications in SSA countries is low, with a median \$2,300 spent per 100,000 population compared with a global median of \$680,800 (WHO, 2011a). As a result of low demand, pharmacies and local dispensaries are not incentivized to procure and store medicines that have low sales and,

therefore, are not profitable. Newer medications are often most affected due to their relatively high cost compared to generics, Gureje said.

The health system in SSA that cares for patients with MNS disorders is characterized by inefficient coordination and limited availability of specialists, Gureje said. Primary health care providers, who constitute the bulk of the service providers, lack the supervision and support needed to give attention to MNS disorders in the context of other competing priorities. Some health care providers lack the confidence to prescribe MNS medications, and become less familiar with their use over time without continual training.

### **Improving Access to MNS Medicines Through Increased Demand**

To begin to address the challenges of demand and access, Gureje explained that Nigeria has been using the mhGAP<sup>4</sup> to scale-up services for MNS disorders. The program includes engagement with policy makers, training of primary care providers, and public education through facility-based programs and media interviews. Results thus far show a dramatic increase in access to care for MNS disorders, Gureje said. There has also been an increase in health care provider competence, resulting in increased detection and treatment, as well as adherence to intervention guidelines. Prescription of MNS medications has increased, as has procurement.

Based on his experience, Gureje offered the following thoughts on how to improve access through increased demand. First, improve help-seeking through public education; enhance detection and treatment through provider training focused on improving skills and reduce negative attitudes toward MNS conditions; and reform the health system so that the few specialists available can spend more time providing supervision and support to first-line providers. Gureje stressed the importance of engaging policy makers to improve procurement. Finally, the ability to pay for medicines needs to be addressed, he said.

A participant suggested that the development of national treatment guidelines and algorithms by key stakeholders (e.g., Ministry of Health and professional associations) might be beneficial. Several participants indicated a potential role for technology to improve training and support continuing education among health care providers.

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<sup>4</sup>See [http://www.who.int/mental\\_health/mhgap/en](http://www.who.int/mental_health/mhgap/en).

## LESSONS LEARNED FOR ADDRESSING INSUFFICIENT DEMAND

As previously mentioned, five example programs addressing access to medicines were presented during the workshop to facilitate exploration of best practices and lessons learned from other programs. The examples were selected by planning committee members and included two country-level programs, an infectious disease project, and two noncommunicable disease programs. Highlights from the presentations of the lessons learned for addressing insufficient demand are provided in Box 2-1. A full description of the examples as presented can be found in Appendix A.

### BOX 2-1

#### Highlights of Lessons Learned from Example Programs: Insufficient Demand

##### Country Programs

##### *National Health Insurance Scheme (NHIS), Ghana*

- The establishment of the NHIS provided access and basic financial coverage to health care services for residents of Ghana. This led to reduced out-of-pocket costs and increased inpatient and outpatient use of the health care system.
- Mental, neurological, and substance use (MNS) disorders have been recently integrated into the health insurance scheme, including premium exemptions for persons with MNS disorders.

##### *The Accredited Drug Dispensing Outlets (ADDO) Program, Tanzania*

- Local drug dispensaries, given their close proximity to the majority of the patient population, provided a critical opportunity for increasing patient and consumer awareness about the importance of treatment adherence and use of quality medicines.
- Local drug dispensaries offered more privacy to patients and flexible payment modalities compared to public-sector facilities.

### **Infectious Disease Program**

#### *Multidrug-resistant Tuberculosis (MDR-TB)*

- Attitudes toward treating MDR-TB had a significant role in implementing successful programs, scaling-up programs, and increasing demand.
- Beyond a need to demonstrate the ramifications of inaction, successful programs for MDR-TB have demonstrated that an increase in access to medicines improves health outcomes.
- Development of guidelines for the management of treatment improved clinical expertise and diagnostic capacity.

### **Noncommunicable Disease Programs**

#### *Diabetes*

- Coordinated approaches with multiple stakeholders were needed to provide accessible and affordable diabetes medicines to patients.
- Specific allocations dedicated to diabetes treatment within government budgets helped to reduce out-of-pocket expenditures from patients, resulting in increased demand.
- Country-level prevalence data were needed to help accurately determine the demand for diabetes care and treatment.

#### *Schizophrenia*

- The simultaneous launch of awareness initiatives aimed at patients and families and training of primary health care providers increased demand.
- Non-promotional education and information programs for professionals, as well as for patients and communities, led to reduced stigma and acceptability of seeking treatment.
- Training primary care providers in basic diagnostic procedures and treatments about MNS disorders boosted demand for medicines.
- Preferential pricing policies for MNS medicines for governmental and other nonprofit procurement stakeholders ensured access to affordable, adapted, and quality medicines.

SOURCE: Presentations by Akpalu, Liana, Zintl, Ilondo, and Bompert. See Appendix A for full discussion and references.

### **CHALLENGES AND OPPORTUNITIES FOR ADDRESSING INSUFFICIENT DEMAND**

In preparation for the focused discussions on insufficient demand, Pamela Collins, director of the Office for Research on Disparities and Global Mental Health at the National Institute of Mental Health (NIMH), summarized the challenges for increasing demand that were discussed in the overview presentation and example programs. Access-related barriers that can influence demand at the health care service delivery level include adequate human resources for MNS disorders and perceived quality of care; in particular, whether providers have the necessary skills to recognize, diagnose, and treat. Poor provider education can increase demand for incorrect medications. Additional barriers include the acceptability of care, affordability of care, and awareness of a need for care. Collins noted that participants discussed the presence of policies that might restrict the ability for certain providers to prescribe medications in some countries, which could also influence demand. The dynamics of supply also influence demand, she said. Insufficient demand can lead to low supply as manufacturers perceive a small market, which ultimately leads to higher costs, which in turn negatively influences demand. Forecasting demand is also a challenge, and requires timely and accurate feedback.

Following the focused discussion, Collins reported that three priority constraints and/or barriers were identified by various participants relative to demand for MNS medicines: (1) inadequate training and education of health care providers and managers; (2) low perceived need for medical care by individuals and families with MNS disorders; and (3) access to prescribers. All constraints and/or barriers and potential opportunities noted by participants are included in Table 2-1.

To address the need for increased and improved training and education of providers and managers about MNS disorders, several participants suggested that implementation of the mhGAP intervention guide and training modules might be a strong first step in addressing this challenge. A few participants suggested that national task forces composed of government officials and key stakeholders might be able to develop training and education plans aimed at addressing treatment gaps in care of patients with MNS disorders.

Collins noted that during the focused discussions, many participants supported the cultivation of champions from within government agencies and across society to increase the perceived need for MNS-specific

medical care by patients and families. This low perceived need might also be addressed through integration of patient- and family-oriented training into general health care facility and community-based programs.

The third barrier, limited access to prescribers by patients, was directly linked to low demand for essential medicines, according to many discussion participants. Collins indicated that a key opportunity identified by some participants was the reduction or removal of policies that limit the types of health care providers who can prescribe medicines and which medications they can prescribe. In particular, a participant highlighted a need for policies aimed at increasing the number of potential nurse prescribers through improved training, knowledge, monitoring and capacity building via the mhGAP tool. Several participants noted that these changes might result in an overall increase in the number of certified prescribers, which in turn might boost demand.

**TABLE 2-1 Opportunities to Address Insufficient Demand for Essential Medicines as Identified by Individual Workshop Participants<sup>1</sup>**

<b>Constraint and/or Barrier</b>	<b>Potential Opportunity</b>	<b>Relevant Outcome(s)</b>	<b>Potential Metric(s) of Success</b>	<b>Suggested Partnership(s)</b>	<b>Secondary Consideration(s)</b>
Inadequate training and education of health care providers and managers about MNS disorders. <sup>b,c,d,e,f,g,h,i</sup>	Implementation of the mhGAP intervention guide and training modules across SSA countries. <sup>b,c,e</sup>	Increased detection, diagnosis, and intervention of MNS disorders. <sup>b,c,g</sup>	Increased number of health care providers trained. Increased case identification of MNS disorders. Increased use of evidence-based interventions based on mhGAP guidelines as demonstrated by increased number of prescriptions. <sup>b,c,d,e,g</sup>	Specialized MNS disorder trainers; primary care providers; pharmacists; facility managers; other administrators. <sup>b,c,d,e,g,h,i</sup>	Use of health information systems with consideration based on funding availability. <sup>b,c,e,g</sup>

<sup>1</sup>This table presents challenges and opportunities discussed by one or more workshop participants. During the workshop, individual participants engaged in active discussions. In some cases, participants expressed unique ideas and/or differing opinions. However, because this is a summary of workshop comments and does not provide consensus recommendations, workshop rapporteurs endeavored to include all workshop participant comments. This table and its content should be attributed to the rapporteurs of this summary as informed by the workshop.



Constraint and/or Barrier	Potential Opportunity	Relevant Outcome(s)	Potential Metric(s) of Success	Suggested Partnership(s)	Secondary Consideration(s)
<p>Inadequate training and education of health care providers and managers about MNS disorders.<sup>b,c,d,e,f,g,h,i</sup></p>	<p>Cultivation of champions within both government and society to identify gaps in addressing MNS disorders and train health care providers and managers.<sup>b,c</sup></p>	<p>Development of a sustainable group of government officials and key stakeholders to comprise a national task force. A national taskforce could advocate for and develop training and education plans that include monitoring and evaluation.<sup>b,d,g</sup></p>	<p>Active participation by members of the task force (e.g., attendance at meetings with diverse representation). Concrete action plans leading to detailed training and education plans.<sup>b,c,g</sup></p>	<p>Policy makers; primary care providers; community members; supply chain representatives; other government agencies; nongovernmental organizations; faith-based organizations; nonprofit organizations; academia; research community; pharmaceutical industry.<sup>b,c,d,e,g,h,i</sup></p>	<p>Consider need for articulating priority conditions based on country conditions and evidence-based medication needs. Incorporate education and training on MNS disorders in medical schools and across all health care professional programs.<sup>b,c,e,g</sup></p>

Constraint and/or Barrier	Potential Opportunity	Relevant Outcome(s)	Potential Metric(s) of Success	Suggested Partnership(s)	Secondary Consideration(s)
<p>A low perceived need for MNS-specific medical care by patients and families.<sup>a,b,c,d,e,f,g,h,i</sup></p>	<p>Integration of patient- and family-oriented training about MNS disorders in health care facilities.<sup>b,c,d,e,f</sup></p>	<p>Increased number of patient education sessions per month focused on MNS disorders. An informed community about MNS disorders and treatment outcomes.<sup>b,g</sup></p>	<p>Increased demand for care and treatment in health care facilities. Reduced community use of non-evidence-based treatments (e.g., punishment, shackling). Increased dialogue about health care needs between patients and providers. Decreases in time to treatment and care.<sup>b,c,d,e,f,g</sup></p>	<p>Facility-based providers; Ministry of Health; advocacy groups; nongovernmental organizations; Ministry of Education.<sup>b,c,e,g</sup></p>	<p>Consider the impact on primary health care providers due to increased demand.<sup>b,c</sup></p>

Constraint and/or Barrier	Potential Opportunity	Relevant Outcome(s)	Potential Metric(s) of Success	Suggested Partnership(s)	Secondary Consideration(s)
<p>A low perceived need for MNS-specific medical care by patients and families.<sup>a,b,c,d,e,f,g,h,i</sup></p>	<p>Integration of training about MNS disorders into existing community-based programs.<sup>b,c,d,e,g</sup></p>	<p>Increased education on MNS disorders for faith leaders, complementary and alternative health care providers, and other community leaders. Improved accuracy of information delivered about MNS disorders.<sup>b,c,d,g</sup></p>	<p>Increased identification of cases. Increased referrals to a health care facility for treatment and care. Decreases in time to treatment and care.<sup>b,e,g</sup></p>	<p>Community-based organizations; faith-based organizations; Ministry of Health; advocacy groups; nongovernmental organizations; Ministry of Education.<sup>b,c,d,e,g</sup></p>	<p>Consider country differences in levels of literacy.<sup>b,d</sup></p>

Constraint and/or Barrier	Potential Opportunity	Relevant Outcome(s)	Potential Metric(s) of Success	Suggested Partnership(s)	Secondary Consideration(s)
Limited access to prescribers by patients. <sup>a,b,c,d,e,g</sup>	Reduce or remove policy limitations on which types of health care providers can prescribe medications and which medications they can prescribe. Changes to be based on human resource needs and recognizing limitations associated with controlled substances. <sup>c,d,g</sup>	Increased number of providers able to prescribe medications. Establish parity in prescription of psychiatric and non-psychiatric medications. Ability to prescribe MNS-specific medications is incorporated into roles, responsibilities, and qualification requirements for adequately trained providers. <sup>b,e,g</sup>	Increased number of certified prescribers. Adequate distribution of providers. Increased evidence-based prescribing of medications. <sup>b,g</sup>	Ministry of Health; Ministry of Finance; patient and family groups; prescriber representatives; training and credentialing organizations. <sup>b,c,d,e,f,g</sup>	Country-based regulations on prescribing practices by different provider levels. <sup>b,e</sup>

<sup>a</sup>Alemu Asgedom  
<sup>b</sup>Pamela Collins  
<sup>c</sup>Oye Gureje  
<sup>d</sup>Charlotte Hanlon  
<sup>e</sup>Steven Hyman

<sup>f</sup>Eric Amin Jeje  
<sup>g</sup>Thomas Kresina  
<sup>h</sup>Adesola Ogunniyi  
<sup>i</sup>Eva Ombaka



### 3

## Challenge: Inappropriate Selection

### Opportunities to Address Inappropriate Selection as Identified by Individual Participants

- Development of a coherent and comprehensive national strategy, based on the World Health Organization Mental Health Gap Action Programme (mhGAP), for the treatment and care of mental, neurological, and substance use (MNS) disorders that receives widespread support and resources by key stakeholders.
- Development of national medicine lists and treatment guidelines for each level of provider based on agreed-upon task-shifting practices.
- Establishment of a learning health system to include review, revision, and periodic updates.
- Increased inclusion of medicines that promote adherence and greater accommodation of a reasonable range of provider and patient medication preferences.
- Promotion of evidence-based selection of medicines through the development of training programs.

NOTE: The items in this list were addressed by individual participants and were identified and summarized for this report by the rapporteurs. This list is not meant to reflect a consensus among workshop participants. For additional attribution information, please refer to the table at the end of this chapter.

The appropriate selection of essential medicines for MNS disorders is critical to providing effective and accessible treatment to patients noted Hans Hogerzeil. The basic concept of essential medicines is that a limited range of carefully selected essential medicines leads to better health care, better medicine management, and lower costs. According to WHO, essential medicines are selected with regard to disease prevalence, evidence of efficacy and safety, and comparative cost-effectiveness (WHO, 2002b, 2013). It is the responsibility of each country to determine those needs and the list of medicines that are essential for their population; globally, most countries have an essential medicines list (WHO, 2002b, 2011c, 2014). Hogerzeil noted the absence of evidence-based treatment guidelines and said these, too, should be considered as important as the medicines included in a country's essential medicines list. The development of these guidelines potentially could be financed and supplied in the public sector (e.g., governments).

Given the many challenges around access to existing medicines and the fact that 98 percent of the medicines on the WHO Model List of Essential Medicines are off-patent, another approach is to consider access to existing medicines that are off-patent and available from multiple sources as an option, rather than access to new, patented medicines that are generally more expensive and from a single source (Abegunde, 2011; Cameron et al., 2011a). In discussing financing and universal access to care, Hogerzeil noted that WHO has defined three dimensions of access to consider: proportion of population covered; proportion of services covered; and proportion of costs reimbursed. Increasing access may involve extending coverage, including additional services, and reducing cost sharing and fees (WHO, 2010b).

To help identify barriers to access, Hogerzeil detailed the nine diagnostic indicators or measurable points of assessment of country-level access to essential medicines drafted by WHO (see Box 3-1) (WHO, 2008a).

**BOX 3-1**  
**Nine Indicators for Measuring Country-Level Assessment**  
**of Access to Medicines Proposed by WHO**

**Government commitment**

- Access to essential medicines/technologies as part of the fulfillment of the right to health, recognized in the constitution or national legislation.

- Existence and year of a published national medicines policy.

**Rational selection**

- Existence and year of a published national list of essential medicines.

**Affordable prices**

- Legal provisions to allow/encourage generic substitution in private sector.
- Median consumer price ratio of 30 selected essential medicines in public and private health facilities.
- Percentage mark-up between manufacturer and consumer price.

**Sustainable financing**

- Public and private per capita expenditure on medicines.
- Percentage of population covered by national health service or health insurance.

**Reliable systems**

- Average availability of 30 selected essential medicines in public and private health facilities.

SOURCES: Hogerzeil presentation, January 13, 2014; WHO, 2008a.

The selection of essential medicines at the individual country level is a two-step process, Hogerzeil explained. The first step selects from all the medicines in the world to those that are registered for use and allowed in the specific country. This step is usually the responsibility of the national regulatory agency and decisions are based on efficacy, safety, and quality. Hogerzeil noted that the number of registered products is likely to be extensive, so the second step is selecting which medicines will be stocked, used, and/or reimbursed. Decisions can be based on which products are the most clinically effective, safe, or cost-effective within therapeutic classes, said Hogerzeil. For example, in an SSA country, a national centralized medicines list may include between 500 and 700 products, and most would be expected to be available at teaching hospitals. A list for a district hospital may include 250 of those medicines; for a health clinic, perhaps 100; and for a center staffed by community health workers, maybe 30 products. Hogerzeil noted that although many medicines are allowed on the market, most are not actively



supplied or reimbursed by health insurance. High-quality medicines needed in the majority of health facilities and available at low cost are considered essential, said Hogerzeil.

### APPLYING THE ESSENTIAL MEDICINES CONCEPT TO MNS DISORDERS

Hogerzeil highlighted several unique challenges for improving access to appropriate medicines for MNS disorders. Internationally, he noted there has been minimal to no political support for addressing issues related to MNS disorders. For example, MNS disorders are not listed in the MDGs<sup>1</sup> or the Alma-Ata Declaration.<sup>2</sup> However, a participant noted that WHO has recently developed a Comprehensive Mental Health Action Plan<sup>3</sup> for 2013-2020 endorsed by 194 member states and adopted by the World Health Assembly.<sup>4</sup>

Focusing on selection, Hogerzeil stated that evidence on the effectiveness of medicines to treat MNS disorders is often unavailable, or is perceived to be unavailable. As a result, patient health outcomes are not yet well defined and are difficult to measure. Hogerzeil added that specialists such as psychiatrists oftentimes prefer to have a broad selection of medicines to prescribe for a specific MNS disorder rather than be confined to the limits of the country's essential medicines list. There is a strong preference for "a range of personal choices" as opposed to the concept of essential medicines. Lastly, Hogerzeil stated that MNS disorders often require chronic treatment that may lead to catastrophic health expenditures, defined as more than 20 percent of income, and poverty due to unaffordable health care costs.

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<sup>1</sup>The United Nations Millennium Development Goals are eight goals that all 191 UN Member States have agreed to try to achieve by the year 2015. The United Nations Millennium Declaration, signed in September 2000, commits world leaders to combat poverty, hunger, disease, illiteracy, environmental degradation, and discrimination against women. See [http://www.who.int/topics/millennium\\_development\\_goals/en](http://www.who.int/topics/millennium_development_goals/en).

<sup>2</sup>International declaration that expresses the need for urgent action by all governments, all health and development workers, and the world community to protect and promote the health of all the people of the world. See [http://www.who.int/publications/almaata\\_declaration\\_en.pdf](http://www.who.int/publications/almaata_declaration_en.pdf).

<sup>3</sup>See [http://www.who.int/mental\\_health/action\\_plan\\_2013/en](http://www.who.int/mental_health/action_plan_2013/en).

<sup>4</sup>See [http://apps.who.int/gb/ebwha/pdf\\_files/WHA66/A66\\_R8-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA66/A66_R8-en.pdf).

### Barriers to Appropriate Selection

The WHO Model List of Essential Medicines includes products for MNS disorders in the areas of psychiatric disorders; mood disorders; anxiety, obsessive-compulsive disorders, and substance abuse; and epilepsy (WHO, 2013). Hogerzeil reiterated the point that most products on the list are generics because most are off-patent. Availability of generic supply in the public sector can be the most cost-effective way of supplying essential medicines, Hogerzeil said. However, low and/or variable availability of generic products in the public sector can drive patients to purchase products from the private sector, with a tendency toward branded products or branded generics that are three to six times the price. One participant noted the importance of further research on the impact of the availability of generic medicines in both the public and private sector on pricing and purchasing patterns. Several participants discussed the “psychology” of generic medicines as a barrier because of an inaccurate perception that more expensive medicines are more effective. A few participants noted that in some SSA countries, more than 30 percent of medicines are found to be counterfeit, fostering a negative attitude toward medications that do not carry a brand label (IOM, 2013b; SPS Program, 2011; WHO, 2008b). Hogerzeil added that poor-quality domestic medicines and counterfeits may be linked to “inadequate regulation and insufficient penalization” (Hogerzeil et al., 2013; WHO, 2010a). Given the small market value and low prices of medicines in SSA, Hogerzeil suggested there might be a lack of commercial interest in supplying medicines.

A central challenge influencing appropriate selection is lack of demand, said Hogerzeil. As discussed by Gureje, lack of public procurement may be due to the lack of diagnosis and treatment capacity in the public sector, patient demand, and political interest. Hogerzeil noted that patients will not seek care if there is no trust in the system to provide affordable and effective health service. Additionally, if health care providers are not trained to request certain medicines to treat MNS disorders, then the medicines will not be available. A participant noted that regulatory bodies in SSA do not always consult health care providers and experts in the field regarding which medicines are essential. Another participant added that staff changes within health facilities may impact the medicines procured for a public-sector pharmacy.

Prescription practices also impact selection, said Hogerzeil, and international evidence-based treatment guidelines are important for MNS

disorders. In the private sector, many health care providers prescribe and dispense. This practice may create a conflict of interest due to economic incentives to sell more expensive medicines. In the public sector, patient demand for medicines is weak due to low expectations of this sector (Basu et al., 2012). According to Hogerzeil, the field might benefit from focusing on building up the public sector by training and supporting health care providers to better treat MNS disorders. A participant pointed out that up-to-date national treatment guidelines are needed to reflect current practice and pricing. Revisions to national essential medicines lists and treatment guidelines can be slow and may include medicines that are not relevant, a participant noted. For example, a participant noted that amitriptyline—an antidepressant—has a higher degree of toxicity, but widely used throughout SSA because it is relatively inexpensive compared to the alternative safe medication, fluoxetine. A participant suggested that if WHO revised the essential medicine list to put fluoxetine ahead of amitriptyline, countries might modify which medication is selected.

Several participants suggested considering improving selection of essential medicines for a range of neurological disorders. However, one participant noted that for many neurodegenerative diseases, there are few effective or cost-effective medicines. WHO now has a special essential medicines list with appropriate dosages for children<sup>5</sup>; however, there remains a lack of safety data for pediatric use of these medicines. Hogerzeil noted that only one-third of national essential medicines lists include pediatric formulations.

The concept of essential medicines is a global concept, Hogerzeil stressed. The selection of essential medicines is closely linked to evidence-based clinical practice guidelines. In summary, Hogerzeil said that universal access to essential care for MNS disorders might be:

- Based on the expansion of outpatient care;
- Performed by trained paramedical personnel;
- Supported by evidence-based treatment guidelines and a national list of essential medicines;
- Supplied as generic medicines; and
- Reimbursed within social health insurance schemes.

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<sup>5</sup>See [http://apps.who.int/iris/bitstream/10665/93143/1/EMLc\\_4\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/93143/1/EMLc_4_eng.pdf?ua=1).

## LESSONS LEARNED FOR ADDRESSING INAPPROPRIATE SELECTION

As previously mentioned, five example programs addressing access to medicines were presented during the workshop to facilitate exploration of best practices and lessons learned from other programs. The examples were selected by planning committee members and included two country-level programs, an infectious disease project, and two non-communicable disease programs. Highlights from the presentations of the lessons learned for addressing inappropriate selection are provided in Box 3-2. A full description of the examples as presented can be found in Appendix A.

**BOX 3-2**  
**Highlights of Lessons Learned from Example Programs:  
Inappropriate Selection**

**Country Programs**

*National Health Insurance Scheme (NHIS), Ghana*

- Creation of an essential medicines list and national treatment guidelines for mental, neurological, and substance use (MNS) disorders assisted with the selection of appropriate medicines.

*The Accredited Drug Dispensing Outlets (ADDO) Program, Tanzania*

- An essential medicines list that is based on community needs, storage conditions, qualifications of personnel, and public health priorities may help to improve selection, particularly for local dispensaries.
- Conducting a biannual review of the essential medicines list can help ensure that the list is accurate according to current treatment guidelines.

**Infectious Disease Program**

*Multidrug-resistant Tuberculosis (MDR-TB)*

- The release of *Guidelines for the Programmatic Management of Drug-Resistant Tuberculosis* by the Stop TB Partnership provided health care providers with recommendations to select appropriate quality medicines to treat MDR-TB.

### **Noncommunicable Disease Programs**

#### *Diabetes*

- Training of health care providers to improve knowledge and understanding of diabetes management improved selection of medicines.

#### *Schizophrenia*

- Allowing local experts to select medicines using the WHO essential medicines list as a guide may improve the selection of medicines.
- A comprehensive treatment guideline with clear algorithms may also help health care providers appropriately treat patients.

SOURCE: Presentations by Akpalu, Liana, Zintl, Ilondo, and Bompert. See Appendix A for full discussion and references.

## **CHALLENGES AND OPPORTUNITIES FOR ADDRESSING INAPPROPRIATE SELECTION**

In preparation for focused discussions on selection, Atul Pande, senior vice president at the Neurosciences Medicines Development Center at GlaxoSmithKline, summarized key challenges that were discussed in the presentations and example programs. In discussing the criteria for selecting appropriate medicines several participants noted that for many of the medicines used to treat MNS disorders, the evidence on effectiveness is poor. In some cases, the designation of essential medicines are based on health care provider preferences as opposed to health outcome data. Likewise, deficiencies in training and supervision allow inappropriate selection to persist Pande noted. The principles of chronic disease management apply equally to MNS disorders as they do to conditions such as diabetes and hypertension.

Following the focused discussion, Pande summarized that three barriers were identified by individual participants relative to selection of MNS medicines: (1) lack of mechanisms to clearly define which MNS disorders to treat; (2) lack of evidence-based approaches for developing essential medicine lists and treatment guidelines; and (3) gaps related to training in developing point-of-care prescription lists and continued awareness of evidence to update individual country lists. All constraints and/or barriers and potential opportunities noted by individual participants are included in Table 3-1.

The need for a national strategy for the treatment and care of MNS disorders was emphasized by several participants, Pande said, but such a strategy that can drive the appropriate selection of MNS medicines is still lacking or inadequate in some countries. A few participants noted that adequate resources, including specific budget allocations, might be needed to promote such a national strategy. Several participants also discussed the value of the WHO essential medicines list and mhGAP treatment guidelines as starting points for developing country-specific lists and guidelines. Pande noted that adoption of the WHO list and mhGAP guidelines might result in greater use of evidence-based approaches to treating MNS disorders. A few participants noted that the selection of medicines at the point of care is variable based on prescriber preference, and the consistent application of treatment guidelines could help to achieve some degree of uniformity. Lastly, many participants discussed the role of continuing education and training to ensure provider awareness and adherence to evidence-based treatments for MNS disorders.

**TABLE 3-1 Opportunities to Address Inappropriate Selection of Essential Medicines as Identified by Individual Workshop Participants<sup>1</sup>**

Constraint and/or Barrier	Potential Opportunity	Relevant Outcome(s)	Potential Metric(s) of Success	Suggested Partnership(s)	Secondary Consideration(s)
Lack of mechanisms to clearly define which MNS disorders to treat, resulting in inappropriate selection of medicines. <sup>a,f</sup>	Develop a national strategy for the treatment and care of MNS disorders that includes specific goals. <sup>a,b,c</sup>	Development of a coherent and comprehensive national strategy, based on mhGAP, supported by the government and other agencies (e.g., private groups, NGOs). Availability of adequate resources to promote a national strategy, including specific budget allocations to implement the national strategy. <sup>c,f</sup>	Economic growth. Increased interest at multiple levels in improving public health. <sup>c,d</sup>	Ministry of Health; Ministry of Finance; health care providers; WHO; patients and families. <sup>b,c,d</sup>	Strategy to be appropriate to the resource constraints found in the country and/or region. Countries and/or regions with constrained resources might require a more limited focus on fewer MNS disorders. <sup>a,b,c,d,f</sup>

<sup>1</sup>This table presents challenges and opportunities discussed by one or more workshop participants. During the workshop, individual participants engaged in active discussions. In some cases, participants expressed unique ideas and/or differing opinions. However, because this is a summary of workshop comments and does not provide consensus recommendations, workshop rapporteurs endeavored to include all workshop participant comments. This table and its content should be attributed to the rapporteurs of this summary as informed by the workshop.

Constraint and/or Barrier	Potential Opportunity	Relevant Outcome(s)	Potential Metric(s) of Success	Suggested Partnership(s)	Secondary Consideration(s)
<p>Lack of evidence-based approaches for developing essential medicine lists and treatment guidelines.<sup>d</sup></p>	<p>Use the WHO list of essential medicines and mhGAP treatment guidelines as a starting point for the development of evidence-based approaches.<sup>e</sup></p>	<p>Development of national medicines lists and treatment guidelines for each level of provider based on agreed-upon task shifting. Establishment of a learning health system to include a review, revision, and periodic updates. Increased inclusion of medications that promote adherence (e.g., tolerability, safety, monitoring) and greater accommodation of a reasonable range of provider and patient medication preferences.<sup>d/f</sup></p>	<p>Uninterrupted access to essential medicines and treatments. Availability of medicines in the public and private sectors; absence of non-essential medicines in the public sector. More than 50 percent of patients treated based on new guidelines. Health institutions and providers have access to and follow guidelines. A national health system that links reimbursement to desired outcomes.<sup>b,c</sup></p>	<p>Health care providers; funders; Ministry of Health; Ministry of finance; insurers; nongovernmental organizations; patients; donors.<sup>b,c,d,e</sup></p>	<p>Inclusion of cost-effective medicines due to a lack of resources. Leveraging successes in similar countries. National guidelines for medicine donations consistent with the essential medicines list. Consideration that cost-effectiveness might be different for acute care versus long-term care.<sup>b,c,d,e,f</sup></p>



Constraint and/or Barrier	Potential Opportunity	Relevant Outcome(s)	Potential Metric(s) of Success	Suggested Partnership(s)	Secondary Consideration(s)
Gaps related to training in developing point-of-care prescription list and continued awareness of evidence to update individual country lists. <sup>c</sup>	Overall promotion of evidence-based selection at the patient level and point of care. Development of training to provide an evidence base to support selection of medicines decisions with a goal of informing point-of-care decisions. Consideration for the impact of task shifting on the selection of medicines. <sup>d,e,f</sup>	Providers adequately trained to recognize, diagnose, and use medications for MNS disorders. <sup>e</sup>	Increase in percentage of patients treated based on guidelines. Increase in percentage of providers having received continuing education each year. <sup>c</sup>	Ministry of Health; professional associations. <sup>c,d,e,f</sup>	Effective dissemination of information about which medications are selected and why. Desirability of a Web-based/mobile e-learning resource. Availability for telehealth/e-health counseling. <sup>c,d,e,f</sup>

<sup>a</sup>Albert Akpalu

<sup>b</sup>Yonas Baheretibeb

<sup>c</sup>Hans Hogerzeil

<sup>d</sup>David Michelson

<sup>e</sup>Atul Pande

<sup>f</sup>Solomon Teferra

## 4

### **Challenge: Ineffective Supply Chains**

#### **Opportunities to Address Ineffective Supply Chains as Identified by Individual Participants**

- Development of an information network systems approach for improved communication among tiers, leading to streamlined and continuous flow of data.
- Training on data collection and analysis leading to improved forecasting and reduced stock-outs and overstocking.
- Learning and leveraging information systems of other vertical supply chain programs.
- Increased training of supply chain staff on logistic management information systems and all levels of health care providers about supply chains and logistics.
- Increased allocation of human resources for supply chains and inclusion of supply chain workers in determining needs for health care systems.
- The use of mobile technology across tiers and/or facilities.
- Establishment of therapeutic committees at health institutions to conduct coordination efforts and consider information on needs, stocks, and supply chain logistics.
- Reduction of the number of tiers between central warehouses and patient distribution points.
- Improved transportation between central warehouses and local distribution points to decrease time and costs for medicines to arrive.
- Increased working capital funds for national medicine supply agencies.

NOTE: The items in this list were addressed by individual participants and were identified and summarized for this report by the rapporteurs. This list is not meant to reflect a consensus among workshop participants. For additional attribution information, please refer to the table at the end of this chapter.

Supply chains are a critical component of a systematic treatment program for disease, said Prashant Yadav, director of the Healthcare Research Initiative at the William Davidson Institute at the University of Michigan. Although many people envision cartons and warehouses, Yadav explained that a supply chain is a complete ecosystem of organizations, people, technology, activities, information, and resources that together ensure that a product travels from where it is manufactured to the patient.

### **THE EFFECT OF DEMAND ON THE SUPPLY CHAINS**

Supply chain management is a well-developed scientific discipline, said Yadav. Supply chains deliver medicines, but also return critical information to planners regarding need, demand, and consumption. In some cases, he said, functioning supply chains can also play a role in demand creation. Yadav expanded on lack of demand as it relates to supply chains, noting that demand is different from need. He described a “low-demand-low-supply trap,” where the delivery system remains stuck in a suboptimal state of low use, low availability, and high cost, unless there is some intervention. If demand is low because of lack of provider or patient awareness, or some other reason such as affordability or availability, then that poor demand implies a small market size. A small perceived market size offers little incentive to invest in supply systems from a business perspective. If supply chains are weak, the margins and mark-ups (i.e., per-unit product costs) become larger, the product availability decreases, and that in turn further lowers demand. According to Yadav, investment in supply systems reflecting true market potential, and not current perceived demand, is needed to get the supply chain out of this trap.

Yadav highlighted some of the differences between supply chains in developed and emerging market pharmaceutical systems, such as those found in developing countries. In developed countries there is a strong presence of public and private insurance and limited out-of-pocket

expenditure; strong, well-defined laws and enforcement of regulations; and distribution by large organizations with nationwide coverage and relatively low mark-ups. By contrast, payment in developing countries is through either out-of-pocket or direct government purchasing of medicines for a government-run system; regulatory structures that can be fragmented and weak with ill-defined and poorly enforced laws; the wholesaling and retail pharmacy system is not strong enough to act as a major mechanism for the supply of medicines, and mark-ups are high. In developing countries, the physical supply of medicines is dominated by a government-run and -owned system with a limited, fragmented private distribution market with little or no nationwide coverage. Patients obtain medicines from private-sector pharmacies, second-tier pharmacies, chemical sellers, or public-sector community health workers, health centers, district hospitals, and medical stores (Smith and Yadav, 2012; WHO, 2011d; Yadav, 2010).

### **Public-Sector Medicine Supply Chains**

In a government, or public-sector, supply chain system, there is a cycle of uncertainty, Yadav said. Manufacturers sell directly to the country's Ministry of Health (MOH), which receives financing from the Ministry of Finance or other sources. MOH purchases feed into a central medical store, after which medicines are distributed to health care facilities. In most cases, there are no processes by which information can be fed back into the system to provide data on what medications were financed, supplied, and distributed. In addition, data on use and demand are not supplied. Improving access requires a concerted effort to understand demand and develop a well-managed financing and procurement process, Yadav said.

Yadav highlighted several factors that lead to poor availability of medicines at health clinics in government-run systems. The timing of funds disbursement from the Ministry of Finance, or other external source, for the purchase of medicines from manufacturers can be variable and uncertain, impacting procurement cycles and supply. Procurement processes can be archaic, he said, and lead times from manufacturers long. Yadav suggested that the government's control on distribution can lead to weak incentives and poor information flow along the length of the supply chain. He added that poor tracking of consumption and staff

capacity to manage inventory, stock, and dispense can be inadequate in some countries.

Another problem is what Yadav described as an unnecessary level of complexity. The structure of the supply chain is mapped exactly to the administrative structure of the country, resulting in multiple tiers and stopping points along the supply chain. Complexity can negatively influence distribution, resulting in a phenomenon called “the bullwhip effect” (Lee et al., 1997). Yadav explained that this effect is the result of small variations in patient demand at the clinic that are amplified as information is processed upstream through stopping points in a multi-tiered distribution system—from health facility to district and provincial stores, central medical store, procurement, and finally, to the manufacturer. Fewer tiers in the distribution system might help it remain in sync with actual demand, Yadav said.

Forecasting demand can also be challenging. If replenishment intervals are frequent (e.g., monthly orders), forecasting of demand can be more accurate. However, procurement departments may place orders once every 1 to 2 years, leading to wide uncertainty that manifests as either stock-outs or excess stock, Yadav said. Currently, information about use is collected through surveys. Although surveys are relevant for evaluation, effective supply chains are based on high frequency or continuous information feedback. A few participants stressed the importance of regular monitoring of systems to check the availability of products and the number of patients in need every month. A participant noted that at the clinic level, managers do not have the tools to assess quantification and determine future medication needs. Within a hospital there is often little or no communication between those prescribing and those ordering the medications. Another participant noted that there are also concerns about medicines expiring, which leads to ordering of limited quantities, increasing the potential for stock-outs. Yadav agreed that the capacity for quantification of procurement might best exist at a district level and not necessarily at a primary health center level. Particularly for unstable demand environments, purchasing should not be based on previous consumption data if the intent is to accurately scale-up the effort, said Yadav.

There are also infrastructure or “last-mile transport” challenges in getting products to primary health centers, which are often in rural areas. However, Yadav said that in his personal experience, even the health center closest to the central medical store or hospital might be out of stock of at least 30 percent of the core medicines. This is not necessarily

an infrastructure challenge, he said, but could be an issue of poor information flow and weak incentives. Providing supervision and training within health facilities on inventory management, forecasting, procurement, and requisitioning, Yadav said, may help to alleviate this issue of stock-outs.

Yadav suggested shifting tasks to where there is greater capacity. For example, in systems with weak clinic-level capacity for ordering/requisitioning, perhaps the district pharmacist or provincial pharmacist can be the locus of decision making. In systems with challenges delivering medicines to rural areas, it may be effective to combine information collection and product distribution. In Zimbabwe's Delivery Team Topping Up<sup>1</sup> system, for example, staff from the district visit every health center to deliver essential products, conduct inventory, and resupply in the same visit. The district staff member is able to capture local knowledge about demand and make decisions about requisitioning—removing the responsibility from the clinic staff. Similar “moving warehouse” pilot programs are under way in Mozambique, Nigeria, and Senegal.

### **Private-Sector Medicine Supply Chains**

Within the private sector, Yadav explained that most pharmacies rely on a “cash-and-carry model,” in which products are bought directly from the wholesaler rather than through a distributor. While large retail pharmacies may receive some form of credit from the wholesaler, small-town rural pharmacies are typically not extended credit and must purchase medicines on a cash basis. Yadav noted that this might result in retail pharmacy owners, with limited working capital, only stocking medications that sell quickly. In addition, pharmacy staff often travel significant distances, with fewer trips for longer distances, resulting in less frequent opportunities to restock supplies. In comparison, Yadav mentioned that private pharmacies and private wholesalers function well, delivering products to even the most remote areas, if incentives are structured appropriately (Yadav et al., 2012). For example, products in high demand in remote areas offer financial incentive to wholesalers to travel long distances given the potential profit. Supply chains that are patient-centric are critical, said Yadav. He suggested that supply chains

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<sup>1</sup>Part of the USAID/Deliver Project. See [http://deliver.jsi.com/dhome/countries/country/news?p\\_persp=PERSP\\_DLVR\\_CNTRY\\_ZW](http://deliver.jsi.com/dhome/countries/country/news?p_persp=PERSP_DLVR_CNTRY_ZW).

be designed as a mechanism to deliver the product to where the patient seeks care, rather than asking the patient to come to where the product is available.

### **Barriers to Getting Product into the Supply Chain**

Before an MNS medicine can enter any supply chain, public or private, it must be registered in the country, said Yadav. If the market size is small and the cost to serve that market is high, the business case to enter the market is weak, Yadav said. Another factor for a manufacturer to consider is high costs associated with time, effort, and resources needed to register a product. During the discussion, Samji noted that the level of complexity of regulations can be a significant barrier. For example, each country requires its own registration number on the product packaging, however, product volumes in these countries are low. Producing country-specific packaging adds complexity and cost for the manufacturer, which can lead to increased prices. Samji suggested a potential solution might be a mutual recognition system among country regulators to reduce the complexity of developing packaging for each individual market.

Although some manufacturers register their products out of corporate social responsibility, given the high costs and relatively small market size, Yadav noted that many do not. When manufacturers choose not to register products in a country, this leaves few or no supply sources, which leads to higher prices, a lack of availability, or both. The question, Yadav said, is whether this perception of low market size or high cost to serve is accurate, or whether it is due to lack of data about the market. Developing strategies to reduce the time, effort, and transaction costs for registration is important, said Yadav. For example, rather than raising registration fees, creating an appropriate financing model for the developing country's regulatory authority may be beneficial.

Several participants discussed leveraging regional block structures<sup>2</sup>—regional areas that share common institutional practices, goals, or currency—to harmonize regulations across local procurement. Yadav noted that there are some initiatives addressing this through harmonization, such as the African Medicines Regulatory Harmonization (AMRH) program.<sup>3</sup> The goal of this program is to improve public

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<sup>2</sup>See [http://www.usitc.gov/publications/332/3650/pub3650\\_ch3.pdf](http://www.usitc.gov/publications/332/3650/pub3650_ch3.pdf).

<sup>3</sup>See <http://www.amrh.org>.

health by increasing access to good quality, safe and effective medicines through the harmonization of medicines regulations, including the reduction of the time taken to register essential medicines for the treatment of diseases. A participant pointed out that the WHO Regional Office for Africa could explain to countries the advantages of pooling orders into larger volumes. However, one participant noted that it may be difficult to harmonize procurement within regional blocks that do not share a common language. Another participant noted the additional regulatory challenges of procurement of controlled medicines for acute management of MNS disorders, such as injectable phenobarbital.<sup>4</sup> Alem added that most medicines are purchased by SSA countries from abroad, and foreign currency is a challenge, as the capacity to generate foreign currency can be low. Although some medicines are now being manufactured locally, companies still struggle with importing raw materials, he added.

Yadav highlighted several additional challenges facing pharmaceutical companies in serving markets in SSA. The lack of good distribution practice (GDP)-compliant distributors, particularly in the private sector, may lead to pharmaceutical companies not wanting to enter the market, due to potential reputational risks associated with loss of integrity (e.g., inappropriate handling or storage) and high distribution fees. In general, Yadav added, the wholesale market in SSA is fragmented. Given the larger quantity of wholesalers and the fixed costs associated with each, patients are subjected to high medicine prices compared to markets with fewer wholesalers. High retail prices are also associated with mark-ups added by intermediaries at multiple levels in the distribution system.

### **Breaking the Low-Demand-Low-Supply Cycle**

In summary, many complex factors contribute to poor availability of medicines. These problems are complex and require action on multiple fronts. However, the complexity and multi-dimensionality of the problem can not be an excuse for inaction, Yadav said. Lessons can be learned from successful supply chains for other consumer products in SSA (Yadav et al., 2013). Coca-Cola, for example, is distributed broadly

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<sup>4</sup>Phenobarbital is a barbiturate used to control seizures, alleviate anxiety, and prevent withdrawal symptoms from barbiturate dependency. See <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a682007.html>.



throughout SSA through independent wholesalers and retailers to reach a larger number of consumers. The company leverages local knowledge about the integrity and pricing of their product once it reaches the consumer to ensure that the distributor is complying with contractual agreements (Yadav et al., 2013).

Yadav concluded by noting that breaking the low-demand-low supply cycle will require discussion and action on:

- Better forecasting and needs assessment, to include inventory management training for staff;
- The redesign and simplification of distribution structures;
- Better information collection and flow;
- The creation of agile procurement structures;
- Higher frequency of deliveries;
- Incentives and accountability in the supply chain;
- Private-sector transport and distribution; and
- Working capital credit for private pharmacies.

### **LESSONS LEARNED FOR ADDRESSING INEFFECTIVE SUPPLY CHAINS**

As previously mentioned, five example programs addressing access to medicines were presented during the workshop to facilitate exploration of best practices and lessons learned from other programs. The examples were selected by planning committee members and included two country-level programs, an infectious disease project, and two noncommunicable disease programs. Highlights from the presentations of the lessons learned for addressing ineffective supply chains are provided in Box 4-1. A full description of the examples as presented can be found in Appendix A.

**BOX 4-1****Highlights of Lessons Learned from Example Programs:  
Ineffective Supply Chains****Country Programs***National Health Insurance Scheme (NHIS), Ghana*

- Decentralizing the control of purchasing within the government, and empowering district hospitals to manage supply, can help create a more effective supply chain to sustain the availability of medicines.

*The Accredited Drug Dispensing Outlets (ADDO) Program, Tanzania*

- Decentralizing of the ADDO program from the Tanzania Food and Drug Authority to local governments allowed the program to be implemented in multiple regions, resulting in increased speed, reduction of costs, and increased local ownership of the distribution process.
- Expanding the list of medicines legally allowed in ADDOs to include medicines to treat mental, neurological, and substance use (MNS) disorders, and offering pooled procurement provided an incentive for suppliers to extend their distribution into regions with ADDOs.
- Establishing ADDO-restricted wholesalers in districts with no pharmacies helped to supply medicines to patients in rural areas.

**Infectious Disease Program***Multidrug-resistant Tuberculosis (MDR-TB)*

- Data on projected demand (number of infected patients) and actual demand (number of patients actually enrolled in treatment and properly managed) can help to accurately forecast the amount of medication needed.

**Noncommunicable Disease Programs***Diabetes*

- Government support and buy-in that treatment for non-communicable diseases is a priority may help increase health care budgets to purchase medicines.
- Improving distribution to rural areas helped increase the supply and availability of medicines to patients.

- Reducing stock-outs in the public sector can help to decrease the number of patients who purchase medicines in the private sector, often at a higher price.

#### *Schizophrenia*

- Maintaining up-to-date data on current stock and demand is important and can decrease the likelihood of both stock-outs and overstocking.
- Selection of potential medicine suppliers would benefit if based on price, and also on quality and reliability of supply.
- Using a prequalification process may be beneficial when screening and selecting potential suppliers. The World Health Organization's prequalification process might be one mechanism; however, it does not currently include MNS medicines.

SOURCE: Presentations by Akpalu, Liana, Zintl, Ilondo, and Bompert. See Appendix A for full discussion and references.

## CHALLENGES AND OPPORTUNITIES FOR ADDRESSING INEFFECTIVE SUPPLY CHAINS

In preparation for the focused discussion on supply chains, Giorgis summarized the issues for supply chains that were discussed in the presentations and example programs. The biggest procurer of MNS medicines in SSA are governments, however, several participants noted that MNS medicines are not always procured in quantities capable of addressing the need. Several participants noted that to ensure medications are available on a timely basis, there is a need for continuous, reliable data monitoring of demand and use. According to a few participants, the capacity of dispensary and pharmacy staff to appropriately requisition and purchase medicines based on demand can impact supply.

Following the focused discussion, Tarun Dua, medical officer in the Department of Mental Health and Substance Abuse at WHO, reported that five priority barriers were identified by various participants relative to selection of MNS medicines: (1) absence of quality, timely information, including data collection and analysis; (2) deficiencies in the allocation and training of human resources for supply chains; (3) lack of coordination at all levels of the procurement chain; (4) inefficiencies across different tiers of the supply chain; and (5) long procurement lead

times with little transparency of the process. All constraints and/or barriers and potential opportunities noted by individual participants are included in Table 4-1.

Dua noted that many participants stressed the need for country-specific solutions because no one-size-fits-all solution can be applied globally. Several participants agreed that each country faces unique challenges related to supply chains.

A few participants noted that development of an information network systems approach for improved communication among tiers might increase the quality and timeliness of information flowing along the supply chain system. In addition, a few participants stressed that training on data collection and analysis might improve forecasting of need and reduce stock-outs and overstocking of medicines. Beyond training of supply chain staff, many participants noted that there are deficiencies in allocation of human resources across supply chains. Dua said several participants suggested that policies to increase the number of workers to supply chains might lead to increased knowledge of the system, again improving forecasting of need.

A few suggestions by different participants were offered as opportunities to improve coordination among tiers of the procurement chain, including the use of mobile technology to improve information flow and the establishment of therapeutic committees at health institutions. One participant noted that these committees could consider information on needs, stocks, and supply chain logistics and conduct coordination efforts across the supply chain.

Dua added that several participants noted inefficiencies across different tiers of the supply chain, including the many layers and steps needed to move medicines. A few participants suggested that reduction in the number of tiers between central warehouses and patient distribution points might result in faster procurement and delivery of essential medicines. Another mechanism suggested by a participant for addressing this challenge was improved transportation and potentially the outsourcing of transportation to private distributors. Finally, Dua noted that one participant emphasized that opportunities could be found through the use of complementary and/or multiple procurement agencies.

Wrapping up the overview of the focused discussion, Dua indicated that early, frequent, and transparent consultations with manufacturers might reduce lead time for procurement, stock-outs, and overstocking. Through reliable and diversified manufacturer sources, Dua noted that

prepositioning of medicines and raw materials might improve, reducing the time for delivery of essential medicines.

**TABLE 4-1** Opportunities to Address Ineffective Supply Chains for Essential Medicines as Identified by Individual Workshop Participants<sup>1</sup>

Constraint and/or Barrier	Potential Opportunity	Relevant Outcome(s)	Potential Metric(s) of Success	Suggested Partnership(s)	Secondary Consideration(s)
A lack of quality, timely information, including data collection and analysis, flowing from each tier in the supply chain system. <sup>b,c,g</sup>	Development of an information network systems approach for improved communication among tiers. Potential for process engineering of procurement system. <sup>b,g</sup>	Streamlined and continuous flow of information. Increased data from health information systems. Hand-collected data integrated into data management systems. <sup>b,c,d,g,h</sup>	Improved forecasting of need and improved accuracy of forecasting. Reduced stock outs and overstocking. <sup>b,d,g</sup>	Data collection sources; telecommunication companies; government ministries. <sup>c,d,f,g</sup>	Accurate country-level and regional-level data collection. Improved understanding of country-specific challenges. Information from country-level groups on partnerships for data collection. <sup>f,g</sup>

<sup>1</sup>This table presents challenges and opportunities discussed by one or more workshop participants. During the workshop, individual participants engaged in active discussions. In some cases, participants expressed unique ideas and/or differing opinions. However, because this is a summary of workshop comments and does not provide consensus recommendations, workshop rapporteurs endeavored to include all workshop participant comments. This table and its content should be attributed to the rapporteurs of this summary as informed by the workshop.

Constraint and/or Barrier	Potential Opportunity	Relevant Outcome(s)	Potential Metric(s) of Success	Suggested Partnership(s)	Secondary Consideration(s)
<p>A lack of quality, timely information, including data collection and analysis, flowing from each tier in the supply chain system.<sup>b,c,g</sup></p>	<p>Training on data collection and data analysis.<sup>b,eg</sup></p>	<p>Improved quality of data and information. Establishment of training programs on supply chain data collection and analysis.<sup>b,d,g</sup></p>	<p>Improved forecasting of need. Reduced stock-outs and over-stocking.<sup>b,c,f,g,h</sup></p>	<p>Groups and universities that have developed training programs focused on supply chain data; World Health Organization.<sup>a,b,d,e</sup></p>	<p>Information from country-level groups on partnerships for training.<sup>b,d</sup></p>

Constraint and/or Barrier	Potential Opportunity	Relevant Outcome(s)	Potential Metric(s) of Success	Suggested Partnership(s)	Secondary Consideration(s)
A lack of quality, timely information, including data collection and analysis, flowing from each tier in the supply chain system. <sup>b,c,g</sup>	Learning and leveraging information systems of other vertical supply chain programs for the broader system. <sup>b,g</sup>	Best practices from vertical programs are integrated into MNS supply chains. <sup>b,g</sup>	Improved forecasting of need. Reduced stock-outs and over-stocking. <sup>b,c,f,g,h</sup>	Relevant program administrators from other disease areas. <sup>b,g</sup>	Consider vertical programs specifically focused on chronic and/or non-communicable diseases. <sup>b,g</sup>



Constraint and/or Barrier	Potential Opportunity	Relevant Outcome(s)	Potential Metric(s) of Success	Suggested Partnership(s)	Secondary Consideration(s)
<p>Deficiencies in allocation and training of human resources for supply chains.<sup>a,b,d,e,g</sup></p>	<p>Training of supply chain staff at multiple tiers within the system.<sup>e,g</sup></p>	<p>Increased knowledge of the supply chain system and understanding of importance of timing. Improved commitment to supply chains. Training on logistic management information systems. SSA-wide effort for improved training.<sup>b,c,d,g</sup></p>	<p>Increased number of qualified staff. Integration of new training opportunities into current programs. Improved forecasting of need. Reduced stock-outs and overstocking.<sup>b,d,g,h</sup></p>	<p>Industry partners; telecommunications; government agencies; professional associations; universities; organizations with expertise in supply chain management training.<sup>c,d,f,g,h</sup></p>	<p>Connect with and develop relationships with groups focused on training in supply chains (e.g., People that Deliver) for improved information and training about MNS disorders.<sup>c,d,g,h</sup></p>

Constraint and/or Barrier	Potential Opportunity	Relevant Outcome(s)	Potential Metric(s) of Success	Suggested Partnership(s)	Secondary Consideration(s)
<p>Deficiencies in allocation and training of human resources for supply chains. <i>a,b,d,e,g</i></p>	<p>Training of all levels of health care providers about supply chains and supply chain logistics. <i>a,c,d,e</i></p>	<p>Increased knowledge of the supply chain system. Improved practice of prescribers and dispensers as they relate to supply chains. <i>a,b,d</i></p>	<p>Increased number of qualified staff. Integration of new training opportunities into current programs. Improved forecasting of need. Reduced stock-outs and overstocking. <i>a,b,d,g</i></p>	<p>Training institutions; organizations with expertise in supply chain management training; professional associations. <i>b,g</i></p>	<p>Connect with training programs focused on supply chains in other disease areas. <i>c,h</i></p>

Constraint and/or Barrier	Potential Opportunity	Relevant Outcome(s)	Potential Metric(s) of Success	Suggested Partnership(s)	Secondary Consideration(s)
<p>Deficiencies in allocation and training of human resources for supply chains. <i>a,b,d,e,g</i></p>	<p>Policies to increase the number of workers to supply chains. <i>a,b,d,g</i></p>	<p>Increased allocation of human resources for supply chains. Increased information on the number of supply chain workers per portion of the population of number of pharmacies. Inclusion of supply chain workers in determining human resource needs for health care systems. <i>a,c,d,e,g,h</i></p>	<p>Increased number of people trained and deployed. Improved forecasting of need. Reduced stock-outs and overstocking. <i>a,b,d,f,g</i></p>	<p>Policy makers; governments. <i>a,b,f,g,h</i></p>	<p>Consider integration with other disease areas. <i>c,h</i></p>

Constraint and/or Barrier	Potential Opportunity	Relevant Outcome(s)	Potential Metric(s) of Success	Suggested Partnership(s)	Secondary Consideration(s)
Lack of coordination at all levels of the procurement chain within closed systems (e.g., hospital, clinic) or among different tiers of the supply chain. To include communication gaps within and across facilities. <sup>b,d,g</sup>	The use of mobile technology for across tiers or facilities. <sup>c,g</sup>	Development of algorithms or reporting tools. Increased use of mobile technology. <sup>b,g</sup>	Improved information flow. Greater coordination and collaboration. Improved forecasting of need. Reduced stock-outs and overstocking. <sup>a,b,d,f/g</sup>	Information technology companies; mobile technology companies. <sup>b,c,d,g</sup>	Network resources may differ across countries and across regions within countries. Costs associated with mobile technology development and procurement. <sup>b,c,d,g</sup>

Constraint and/or Barrier	Potential Opportunity	Relevant Outcome(s)	Potential Metric(s) of Success	Suggested Partnership(s)	Secondary Consideration(s)
<p>Lack of coordination at all levels of the procurement chain within closed systems (e.g., hospital, clinic) or among different tiers of the supply chain. To include communication gaps within and across facilities. <i>b,d,g</i></p>	<p>Therapeutic committees at health institutions to conduct coordination efforts. Committees to consider information on needs, stocks, and supply chain logistics. <i>e,g</i></p>	<p>Establishment of therapeutic committees that function well. Improved communication between committees and critical procurement managers. Committees to be recognized as a critical component and need by leadership. <i>a,b,e,g</i></p>	<p>Integration of committee recommendations into conversations around supply chains. Initiation of Ministry of Health to establish these committees. Transparency of committee agendas and conversations. Improved forecasting of need. Reduced stock-outs and overstocking. <i>b,c,d,e,g,h</i></p>	<p>Ministry of Health; closed system leaders; already established therapeutic committees for guidance; medical center directors. <i>b,g</i></p>	<p>N/A</p>

Constraint and/or Barrier	Potential Opportunity	Relevant Outcome(s)	Potential Metric(s) of Success	Suggested Partnership(s)	Secondary Consideration(s)
<p>Inefficiencies across different tiers of the supply chain, including multiple steps/layers.<sup>a,b,c,d,e,f,g,h</sup></p>	<p>Reduction in the number of tiers between central warehouses and patient distribution points. Procurement at regional levels.<sup>d,e,g</sup></p>	<p>Faster procurement. Removal of tiers through understanding of evidence and identification of inefficiencies. Improved assessment of needs.<sup>a,b,c,d,e,f,g,h</sup></p>	<p>Reduction or diffusion of cost of medicines. Removal of some portion of tiers within the supply chain. Faster procurement and delivery of medicines.<sup>b,c,d,g,h</sup></p>	<p>Governmental agencies; supply chain managers; manufacturers; distribution centers.<sup>b,g</sup></p>	<p>Medication needs assessment on a case-by-case basis (e.g., country, region). Evidence gathering and understanding of inefficiencies might be country-specific.<sup>b,c,g,h</sup></p>

Constraint and/or Barrier	Potential Opportunity	Relevant Outcome(s)	Potential Metric(s) of Success	Suggested Partnership(s)	Secondary Consideration(s)
<p>Inefficiencies across different tiers of the supply chain including multiple steps/layers.<sup>a,b,c,d,e,f,g,h</sup></p>	<p>Improvement in transportation among central warehouses and local distribution points with a focus on both time and cost. Potential for outsourcing transportation to private distributors.<sup>b,c,d,f,g,h</sup></p>	<p>Decreases in time and cost for medicines to arrive at distribution points. Shared transportation costs across the system.<sup>a,b,c,d,g</sup></p>	<p>Reduced time and cost of transportation. Reduced stock-outs. Agreements with private-sector distributors.<sup>a,b,c,d,f,g,h</sup></p>	<p>Governmental agencies; supply chain managers; manufacturers; distribution centers; private distributors.<sup>b,g</sup></p>	<p>Transportation inefficiencies might be country- and region-specific.<sup>b,c,d</sup></p>

Constraint and/or Barrier	Potential Opportunity	Relevant Outcome(s)	Potential Metric(s) of Success	Suggested Partnership(s)	Secondary Consideration(s)
Inefficiencies across different tiers of the supply chain, including multiple steps/layers. <sup>a,b,c,d,e,f,g,h</sup>	Complementary and/or multiple procurement agencies. <sup>c,d,g</sup>	Competition resulting in lower prices associated with procurement. <sup>b,c,d,f,g,h</sup>	Improved efficiency and availability of medicines. Reduced stock-outs. <sup>a,b,c,d,e,f,g,h</sup>	Governmental agencies; supply chain managers; manufacturers; distribution centers; private distributors. <sup>b,g,h</sup>	Presence of complementary or other procurement agencies might be country-specific. <sup>b,d,g,h</sup>



Constraint and/or Barrier	Potential Opportunity	Relevant Outcome(s)	Potential Metric(s) of Success	Suggested Partnership(s)	Secondary Consideration(s)
<p>Long procurement lead times with little transparency of the procurement process.<sup>a,b,c,d,e,f,g,h</sup></p>	<p>Early and frequent consultations with manufacturers.<sup>c,d,f,g,h</sup></p>	<p>Improved transparency with all eligible suppliers. Ability to systematically determine manufacturers with increased capabilities of supplying high-quality medicines efficiently. Positioning of medicines and raw materials. Increased confidence in production and lower lead times by manufacturers.<sup>a,b,c,d,e,f,g,h</sup></p>	<p>Reduced lead-time for procurement, stock-outs and overstocking. Diversified source of manufacturers. Reliable manufacturing.<sup>b,c,d,f,g,h</sup></p>	<p>Public procurement agencies; manufacturers; international federations or regional federations of manufacturers.<sup>b</sup></p>	<p>Integrated information system across diseases with the inclusion of MNS disorders. For large markets diversified sources might apply broadly to generics and the full essential medicines list while smaller markets might focus specifically on medicines for MNS disorders.<sup>b,c,g,h</sup></p>

Constraint and/or Barrier	Potential Opportunity	Relevant Outcome(s)	Potential Metric(s) of Success	Suggested Partnership(s)	Secondary Consideration(s)
Long procurement lead times with little transparency of the procurement process. <sup>a,b,c,d,e,f,g,h</sup>	Increased working capital funds for national medicine supply agencies. <sup>b,c,g</sup>	Timeliness of procurement initiation and prepayment. <sup>c,d,f/g</sup>	Agency is able to pay for desired medicines when procurement is optimal. Reduction in financial-approval-related delays in ordering. <sup>b,g</sup>	Central banks; Ministry of Finance; World Bank; IFC. <sup>e,g,h</sup>	N/A

<sup>a</sup>Atalay Alem  
<sup>b</sup>Tarun Dua  
<sup>c</sup>Mapoko Ilondo  
<sup>d</sup>Jafary Liana

<sup>e</sup>Mamuye Mussie  
<sup>f</sup>Ismet Smaji  
<sup>g</sup>Prashant Yadav  
<sup>h</sup>Paul Zintl



## 5

### **Challenge: High Pricing and Poor Financing**

#### **Opportunities to Address High Pricing and Poor Financing as Identified by Individual Participants**

- Evidence-based policies to impact pricing and financing of medicines.
- Increase in evidence-based prioritization of funds for mental, neurological, and substance use (MNS) disorders by governments, not-for-profit, and for-profit partners.
- Increased competition and lower barriers for entry into the market, leading to an increased number of stakeholders and affordable medicine options.
- Implementation of simpler and clearer regulations, requirements, and procedures.
- Streamlined procurement of medicines at efficient prices and passing along of low procurement prices to patients, leading to a decrease in the overall unit cost of medicines.

NOTE: The items in this list were addressed by individual participants and were identified and summarized for this report by the rapporteurs. This list is not meant to reflect a consensus among workshop participants. For additional attribution information, please refer to the table at the end of this chapter.

### THE COST OF ACQUIRING ESSENTIAL MEDICINES

Although the methodology exists to measure availability, prices, and affordability of medicines, there are very little data specifically about medicines to treat MNS disorders, said Margaret Ewen, a pharmacist in the global office of Health Action International (HAI). Between 2007 and 2013, nine surveys were completed in SSA using WHO/HAI methodology, some of which included medicines for epilepsy and depression (WHO/HAI, 2008, 2013). The greatest amount of data in SSA were found for the following medicines: carbamazepine, an antiepileptic; amitriptyline, a tricyclic antidepressant; and diazepam, used to treat anxiety disorders, alcohol withdrawal symptoms, or muscle spasms. The surveys found that availability of these medicines was generally poor across all sectors—public, private, and nongovernmental organizations. Ewen noted that analysis of WHO/HAI survey data suggests that the availability of medicines for chronic diseases in developing countries is lower than that for acute conditions (Cameron et al., 2011b).

Prices for amitriptyline, carbamazepine, and diazepam were compared across countries in SSA using the Management Sciences for Health (MSH) International Drug Price Indicator Guide<sup>1</sup> as a benchmark. MSH is a nonprofit organization that strives to improve health outcomes in poor and vulnerable populations by closing the gap between knowledge and action in public health (MSH, 2014a). The purpose of the guide is to make price information for medicines more widely available to facilitate procurement of quality-assured medicines at the lowest price (MSH, 2014b). Ewen said that government procurement prices for generic medicines were reasonable, with mean procurement prices often below the MSH international reference price; however, prices in some countries were much higher (Cameron et al., 2012).

Patient prices, however, can be high even for the lowest priced generics. In many SSA countries, medicines are available at no cost in the public sector. However, in cases Ewen surveyed where purchase price data were available for the public sector, patients paid just over twice the international reference price for amitriptyline. Low procurement prices are generally not passed on to patients, Ewen said, and there are examples of patients paying 80 to 330 percent more than the procurement price (Cameron et al., 2009). Ewen noted that the NGO

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<sup>1</sup>See <http://erc.msh.org/mainpage.cfm?file=1.0.htm&module=dmp&language=english>.

sector, as expected, had pricing similar to the public sector. During the discussion a participant noted that even in cases where medicines are provided at no cost to the patient, access is limited or unavailable due to supply chain interruptions.

Affordability of medicines becomes a challenge when availability in the public sector is low and patients can only purchase their medicines in the private sector. The median price paid by patients for the lowest priced generic equivalent for carbamazepine was up to 10 times the MSH international reference price. Similar to the public sector, prices were generally higher for originator brands in the private sector. In the study by Cameron and colleagues (2012), affordability was measured as the number of days the lowest paid, unskilled government worker has to work to be able to buy 30 days of standard treatment for a chronic condition. In Tanzania, for example, this person would have to work 0.4 days to be able to buy 1 month's supply of the lowest priced generic carbamazepine in the public sector, but at 38 percent availability, patients would likely buy this medication via the private sector, where the cost is equivalent to 1.6 days' wages (Cameron et al., 2012).

### **Improving Access to MNS Medicines by Reducing Pricing**

Multiple factors determine the final price of a medicine, including whether the medicine is purchased in the public or private sector, branded or generic, imported or locally manufactured, and subject to mark-ups and taxes. Given the challenges associated with data collection, Ewen noted that little data are available about these price components for medicines to treat MNS disorders in SSA. Mark-ups tend to be fixed percentages along the supply chain that are often unregulated and can more than double the manufacturer's selling price. Taxes (e.g., value-added tax [VAT]; regional and local taxes) are often applied to medicines throughout the supply chain. Ewen explained that taxes on medicines can be highly regressive,<sup>2</sup> which can result in reduced purchasing by low-income patients. In addition to mark-ups and taxes, import duties on raw ingredients and finished products may also increase the final price. Ewen said there are currently few incentives for stocking and dispensing lower priced medicines given the greater profit dispensaries can make selling higher priced medicines.

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<sup>2</sup>Low-income populations pay a larger amount of taxes.

Ewen noted that there are several opportunities to improve pricing and affordability, including controlling the manufacturer's selling price; reducing mark-ups, taxes, and duties; and adjusting reimbursement amounts. Another method, Ewen explained, might be to consider policies that specifically reduce pricing and increase affordability of medicines to patients, including policies directed at generic substitutions, prescribing, and reference pricing. For example, eliminating patient consent before a health care provider prescribes a generic rather than a branded medicine may help to reduce cost to the patient. Prescribing policies that limit which medicines are dispensed could help alleviate the risk of patients receiving low-quality medicines. Lastly, Ewen noted that reference pricing policies might increase the affordability of medicines by setting maximum median local price ratios to that of MSH. Ewen observed that countries sometimes introduce pricing policies without careful consideration of the various options and the potential impact of each option relative to their national situation. In addition, Ewen noted that many countries do not monitor the impact of policies once implemented and stressed that some policies are simply not feasible. Given the array of challenges associated with supplying affordable medicines to patients in SSA countries, Ewen suggested that countries take a multifaceted approach to address this issue.

One participant highlighted that affordability needs to be addressed across the entire system of care. For example, even when medications are off-patent and affordable, patients often cannot afford the associated routine diagnostic tests. Lithium, for example, is available and free to patients in Ethiopia; however, it might not be prescribed because thyroid tests are not reliably available to assess if thyroid dysfunction, a common side effect, occurs with treatment.

A few pharmaceutical company participants described tiered or differential pricing approaches for supplying medicines to the least developed countries during discussions. These individual participants noted that there are challenges to differential pricing and outcomes are not always as expected; differential pricing might not necessarily increase demand. A participant also mentioned there is a limit below which prices cannot go without impacting quality. A participant noted that this might be where other financing schemes, such as subsidies, can be beneficial.

### **Financing the Costs of Essential Medicines**

As discussed by Hogerzeil, WHO conceptualized universal health coverage in three dimensions: what services are covered, who is covered, and the proportion of the cost covered (WHO, 2010b). Applying this concept to essential medicines, Daniel Chisholm, health economist in the Department of Mental Health and Substance Abuse at WHO, said the dimensions could be as follows: what is the range of medicines on the essential medicines list or which conditions are prioritized; the proportion of people who actually have access to those medicines; and who is paying for the medicines (e.g., public versus private, out-of-pocket, health insurance). Chisholm noted that this third dimension, who is paying, is a critical component in the financing of essential medicines in many SSA countries.

An analysis of health care usage and expenditure in several representative SSA countries found that medicine was the largest element of out-of-pocket spending (Saksena et al., 2012). Out-of-pocket health expenditures are a significant concern at the household level in SSA, Chisholm explained. Many families, even those at the highest income levels, resort to selling assets or borrowing to finance payments (Leive and Xu, 2008).

Essential medicines for target conditions are intrinsically expensive, and should account for only a small proportion of the total cost of treatment, Chisholm said. In many SSA countries, however, prices are high and unaffordable to many. This is due to a mixture of factors, including inefficient procurement; inadequate regulation; excessive mark-ups and taxes; and waste and corruption, he summarized. Efforts to lower prices and improve affordability could benefit from a systems approach, Chisholm concluded, starting with better governance, regulation, and policy, but also extending to more efficient procurement and distribution, as well as the establishment of financial protection measures for the poor and vulnerable. Taking a health system's perspective, Chisholm explored some of the critical challenges precipitating and associated with pricing and financing issues, as well as some suggested solutions (see Table 5-1).



**TABLE 5-1** Critical Challenges Impacting Pricing and Financing, and Potential Solutions

Challenge	Potential solution(s)
Unclear policy, planning, and budgeting	<ul style="list-style-type: none"> <li>• Employ rational selection and prioritization procedures</li> <li>• Promote and enhance task-shifting approach to treatment</li> <li>• Build on or integrate with existing programs</li> <li>• Forecast future medicine and human resources needs and costs</li> </ul>
Inadequate regulation	<ul style="list-style-type: none"> <li>• Carry out regular quality control and assurance</li> <li>• Assess and react to key cost drivers</li> </ul>
Inefficient procurement, supply, and distribution	<ul style="list-style-type: none"> <li>• Monitor product availability</li> <li>• Establish drug facility</li> </ul>
High prices	<ul style="list-style-type: none"> <li>• Promote and prioritize low-cost generics</li> <li>• Reduce or remove tariffs, taxes, and mark-ups</li> <li>• Establish reference prices for reimbursement</li> </ul>
High out-of-pocket payments/Inadequate financial protection	<ul style="list-style-type: none"> <li>• Include essential MNS medicines in reimbursement/insurance schemes and international financing mechanisms</li> <li>• Reduce charges or co-payments; with a focus on generics</li> </ul>

SOURCE: Chisholm presentation, January 13, 2014.

### LESSONS LEARNED FOR ADDRESSING HIGH PRICING AND POOR FINANCING

As previously mentioned, five example programs addressing access to medicines were presented during the workshop to facilitate exploration of best practices and lessons learned from other programs. The examples were selected by planning committee members and included two country-level programs, an infectious disease project, and two noncommunicable

disease programs. Highlights from the presentations of the lessons learned for addressing high pricing and poor financing are provided in Box 5-2. A full description of the examples as presented can be found in Appendix A.

**BOX 5-2**

**Highlights of Lessons Learned from Example Programs:  
High Pricing and Poor Financing**

**Country Programs**

*National Health Insurance Scheme (NHIS), Ghana*

- The NHIS increased the affordability and usage of medicines and health care services for patients by providing access and financial coverage to basic health care for residents in Ghana through district-level and private health insurance schemes (NHIA, 2012).
- Revenue from a variety of sources, including taxes, premiums, investment income, and contributions from the national pension scheme, helps fund the NHIS.
- Potential cost containment efforts to improve the financial stability of the NHIS include
  - performing clinical audits to ensure compliance with standard treatment guidelines;
  - piloting capitation, which is the use of a set fee to health care providers for each NHIS-enrolled patient regardless of the services provided;
  - establishing a claims processing center to consolidate and streamline payments;
  - creating a uniform and serialized prescription form to reduce errors, abuses, and fraud;
  - linking diagnosis to treatment and e-claims according to codes for easier processing; and
  - negotiating prices for NHIS medicines to reduce cost to patients.

*The Accredited Drug Dispensing Outlets (ADDO) Program, Tanzania*

- The availability of wholesalers closer to ADDOs can reduce distribution costs and medicine prices due to reduced travel distances and easier procurement.
- There are benefits to reviewing lessons learned from other successful programs that have shown that subsidies for

essential commodities provided in the private sector are feasible (e.g., malaria).

- Linking ADDOs with health insurance schemes has reduced the out-of-pocket payments for individuals.
- Microfinancing loans to ADDOs may improve availability of medicines.

### **Infectious Disease Program**

#### *Multidrug-resistant Tuberculosis (MDR-TB)*

- A structured financing and pricing system might ensure payments for medicines are forthcoming, resulting in increased confidence by suppliers in market strength and creation of a market that is transparent with low prices.

### **Noncommunicable Disease Programs**

#### *Diabetes*

- Price components such as mark-ups and taxes may increase the price of medicines in both the public and private sectors.
- Reducing stock-outs within the public sector may help to decrease the number of patients who purchase higher priced medicines from the private sector.
- Developing a system or scheme for financing health care and medicines may help to reduce out-of-pocket costs for patients.
- Partnerships among manufacturer and regional patient associations can help to monitor patient prices in the public and private sectors; in addition, these partnerships can detect if medicines are diverted from the public sector into the private sector.

#### *Schizophrenia*

- Affordability of medicines might be improved using a tiered-pricing policy, including providing generics to patients below the poverty line at low costs.
- Addressing pricing and financing through both public and private channels can be more effective than a single focus.
- Controlling profit margins throughout the supply chain can help to ensure the affordability of medicines.

SOURCES: Presentations by Akpalu, Liana, Zintl, Ilondo, and Bompert. See Appendix A for full discussion and references.

### **CHALLENGES AND OPPORTUNITIES FOR ADDRESSING HIGH PRICING AND POOR FINANCING**

In preparation for the focused discussion on pricing and financing, Chisholm summarized key challenges that were discussed in the presentations and example programs. Pricing and financing are important factors that influence whether a patient has access to essential medicines to treat MNS disorders. Particularly for low-income countries, the affordability of accessing medicines can be a barrier to seeking care.

Several participants noted the value of real-time data collection and monitoring on the availability and price of medicines for MNS disorders. Given frequent stock-outs in the public sector, patients many times will purchase medicines in the private sector at higher costs or do without their medications. A few participants suggested that regulatory cost containment measures and negotiated prices around profit margins and differential pricing might increase the accessibility and affordability of medicines to patients. Due to the small market size and lack of incentives, a few participants noted that some manufacturers do not want to invest in SSA country markets. Many participants discussed how price components, such as mark-ups and taxes, can significantly increase the price of medicines to patients.

The discussion on financing focused on models for achieving a greater degree of protection against high costs of medicines and related care. Sustainability of financing was stressed by several participants, especially in the face of changing priorities and personnel. Innovative sources of funding were also discussed, such as mobile phone taxes, road taxes, or “sin taxes” on tobacco and alcohol.

Following the focused discussion, Chisholm reported that four priority constraints and/or barriers were identified by various participants relative to pricing and financing of MNS medicines: (1) lack of market analysis and data collection for making evidence-based decisions; (2) lack of or low public and private investment in MNS disorders; (3) a weak pharmaceutical market, including a lack of price competition and government regulation; and (4) poor access to affordable medicines for the insured and uninsured. All constraints and/or barriers and potential opportunities noted by participants are included in Table 5-2.

During the discussions many participants stressed the importance of conducting a full market analysis, including analysis of need, usage, prices, personnel, availability, quality, and supply chain elements.

Chisholm noted that this might enhance transparency and increase evidence-based decision making on policies impacting pricing and financing of medicines for MNS disorders. A few participants noted a need for an increase in priority given to MNS disorders for resource allocation, and highlighted roles for governments as well as NGOs, the pharmaceutical industry, professional organizations, and patient groups.

Several participants suggested that pharmaceutical markets for MNS treatments in SSA might be improved by increasing competition for different products, lowering barriers to entry into the market, and strengthening governance and regulation. In theory, Chisholm explained, more competition among different suppliers would lead to lower prices. He went on to note that improved regulation could help to eliminate non-quality assured products in the market, and control price mark-ups along the supply chain.

The lack of or low public and private investment in MNS disorders is a significant challenge for improving pricing and financing. To address this challenge, several participants stressed the importance of prioritizing the focus on these disorders by governments, nonprofits, and for-profit partners. One potential option would be to partially base health budget allocations on disease prevalence and burden to allow for a balanced approach relative to other communicable and non-communicable diseases.

Finally, Chisholm described the discussions for the challenge of poor access to affordable medicines for both the insured and uninsured. Many participants suggested that promotion of MNS medicines for inclusion on country-specific essential medicines list and health insurance schemes might increase coverage for these medicines. A second opportunity, highlighted by several participants, could be streamlined government procurement practices. Chisholm noted that these same participants stressed that this could only be effective if low procurement prices are passed along to patients, resulting in costs that are closer to international reference prices.

**TABLE 5-2** Opportunities to Address High Pricing/Poor Financing of Essential Medicines as Identified by Individual Workshop Participants<sup>1</sup>

Constraint and/or Barrier	Potential Opportunity	Relevant Outcome(s)	Potential Metric(s) of Success	Suggested Partnership(s)	Secondary Consideration(s)
Lack of market analysis and data collection for making evidence-based decisions. <sup>c,d,e</sup>	Enhance transparency through the conduction of market analysis, including analysis of need, usage, prices, personnel, availability, quality, manufacturers, distributors, and supply chain elements. <sup>a,b,c,d,e</sup>	Evidence-based decision making on policies impacting pricing and financing of medicines for MNS disorders. <sup>c,d,e</sup>	Availability, publication, and use of market analysis. Regular and continuing analysis and data updates. <sup>c,d</sup>	WHO; HAI; Ministry of Health; regulatory bodies; health insurers; associated national health researchers. <sup>a,b,c,d,e</sup>	Resources (e.g., financial, human) for analysis may vary by country. <sup>c,d</sup>

<sup>1</sup>This table presents challenges and opportunities discussed by one or more workshop participants. During the workshop, individual participants engaged in active discussions. In some cases, participants expressed unique ideas and/or differing opinions. However, because this is a summary of workshop comments and does not provide consensus recommendations, workshop rapporteurs endeavored to include all workshop participant comments. This table and its content should be attributed to the rapporteurs of this summary as informed by the workshop.

Constraint and/or Barrier	Potential Opportunity	Relevant Outcome(s)	Potential Metric(s) of Success	Suggested Partnership(s)	Secondary Consideration(s)
Lack of or low public and private investment in MNS disorders, including low donor interest. <sup>c,d,e</sup>	Increased priority of funds for MNS disorders at governmental levels. Evidence-based prioritization. <sup>c,d,e</sup>	Increased focus on MNS disorders, including balanced attention relative to other diseases. Improved transparency of budget allocation for MNS disorders based on disease prevalence and needs of population. <sup>c,d,e</sup>	Increased funding and resource allocation for MNS-related services. Improved patient outcomes. <sup>b,c,d,e</sup>	WHO; patient advocacy groups; Ministry of Health; Ministry of Finance. <sup>a,b,c,d,e</sup>	N/A

Constraint and/or Barrier	Potential Opportunity	Relevant Outcome(s)	Potential Metric(s) of Success	Suggested Partnership(s)	Secondary Consideration(s)
Lack of or low public and private investment in MNS disorders, including low donor interest. <sup>c,d,e</sup>	Increased priority by supra-national and nongovernmental, not-for-profit, and for-profit partners. <sup>b,c,d,e</sup>	Increased focus on MNS disorders, including balanced attention relative to other diseases. <sup>b,c,d,e</sup>	Greater availability of competitively priced medicines. Increased public awareness and advocacy. <sup>b,c,d,e</sup>	Pharmaceutical companies; nongovernmental agencies; professional associations; physician groups. <sup>a,b,c,d,e</sup>	N/A



Constraint and/or Barrier	Potential Opportunity	Relevant Outcome(s)	Potential Metric(s) of Success	Suggested Partnership(s)	Secondary Consideration(s)
<p>A weak pharmaceutical market for MNS disorder medicines, including a lack of price competition, poor government regulation of pricing, and poorly organized markets.<sup>a,b,c,d,e</sup></p>	<p>Increased competition and lower barriers to entry into the market to include sharing of best practices.<sup>a,b,c,d</sup></p>	<p>Increased number of stakeholders involved in medicines for MNS disorders. More affordable product options for MNS disorders.<sup>a,b,c,d,e</sup></p>	<p>Lower prices for MNS disorder medicines.<sup>c,d</sup></p>	<p>Manufacturers; regulators; trade ministries; regional trading blocs; tax authorities.<sup>a,b,c,d,e</sup></p>	<p>N/A</p>

Constraint and/or Barrier	Potential Opportunity	Relevant Outcome(s)	Potential Metric(s) of Success	Suggested Partnership(s)	Secondary Consideration(s)
<p>A weak pharmaceutical market for MNS disorder medicines, including a lack of price competition, poor government regulation of pricing, and poorly organized markets.<sup>a,b,c,d,e</sup></p>	<p>Strengthened governance and regulations.<sup>b,c,e</sup></p>	<p>Full implementation and enforcement of simpler and clearer regulations, requirements, and procedures. Elimination of approval of non-quality-assured products.<sup>b,c,d,e</sup></p>	<p>Reduced level and range of mark-ups. Delisting of poorer quality products from medicines lists.<sup>d,e</sup></p>	<p>WHO prequalification system and good governance for medicine principles; regulatory authorities; groups that can influence distribution channels of products (e.g., trade unions); providers; professional associations; civil society; Ministry of Health.<sup>b,c,d,e</sup></p>	<p>N/A</p>

Constraint and/or Barrier	Potential Opportunity	Relevant Outcome(s)	Potential Metric(s) of Success	Suggested Partnership(s)	Secondary Consideration(s)
<p>Poor access to affordable medicines for both the insured and uninsured, including unaffordable out-of-pocket expenses, and catastrophic spending for the insured.<sup>b,c,d,e</sup></p>	<p>Promotion of MNS medicines for inclusion on essential medicine lists and disease management in health insurance schemes.<sup>c,d,e</sup></p>	<p>Increased needs-based coverage and financial protection.<sup>d,e</sup></p>	<p>Reduced out-of-pocket payments for MNS medicines. Reduction of the treatment gap.<sup>c,d,e</sup></p>	<p>Ministry of Health; Ministry of Finance; Ministry of Trade; insurers; advocacy groups; consumer groups; international partners; public-private partnerships<sup>a,b,c,d,e</sup></p>	<p>Bundle medicines with other aspects of care (e.g., non-pharmaceutical tools, monitoring).<sup>b,c,d,e</sup></p>

Constraint and/or Barrier	Potential Opportunity	Relevant Outcome(s)	Potential Metric(s) of Success	Suggested Partnership(s)	Secondary Consideration(s)
<p>Poor access to affordable medicines for both the insured and uninsured, including unaffordable out-of-pocket expenses, and catastrophic spending for the insured.<sup>b,c,d,e</sup></p>	<p>Streamlined government procurement of medicines at efficient prices while passing along low procurement prices to patients and promoting exemption of taxes on MNS medicines.<sup>c,d,e</sup></p>	<p>Decrease in overall unit cost per end-user.<sup>c,d</sup></p>	<p>End-payers pay close to international reference prices for the public sector.<sup>c,d,e</sup></p>	<p>Ministry of Health; Ministry of Finance; Ministry of Trade; insurers; international partners; public-private partnerships<sup>a,b,c,d,e</sup></p>	<p>N/A</p>

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<sup>a</sup>Michelle Akande  
<sup>b</sup>Francois Bompart  
<sup>c</sup>Dan Chisholm  
<sup>d</sup>Margaret Ewen  
<sup>e</sup>Frances Jensen



## 6

### Perspectives on Next Steps

#### **Potential Opportunities for Addressing the Four Challenge Areas as Presented by Individual Participants**

##### **Insufficient Demand**

- Implementation of the Mental Health Gap Action Programme (mhGAP) intervention guide and training modules to increase detection, diagnosis, and treatment.
- Development of national task forces composed of government officials and key stakeholders to advocate for and develop training and education plans for mental, neurological, and substance use (MNS) disorders.
- Integration of patient- and family-oriented training into existing community-based programs to develop an informed population about MNS disorders and treatment outcomes.
- Reduction or removal of policy limitations on which levels of health care providers can prescribe medications and which medications they can prescribe, leading to an increased number of available prescribing providers.

##### **Inappropriate Selection**

- Development of a coherent and comprehensive national strategy, based on mhGAP, for the treatment and care of MNS disorders that receives widespread support and resources by key stakeholders.
- Development of national medicine lists and treatment guidelines for each level of provider based on agreed-upon task-shifting practices.

- Establishment of a learning health system to include review, revision, and periodic updates.
- Increased inclusion of medicines that promote adherence and greater accommodation of a reasonable range of provider and patient medication preferences.
- Promotion of evidence-based selection of medicines through the development of training programs.

#### **Ineffective Supply Chains**

- Development of an information network systems approach for improved communication among tiers leading to streamlined and continuous flow of data.
- Training on data collection and analysis, leading to improved forecasting and reduced stock-outs and overstocking.
- Learning and leveraging information systems of other vertical supply chain programs.
- Increased training of supply chain staff on logistic management information systems and all levels of health care providers about supply chains and logistics.
- Increased allocation of human resources for supply chains and inclusion of supply chain workers in determining needs for health care systems.
- The use of mobile technology across tiers and/or facilities.
- Establishment of therapeutic committees at health institutions to conduct coordination efforts and consider information on needs, stocks, and supply chain logistics.
- Reduction of the number of tiers between central warehouses and patient distribution points.
- Improved transportation between central warehouses and local distribution points to decrease time and costs for medicines to arrive.
- Increased working capital funds for national medicine supply agencies.

#### **High Pricing and Poor Financing**

- Evidence-based policies can impact pricing and financing of medicines.
- Increase in evidence-based prioritization of funds for MNS disorders by governments, not-for-profit, and for-profit partners.
- Increased competition and lower barriers for entry into the market leading to an increased number of stakeholders and affordable medicine options.

- Implementation of simpler and clearer regulations, requirements, and procedures.
- Streamlined procurement of medicines at efficient prices and passing along of low procurement prices to patients, leading to a decrease in the overall unit cost of medicines.

NOTE: The items in this list were addressed by individual participants and were identified and summarized for this report by the rapporteurs, not workshop participants. This list is not meant to reflect a consensus among workshop participants.

SOURCE: Adapted from chapter tables and presentations by Collins, Pande, Dua, Chisholm, and Jensen. For additional attribution information, please refer to individual tables for each challenge area.

### CONSIDERATIONS FOR MOVING FORWARD

In the final session, individual workshop participants discussed the practicalities of drawing attention to and beginning to take action on the four challenge areas of insufficient demand, inappropriate selection, ineffective supply chains, and high pricing and poor financing. Hans Hogerzeil reiterated that SSA is made up of regions, countries, and people of many different languages and cultures, and there is no one-size-fits-all approach for access to essential medicines for MNS disorders. He emphasized country-based solutions based on the unique challenges in each country. Daniel Chisholm noted that the strategies discussed throughout the workshop are really a menu of potential options for countries to consider based on their current systems and situation. A participant noted that countries might be able to better strategize potential solutions if best practices and examples of successful access to medicines programs were disseminated widely. In particular, many participants noted that efforts to increase access to antiretroviral therapy (ART) for HIV/AIDS might be an additional program to explore, one not discussed in detail at the workshop. It was noted that rapid scale-up of access to ART was the result of advocacy efforts, political commitments, reductions in the cost of medicines, and increases in foreign assistance (IOM, 2013a). For low-income countries, scale-up was also successful due to an increased recognition among a range of stakeholders of the growing impact of HIV/AIDS on health, economics, and development along with growing evidence that it was possible to treat HIV/AIDS



(IOM, 2013a). Beyond infectious diseases, several participants pointed out that similar efforts are under way to address access to essential medicines for noncommunicable diseases in SSA and that concepts and strategies from these efforts could be applied to MNS disorders (Hogerzeil et al., 2013a).

Although the focus of the workshop was improving access to medicines to treat MNS disorders, individual workshop participants discussed the broader challenge of increasing access to MNS treatment and care. Several participants discussed national MNS programs that address access to treatment and care, as well as social and cultural issues such as stigma. The general lack of attention to MNS disorders was a central barrier across all four challenge areas and the need to encourage countries to address MNS disorders in the context of their overall health needs and national programs was emphasized by many participants. They stressed that access to medicines to treat MNS disorders can be integrated into existing activities and health care systems. In resource-limited environments, a few participants noted the importance of highlighting the return on investment for health in general, not just mental and neurological health. Addressing supply chain issues, for example, can impact access to medicines for many conditions. According to several participants, challenges associated with access to medicines are not specific to MNS disorders, but working to address MNS disorders could be positioned in policy discussions as an entry point for making changes in the country to address broader system issues. As an example, it was noted that programs such as the Emerging mental health systems in low- and middle-income countries (EMERALD) project<sup>1</sup> are trying to include improvement of MNS disorder outcomes as a component of overall health-systems strengthening initiatives.

In addition, several participants discussed demonstration projects that could be developed in partnership with government agencies to assess the feasibility of improving access to medicines. These demonstration projects could be implemented at the local level to achieve tangible results and provide evidence to support scale-up efforts. To be most effective, several participants suggested a need to focus on a few medicines or disorders for these demonstration projects. The evidence collected could empower champions to drive demand and push for systemic change, a participant noted. Champions can be public figures that draw attention to MNS disorders and help reduce stigma, clinicians

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<sup>1</sup>For further information see <http://www.emerald-project.eu>.

in the field who have first-hand experience with the needs of patients and the treatment gap, or others in the country or community engaged in the demonstration projects. Several participants reiterated that continuous monitoring of such projects is important for sustainability to assure officials that investments have been spent wisely and resulted in reduced costs, improved health outcomes, and/or reduced burden of disease.

Lastly, many participants discussed how partnerships with key stakeholders are essential to help foster action. Key stakeholders may include

- Government agencies (ministries of health, finance, and trade);
- Pharmaceutical manufacturers (generic and non-generic);
- Supply chain management professionals;
- Global and local nongovernmental organizations (e.g., WHO, the World Bank);
- Health care providers;
- Professional associations;
- Patient groups;
- Health educators; and
- Donors and foundations.

Multiple roles for WHO and other key stakeholders were suggested, such as creating consortia for guidelines and best practices; education and credentialing aligned with the use of guidelines; and incorporating tools and strategies from workshop proceedings into mhGAP programs. It was suggested that the annual mhGAP forum, which brings together governments, international NGOs, researchers and other stakeholders, could be one venue to reach out to the target audience for many of the concepts discussed during the workshop. Individual participants were also eager to see MNS disorder outcomes linked to the MDGs.

### **CLOSING COMMENTS**

Although it was acknowledged that the challenges associated with improving access to essential medicines for MNS disorders have been discussed for decades, many participants believe there is an opportunity now to conduct an all-inclusive exploration and develop system-wide solutions to the barriers impacting access to MNS medicines. The strategies discussed by many workshop participants may help

countries conduct individual assessments of their needs. The potential opportunities and strategies to improve demand, selection, supply chains, and pricing and finance, rely heavily on increasing public and political awareness of, and provider training in MNS disorders. Lastly, applying global knowledge from other chronic disease areas, sharing best practices that can be adapted to a country's policies, and leveraging existing systems may offer additional insights on potential solutions. As potential next steps, a few participants discussed the value of developing a toolkit that countries could use to assess their individual country needs and inform their decisions and system improvements. Several participants also reiterated the role and potential value of small, focused demonstration projects in developing the evidence base to support incremental and sustainable systemic change at a national level.

## A

### **Access to Essential Medicines: Program Examples**

#### **COUNTRY PROGRAMS**

##### **National Health Insurance Scheme–Ghana**

Albert Akpalu, a neurologist at the Korle Bu Teaching Hospital in Ghana, began by emphasizing that Ghana’s national drug policy is to “improve and sustain the health of the population of Ghana by ensuring the rational use and access to safe, effective, good-quality, and affordable pharmaceutical products.” He went on to explain that in the mid-1980s, Ghana had a “cash and carry” health care system in which payments from patients were required prior to receiving services. Due to high out-of-pocket expenses and low usage of services, the system excluded a majority of the population from access to health care. In the 1990s, community-based mutual health insurance schemes were introduced in which members paid enrollment fees and premiums to receive health insurance coverage with minimum copayments. However, benefit packages were limited to a few health care providers due to the limited ability of patients to make payments and no additional financial support from the government. Akpalu noted that by 2000, it became clear that this scheme was neither sustainable nor able to reach the population beyond the 1 to 2 percent that was covered in these schemes in Ghana (Blanchet and Acheampong, 2013).

In 2003, the Ghana National Health Insurance Scheme<sup>1</sup> (NHIS) was established, with the support of both public and private stakeholders, to provide financial access to basic healthcare services through district-level and private health insurance schemes (NHIA, 2012). The goal was to “increase affordability and utilization of drugs and health services in general, and among the poor and most vulnerable populations in particular” (Blanchet et al., 2012). Expenses associated with the NHIS are covered by the National Health Insurance Fund which receives revenue from a variety of sources (e.g., taxes, premiums) (NHIA, 2012). Akpalu emphasized that, although certain health services are excluded from the scheme (e.g., computed tomography [CT] scans, magnetic resonance imaging [MRI], cancer treatments), enrollees are not subject to copayments, deductibles, or lifetime limits.

In 2012, revisions were made to improve transparency, reduce opportunities for corruption, and increase effective governance. For the first time, mental, neurological, and substance use (MNS) disorders have been recently integrated into the health insurance scheme, including premium exemptions for persons with MNS disorders. Currently about 50 percent of the population has active membership in the NHIS (NHIA, 2012). He added that since 2005, payments on insurance claims have increased about 81-fold along with significant increases in patient use and active membership (Blanchet et al., 2012; UHCC, 2013). Akpalu referred to the recently enacted Mental Health Bill, drafted with assistance from the World Health Organization (WHO), that includes provisions for improved access to mental health care and regulation of providers, and efforts to combat stigma and discrimination (Doku et al., 2012).<sup>2</sup> Overall, Akpalu noted, the implementation of the NHIS in Ghana significantly increased healthcare coverage, availability of services, and use among residents.

Using epilepsy as an example of the need for increased access to appropriate essential medicines, Akpalu said 80 percent of those with epilepsy in Africa do not receive treatment (WHO, 2002a). Addressing the four challenges areas highlighted during the workshop, he noted that low demand can be the result of a lack of providers with the knowledge to treat epilepsy. The low number of facilities dedicated to treating MNS disorders results in integration of patients into the primary health care system regardless of a lack of human resources. Akpalu also noted there are insufficient community-based interventions and support for people

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<sup>1</sup>See <http://www.nhis.gov.gh>.

<sup>2</sup>For more information see [http://www.who.int/mental\\_health/policy/country/ghana/en](http://www.who.int/mental_health/policy/country/ghana/en).

with epilepsy, which can be exacerbated by the stigma surrounding MNS disorders. He went on to say that selection of antiepileptics remains a challenge due to unreliable data on the size of the patient population. Focusing on supply chain issues, he noted that poor integration of MNS disorders into primary health care has led to fragmented supply and distribution of antiepileptics. Lastly, financing for such medicines continues to be a challenge. Akpalu noted that Ghana needs to clarify the national, regional, and district positions on financing antiepileptic medications before the medicines can become part of the NHIS.

### *Lessons Learned*

Akpalu discussed several examples of how Ghana is addressing the four challenge areas (i.e., demand, selection, supply chains, pricing/financing) and provided potential lessons on these issues as they relate to access for MNS disorder medicines. Ghana is looking to improve the demand for services by establishing a health insurance institute to improve and promote NHIS to all residents, with particular emphasis to the poor. The country is also working to improve issuance of membership identification cards to decrease potential service delays. One program aimed at increasing demand is the Ghana Fights Against Epilepsy Initiative (GFAEI), which seeks to strengthen the referral system and develop treatment protocols for the management of epilepsy. In addition, GFAEI is focused on improving the supply of antiepileptic medications and developing mechanisms for better patient follow-up. Another program is the Parkinson's Disease in Ghana project, which seeks to increase demand by improving provider knowledge and providing free long-term medicines for patients.

Ghana has several initiatives targeting selection challenges, including the development of national treatment guidelines and an essential medicines list; in addition, a new national guideline for epilepsy drugs will be released soon.

Akpalu highlighted lessons learned about pricing and financing, including several potential measures to enhance sustainability through cost containment and increasing financial resources. From a cost containment perspective, clinical audits can help ensure that providers are complying with standard treatment guidelines. Ghana is currently piloting a capitation system, in which a set fee is paid to health care providers for each NHIS-enrolled patient, regardless of the services provided. A consolidated premium payment account with a one-time

premium for free health care for life is also being considered; however, Akpalu noted that this approach may not be sustainable. Other potential approaches to contain costs include

- Developing a claims processing center with computerized operations to streamline payments (e.g., electronic claims);
- Creating a uniform and serialized prescription form to reduce errors, abuses, and fraud;
- Linking diagnosis to treatment and e-claims through a coding system for easier processing;
- Piloting NHIS medicines at negotiated prices; and
- Purchasing medicines via contracts to help reduce prices of branded medicines.

Further funding for sustainability includes an increase in national health insurance levies and taxes. Ghana also plans to strengthen audit and risk management systems, as well as programs to reduce fraud and abuse. High-level, evidence-based research on health insurance policy challenges may help inform the direction of future initiatives.

Akpalu closed by noting that while challenges remain related to financial sustainability, patient ability to pay premiums, quality of care, pricing of medicines, and supply chains, Ghana is actively working to address each area.

### **Accredited Drug Dispensing Outlets (ADDO)–Tanzania**

In sub-Saharan Africa (SSA), patients typically purchase medicines from the nearest available supplier, said Jafary Liana, senior technical advisor at Management Sciences for Health and the Sustainable Drug Seller Initiatives (SDSI). Tanzania has more than 9,000 drug dispensaries compared to only 800 registered pharmacies. Ninety-five percent of the population lives within 5 km of a drug dispensary. Local drug dispensaries, given their close proximity, provide a critical opportunity for improving access to medicines for rural populations. There is also a perception that a local dispensary is more personal, offers patients more privacy to discuss concerns with dispensers, and has more flexible payment modalities. For local drug dispensaries, however, there are challenges associated with level of support from the government, training

of personnel, and inadequate regulatory enforcement (e.g., sale of unauthorized medicines, poor quality medicines, high prices).

ADDO was designed to help address these challenges through a series of steps aimed at enhancing regulatory compliance, improving health care provider skills, developing incentives for the legal sale of medicines, and increasing consumer education on the importance of treatment adherence and the quality of medicines. The objective of the ADDO program is to improve the quality, affordability, and availability of medicines in local drug dispensaries (Center for Pharmaceutical Management, 2008). The Tanzania Ministry of Health worked with Management Sciences for Health<sup>3</sup> on the development of a comprehensive approach based on the following strategies:

- Increase broad-based stakeholder support through the engagement of both national and local authorities, and professional and commercial associations. These and other stakeholder groups, are encouraged to participate in project design and implementation.
- Develop guidelines for a public-sector-based system responsible for inspecting and regulating processes and capacities at local dispensaries.
- Provide training to dispensary owners to improve business and stock management skills, and to dispensary attendants to strengthen dispensing, record-keeping, and communication skills. Dispensary associations may offer additional support to local owners and dispensers through mentoring.
- Provide incentives, such as loans, for dispensaries to improve the quality and quantity of available medicines. Expand the list of medicines that shops are legally allowed to stock and sell.
- Enhance the availability and quality of approved medicines in accredited dispensaries.
- Ensure quality pharmaceutical services by educating, training, and monitoring dispensary staff.
- Increase patient and consumer awareness about the importance of treatment adherence and use of quality medicines through marketing, information, and education.

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<sup>3</sup>For more information see <https://www.msh.org/our-work/projects/sustainable-drug-seller-initiatives>.



Implementation of the ADDO program spanned 10 years (2001-2010) from conception through scale-up. The program is now in the maintenance and sustainability phase, with efforts to integrate public health into the program. As noted earlier, Liana stressed that local community residents feel comfortable going to local dispensaries and as a result these dispensaries serve as the first line of triage for individuals with health concerns. For examples, educating dispensers on early signs of childhood pneumonia and the appropriate actions to take (e.g., referral to a health care provider) may help improve health outcomes.

Liana pointed out that a critical component after the pilot phase was determining how to take the program countrywide. The original centralized implementation approach, with the Tanzania Food and Drug Authority as the implementing organization, was revised to a decentralized model in which local governments now facilitate implementation. This allowed for rollout of the ADDO program in multiple regions at the same time—increasing speed, reducing costs, and increasing local ownership of the process. Public–private partnerships and collaborations were essential for successful implementation. With the government of Tanzania as the lead organization, partners included private owners and dispensers, international foundations, and local organizations.

The accreditation process for ADDOs is based on a set of standard criteria. For example, there are standards for the premises, and the owner is given a guide on how to bring their outlet to compliance. There are training and qualification standards, including minimum qualifications for a worker in the outlet, and additional training for pharmaceutical dispensing and recordkeeping. Once owners have their shop inspected and accredited, they are required to adhere to dispensing from a standard list of medicines.

Liana highlighted several challenges to implementation of the program. Consumer awareness about services was an important component and affected demand, especially in poor areas where there were unique challenges. The lack of trained personnel to run the dispensaries resulted in limits to the type and quantity of medicines dispensed. The initiative required revisions to existing laws and regulations, which was a complex process. Liana noted there was a need to balance the focus on public health and quality of service with pricing issues in a for-profit environment. Resource mobilization for full scale-up was a significant challenge, as was ensuring consistent local regulatory oversight of the large number of ADDOs around the country.

A limitation was inadequate budgeting by districts to cover the necessary inspections and provide supervision to the dispensaries.

### *Lessons Learned*

ADDOs are private health outlets that serve the needs of the community and are a major source of medicines at the household level. ADDOs are often preferred because they are convenient and can offer personalized service and payment options, Liana said. In addition, ADDOs can fill the gap when products are out of stock in the public health sector. In the case of Tanzania, the challenges associated with demand were low; however, other challenges associated with access to essential medicines are present, said Liana.

Selection of authorized medicines for ADDOs was based on community needs, storage conditions, qualifications of personnel, and public health priorities. Medicines were also selected based on prevalent acute childhood conditions such as malaria, and chronic illness such as hypertension. Regular reviews and updates of the list to address public health needs are important, Liana stressed, with regulations requiring review every 2 years.

The expanded list of medicines legally allowed in ADDOs provided an incentive for suppliers to extend their distribution into regions with ADDOs, thereby addressing some of the challenges associated with the supply chain. In addition, a new category of ADDO-restricted wholesalers was established, licensed to operate in districts with no pharmacies. Another mechanism for improve the supply chain involved the pooling of procurements by coordination through district-based ADDO associations.

The availability of wholesalers closer to these drug outlets tends to reduce the prices, Liana explained, because travel distances are reduced and it is easier to procure medicines. Experience with the family planning and malaria programs in Tanzania has shown that subsidies for essential commodities provided in the private sector are feasible. Microfinancing loans to ADDOs can also improve availability of medicines. Linking ADDOs with health insurance schemes has reduced the out-of-pocket payments for individuals.

The ADDOs have been used as a platform for community-based public health interventions (e.g., malaria, family planning) and are likely to be a good place to build MNS community-based programs, Liana said. ADDO's extended list of medicines broadens access to quality-assured

pharmaceutical medicines, especially in rural settings, and the list could be expanded to include essential MNS medicines. Liana noted that households needing access to MNS medicines are already served by ADDOs. Introduction of MNS medicines, like any new intervention, would require training, mentoring, supervision, and regular monitoring of dispensers. Linking with insurance schemes could help MNS patients reduce out-of-pocket spending for medicines. The keys to the success of the ADDO program are stakeholder buy-in, local ownership, and the involvement of government champions and private-sector and development partners.

## INFECTIOUS DISEASE PROGRAM

### Multidrug-Resistant Tuberculosis

Treatment of multidrug-resistant tuberculosis (MDR-TB) remains a significant unmet medical need, particularly in the developing world (IOM, 2014; WHO, 2011b). Paul Zintl, senior advisor for planning and finance in the Program in Infectious Disease and Social Change at Harvard Medical School, shared the example of MDR-TB to highlight the obstacles to scaling up treatment efforts, and the delays in treatment of patients resulting from a lack of access to quality-assured medicines.

In 1996, policies were in place that recommended poor countries not treat patients with MDR-TB because (1) there was a perception that it was not possible to cure patients in resource-poor countries; (2) treatment with second-line TB medicines, which require a 2-year treatment regimen and are typically weak, would increase resistance; and (3) a focus on MDR-TB would divert resources and attention from curing the resurgence of drug-sensitive TB. From 1998 until 2006, Partners in Health<sup>4</sup> and other nongovernmental organizations (NGOs), together with country partners, worked to prove that patients in resource-poor settings could be treated and cured of MDR-TB. The project, dubbed “DOTS-Plus,”<sup>5</sup> was done in conjunction with WHO and the Green Light Committee (IOM, 2009b, 2013c; WHO, 2006a). During this time, ambivalence about scaling up treatment efforts remained despite policy

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<sup>4</sup>See <http://www.pih.org>.

<sup>5</sup>DOTS, or directly observed therapy short-course, is the WHO recommended strategy for TB control. DOTS-Plus employs the elements of the DOTS strategy to address the management of MDR-TB using second line drugs (WHO, 2006b).

changes; this resulted in devastating outcomes to those affected by MDR-TB.

Zintl highlighted a 2006 review by the Stop TB Partnership that found that two-thirds or more of patients in DOTS-Plus were being cured and that there was no meaningful spread of drug resistance as a result of this treatment. Around the same time, research demonstrated that primary transmission of MDR-TB was possible despite prior skepticism that the organisms were not fit enough for transmission; co-infection with MDR-TB and HIV was also having devastating effects in many countries, particularly in SSA; and the emergence of extensively drug-resistant TB (XDR-TB) was a cause for serious concern (Gandhi et al., 2006). As a result, in late 2006 the policy recommendations were revised to instruct any country with a significant rate of MDR-TB, and a well-functioning TB program to begin treatment of patients.

Although there were shortcomings in the scale-up projects for access to MDR-TB medicines, Zintl noted there are several lessons learned around the four challenge areas that could apply to MNS disorders.

#### *Lessons Learned*

Zintl noted that the initial pilot project included only a small number of patients NGOs working together with local partners to gain access to MDR-TB medicines. Medicine procurement was typically done with one or two suppliers who discounted their prices for some key second line medicines. In 2007, following the revised recommendations, countries began to scale up treatment; however, increased demand coupled with a lack of effective supply chains and additional infrastructure components resulted in medicine shortages and long lead times, Zintl explained. In addition, projects using Global Fund resources needed preapproval for purchases and procurement through the global drug facility, resulting in further delays. Although there was demand in the sense that there were many patients in need, there was limited clinical expertise and diagnostic and laboratory capacity to determine the resistance profile and treatment course. Some of these challenges were solved when the *Guidelines for the Programmatic Management of Drug-Resistant Tuberculosis*<sup>6</sup> was released by the Stop TB Partnership. The guidelines included health care provider-specific recommendations for the diagnosis and care of MDR-TB patients.

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<sup>6</sup>See [http://www.stoptb.org/assets/documents/resources/publications/technical/tb\\_guidelines.pdf](http://www.stoptb.org/assets/documents/resources/publications/technical/tb_guidelines.pdf).

Zintl noted that reliable estimates of patient demand may have helped alleviate issues related to supply chains. For example, countries may inaccurately estimate demand if supply levels are determined based on the projected number of patients instead of the actual number currently enrolled in medication regimens. These inaccurate estimates can lead to decreased confidence by suppliers and result in a market that is small and opaque with high prices. Uncertainties within the supply chain may be decreased with a structured financing and pricing system to ensure payment for medicines.

Zintl summarized that due to the lack of access to quality MDR-TB drugs, the threat of drug resistance tuberculosis still remains a concern; however, Zintl noted, this does not have to be the case for MNS disorders. The concept that ignoring MDR-TB would have devastating ramifications had been demonstrated for years and was further emphasized by the findings of primary transmission and MDR-TB and HIV co-infection. Based on his experience with MDR-TB, Zintl cautioned that it is not sufficient to make the case that MNS disorders, if ignored, will have a devastating impact. He stressed that it is necessary to also demonstrate that targeted access to medicines programs improve overall population health outcomes and are feasible.

## NONCOMMUNICABLE DISEASE PROGRAMS

### Diabetes

Worldwide, 382 million people are diabetic with half of those undiagnosed, said Mapoko Mbelenge Ilondo, senior advisor for Corporate Stakeholder Engagement at Novo Nordisk A/S, Denmark. Four out of five people with diabetes live in low- and middle-income countries; the disease affects approximately 20 million people in Africa (IDF, 2013). Although diabetes cannot be cured, it can be treated and controlled with medication (e.g., glibenclamide, metformin, insulin). Lack of proper disease management can lead to serious complications such as amputation, blindness, and renal failure; management is especially important in SSA due to limited facilities for dialysis treatment due to kidney failure.

Access to insulin in SSA, like many essential medicines for non-communicable diseases, is limited in both the public and the private sectors, Ilondo said, adding that the leading cause of death for a child

with diabetes in SSA is lack of insulin. Even when insulin is available, however, many children die because of lack of access to qualified health care professionals.

The actual number of people with diabetes in most SSA countries is unknown. Diagnostic rates are low, especially in rural areas, due to lack of awareness among health care providers and the general population. Therefore, procurement of medicines by governments is sometimes based on arbitrarily determined budgets and not on actual demand. Ilondo noted that because insulin is generally not available at the primary care level, patients often travel long distances to access treatment; transportation-associated costs become a limiting factor in demand. In SSA, the lack of qualified health care providers in the field of diabetes is a major barrier to access to proper diabetes treatment. This in turn impacts access because selection of diabetes medicines depends partly on provider knowledge and understanding of diabetes management.

Ilondo described challenges around supply chains due to limited government health care budgets in SSA countries and low priorities assigned to noncommunicable diseases, such as diabetes. Due to logistical challenges, diabetes medicines are generally available only in major cities in SSA. In the public sector, central medical stores within the Ministry of Health organize the distribution to government hospitals and health centers. However, distribution to rural areas is deficient, especially for insulin, which requires adequate facilities for temperature-controlled transportation and storage (cold chain). Ilondo noted that stock-outs are common in the public system as a result of both inadequate procurement and product being diverted to the more lucrative private-sector market, where diabetes medicines are imported and distributed to private hospitals and pharmacies.

Limited government budgets for the purchase of medicines often leads to a reliance on donor funds. In the public sector, prices are typically low because of the competitive nature of the tender (i.e., bidding) system. However, that low price is not always passed on to the patient (e.g., price mark-ups to cover distribution costs). In the private sector, patient prices can be high due to import duties, taxes, and serial mark-ups along the distribution chain, often three to five times the price in the government system. Given frequent shortages in the public system, many patients purchase their diabetes medicines at high prices from private pharmacies. In many SSA countries, there is no system for financing of health care, so patients typically pay out-of-pocket for medicines.

*Lessons Learned*

Ilondo described several steps Novo Nordisk has taken to attempt to address challenges associated with access to diabetes medicines. In the public sector, Novo Nordisk implemented differential pricing for the least developed countries; however, this did not increase procurement as expected. Training in stock management was provided, but this was often perceived as a conflict of interest coming from a manufacturer. Ilondo noted that manufacturers have little leverage in the private sector beyond trying to negotiate profit margin in contracts. In addition, Novo Nordisk worked to strengthen distribution channels to ensure medicines reach rural areas. He added that Novo Nordisk worked with regional diabetes associations to conduct spot checks of end-user prices in the public and private sectors to detect if products were being diverted from the public system to the private system.

Ilondo stated that the experience of Novo Nordisk in many countries indicates that accessibility and affordability of diabetes care and medicines is a complicated issue that requires coordinated approaches with multiple stakeholders. Securing cooperation and commitments from key stakeholders such as the ministry of health, regional and district medical officers, industry partners, importers and wholesalers, patient associations, and community organizations is critical to improving treatment of diabetes, noted Ilondo. Moving forward, Ilondo highlighted the need for government involvement in conducting needs estimates; health care provider training on recognition, diagnosis, and evidence-based treatment; and community awareness. Limited health care capacity, inefficient procurement and distribution practices, and inadequate transportation and facilities for storage of insulin are additional challenges. What is needed, he said, is a patient-centered approach, including dedicated clinics with insulin in stock at an affordable price and trained personnel available when patients arrive.

**Schizophrenia**

As part of its corporate social responsibility activities, Sanofi has an Access to Medicines program<sup>7</sup> that spans pandemic diseases, neglected tropical diseases, and chronic diseases, including MNS disorders, said

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<sup>7</sup>See [http://en.sanofi.com/csr/patient/priorities/access\\_to\\_care/access\\_to\\_medicines/access\\_to\\_medicines.aspx](http://en.sanofi.com/csr/patient/priorities/access_to_care/access_to_medicines/access_to_medicines.aspx).

Francois Bompert, medical director of the Access to Medicines department at Sanofi. The Access to Medicines approach for MSN disorders includes

- Tiered pricing for sustainably affordable medicines;
- Non-promotional education and information programs for professionals on diagnosis and care, as well as for patients, and communities including psychosocial support and efforts to reduce stigma; and
- Industrial expertise (e.g., high quality manufacturing, research and development) to meet emerging needs and transfer knowledge to developing countries.

Bompert noted that all three approaches rely on partnerships for success, including ministries of health, NGOs, local experts in the field, the World Association of Social Psychiatry, and patient associations. Ultimately, the patients are at the center of the Access to Medicines program, he said, and attention must be paid simultaneously to addressing the issues surrounding diagnosis and care, affordable quality medicines, and awareness. Simply diagnosing an MNS disorder is not enough, opined Bompert; having access to medicines is critical, as is minimizing stigma which prevents patients from receiving access to care. Only initiatives which simultaneously address the three types of issues outlined above can success be sustained.

As examples, Bompert described pilot programs Sanofi is conducting in Mauritania and Morocco. Mauritania is a country of 3 million people served by three psychiatrists resulting in little psychiatric care outside of the capital city. A 2003 survey indicated that 35 percent of the population had at least one MNS disorder (Gérard and Bompert, 2013). Morocco has 30 million people and 350 psychiatrists, most of whom are in major cities. The same survey found that 49 percent of the population has or had at some point in time at least a minor psychiatric disorder.

The Sanofi pilot programs were designed to test a comprehensive, scalable model for sustainably improving access to health care for those with schizophrenia. Sustainability is essential because these are chronic, lifelong diseases, Bompert noted. The basic method was to include MNS care in the primary public health care system. Initially political decision makers were informed about the importance of MNS disorder care programs; the pilot project gained support by increasing awareness and through advocacy efforts.



Sanofi was able to increase demand by simultaneously launching awareness initiatives aimed at patients and families and training of primary health care providers. Patients and families received education and psychosocial support via an array of educational materials, including flip charts and comics strips for patients and families developed by Sanofi. The materials convey the same messages, but the text and pictures are adapted to the country (e.g., language, style of dress). Primary health care providers were trained in basic diagnostic procedures and treatment through slide kits, videos of patients, clinical case review and patient interviews. Bompert added that the program also included monthly supervision of providers and innovative new tools such as the use of telemedicine and an interactive version of the WHO Mental Health Gap Action Programme (mhGAP) guide on tablets.

Affordability of medicines was addressed through the tiered-pricing policy based on income level. Bompert noted that the most affluent people in the country pay market price in the private sector while in the public sector generics are available at lower prices. However, patients with incomes below the poverty line are only able to access medicines at street markets where prices are affordable but quality can be low. Sanofi's Access to Medicines Program sought to address this challenge by providing tiered-pricing generics to those below the poverty line; medicines were provided through national tender processes to governmental structures.

As a result of the pilot program in Nouadhibou, Mauritania, 6 new outpatient clinics focusing on MNS disorders were opened in the city, nearly 40 health professionals were trained, and medicines were provided at low cost by the National Hospital pharmacy. In addition, more than 1,000 people attended informational meetings, 1,200 patients were followed in clinics, and 342 new patients with schizophrenia were seen over the course of 30 months, reducing the treatment gap from 93 percent to less than 60 percent in that region. Similar results were obtained in Morocco, Bompert said (Gérard and Bompert, 2013).

### *Lessons Learned*

Bompert shared some of the lessons learned from the pilot programs relative to the challenge areas. Stimulating demand, he reiterated, requires a comprehensive approach, including community awareness, health care provider training, and availability of affordable medicines. Pilot programs such as Sanofi's can stimulate demand at the ground level

and raise awareness at the political level, he said. Although the initial focus of the two presented programs was on schizophrenia, these programs can address all MNS disorders.

Bompart suggested that the best approach to selection of medicines might be to have local experts select from the WHO list of essential medicines based on transparent criteria. The country list should be limited and sustainable, and accompanied by easy-to-follow treatment guidelines, he said.

Medicines must be available at the community level, Bompart continued. Shortages are very detrimental to patients and result in treatment interruption; overstocking should also be avoided. Bompart cautioned not to underestimate the complexities of data collection in low-priority programs in resource-poor countries. Choice of supplier cannot be limited to price alone, but also consider quality and reliability of the supply as well. Bompart suggested that the WHO prequalification process could add value. He emphasized that pricing and financing be considered in a manner that could address both public and private channels. Affordability means not just low purchase price but also controlled profit margins throughout the supply chain. One size does not fit all, Bompart concluded, and initiatives need to be modified on a country-by-country basis. Many programs initially rely on the energy and the charisma of a single individual as a champion. Sustained local political support is vital for long-term success.



## B

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### Workshop Agenda

**Improving Access to Essential Medicines for Mental, Neurological,  
and Substance Use Disorders in Sub-Saharan Africa:  
A Workshop**

**January 13-14, 2014  
Addis Ababa, Ethiopia**

**Background:**

Sub-Saharan Africa (SSA) has one of the largest treatment gaps for mental, neurological, and substance use (MNS) disorders in the world. In 2011 the Grand Challenges in Global Mental Health initiative identified priorities that will make a significant impact on the lives of people living with MNS disorders. The reduction of cost and improvement of the supply of effective medications was highlighted as one of the top five challenges. Critical to the success of any effort to reduce the treatment gap is a demonstration that ignoring MNS disorders is not only devastating for overall population health but that it also undermines efforts to prevent and treat other causes of disease burden. Efforts in this area should not try to compete for resources used to combat infectious diseases, but should, instead, try to leverage those ongoing activities with initiatives targeted to MNS disorders. For low- and middle-income countries improving access to essential medicines can be a tremendous challenge and a critical barrier to scaling-up care for MNS disorders. Given the importance of access to essential medicines this workshop will bring to-

gether key stakeholders to discuss opportunities for achieving long-term affordable access of medicines for MNS disorders.

### **Meeting Objectives:**

Participants will be invited to:

- Identify critical barriers that impact the procurement of essential medicines for MNS disorders.
  - Explore challenges and opportunities for improving access to essential medicines in four critical areas: demand, selection, supply chains, and financing and pricing
- Examine successful activities that increase access to essential medicines both within SSA and in other developing countries.
  - Identify critical components of these models that might be features in SSA programs focused on MNS disorders.
- Consider the role of governments, nongovernmental organizations, and private groups in procurement of essential medicines for MNS disorders.
  - Examine current funding and payment practices at each level.
  - Explore the impact of prescription practices on determining priority setting for acquiring essential medicines.
- Identify the key components of a distribution framework that may serve as a demonstration project focused on increasing access for these essential medicines.

## **DAY ONE**

8:30 a.m.      **Welcome**

**H. E. DR. KESETEBIRHAN ADMASU**  
Minister of Health, Ethiopia

8:35 a.m.      **Opening Remarks**

**STEVEN HYMAN, *Chair***  
Director, Stanley Center for Psychiatric Research  
The Broad Institute

8:40 a.m. **Access to essential medicines for MNS disorders with the greatest burden: Focus on depression, psychosis, and epilepsy**

**ATALAY ALEM**  
Professor of Psychiatry  
Addis Ababa University

9:00 a.m. **Current look at the supply of essential medicines for MNS disorders versus other disease areas (e.g., HIV/AIDS, malaria, tuberculosis)**

**PRASHANT YADAV**  
Director, Healthcare Research  
William Davidson Institute, University of Michigan

9:20 a.m. **Exploring successful access to medicine frameworks**

**HANS HOGERZEIL**  
Professor of Global Health  
Groningen University

9:40 a.m. **Charge to participants: workshop objectives and deliverables**

**TEDLA GIORGIS**  
Advisor, Officer of the Minister  
Ministry of Health, Ethiopia

<b>SESSION I: CHALLENGES AND OPPORTUNITIES FOR IMPROVING ACCESS TO ESSENTIAL MEDICINES</b>
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Session Objectives: Explore feasible opportunities for improving access to essential medicines in four challenge areas: demand, selection, supply chains, and financing/pricing. Examine how progress in one of these areas can impact the others. Consider current government, nongovernmental organizations, and private group decision-making strategies.

9:50 a.m. **Overview and Session Objectives**

**DAVID MICHELSON**, *Session Chair*

Vice President, Clinical Neuroscience and  
Ophthalmology  
Merck Research Laboratories

10:00 a.m. **Challenge 1: Insufficient Demand**

How is patient demand adversely affected by:

- The prevailing standard of care for MNS disorders?
- Provider training, prescribing ability, and prescribing knowledge?
- Ability of providers to monitor drug adherence and efficacy?
- Low awareness about availability of common medicines?
- Concerns around cost of both medicines and health care system use?
- Public stigma around MNS disorders?

**OYE GUREJE**, Professor

Department of Psychiatry  
University of Ibadan

10:25 a.m. **Challenge 2: Appropriate Selection**

How is appropriate selection of medicines adversely affected by:

- Low and/or variable availability?
- Regulatory and procurement procedures?
- Prescription practices and patient demand?
- Prioritizations based on disease area, cost, generation?

**HANS HOGERZEIL**, Professor of Global Health  
Groningen University

10:50 a.m. **BREAK**

- 11:05 a.m.      **Challenge 3: Ineffective Supply Chains**  
 How are supply chains for medicines adversely affected by:
- Absence of or delays in registration of drugs?
  - Absence of monitoring of drug supplies?
  - Transportation deficiencies?
- PRASHANT YADAV**  
 Director, Healthcare Research  
 William Davidson Institute  
 University of Michigan
- 11:30 a.m.      **Challenge 4: High Pricing/Poor Financing**  
 How are pricing and financing of medicines adversely affected by:
- Tariffs and taxes placed on supply prices?
  - High mark ups by suppliers and wholesalers?
  - Inadequate financial price off-setting by distributors?
- MARGARET EWEN (PRICING)**  
 Pharmacist  
 Health Action International
- DAN CHISHOLM (FINANCING)**  
 Health Economist  
 World Health Organization
- 12:10 p.m.      **Response Panel**
- Is there one area that could be considered the greatest barrier to improvement or are all four areas equal in burden?
- Government Perspective*  
**ATALAY ALEM**  
 Professor of Psychiatry  
 Addis Ababa University

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ESSENTIAL MEDICINES FOR MNS DISORDERS IN SSA

*Nongovernmental Organization Perspective*

**CHRISTINA NTULO**

Basic Needs

Uganda

*Private-Sector Perspective*

**ISMET SAMJI**, Director

Portfolio Expansion

GlaxoSmithKline

12:40 p.m.

**Panel discussion with session speakers and participants**

- How would changes in one area impact the other areas? For example, would increases in demand positively boost willingness of groups to finance essential medicines for MNS disorders?

**DAVID MICHELSON**, *Session Chair*

Vice President, Clinical Neuroscience and

Ophthalmology

Merck Research Laboratories

1:10 p.m.

LUNCH

**SESSION II: SUCCESSFUL PROCUREMENT OF ESSENTIAL MEDICINES**

Session Objectives:

Examine successful activities that have increased access to essential medicines both within SSA and in other developing countries. Explore acquisition and distribution models for other disease areas (e.g., diabetes, HIV/AIDS). Identify critical components that might be featured in programs focused on MNS disorders.

2:10 p.m.

**Overview and Session Objectives**

**EVA OMBAKA**, *Session Chair*

Senior Lecturer

St. John's University of Tanzania

Speakers will focus on the following questions:

- What were the challenges in developing and executing the project?
- What partnerships were critical to the success of the project?
- How were issues around demand, selection, supply chains, and pricing/financing addressed?
- Are there specific lessons learned that could be applied to efforts around MNS medicines?

2:20 p.m. **Set One—Country Programs**

*Example I—National Health Insurance*  
**ALBERT AKPALU**, Neurologist, Ghana

*Example II—Government Storage with Private Groups*  
**JAFARY LIANA**, Accredited Drug Dispensing Outlets (ADDO), Tanzania

3:00 p.m. **Set Two—Infectious Disease Programs**

*Example III—MDR-TB*  
**PAUL ZINTL**  
 Senior Advisor for Planning and Finance  
 Program in Infectious Disease and Social Change  
 Harvard Medical School

3:20 p.m. **BREAK**



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ESSENTIAL MEDICINES FOR MNS DISORDERS IN SSA

3:40 p.m. **Set Three—Noncommunicable Disease Programs**

*Example IV—Diabetes*

**MAPOKO MBELENGE ILONDO**, Senior Advisor  
Corporate Stakeholder Engagement  
Novo Nordisk A/S, Denmark

*Example V—Schizophrenia*

**FRANCOIS BOMPART**, Medical Director  
Access to Medicines  
Sanofi

4:20 p.m. **Lessons Learned—Discussion with Speakers and Participants**

- What components of the examples presented might translate well into a project around MNS medicines?
- What common challenges and opportunities would a demonstration project need to address early on?

**EVA OMBAKA**, *Session Chair*  
Senior Lecturer  
St. John's University of Tanzania

5:15 p.m. WRAP-UP AND ADJOURN

**DAY TWO**

8:15 a.m. **Day Two Welcome**

**STEVEN HYMAN**, *Chair*  
Director  
Stanley Center for Psychiatric Research  
The Broad Institute

8:20 a.m. **Day One Panel Review: Defining the Challenges,  
Understanding the Lessons**

**PAMELA COLLINS**

Director

Office for Research on Disparities & Global Mental  
Health, National Institute of Mental Health

**ATUL PANDE**

Senior Vice President, Neurosciences

Neurosciences Medicines Development Centre  
GlaxoSmithKline

**TEDLA GIORGIS**

Advisor

Officer of the Minister  
Ministry of Health, Ethiopia

**DAN CHISHOLM**

Health Economist

World Health Organization

**SESSION III: A ROADMAP FORWARD—ADDRESSING THE  
CHALLENGES**

Session Objectives: Identify a roadmap forward to address the four challenge areas: demand, selection, supply chains, and pricing/financing. Consider country income levels (e.g., low, middle, and high) and MNS disorders (e.g., depression, psychosis, epilepsy) when discussing potential solutions.

8:50 a.m. **Session Objectives and Goals**

**FRANCES JENSEN**, *Session Chair*

Professor and Chair, Department of Neurology  
University of Pennsylvania Health System

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ESSENTIAL MEDICINES FOR MNS DISORDERS IN SSA

9:00 a.m.

**Challenge Area Discussions**

- Identify components of a roadmap to address the challenge area. Discuss barriers and opportunities at the level of country income and MNS disorder.

*Challenge Area 1: Demand*

**PAMELA COLLINS**, *Challenge Facilitator*

*Challenge Area 2: Selection*

**ATUL PANDE**, *Challenge Facilitator*

*Challenge Area 3: Supply Chains*

**TEDLA GIORGIS**, *Challenge Facilitator*

*Challenge Area 4: Pricing/Financing*

**DAN CHISHOLM**, *Challenge Facilitator*

12:30 p.m.

LUNCH

1:30 p.m.

**Building a Roadmap Forward—Within and Across Challenge Areas**

**Challenge Facilitators**

**PAMELA COLLINS**, *Challenge Facilitator—Demand*

**ATUL PANDE**, *Challenge Facilitator—Selection*

**TEDLA GIORGIS**, *Challenge Facilitator—Supply Chains*

**DAN CHISHOLM**, *Challenge Facilitator—Pricing/Financing*

3:00 p.m.

**Discussion with Leaders and Participants**

- Identify potential obstacles and opportunities to implementation

**FRANCES JENSEN**, *Session Chair*

Professor and Chair, Department of Neurology

University of Pennsylvania Health System

3:30 p.m.

BREAK

**SESSION IV: NEXT STEPS—IMPLEMENTING THE ROADMAP FORWARD**

Session Objectives: Explore available resources that could support a demonstration project. Identify tangible next steps for launching a demonstration project for MNS disorders.

- 3:45 p.m.      **Overview**  
**STEVEN HYMAN**, *Chair*  
Director  
Stanley Center for Psychiatric Research  
The Broad Institute
- 3:50 p.m.      **Discussion with workshop session chairs, facilitators, and participants**
- Identify potential next steps for launching a demonstration project
  - Who would be critical partners to facilitate such a project?
- 4:30 p.m.      **Closing Remarks**
- 4:45 p.m.      ADJOURN



## D

### Registered Attendees

Michelle Akande  
Johnson & Johnson

Albert Akpalu  
Korle Bu Teaching Hospital

Atalay Alem  
Addis Ababa University

Alemu Asgedom  
Federal Prison Administration

Yonas Beheretibeb  
Addis Ababa University

Desalegn Bekele  
Addis Ababa University

François Bompert  
Sanofi

Andrea Bruni  
World Health Organization

Dan Chisholm  
World Health Organization

Pamela Collins  
U.S. National Institute of  
Mental Health

Tarun Dua  
World Health Organization

Margaret Ewen  
Health Action International

Tedla Giorgis  
Ministry of Health, Ethiopia

Oye Gureje  
University of Ibadan

Alemayehu Haile  
Government of the District of  
Columbia

Charlotte Hanlon  
Addis Ababa University

Hans Hogerzeil  
Groningen University

Steven Hyman  
The Broad Institute of MIT  
and Harvard University

Mapoko Ilondo  
Novo Nordisk

Eric Amin Jeje  
Gefersa Mental Health  
Rehabilitation Center

Frances Jensen  
University of Pennsylvania  
Health System

Kidane Kiros  
I-TECH

Thomas Kresina  
U.S. Substance Abuse and  
Mental Health Services  
Administration

Gebrezgi Gidey Lemma  
Mekelle University

Jafary Liana  
Management Sciences for  
Health

Negussu Mekonnen  
Management Sciences for  
Health

David Michelson  
Merck Research Laboratories

Mamuye Mussie  
Mekelle Hospital

Eva Ombaka  
St. John's University of  
Tanzania

Atul Pande  
GlaxoSmithKline

Ismet Samji  
GlaxoSmithKline

Manuel Sibhatu  
I-TECH

Abebe Solomon  
Addis Ababa University

Hailu Tadeg  
Management Sciences for  
Health

Solomon Teferra  
Addis Ababa University

Seblework Teklehaymanot  
Ministry of Health, Ethiopia

Markos Tesfaye  
Jimma University

Gert Wourters  
Universitair Psychiatrisch  
Centrum Kortenbergh

Prashant Yadav  
William Davidson Institute

Lidya Yismaw  
Gefersa Mental Health  
Rehabilitation Center

Paul Zintl  
Harvard Medical School