



**World Health
Organization**

Monitoring the components and predictors of access to medicines

Delhi, India | February 2019

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Acronyms and abbreviations

AMR	Antimicrobial resistance
API	Active pharmaceutical ingredient
AWARE	Access, Watch and Reserve
DDD	Defined daily dose
EML	Essential Medicines List
GBT	Global Benchmarking Tool
IP	Intellectual Property
LMICs	Low- and middle-income countries
MSF	Médecins Sans Frontières
NRA	National Regulatory Authority
OOP	Out of pocket
OTIF	On time and in full
PSS	Pharmaceutical system strengthening
PV	Pharmacovigilance
R&D	Research and development
SDG	Sustainable Development Goal
SF	Substandard and falsified medicines
STG	Standard treatment guidelines
UHC	Universal health coverage
UN	United Nations
WHO	World Health Organization

Note to reader

This report aims to capture key messages that emerged from the discussion rather than attempting to provide a chronological account of the meeting. The key messages include suggestions made by all participants, and do not necessarily imply consensus.

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Executive summary

With the UN approval of an official Sustainable Development Goal (SDG) indicator on access to medicines in 2018, countries will start formally reporting on two key aspects of access — availability and affordability—to the global development community for the first time in a decade.

Availability and affordability are shaped by multiple drivers, or ‘core functions’, across the pharmaceutical system. That means that governments wanting to improve access to essential medicines need to be able to monitor and manage these functions both individually and systematically. In February 2019, WHO convened a meeting of experts in Delhi, India to identify a short list of indicators to help countries in this endeavour. The ‘access dashboard’ is intended to provide a high-level view of the core functions of the pharmaceutical systems that shows broadly if they are performing as expected, and to signal areas for improvement.

Using a framework of twelve core functions (and two cross-cutting enablers) for access (presented on page 14, figure 3), participants considered which specific indicators should be used in the dashboard and why. As part of their discussion, they identified a set of criteria to guide indicator selection. Participants agreed that each indicator should be: intended for high-level policy makers, outcome-focused, feasible and actionable. As a set, they should: focus principally on low- and middle-income countries (LMICs), support a compelling narrative to resonate with policy-makers, and avoid redundancy or duplication.

Together, participants first identified a “long-list” of more than 100 potential indicators for the access dashboard. Agreeing that this is impractical, they then selected a reduced list of 22 indicators classified as of high relevance to stakeholders and high feasibility in data collection. Individual indicators now need to be further defined and refined into a usable set. Participants discussed the principles and priorities to guide that process. Twenty recommendations emerged from their deliberations listed in Part IV and summarized in Table 1 below.

Table 1. Recommendations to guide the defining and refining of indicators identified in Delhi.

Expert recommendations	
Designing a dashboard	<ul style="list-style-type: none"> • Keep a high-level policy-making audience in mind. • Ensure the dashboard is informative for improving access to medicines. • Think about how to measure equity and unmet needs.
Collecting the data	<ul style="list-style-type: none"> • Reduce the burden of reporting and avoid duplication. • Harmonise efforts and build a stronger data-sharing culture. • Build on existing datasets and data collection systems. • Use incomplete data if necessary to get started. • Make optimum use of innovative technologies (e.g. cell-phones).
Using the dashboard	<ul style="list-style-type: none"> • Share information regularly and develop a strong and compelling narrative. • Think beyond health to ministries of finance, trade and industry. • Make the dashboard easy to access and easy to use. • Focus on country improvement rather than international comparison. • Use the dashboard to signal problems and trigger further investigation.
Ways of working	<ul style="list-style-type: none"> • Foster country ownership at all levels. • Promote good practices through knowledge exchange. • Triangulate data to validate and interpret results. • Leverage opportunities to gain political support. • Engage diverse stakeholders and build partnerships. • Take the list to the field and improve it through use.

Part I. Background

Introduction

Access to affordable, safe, effective and quality-assured medicines is an essential component of universal health coverage (UHC) and a key determinant of good health outcomes. The role of access to medicines in supporting global health goals has risen steadily over the past decade: it has been the subject of nearly 100 World Health Assembly resolutions, a UN High-Level Panel and countless civil society initiatives. Today, it sits firmly at the centre of WHO's work to have 1 billion more people benefitting from universal health coverage (UHC) by 2023 through the Thirteenth General Programme of Work, 2019–2023 and Road Map for Access to Medicines, Vaccines and Other Health Products (2019-2023). Expanding access to medicines—especially for disadvantaged and vulnerable groups—is also a human rights imperative and a common objective of health programmes in many LMICs.

The emphasis on improving access to medicines at both country and global levels makes monitoring an imperative: you cannot track progress, or drive improvement, without measuring performance, however this is often hampered by limited and fragmented systems for collecting, analysing and reporting data. With the UN approval of an official SDG indicator in 2018, countries will start formally reporting on two key aspects of access - availability and affordability - to the global development community in a standard way for the first time in a decade.

But while the new SDG indicator will help countries shine a light on where their gaps in access are, it has limited value in directing national decision-makers to fill those gaps. This is because access is multi-dimensional. Apart from the availability, affordability, quality and safety of products along with quality use and coverage are other intermediate outcomes which are influenced by the performance of 'core functions' of the pharmaceutical system.

Although improving pharmaceutical system performance requires a diagnostic assessment of each of the core functions to identify the root causes of low performance policy-makers only require a high-level perspective that enables overall performance assessment. In short, they need a simple "access dashboard", made up of key indicators, to show broadly how the functions are performing, and to signal areas where improvement is needed.

An expert consultation

In February 2019, WHO convened a meeting of around 40 experts in Delhi, India and tasked them with identifying a set of high-level indicators that countries can actively use to monitor the core functions of their national pharmaceutical system.

The meeting had four specific objectives:

- Understand the information needs of national policymakers when making decisions on actions to increase the availability and affordability of medicines.
- Identify and agree key performance indicators to monitor core functions of the national pharmaceutical system.
- Identify data availability and capacity building needs to address potential gaps.
- Agree on next steps for piloting an adaptation of a dashboard of indicators to ensure it is fit-for-purpose at regional and country level.

Part II. Choosing a framework

Some existing frameworks and tools

While there are many tools for measuring individual elements of the pharmaceutical system, there is relatively little work on viewing the system as whole. Participants at the Delhi meeting heard about two recent initiatives to provide a framework for measuring and monitoring how the pharmaceutical system contributes to access to, and use of, medicines.

1. Pharmaceutical Systems Strengthening (PSS) Measurement Framework

The PSS measurement framework and corresponding indicators were developed to measure and monitor whether investments in PSS work. The framework, which was developed in consultation with partners and experts, defines key terms in PSS. It also identifies a list of seven critical system components as essential for monitoring progress in PSS, two system attributes and two primary outcomes:¹

- **Critical system components:** pharmaceutical products and related services; policy, laws and governance; regulatory systems; innovation, research and development, manufacturing and trade; financing; human resources; and information.
- **Key attributes:** performance and resilience.
- **Primary outcomes:** access and use.

Each component of the PSS measurement framework has a number of ‘elements’ to it, each of which then define a core set of structural, process and outcome indicators. Together, these comprise 117 indicators, including a mix of existing and aspirational measures. They are not intended to be exhaustive; rather, they aim to provide a high-level picture of how the pharmaceutical system functions holistically.

2. Lancet Commission accountability framework

The accountability framework developed by the Lancet Commission on Essential Medicines Policies was proposed to overcome fragmented data systems, limited reporting and lack of transparency and incentives that characterize current efforts to measure progress in access to medicines.²

The framework includes 24 core indicators and 12 complementary indicators; and a further 9 indicators specifically to measure National Regulatory Agency (NRA) performance. These focus on outcomes (rather than processes) and were chosen based on four criteria: relevance to policy-makers; susceptibility; scientific soundness; and data availability. They include specific indicators for measuring equity.

Beyond indicators, the Lancet Commission’s accountability framework also emphasizes the need for independent reviews of data by multiple institutions, and incentives (for example, benchmarking) for corrective action.

¹ Hafner T, Walkowiak H, Lee D, Aboagye-Nyame F. 2017. Defining pharmaceutical systems strengthening: concepts to enable measurement. *Health Policy and Planning* 32(4), 572–584. (<http://apps.who.int/medicinedocs/documents/s21851en/s21851en.pdf>, accessed 1 March 2019).

² Wirtz VJ, Hogerzeil HV, Gray AL, Bigdeli M, de Joncheere CP, Ewen MA *et al* Essential medicines for universal health coverage. *The Lancet*. 2016;389:403–476. doi: [https://doi.org/10.1016/S0140-6736\(16\)31599-9](https://doi.org/10.1016/S0140-6736(16)31599-9)

Regional frameworks

WHO regional representatives summarized the frameworks and tools used in their regions to support monitoring of access to medicines. A selection of examples follows below.

Africa

- The regulation and access framework, with 15 indicators across five areas, provides a helicopter view of regulatory systems.
- The substandard and falsified prevention, detection and response framework has 19 indicators across policies, enforcement, coordination and response.
- The Afro Surveillance and Monitoring System of Medicine Prices, Availability and Affordability (APRAMED) includes eight indicators.

The Americas

- The *Sustainable Health Agenda for the Americas 2018-2030* and SDG 3 provide the overarching framework for work in the region.
- The PAHO-Biennial Workplan includes six key indicators for access and rational use, which are linked to existing tools wherever possible. For example: *the number of countries with regulatory systems reaching level 3 on the Global Benchmarking Tool (GBT)*.
- The Regional Platform on Access and Innovation for Health Technologies (PRAIS) is designed to bring information together across programmes and countries; it includes specific indicators on access and rational use of medicines and other health products.

Europe

- The European Health Information Gateway hosts centrally reported data on a broad range of indicators, including two for access.
- Country priorities provide the framework for other access indicators, which are set through networks of experts. These networks come together to gather evidence and provide comparative reviews or country profiles on specific elements of access, for example pricing and reimbursement, or antimicrobial medicines consumption.

Southeast Asia

- Country profiles, built using situation analyses and secondary data, use indicators across five areas to give an overview of access in individual countries.
- The SEARO PSS strategic directions and the *Delhi Declaration 2018* serve as key overarching frameworks for improving access to medicines in the region.

In addition to these frameworks, a number of civil society initiatives also exist such as Stop Stockouts which helps to monitor the availability of essential primary health care (PHC) medicines and children's vaccines in South Africa.

3. SDG Indicator 3.b.3

In November 2018, the UN approved SDG Indicator 3.b.3, which measures the *proportion of health facilities that have a core set of relevant essential medicines available and affordable on a sustainable basis*. In this context, a medicine is considered to be available if the data collector finds it at the sampled facility during a visit. A medicine is affordable if the lowest paid unskilled government worker does not need extra daily wages to buy a month's worth of treatment. While SDG Indicator 3.b.3 does not capture potential financial coverage schemes or a population's overall needs for the medicine, it does provide an opportunity to gather and monitor data on actual access (including availability and affordability) that is currently not regularly monitored.

Towards an access dashboard: what's needed?

The idea behind the access dashboard is simple: to provide national policy-makers with a high-level view of the core functions of a pharmaceutical system to see how it is functioning and to indicate areas that need to be strengthened. The right mix of dashboard indicators should enable policy-makers to:

- know the system's status;
- track progress against national goals;
- better understand local contexts and set priorities for action;
- monitor whether that action is making a difference; and
- secure accountability, sustainability and value for money in PSS investments.

Designing a dashboard that is fit for purpose was the subject of the Delhi meeting. In order to support participants in their deliberations, a selection of country experts and stakeholders reflected on lessons learnt from their own experiences.

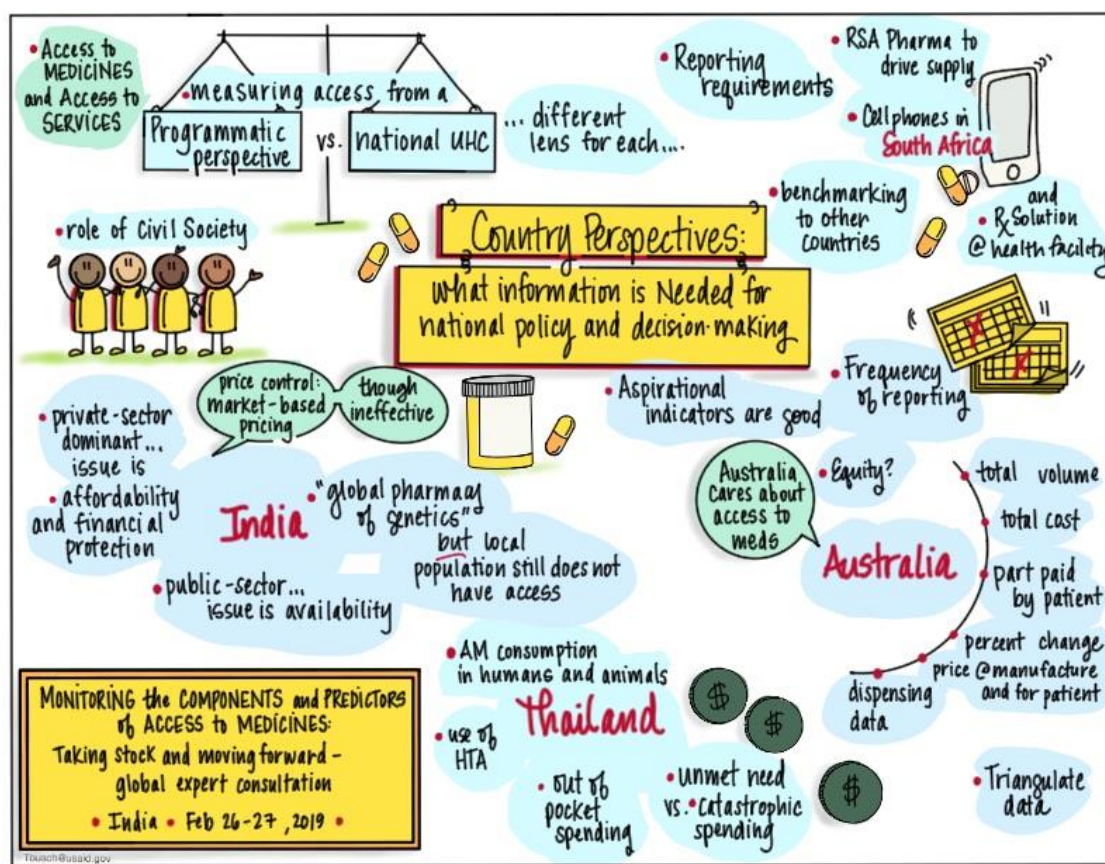
Country perspectives

Several participants emphasized the fact that the context and capacity for monitoring shows great variation between countries. In some cases, it can even vary significantly within a single country. For example, in India, 90% of healthcare delivery happens at state level, so measurement and monitoring needs to be managed accordingly.

Against a backdrop of varying contexts and capacities, speakers from five countries—Australia, India, Indonesia, South Africa and Thailand—described their needs for measurement and monitoring of access to medicines (see Figure 1).

“Putting information in front of people and pointing out the gaps is what got things done.”

Figure 1. Country perspectives on key issues in measuring and monitoring access (Source: Tobey Busch).



It was clear from the discussion that different countries have different priorities in selecting indicators for monitoring access. Most emphasized the need for robust data on volume, price, risk protection, unmet need and patient contribution, among others. In many countries, the data available for choice indicators are of poor quality or incomplete. However, participants suggested that even incomplete data can be useful in directing action if it is presented with a clear understanding and narrative about what they mean and what the problems are.

Country representatives highlighted four key ingredients for success.

1. Strong leadership

High-level political buy-in and leadership help drive action. Speakers described how the involvement of ministers and senior government officials has helped enforce routine reporting from individual health facilities in one case; and drive down the price of key medicines in another.

2. Good narrative

Compelling narratives—presented in terms that high-level decision-makers understand and care about—can inform strategic decisions and mobilize resources to improve access. For example, a story about how resources can be saved is much more captivating than talking about the proportion of a market made up of generics.

"We've got to get those soundbites that get decision-makers to sit up."

3. Consistent reporting

Experience suggests that consistent reporting is more important than complete reporting in providing a high-level picture of access to medicines and signalling problem areas. The timing of reports should be tailored to the audience: for example, monthly reports within ministries of health and quarterly ones for broader government. Longitudinal reports are more informative than static “snap-shot” data.

“If the data come in year after year and show the direction of travel, that’s what matters.”

4. Useful indicators

Indicators need to be sufficient to paint a useful picture of what is going on, but few enough to ensure they can be realistically produced and consumed. Indicators should also be achievable, although some aspirational indicators are useful to keep problem areas in sight for which no easy indicators are available. In most cases, indicators should focus on concrete systemic outputs – they should avoid being tied to health outcomes because the multiple determinants of health make it difficult to directly attribute positive health gains to the pharmaceutical system.

Partner perspectives

Speakers from three major global health stakeholders summarized their ongoing activities to help measure and monitor the core functions that support access to medicines.

The Global Fund

The Global Fund gathers data for two indicators designed to measure the extent to which investments in strengthening the pharmaceutical system contribute to availability. Some data are gathered from existing sources; some are collected through country visits.

“I want to reassure you that there’s a real effort not to ask countries to report for the sake of reporting.”

Médecins Sans Frontières (MSF)

MSF gathers data and tracks indicators to inform both its operational and advocacy work. It focuses on several components of the pharmaceutical system, including: pricing, procurement, IP and pharmacovigilance (PV).

USAID

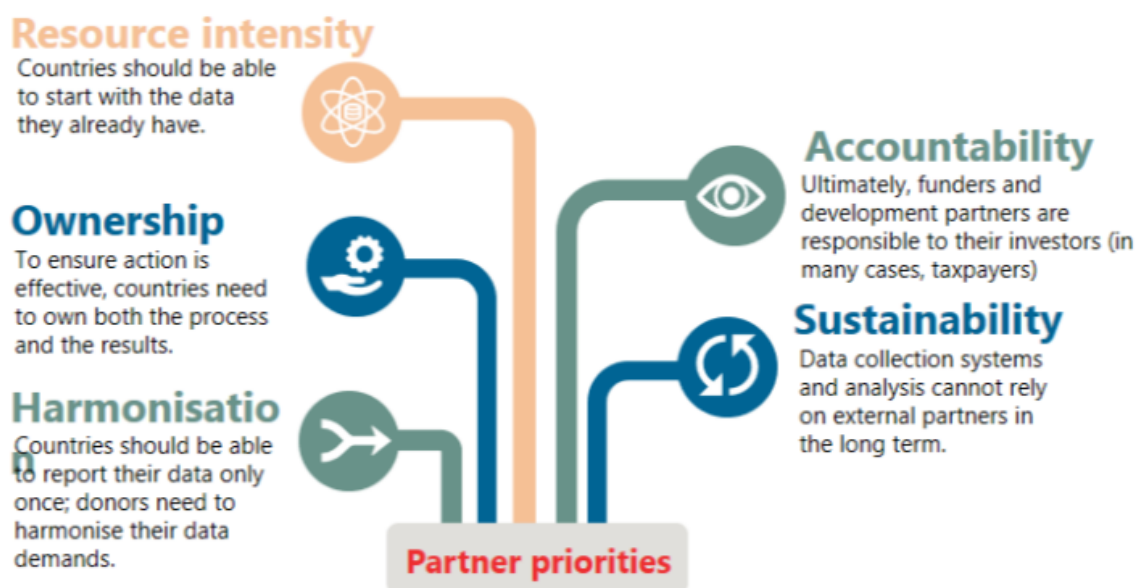
USAID uses two data collection tools to evaluate the effectiveness of their investments in pharmaceutical system strengthening and assess their value of money. These are a national supply chain assessment tool, and the PSS Insight tool, which measures the strength of a system using the PSS Framework (see Part II above).

Collectively, the speakers suggested there is a lot funders can do to help countries collect, analyse and use monitoring data. This includes, for example, harmonizing reporting requirements so that countries only have to report a single set of data, once and in a single format. This approach has been used to great effect in South Africa, where all donors in the medicines space meet once a quarter to go through project plans and get a single report that they can use as and when needed. In Bangladesh, a similar ‘partnership of funders’ approach, led by the NRA, is used to develop coordinated plans and activities for in-country work.

“We now report one set of data and all the donors process it how they want downstream... it has revolutionized how we work.”

The speakers also emphasised five key issues that funders and countries must consider when designing and investing in work to measure and monitor availability and affordability (see Figure 2).

Figure 2. Priority issues from a partner perspective.



The chosen framework

A framework for the dashboard was proposed to the participants. It uses the PSS measurement framework definition of a pharmaceutical system:

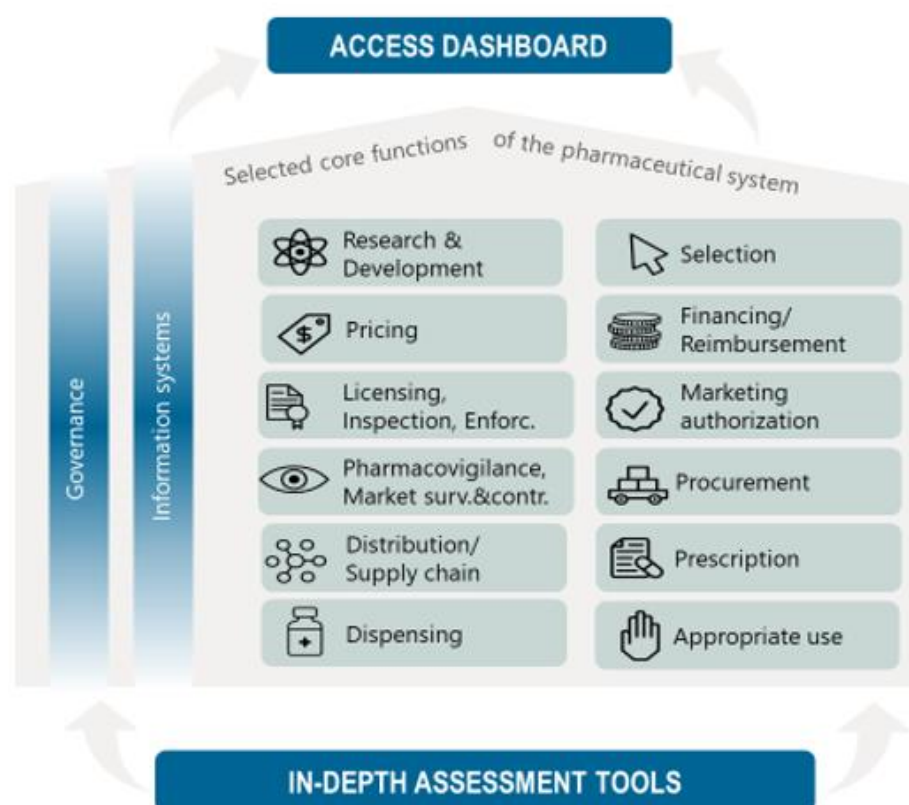
“All structures, people, resources, processes, and their interactions within the broader health system that aim to ensure equitable and timely access to safe, effective, quality pharmaceutical products and related services that promote their appropriate and cost-effective use to improve health outcomes.”³

The proposed framework is an adaptation and simplification (proposed by WHO) of the PSS measurement framework which identified system components critical for measuring pharmaceutical system strengthening⁴. This simplified framework identifies 12 core functions and two cross-cutting enablers of the pharmaceutical system. It is designed to focus on concrete outcome indicators rather than structural or process ones, although it does acknowledge that some structural assessment may be useful as a first step in tailoring the dashboard to individual countries (see Figure 3).

³ Source: T Hafner, H Walkowiak, D Lee, F Aboagye-Nyame. 2017. Defining pharmaceutical systems strengthening: concepts to enable measurement. *Health Policy and Planning* 32(4), 572–584

⁴ See above footnote.

Figure 3. The proposed framework for identifying indicators to populate the access dashboard.



Part III. Identifying the indicators

The sections that follow highlight the key discussion points to emerge from each assessment of core functions. They include a brief summary of the high-level thinking behind the choice of indicators; a full list of agreed indicators is included in Annex I.

Organizers of the meeting chose to “bundle” some core functions where this was deemed helpful and practical (for example, selection, prescription, dispensing and appropriate use are included together) only for the purposes of the group work during the consultation.

Criteria for selection

Participants were asked to apply eight criteria when identifying indicators for the access dashboard. Specifically, they were asked to ensure that indicators are:

1. **Few in number.** There should be no more than five, and ideally three, indicators per function.
2. **Outcome-focused.** Indicators should measure effective performance; that is, they should focus on concrete outcomes, rather than processes.
3. **Universal.** Indicators should not be disease-specific.
4. **Feasible.** Countries should be able to practically measure indicators using existing and easy-to-define data sources.
5. **Established.** Indicators should be measurable (or already measured) with established (or easy-to-establish) data sources.
6. **Actionable.** Policy-makers should be able to easily understand the indicators and use them to take action.
7. **Reflect change.** Indicators should be able to reflect change over time and be sensitive to changes in context.
8. **Relevant.** Indicators should provide insight into the function's performance and inform decision-making.

1. Selection, prescription, dispensing and appropriate use of medicines

The objective of medicines selection is to have a national list of medicines chosen to promote therapeutically sound prescribing and ensure prudent use of resources.⁵ Lists are linked to evidence-based clinical guidelines and are revised regularly; they form the basis of drug selection by primary, secondary and tertiary public health-care institutions.⁶

Appropriate use of medicines requires that “patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period, and at the lowest cost to them and their community”.⁷ Prescription is the selection of an appropriate medicine based on an evaluation of an established therapeutic objective. Dispensing refers to the process of preparing and giving medicine to a named person based on a prescription. Prescription and dispensing are both vital elements of the rational use of medicines.⁸

Participants identified a range of core and complementary indicators. Most focused on prescription/dispensing based on either:

- a. national essential medicines list (EML); or
- b. standard treatment guidelines (STGs).

⁵ <http://collections.infocollections.org/whocountry/en/d/Js6865e/9.1.html>

⁶ <http://apps.who.int/medicinedocs/en/d/Js7919e/6.html>

⁷ The Pursuit of Responsible Use of Medicines: Sharing and Learning from Country Experiences. Geneva: World health organization; 2012 (Who/EMP/MAR2012.3; https://www.who.int/medicines/areas/rational_use/en/, accessed 31 January 2019)

⁸ Management Sciences for Health. 2012. *MDS-3: Managing Access to Medicines and Health Technologies*. Arlington, VA: Management Sciences for Health

Key messages from discussion

- Measuring adherence to the national EML is much easier to measure than measuring adherence to clinical guidelines. The former can be easily derived from prescription data while the latter needs detailed analysis of prescriptions.
- Focusing only on prescription is not always the best approach: in many LMICs contexts dispensing can be the most appropriate function for analysis.
- Many of the proposed indicators rely on access to electronic prescribing. If this is not (yet) available, data from sentinel sites are needed. Both methods may constitute a challenge for LMICs.
- The indicators offering insight to antimicrobial resistance (AMR) needs to look beyond volume alone (e.g. % of prescriptions with one or more antibiotics; or DDD per 1000 Population) to reflect appropriate use. That might be achieved, for example, by tying antibiotic use to the Access, Watch and Reserve (AWARE) categories defined by WHO.
- 'The percentage of people diagnosed receiving medicines' is absent from the list. This is because while it may be a good indicator for vertical programmes, it would be hard to measure in an integrated way. In LMICs with limited access to diagnostics, it would be even harder.

2. Pricing and reimbursement

A fair price, as defined by WHO, is one that is affordable both for the health system and for patients while - at the same time - providing sufficient market incentive for the industry to invest in the research and development of medicines. Fair pricing does not replace the principle of affordability.⁹

Schemes to reimburse the costs of medicines vary from country to country, and can be based on one or more criteria, including the medicine or the disease it aims to treat. Eligibility can also be linked to specific groups or the total amount a patient spends on medicine within a given timeframe.

Participants identified many potential indicators for pricing and reimbursement, all of which are designed to answer one of three critical questions:

- a. Where are funds being spent?
- b. Is it a fair price?
- c. How much of it are consumers paying?

Key messages from discussion

- The feasibility of some of these indicators will depend on the organisation of the health system.
- Government spending can go up while out of pocket (OOP) spending goes up too (because the efficiency goes down).
- In considering government spending, some participants mentioned that ideally the denominator is essential medicines because there is often a lot of OOP expenditure, sometimes catastrophic, on medicines of unproven efficacy and safety.

3. Procurement

Procurement involves efforts to quantify medicines requirements, selecting appropriate procurement methods, and prequalifying suppliers and products. It also involves managing tenders, establishing and maintaining contract terms, assuring medicines quality and obtaining

⁹ https://www.who.int/medicines/access/fair_pricing/en/

best prices. Procurement methods need to be strengthened to ensure alignment with national medicines lists and prescribing patterns.

Participants identified several highly feasible indicators related to quality, price or on time and in full (OTIF) delivery.

Key messages from discussion

- The diversity of procurement systems, even within countries is a key element. Participants agreed that the focus should be on indicators that can meet the needs of all countries at the national level.
- Even before considering performance, a country needs to understand its market and strategy. There is therefore a need to consider what mechanism is in place to define the procurement strategy for the country to achieve fair price and consistent availability. For example, is there any kind of market analysis (e.g. ABC or VEN) done?
- For the purpose of this exercise, the focus is on the outcomes of price and delivery – countries can always follow up on structure and process to identify root causes of detected problems.
- Indicators should be relevant to countries with pooled or fragmented procurement systems.

4. Distribution/Supply Chain

A well-managed distribution system focuses on measures that ensure product integrity and quality throughout the distribution channel of the medicines. That includes maintaining a constant supply of medicines, keeping them in good condition and minimizing loss through spoilage and expiry. It involves keeping accurate inventory records, rationalizing storage points, using transport resources efficiently, and taking measures to reduce theft and fraud. Distribution from the main storage point to a lower level store or health facility may follow the push or pull system or a combination of both. The choice of a push or a pull system depends on the needs of the country. In a pull system medicines requests are sent from the lower level. A push system is used mainly in emergency where there is no adequate storage space or personnel to manage a range of products. In this case, a limited list of products is pushed from the higher-level warehouse to the health facilities during a defined time frame.

Participants identified five core and complementary indicators centred around:

- a. stockouts;
- b. SDG Indicator 3.b.3; and
- c. track and trace.

They also suggested that having an information system to support procurement should be a basic requirement. Without an information system that is linked to planning, budgeting etc, emergency procurement and stock outs are inevitable.

Key messages from discussion

- Stock-outs are difficult to measure at facility level, even for countries with good electronic systems and an emphasis on the duration of stock-outs could imply that some level of stock out is acceptable so there is a need to be cautious with how this is framed.

- Being able to measure and monitor wastages is important. Pharmaceutical waste management has an indirect impact on access because improper management increases the prevalence of substandard and falsified (SF) medicines.
- The track and trace indicator is a structural one, included to indicate the maturity of a supply system. In many countries it will be an aspirational indicator but such systems are likely to mature with time.
- There is a need for some higher-level indicators to capture the idea, within the distribution and supply chain, of who is being served and by whom. The proposed indicators start with the assumption that everything can be accessed through the public sector; they have little relevance to fragmented systems that have multiple health service suppliers, mostly in private sector.

“All the indicators here are only appropriate for consolidated systems.”

5. Licensing, inspection and enforcement

Licensing activities are considered fundamental, together with inspections activities, for guaranteeing the quality, safety and efficacy of medical products used within or exported out of a country. Coordinated by NRAs, licensing activities should be supported by published and readily available legal provisions, regulations and guidelines to ensure that licensing is based on compliance with good practices; and that the NRA is empowered to issue, suspend or revoke licences in cases of non-compliance. The NRA should also be empowered to issue, suspend or revoke licenses for premises and establishments. Premises, facilities, establishments and companies throughout the supply chain should possess a license to operate issued by the NRA.

Participants again emphasized the need for an initial structural indicator to assess the maturity of the regulatory system; they again suggested using the GBT score for this. Then outcome indicators are needed to assess:

- a. compliance with good practices;
- b. frequency of violations and how these are enforced; and
- c. renewal of licences.

Key messages from discussion

- Inspections should be based on an established list of facilities.
- Compliance with good practices (for manufacturing, distribution etc) is critical to ensure access to quality assured products.
- An additional indicator could be the proportion of products sold on the market with valid authorization (which should be 100%).

6. Marketing authorization

Marketing authorization (MA) refers to a procedure for approval of a medical product for marketing after it has undergone a process of evaluation to determine the safety, efficacy and quality of the product and the appropriateness of the product information. The objective of this regulatory function is a system which ensures that only medical products which have been duly authorized by the NRA can be manufactured, imported, distributed, sold or supplied to end-users.

Participants agreed that before even considering which performance indicators are required, the first question to ask is: does the country have a regulatory authority? If the answer is 'no', there is little point trying to track other indicators. If the answer is 'yes', then a key structural indicator to assess will be the authority's GBT score for maturity level. Two further outcome indicators to assess would then be centred around:

"If the country has no regulatory authority, there is little left to ask."

- a. how long it takes to review and approve generic medicines; and
- b. how many medicines on the EML have at least three registered products on the market.¹⁰

Key messages from discussion

- Procurement systems are diverse, in many cases even within countries. Participants discussed the need for the NRA to be aligned to the procurement mechanism of the country (i.e. access to/use of UN procurement, "mature" system so independent procurement, pooled procurement, etc.) as the needs would be different in terms of market authorization function (i.e. refer to other functional/listed NRAs for procurement of products already approved, use of PQ system, participation to pooled procurement for certain categories of products as vaccines and PAHO revolving fund).

7. Pharmacovigilance and Market surveillance and control

Market surveillance and control is essentially about: controlling imports, detecting and preventing SF medicines, monitoring medicine quality across the supply chain, and controlling promotional activities. Pharmacovigilance (PV) is about detecting, assessing, understanding and preventing adverse effects or any other drug-related problem. Done well, PV both enhances patient care and safety and supports public health programmes by enabling accurate risk-benefit profiles of drugs.

Participants agreed that, like other core regulatory functions, market surveillance and control and PV need an initial assessment to establish the maturity of the system, which could be provided through the GBT. In short, they suggested that countries would want to know three things:

- a. Is there a PV and risk-based market surveillance system in place?
- b. Are these being implemented and used?
- c. Are they generating actionable information?

Key messages from discussion

- Indicators for the access dashboard must 'go beyond' those captured in the GBT.
- Be careful in using indicators that rely simply on tracking the number of adverse events: a higher number does not necessarily correlate with a worse system because those systems that do good PV are better at spotting adverse events so can have higher numbers.
- To make the market surveillance indicator more palatable to policy-makers, reframe it using more positive language (how many products comply vs how many products fail).

"In my view, PV is best measured by maturity level."

8. Research and development (R&D)

¹⁰ This is market-dependent, has not been used in practice and would therefore not be an established indicator nor comply with the "established" criteria. There is also unresolved debate on whether three registered products is the most appropriate number.

R&D that is guided by public health needs can improve access to medicines. Governments can support it by investing part of their national budgets into targeted R&D activities, incentivising investment targeting health needs, and ensuring effective oversight of clinical trials.

Participants proposed three indicators:

- a. No. clinical trials registered in the country (in which the country participates).
- b. Government spending on R&D in drug development or formulation of priority items.
- c. Existence of national framework for investment in health needs driven R&D. They agreed that intellectual property rights also need to be considered.

Key messages from discussion

- The level of manufacturing needs to be defined to ensure it is adding to real capacity. One participant suggested defining manufacturing as from formulation onwards.
- The clinical trials indicator needs refining to:
 - make it relevant to country priorities;
 - focus only on those trials with ethical and regulatory approval; and
 - capture only those trials that benefit the host country (countries can host many clinical trials with no local value because data goes back to the external manufacturer).
- Efficiency in approval of clinical trials may be a better way of gauging a country's broad capacity for R&D.

"We don't want to send the message that lots of clinical trials are good for your country without regulation."

9. Governance

Governance is increasingly acknowledged as a crucial factor for universal access and sector performance. Good governance in the pharmaceutical sector boosts transparency and accountability in regulatory and supply management systems and promotes individual and institutional integrity.¹¹

Participants did not define specific indicators for governance, although they agreed on the need for:

- a. One overarching indicator to capture broader aspects of accountability, such as civil society engagement, level of public data and management of conflict of interest.
- b. A subset of process indicators built into each individual core function, particularly selection, procurement and regulation.

Key messages from discussion

- In part, good governance is about governments publishing their data, including on the indicators decided by this meeting.
- Indicators should focus on the principles of good governance: for example, adherence to standard operating procedures, accountability, inclusiveness and equity.

"If equity is not embedded as a principle, you'll end up having a system favouring certain groups."

10. Information systems

The health information system provides the underpinnings for decision-making and has four key functions: (i.) data generation, (ii.) compilation, (iii.) analysis and synthesis, and (iv.)

¹¹ WHO. Good Governance for Medicines (GGM). www.who.int/medicines/ggm

communication and use. The health information system collects data from the health sector and other relevant sectors, analyses the data and ensures their overall quality, relevance and timeliness, and converts data into information for health-related decision-making. A pharmaceutical management information systems (PMIS) is an organizing system for collecting, processing, reporting and using information for decision making. The PMIS integrates pharmaceutical data collection and the processing and presentation of information that helps staff at all levels of a country's health system make evidence-based decisions to manage pharmaceutical services.

Participants agreed that information systems cut across all the other core functions as key enablers. For this reason, monitoring them should take a different approach to the core functions and focus on a structural assessment, and possibly a rating (rather than using outcome ones). Together, these indicators should be able to describe the quality, quantity and availability of information. To that end, they should answer three questions:

- a. How reliable is the information?
- b. How comprehensive is the information?
- c. Is the information used?

Key messages from discussion

- The information system indicators should aim to cover the whole health management system (not just the pharmaceutical one) and cover both:
 - 'know your patient' data (input from national public health programmes); and
 - 'know your product' data (input from pharmaceutical management systems).
- The IT maturity of the country will determine the extent to which these indicators can be measured.
- The type of information system that is needed will be determined by the final set of indicators (and their underpinning data) agreed for all core functions.

Part IV. Defining and refining the indicators

The view from countries

The agreed indicators set out in Part III and Annex I need to be further refined and defined before they can be used in a national access dashboard. In all cases, it is unlikely that every indicator will be used by every country—the idea is that countries should consider their own context and capacity and then tailor their dashboard to suit their needs. Thailand has already done some work in this direction, developing its own list of priority indicators (see Annex II).

When it comes to defining and refining the dashboard indicators as a whole, participants identified four basic criteria for ensuring that the indicators could be used by different countries (see Figure 4). In addition to these basic criteria, participants made a broad range of recommendations to guide the defining and refining of the dashboard indicators. These are listed in the sections that follow, grouped into four overarching categories.

Figure 4. Four key issues for countries when developing a list of priority indicators.

Gaps in measuring access

Gaps in current efforts to measure and report access to medicines include:

1. **Price transparency.** This includes costs associated with lack of price transparency as well as the costs borne by the minority that does provide transparent pricing.
2. **Treatment coverage.** This includes the extent to which treatment coverage is related to the pharmaceutical system. If it is susceptible to changes in the system around availability, then it should be included in the access dashboard.
3. **Economic impact of noncommunicable diseases (NCDs).** Their impact on households and whether this can be modified through access to medicines.
4. **Global accountability.** What a global accountability framework looks like, who would need to be involved, and which mechanisms and incentives are needed to make it work.
5. **Interrelationship between access to medicines and macro-economic outcomes.** The assessment of access to medicines takes place in isolation from other macro-economic performance measure (e.g. employment, trade, tax returns). However, in practice access to medicines, e.g. prices of medicines, influence broader economic factors. Studying the broader economic factors of access to medicines is important.

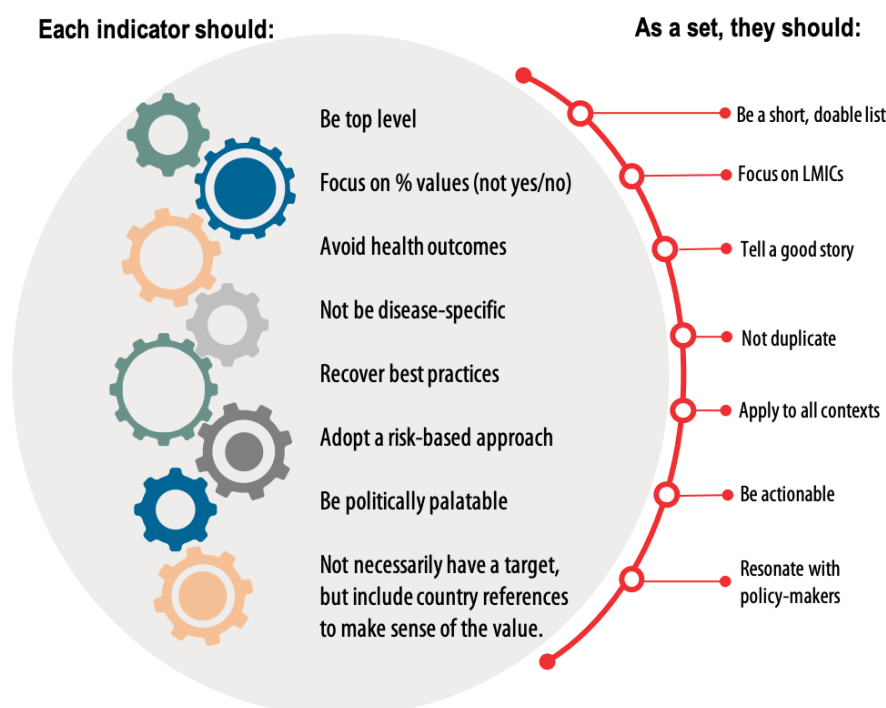
1. Designing a dashboard

In all cases, participants agreed that the access dashboard should be:

- **Designed for high-level policy-makers.** This means it must be easy to use and easy to interpret. It must be defined and communicated in a way that fosters a culture of using data to inform policy decisions. To that end, the dashboard must spark and maintain policy-makers' interest; and it must enable them to spot problem areas and trigger further investigation.
- **Informative for improving access.** The dashboard is intended as a tool for countries to manage their own pharmaceutical system for better access to medicines. This implies that it must focus on those elements of the system that can really make a difference to access; and that the indicators should be quantitative to measure progress. Each country will need to distil what is most useful from the proposed list of indicators.
- **Capable of measuring equity and unmet needs.** To measure equity, indicators on access, coverage and quality of care need to be stratified by gender, economic wealth, geographical location of residence, education and ethnicity. To measure unmet needs, household surveys are the tool of choice, although it can also be achieved to a certain extent through total medicines consumption data when these are disaggregated by geographical area.

Participants also identified five key gaps in current efforts to measure access (see Box 'Gaps in measuring access') and several criteria for the indicators that make up the dashboard (see Figure 5).

Figure 5. Criteria for refining and defining indicators (in addition to criteria defined in Part III above).



2. Collecting the data

Reduce the burden of reporting.

This includes developing or supporting a culture of routine data collection and ensuring that reporting efforts are not duplicated. For example, by making the dashboard coherent with existing national governance reporting frameworks, embedding data collection into bigger information systems, and ensuring indicators can be easily managed within the day-to-day job of ministries. As a start, the GBT should be integrated into the dashboard as an overarching indicator linked to all the regulatory core functions, so that these data do not need to be collected twice.

“What we do must not be onerous on governments.”

Harmonise efforts.

This applies at multiple levels, for multiple stakeholders. Donors need to harmonise their expectations and align these with country reporting frameworks and priorities. Countries need to integrate their systems wherever possible, bringing information together and supporting interoperable systems with compatible data. Civil society initiatives in monitoring access to medicines should also be integrated. That may require efforts to create a stronger data-sharing culture within and across sectors and stakeholders.

“How can we foster a willingness at national level to use each other’s data?”

Build on existing systems.

This includes using data from existing datasets—such as insurance claims or sales data—to give a proxy or actual source to compile information for an indicator. It also includes building on existing data collection systems to address individual indicators: for example, adding a health question into national surveys, incorporating price and availability into national epidemiology sentinel systems, or expanding antibiotic surveillance systems to include other drugs.

“It’s so hard to get data that we should use what data we have as much as possible.”

Use incomplete data if necessary.

Countries may not have information immediately available on everything they require. In some cases, there may be proxies available to compensate for gaps. But even if the data are incomplete, they can still be useful in identifying problems at a high level and in encouraging policy-makers to act—if the data speaks to an issue that the policy-maker cares about, and the policy-maker understands what data are missing and why. Incomplete data can also create a demand for better data.

“Start with bad data, show people, tell them what it means and what the problem is.”

Choose appropriate technologies.

This applies in terms of both country infrastructure and local data systems as well as information needs. The technologies available vary enormously, from e-data to sentinel data to household survey data. In all cases, countries should be looking ahead and making use of innovative technology that supports digitization and leapfrogging (for example, smart phones, blockchain, track and trace, e-health records, e-prescribing).

3. Using the access dashboard

Communicate well.

Good communication has multiple dimensions to it. In part, it is about sharing information regularly to ensure issues are consistently reviewed and problem areas remain on the political agenda. In part, it is about developing a strong and compelling narrative that speaks to policy-makers and enables them to take informed decisions that will benefit access to medicines.

“The dashboard should tell a good story to powerful people.”

Think beyond health.

“Our lenses are myopic: we quite often don’t think about the ministry of finance; and hardly ever of the ministry of trade and industry.”

In all cases, communicating well means thinking outside the health sector and talking to all the different ministerial groups with a stake in the core functions of the pharmaceutical system that affect access to medicines. This includes ministries of finance and trade. High-level decision-makers need to balance public health with fiscal drag and economic growth; they cannot afford to isolate their decisions about the pharmaceutical system. In many LMICs local manufacturing is growing fast; decisions

around the value chain cannot disregard their role in boosting the economy. Ultimately, the purpose of the dashboard is to strengthen access, but also to manage tensions across stakeholder groups and find a common space for managing the pharmaceutical system for access.

Make the dashboard easy to use.

The dashboard will not be used unless it is easy to access, interpret and manage. Experience shows that an impractical and clunky interface can render systems unusable. In designing a user interface, we must consider how different users (both policy-makers and technocrats) will use the dashboard and build the functionality and usability they need.

Focus on country improvement, not on international comparison.

The dashboard is designed to help a country manage and improve the core functions within its own pharmaceutical system. It is not intended as a tool for comparing systems across countries. Of course, international comparisons can be useful in driving improvement, but they can also be dangerous if they are used to draw comparisons across different contexts and capacities. The dashboard must avoid making data look like some countries are better benchmarked than others. Participants suggested that countries should use selective (rather than blanket) benchmarking as and where appropriate to support decision making. This includes, for example, international benchmarking to set internal medicine price targets or for assessing in-country differences.

“We benchmark where we think we can learn something.”

Use the dashboard to trigger action.

The dashboard is intended to provide a helicopter view of core functions and signal problem areas that can then trigger further investigation and action. As such, it should focus on the direction of travel, rather than the final destination, for each indicator. For example, by using dynamic timeseries rather than point estimates.

Figure 6. Buzz words and takeaway messages from the discussion (Source: Tobey Busch).



4. Ways of working

Foster country ownership.

To ensure the dashboard is both effective and sustainable, countries need to understand it and own both the data collection and use as much as possible. Strong country ownership can also help align donor reporting frameworks and reduce demands for data by building confidence in local data systems and management. Ownership is about getting all stakeholders on board including at ministerial level and those people whose performance is being measured.

Promote good practices.

This includes promoting knowledge exchange across countries and regions to share lessons learnt and promote best practice. Countries should be encouraged to share their success stories to show what can be done and how. Such stories can then be used to advocate for investment: “this is what we can do with our existing data; here’s what we could do with more resources”.

Triangulate data.

Triangulating data is important to verify the accuracy of data obtained in the field. But an indicator by itself is never causal, so triangulating against other data is also important to make sense of results, put them into context and give early signals of problem areas.

“We shouldn’t look at one indicator in isolation.”

Leverage opportunities to get political buy-in.

At a global level, this includes:

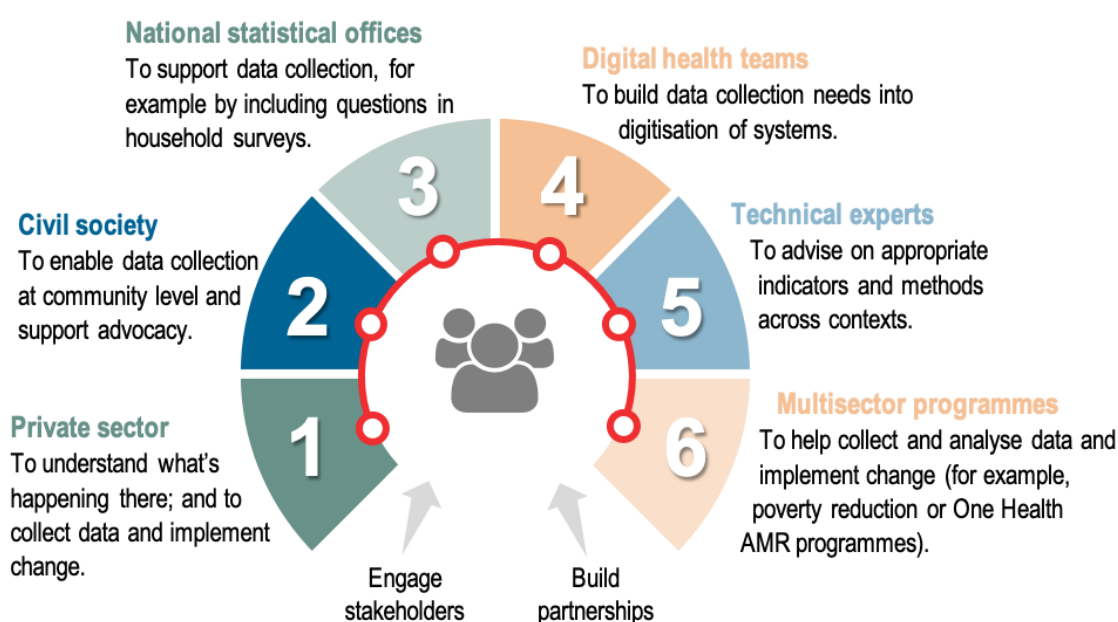
- Using the SDGs, and the recently approved SDG Indicator 3.b.3, as a framework for advocacy;
- Getting text on access to medicines into the political declaration that will be agreed at the UN General Assembly on UHC in September 2019; and
- Using the global UHC Day on 12 December as a platform for advocacy and awareness raising.

At a regional level, leveraging opportunities includes looking for national or regional events, such as the Southeast Asia meeting on frontline service delivery that is being organised in July, to promote access to medicines and the need to measure and monitor it.

Engage stakeholders.

Many different stakeholder groups can help to make the access dashboard work—whether that be through advocating its use, contributing data or supporting action to improve the system. Getting good stakeholder engagement should be a priority in all countries and regions. Examples of the different stakeholder groups to engage include private healthcare companies, civil society, national statistical offices and cross-sector programmes (see Figure 7).

Figure 7. Some examples of different stakeholders to engage.



Get started.

Participants were clear that the list of indicators to emerge from this meeting should be taken to the field soon and piloted in different contexts and then adjusted through use. Pilot countries should be chosen both on their suitability as test cases as well as their potential to become good champions for the dashboard in their regions later.

“Let’s get going quickly at country level, not wait for the perfect set of

Part V. The view ahead

Regional priorities

In convening the Delhi meeting, WHO hoped to provide a stepping stone towards targeted work with countries and partners in order to:

- improve data availability for monitoring access to medicines; and
- build capacity for collecting and analysing information to monitor progress in key indicators.

Before the meeting closed, each regional WHO representative offered their own perspective on some of the next steps and priorities for action in their region (see Table 2).

Table 2. Next steps and priorities for action for each of WHO’s regional offices.

WHO Region	Priorities for action
Africa	<ul style="list-style-type: none"> • Refine and define indicators within each country context. • Look for country buy-in by building understanding and showing impact. • Once endorsement is in place, start to support implementation (although this is likely to be years away).

Americas	<ul style="list-style-type: none"> • Promote ownership of the dashboard by showing countries that it will not be a burden and showing them how they will profit from using it. • Ensure sustainability by supporting political advocacy and investment. • Pilot the dashboard sooner rather than later, and refine it through use.
Europe	<ul style="list-style-type: none"> • Look to rationalise work at country level between partners and donors to reduce the burden of reporting. • Find ways to support data sharing across organizations. • Explore potential synergies with digitisation teams supporting the fast-digitising systems in Europe, especially within Russian-speaking countries.
Southeast Asia	<ul style="list-style-type: none"> • Refine the dashboard indicator list for regional context and consult on it. • Test revised country profiles based on the new regional list. • Establish a regional technical working group to support further refinement of the dashboard as it is used. • Promote use of a smart phone app to support data collection.
Western Pacific	<ul style="list-style-type: none"> • Consider variable country contexts and capacities for how to take monitoring forward. • Situate this work on the pharmaceutical system within broader health systems work.

Next steps for WHO

WHO's next steps from the Delhi meeting include:

- **Publish meeting report.** Draft and share a meeting report with participants for review and comment before publishing it online.
- **Work on individual indicators.** Refine and reduce the list of indicators agreed at the meeting, including defining some of those that were agreed as 'concepts' only.
- **Consult.** Consider the need for a public consultation.
- **Define metadata.** Define the metadata for each indicator.
- **Pilot.** Identify and support a few candidate countries to test the indicators.
- **Finalize indicators.** Based on consultation and pilot, agree a final list of indicators for the access dashboard.
- **Design dashboard.** Design a dashboard using the agreed indicators.
- **Create a standing technical expert group** that are responsible for the revisions of indicators, gather feedback from different stakeholders and advise on the development of a dashboard that is routinely updated.

Immediately following the Delhi meeting, a Southeast Asia regional meeting was convened to discuss how the agreed set of indicators could be tailored to the region. An initial draft summary of this meeting's discussion and outcomes is available in annex III.

Selected high level reference list of indicators for global monitoring

An initial “cleaned” version of the long list of indicators proposed in this meeting is presented below. This version focuses on the proposed indicators classified as of high importance to stakeholders and high feasibility of data collection and removes the duplications and the “structural” indicators.

Table 3. High level reference list of indicators for global monitoring.

nr	CORE FUNCTION	ORIGINAL INDICATOR
1	Pricing and reimbursement	% government expenditure out of total expenditure on pharmaceuticals
2	Pricing and reimbursement	ABC analysis (top medicines by expenditure/volume)
3	Pricing and reimbursement	% pharmaceutical expenditure out of total health expenditure
4	Pricing and reimbursement	% of the reimbursement volume spent on essential medicines
5	Pricing and reimbursement	% of household income on medicines ± assistive technologies
6	Pricing and reimbursement	% of population covered by health insurance that includes pharmaceutical benefits
7	Pricing and reimbursement	Per capita expenditure on pharmaceuticals
8	Selection, prescription	% of prescriptions based on EML
9	Selection	% of procurement based on EML (core)
10	Selection, dispensing	% of medicines dispensed based on EML
11	Procurement	% of invoices paid on-time
12	Procurement	% of orders received on time in full (OTIF)
13	Procurement	Ratio of median price of products procured and the international median reference price
14	Supply chains and distribution	Average stockout duration (in nr of days)
15	Market authorisation	Average days for review and granting MA for generic medicines
16	Market authorisation	% of EML with at least 3 registered products
17	Licensing-Inspections-Enforcement	% licensed premises that have valid licences within the relevant local legislation timeframes
18	Licensing-Inspections-Enforcement	% licensed establishments compliant with GXP
19	Licensing-Inspections-Enforcement	% inspection finding violations for which regulatory and legal action were taken
20	Licensing-Inspections-Enforcement	% of products inspected with valid market authorization
21	Market Surveillance and Control	Ratio of drugs that failed quality testing against the number that were sampled
22	Pharmacovigilance	No. adverse events following immunization per million population

Annex I. Indicators from group discussion

The full list of agreed indicators, categorized according to importance and feasibility, for each pharmaceutical system component (or group of components) that was discussed at the Delhi meeting is included in the tables below.

Selection, prescription, dispensing and rational use

		Feasibility of data collection		
		High	Medium	Low
Importance for stakeholders	High	% of prescriptions based on EML % of procurement based on EML (core) % of medicines dispensed based on EML	% of prescriptions containing one or more antibiotic(s) (AMR perspective) (core) Updated EML available	% of prescriptions based on STGs (core) Updated STGs available % of medicines dispensed based on STDGs
	Medium	% of prescriptions based on EML % of procurement based on EML (core) % of medicines dispensed based on EML	% of prescriptions containing one or more antibiotic(s) (AMR perspective) (core) Updated EML available	% of prescriptions based on STGs (core) Updated STGs available % of medicines dispensed based on STDGs
	Low	% of prescriptions based on EML % of procurement based on EML (core) % of medicines dispensed based on EML	% of prescriptions containing one or more antibiotic(s) (AMR perspective) (core) Updated EML available	% of prescriptions based on STGs (core) Updated STGs available % of medicines dispensed based on STDGs

Pricing and reimbursement

		Feasibility of data collection		
		High	Medium	Low
Importance for stakeholders	High	% government expenditure out of total expenditure on pharmaceuticals % pharmaceutical expenditure out of total health expenditure ABC analysis (top medicines by expenditure/volume)		% of essential medicines reimbursed % medicines (essential medicines) reimbursed out of all expenditure
	Medium	% cost of medicines (essential medicines) for health system (for government or insurer)		
	Low			

Procurement

		Feasibility of data collection		
		High	Medium	Low
Importance for stakeholders	High	% of invoices paid on-time % of orders received on time in full (OTIF) Ratio of median price of products procured and the international median reference price		
	Medium	% of products procured through a competitive process (optional) % of shipments rejected for noncompliance with contract % of products on EML that is procured centrally or through pooled procurement Is there any kind of market analysis done		
	Low			

Supply chain and distribution

		Feasibility of data collection		
		High	Medium	Low
Importance for stakeholders	High	Average stockout duration Track and trace system/ tech in place	% of facilities with availability of a basket of medicines (SDG indicator)	MPR of tracer medicines based on price to the consumer
	Medium			% of health facilities that received their orders OTIF
	Low			

Marketing authorization

<p>Selection Criteria/Rationale:</p> <p>Role of regulatory authority and regulatory oversight through MA function:</p> <p>Entry questions:</p> <p>1. Existence of regulatory authority:</p> <p>A. No: Stop other questions</p> <p>B. Yes: GBT ML level for MA function:</p> <p>ML1 and 2 or ML3 and 4</p>			Feasibility of data collection		
			High	Medium	Low
	Importance for stakeholders	High	Average days for review and granting MA for generic medicines % of EML with at least 3 registered products		
		Medium			

		Low			
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Licensing, inspection and enforcement

		Feasibility of data collection		
		High	Medium	Low
Importance for stakeholders	High	% licensed premises that have renewed licences within the relevant local legislation timeframes % licensed establishments compliant with GXP % inspection finding violations for which regulatory and legal action were taken		
	Medium	% licensed facilities inspected No. licences revoked, suspended and withdrawn for non-compliance	Risk management plan for inspection	
	Low	List of licensed manufacturing, distribution etc that are publicly available Maturity level of licensing defined/GBT indicator % of products inspected with valid market authorization		

Market surveillance and control

		Feasibility of data collection		
		High	Medium	Low
Importance for stakeholders	High	Is there a system in place? Is it being used? Are they generating information that is actionable? Ratio of drugs that failed quality testing against the number that were sampled		
	Medium			
	Low			

Pharmacovigilance

		Feasibility of data collection		
		High	Medium	Low

Importance for	High	Is there a system in place? Is it being used? Are they generating information that is actionable? No. adverse events following immunization per million population	Are decisions being made based on causality assessments?	
	Me			
	Low			

Information systems

		Feasibility of data collection		
		High	Medium	Low
Importance for stakeholders	High	Is there a national mechanism collecting information on utilization/sales? public/private prescribed/not-prescribed Is there a track and trace system/tech in place?	% of the market covered by the information system	
	Medium	Use of a unique product code throughout the system as a structure indicator % of products that can be tracked through the system as an outcome indicator		
	Low			
Unplaced: <ul style="list-style-type: none"> Is a unique patient identifier used for prescribing used as part of the whole HMIS? % of individuals diagnosed -> treated -> follow-up -> controlled 				

Annex II. Thai example of priority indicators

Key outcome indicators	Data sources	Feasibility*
Safety		
Quality of prescribing / dispensing in public and private facilities	Prescription analysis or dispensing survey; sentinel site monitoring	2–5
No. of adverse events per million population	National PV reporting	5
% fail of post-marketing quality assurance	SF drug survey	5
Access		
SDG 3.b.3 on availability and affordability	Sentinel site monitoring; routine monitoring	4
% of public and private facility stockouts	Health facility surveys	3
Average days of market authorization approval (for new and generic drugs)	Food and Drug Administration	5
Financial protection		
Household OOP expenditure on drugs (% of OOP on health)	Household income and expenditure surveys	4
Government expenditure on drugs as % of total government health expenditure	Insurance fund routine admin records/reports	4
Efficiency		
MPR of EML procured/international reference price	Administrative data	3

**Feasibility of data collection score 1–5 (low to high)*

Annex III: List of Participants

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**Monitoring the enablers of access to medicines:
taking stock and moving forward**
The Imperial Hotel, New Delhi, 26 - 27 February 2019

Informal expert consultation

Monitoring the enablers of access to medicines: taking stock and moving forward – Regional Consultation

28 February 2019, Delhi, India

Meeting report

Background

The discussion of the Global Informal Expert Consultation on Monitoring the Enablers of Access to Medicines on the 26-27 February 2019 produced approximately 60 indicators requiring further refine and selection. A regional informal expert consultation was organized to reduce this list of indicators and select which were best fit and feasible for the South East Asian regional reporting.

Informal Consultation Objectives

1. Consider what type of monitoring and indicators can be most helpful to national policymakers when developing strategies, interventions to increase access to essential medicines in the South East Asia Region
2. Select a small set of indicators in light of previous two-days Global expert consultation that should be promoted for regular monitoring by all South East Asian countries
3. Critically examine feasibility of data collection and consider / recommend use of new tools needed for regular national monitoring
4. Develop recommendations on what additional indicators should be included and reported in the Country Pharmaceutical profiles, that are published biennially by SEARO.

Discussions

The meeting was held in the form of a working group session in which indicators were assessed by their function and importance. The experts selected 11 total core indicators to measure Financial Protection (2), Pricing (1), Rational Use (1), Selection (1), Availability (2), Regulation (3), and Pharmacovigilance (1). Two indicators were determined as critically important, but aspiration given current health information infrastructures in LMICs. Experts identified 1 complementary indicator – an ABC analysis to determine the top medicines by expenditure and volume in each country – as a useful way to determine efficiency of selection as well as diagnose areas for pricing interventions. Experts also noted several important complementary indicators that could be derived from core indicators on financial protection. Core, aspirational, and complementary indicators are presented below.

The WHO South East Asian Regional Country Profiles were also presented for expert review. Experts noted that the current profile layout described well the national pharmaceutical sector structures for the Region; but indicated areas for augmentation to improve the country narratives. Expert suggestions are noted below.

Core Regional Monitoring Indicators

Availability <ul style="list-style-type: none"> • SDG 3.b.3: Proportion of health facilities that have a core set of relevant essential medicines available and affordable on a sustainable basis • SDG 3.b.1 Proportion of the target population covered by all vaccines included in their national programme
Financial Protection <ul style="list-style-type: none"> • Total expenditure on medicines, US\$ per capita • Share of public and OPP spending on medicines (US\$ and %)
Pricing <ul style="list-style-type: none"> • Median price ratio (PPP\$) per basket of medicines above reference price
Rational Use <ul style="list-style-type: none"> • Quality of prescribing / dispensing in public and private facilities: <ul style="list-style-type: none"> • A. % EML, • B. % generics • C. % antibiotics • D. % injectable (optional) • E. %poly-pharmacy (optional)
Selection <ul style="list-style-type: none"> • % of public procurement based on EML
Regulation <ul style="list-style-type: none"> • NRA Maturity Level according to GBT: <ul style="list-style-type: none"> • A. based on self-assessment • B. based on WHO-assessment • C. with assessment information publicly available • Proportion of products at point of dispensing that have market authorization • Proportion of failed tests out of total sampled and tested medicines at point of dispensing (specifying whether risk-based sampling was used) <ul style="list-style-type: none"> • A. in total • B. with results publicly available
Pharmacovigilance <ul style="list-style-type: none"> • Number of adverse events per million population

Complementary and Aspirational Regional Monitoring Indicators

Dimension	Indicator	Type
Supply Chain	% of essential medicines list medicines monitored through a tracking, traceability, or authentication system	Aspirational: requires further refinement
Pharmacovigilance	% of ADRs reported, investigated, and acted upon	Aspirational: requires further refinement
Selection	ABC analysis (top medicines by expenditure/volume)	Complementary
Financial Protection	Government expenditure on medicine as proportion of total government health expenditure	Complementary/Derived Indicators
Financial Protection	Out of pocket expenditure on medicines as proportion of out of pocket expenditure on health	Complementary/Derived Indicators
Financial Protection	Out of pocket expenditure on medicines as a proportion of total expenditure on medicines	Complementary/Derived Indicators



ACCESS TO
MEDICINES

- Indicators included in the 2017 profiles are proxies for access to medicines until more information is collected for the SGD indicator
- Include additional indicator in progress towards global NCD target
- Include civil society maps on opioid consumption



KEY MEDICINES
POLICIES AND
GUIDANCE

- Include indicators on existence of 1) generic substitution policy; 2) price control policy; 3) National Essential Medical Devices, Assistive Technologies, and Diagnostics Lists; and 4) Policy for Evidence-Based Selection of Medical Products



Market
Authorization/
Licensing/Quality
Assurance

- Include new regulatory indicators listed above
- Include block of indicators for "Medicines Safety and Use"



Pricing and
Reimbursement

- Identify institution responsible for health technology assessment
- Indicate if price negotiation processes exist within the country



Informal expert consultation on monitoring of progress on
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Immediate Next Steps:

1. Survey SEAR countries on feasibility of reporting newly selected regional indicators
2. Begin inclusion of new regional monitoring indicators in SEAR Country Pharmaceutical Sector Profiles
3. Discuss aspiration regional monitoring indicators with Member States at the Southeast Asian Regulatory Network Meeting in April 2019
4. Begin routine medicine price and availability monitoring pilots using WHO EMP MedMon in Thailand and Bangladesh.