WORKING PAPER

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BUSINESS LEADERSHIP FOR AN INCLUSIVE ECONOMY

Advancing Access to Healthcare Metrics

A proposed sectoral approach to performance measurement and communication

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Guiding Principles
on Access to Healthcare

About This Paper

This working paper has been prepared on behalf of the Healthcare Working Group, a group of 15 global healthcare companies hosted by BSR, as part of an ongoing work program initiated by the launch of the Guiding Principles on Access to Health (GPAH) in 2013. The GPAH is a set of five principles that frame and describe the healthcare industry's approach to reducing the global burden of disease and advancing access to healthcare.

We prepared this paper to help pharmaceutical and medical device companies improve their ability to measure and report performance on access to healthcare. It sets out to achieve this objective by improving the quality, comparability, and outcomes focus of metrics employed, and by providing related guidance on monitoring and evaluation (M&E) methodology.

This working paper is the result of a research process conducted in 2015 and 2016 that included desktop research coupled with a consultative process including BSR healthcare member companies, public health stakeholders, and M&E specialists. This document represents one step in a longer journey; more research, company implementation, and continuous improvement are needed—especially with respect to outcomes metrics and methodologies.

The authors of this paper are Dorje Mundle, Cecile Oger, Meghan Ryan, and Andrew Matthews, with additional contributions generously provided by the individuals listed in Appendix 2: Contributors. Any errors that remain are those of the authors. Please direct comments or questions to Cecile Oger at coger@bsr.org or at gpah@bsr.org.

DISCLAIMER

ABOUT BSR

BSR is a global nonprofit organization that works with its network of 250 member companies to build a just and sustainable world. From its offices in Asia, Europe, and North and South America, BSR develops sustainable business strategies and solutions through consulting, research, and cross-sector collaboration. Visit www.bsr.org for more information about BSR's more than 20 years of leadership in sustainability.

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Executive Summary

As healthcare companies continue their work to expand access to healthcare (hereafter, access), a parallel need exists to better track and analyze the data underpinning those efforts. Most healthcare companies use a wide variety of performance metrics that vary considerably from one access program to another, limiting the potential to compare and aggregate the impacts of these programs at an enterprise-wide level. Similar comparability and aggregation challenges apply when comparing the performance of different companies. In addition, there is a growing desire among companies to go beyond expenditure and activity reporting and to measure the outcomes of their access programs.

This working paper was prepared by BSR and its Healthcare Working Group member companies to help pharmaceutical and medical device companies improve their performance measurement and reporting on access to healthcare. It does so by providing a set of core metrics that create a basis for improved quality, comparability, and outcomes-focus compared with current industry practice. It also provides related guidance on monitoring and evaluation (M&E) methodology. A core set of standard metrics for use across multiple programs will provide more useful management information that can in turn improve program performance management and impact, resource allocation between programs, cost effectiveness, communications, and reporting.

From a baseline of more than 60 input and output metrics used by the companies surveyed, this paper proposes a core list of 19 input and output metrics, and nine outcomes metrics. These metrics are anchored in the Guiding Principles on Access to Healthcare (GPAH) and align with other key frameworks such as the Access to Medicines Index (ATMI), and are relevant to the majority of the healthcare industry's philanthropic and commercial access programs. They are not intended as a mandatory list, but rather a list from which companies have the option to select and align with, as befits their product portfolios and the distinct profile of their access to healthcare programs.

The proposed input and output metrics span access topics including R&D, pricing, commercialization and capacity-building.

Recommended outcomes metrics address health outcomes, health systems outcomes, and business outcomes metrics. Key highlights from the report include:

- Non-disease-specific **health outcome** metrics such as quality-adjusted life-year or disability-adjusted life-year (QALY or DALY) are challenging and should be used with discretion. The metrics' methodological complexity makes them expensive to use, although they can add rigor to performance management. Therefore, they should only be used where there is a compelling need to make this investment, such as for flagship projects spanning multiple diseases or situations with high external scrutiny.
- Current industry measurement of **health systems outcomes** is limited, but progress here is critical for expanding access and also has the potential to be valuable commercially. Measuring facility-level availability and price helps manage stock-outs as well as comparing product pricing with competitors. A more refined understanding of affordability (and elasticity of demand) can help companies optimize margins, volumes, and patient access. Collectively, these insights can help competitive positioning and sales penetration in mass-market segments. Measuring patient and health-worker training outcomes appears to be nascent within the industry, so companies should learn from best practices in other sectors, such as development agencies.
- Measuring **business outcomes** of access programs**,** such as sales or market share, also appears to be a nascent practice. Access-related business outcomes are rarely reported externally and few companies even measure them internally, though some do so and report this up to board-level. The growing company implementation of inclusive and shared-value business models that drive sales and patient access highlights the need and opportunity for companies to innovate and show leadership on performance measurement.
- As outcomes metrics are often resource-intensive to implement, **low-cost methodologies and tools for performance measurement** are needed to expand their adoption.

In addition to improved metrics, this paper recommends that companies use theories of change as a standard practice in their access programs, to improve both M&E and program impact.

Finally, this paper highlights the importance of accompanying improved metrics with improved narrative in company reporting (especially for outcomes) to ensure that the target audience is appropriately informed and engaged.

Recommended metrics

Inputs

- Expenditure on all access programs (financial, in-kind, and product; cost to company)
- Percentage of total R&D expenditure spent on new or adapted products for ATMI-indexed diseases and other priority health topics*
- Expenditure on R&D capacity-building in low- and middle-income countries (LMICs)
- Number of products provided to product development partnerships, patent pools and other open research platforms
- Number of countries in which products are available through equitable pricing schemes (absolute number and percentage of total number of countries operated in)
- Financial value and volume** of products donated or provided on an at-cost basis (cost to the company)
- Volume of products sold through equitable pricing in LMICs, both absolute and as a percentage of total LMIC sales
- Number (and list) of Least Developed Countries in which products for ATMI-indexed diseases and other priority health topics are registered
- Volume of products sold through public sector tender in LMICs
- Expenditure on activities that strengthen health systems

Outputs

- Number of people reached by all access programs
- Number of products in the pipeline that address ATMI-indexed diseases and other priority health topics
- Number of clinical trials in LMICs
- Number of active clinical trial sites (conducted by the company and through third parties) in LMICs
- Number of patients reached with products through equitable pricing
- Number of patients reached with products through donations
- Number of people (community) reached through Health Systems Strengthening initiatives (e.g., disease awareness programs)
- Number of patients reached with Health Systems Strengthening initiatives (e.g. screening, education, infrastructure)
- Number of healthcare and government personnel trained through programs and partnerships

Outcomes

Health outcomes

- QALYs gained / DALYs averted
- Mortality avoided / Lives saved

Health system outcomes

- Facility-level availability: Percentage of facilities with products in stock
- Average end user price per course of treatment for products in LMICs
- Affordability of treatments for low-income patients in LMICs
- Percentage of health system workers receiving training that achieve predefined training goals (e.g., increased knowledge of symptoms or treatment protocols, application of that knowledge, or improved quality of care)
- Percentage of patients / community members receiving training that achieve predefined training goals (e.g., increased knowledge of symptoms, change in health-seeking behavior, or adherence)

Business outcomes

- Sales and profits generated through equitable pricing initiatives
- Market share of key products for ATMI-indexed diseases and other priority health topics in LMICs

* As defined by the WHO Global Health Observatory (http://apps.who.int/gho/data/node.resources).
** For metrics that refer to the volume of products or are calculated by deriving from volume of products (e.g., patients reached), see key guidance on page 12.

Introduction

The Healthcare Working Group (HCWG) was established in 1999 for healthcare companies to come together to discuss and collaborate on addressing CSR issues faced by the sector. The group is facilitated by BSR and today consists of 15 of the world's largest healthcare companies representing pharmaceuticals, vaccines, diagnostics, and medical devices. The group's overarching objective is to drive improved understanding of key CSR issues impacting companies in the healthcare sector.

In 2013, the HCWG developed the Guiding Principles on Access to Healthcare (GPAH), a set of five principles that frame and describe the industry's approach to advancing the access agenda. The GPAH have been endorsed by 13 CEOs of major healthcare companies. A GPAH status report published in 2014[1] recognized that measurement is key to evaluating and driving progress, and that there is a clear need for greater consistency and comparability of access metrics. On that basis, the HCWG undertook a collaborative research process to develop a common set of metrics. This paper is the outcome of this process.

Context

Many healthcare companies find they have a long list of disparate metrics that vary considerably from one access program to another, limiting the potential to compare and aggregate impacts of these programs at an enterprise-wide level. Similar comparability and aggregation challenges apply when comparing the performance of different companies.

Having a core set of standard metrics for use across multiple programs provides more useful management information that can improve:

- program performance management and impact
- resource allocation between programs
- cost-effectiveness
- communications and reporting

In addition, there is a growing desire among companies to go beyond expenditure and activity reporting and to measure the outcomes of their access programs. Similar efforts are underway in other sectors, though this represents a challenging task and BSR is not aware of any sectors that have yet succeeded.

Objectives

The objectives of this paper are threefold. First, we propose a set of core metrics to help the healthcare sector more consistently and comparably measure and report their access activities; second, to help the sector increase the measurement and reporting of outcomes metrics; and third, to provide qualitative guidance to inform and facilitate the M&E implementation process among healthcare companies.

Scope

This paper covers how companies in the healthcare industry measures and reports their access activities. The industry is actively engaged in a wide variety of access programs, including product-related (such as R&D or pricing) and health-system related (such as capacity-building programs). Accordingly, the intent of this paper is to set out recommended metrics and accompanying guidance that span the range of programmatic activities undertaken by the healthcare sector. Furthermore, this paper seeks to ensure appropriate coverage of input, output, and outcome metrics as defined below:

- **Input indicators** measure the financial and physical resources dedicated to a goal. These include the resources used (funds, staff, materials) and the activities undertaken (conducting a training workshop, meeting with communities, meeting with government officials, or undertaking operational field research) to bring about a result.

[1] BSR, "2014 Status Report: The Guiding Principles on Access to Healthcare: From Aspiration to Action," www.bsr.org/reports/BSR_GPAH_Status_Report_2014.pdf.

- **Output indicators** measure the goods and services that are produced by the inputs. These demonstrate the immediate results of project or program activities, such as the number of healthcare workers trained, patients educated, or number of children vaccinated.

- **Outcome indicators**[2] measure the changes or benefits that result from the program intervention. Three types of outcomes are evaluated in this paper: health outcomes, health systems outcomes, and business outcomes. Outcomes can usually be measured during the lifetime of a project or program. The longer-term health and socioeconomic impacts that can result from improved health are not included within the scope of this paper.

This paper does not focus on disease-specific metrics such as A1c, lung function, or visual acuity, but instead addresses metrics with broad applicability across multiple therapeutic areas. We envisage that these broad-based metrics will be used alongside program-specific metrics that reflect the therapeutic focus and nature of the interventions conducted.

We developed the metrics proposed in this paper to align, as appropriate, with other key frameworks and metrics, including the Access to Medicines Index (ATMI), and the Guiding Principles on Access to Healthcare (GPAH).

The proposed metrics are not intended as a mandatory list, but rather a list from which companies have the option to select and align with, as befits their product portfolios and the specific profile of their access to healthcare programs.

Methodology

We used primary and secondary data collected from the following sources to write this report:

- Desktop research conducted on publicly available data, including company annual and CSR reports, corporate websites, and publications from NGOs, multilateral organizations, and academic journals.
- Perspectives and feedback collected from HCWG members throughout the process, in group sessions as well as through bilateral conversations.
- Perspectives from NGOs, multilateral organizations, academics, and investors collected through one-on-one interviews and an in-person workshop. A list of contributors is available in Appendix 2.

The methodology used to conduct this research involved three main phases:

More details on the Methodology can be found in Appendix 3.

[2] Please note, outcomes are typically actions, behaviors, or approaches undertaken by a company, organization, decision maker, or other relevant entity that results from the program intervention. Outcomes are finite and often measurable changes with typically pre-defined scope and reach. Outcomes are short- to medium-term effects of the program intervention and represent changes in conditions that occur between the completion of outputs and the achievement of impact. Impacts are broader in scope and characterized as longer-term effects of an outcome or longer-term changes in the external world. For instance, the broader socioeconomic outcomes of health interventions are considered to be impacts.

Guidance on Monitoring and Evaluation

This research builds upon past and ongoing efforts from a number of organizations and collaborations focused on advancing access to health measurement. Our goal is to contribute to this existing discourse. Therefore, the implementation guidance provided here combines the most relevant insights from previous efforts with new insights gleaned through interviews and research conducted during this project.

Based on BSR research and interviews with external experts and HCWG members, we provide the following M&E guidance to inform access metrics development and implementation at three phases of the program life cycle: planning and design, implementation, and reporting and communications.

This guidance does not represent a comprehensive list of all considerations for companies planning their access monitoring and reporting activities, as this would represent a much larger scope of work that goes beyond the goals of HCWG companies. Rather, these recommendations summarize the most salient feedback provided by the stakeholders we interviewed.

PLANNING & DESIGN

Recommendation	Suggested Tactics
Develop and articulate a theory of change	• Define a theory of change that underpins your company's access approach and is applicable developing outcomes metrics as well as inputs and outputs metrics. • Define the desired long-term health, health system, and business for your program, then: a) map backward to identify the interim short- and medium-term outcome goals needed to achieve the long-term goals; b) identify the program resources and activities needed and map the causal linkages between program activities and the achievement of the short-, medium-, and long-term goals. • Clarify which health, health system, and business outcomes are relevant to the program and will be measured. Business outcomes should be aligned with the company's corporate and access strategy. • Assess the potential for—and ensure measurement of—any significant unintended adverse effects of access interventions. • Consider the different ways in which access initiatives create value for the business, whether commercial activities in certain income bands in least-developed countries, tender sales, market share, reputation, or customer relationships. • Determine the extent to which the program is scalable, sustainable, and equitable or inclusive; identify metrics to measure these traits. • Ensure that your theory of change is the through-line that guides your access strategy, activities, tactics, monitoring, and evaluation.

Align with national and international priorities	• Discuss and decide how your metrics—especially outcomes metrics—align with national health priorities, the Sustainable Development Goals (SDGs), as well as other external points of reference, such as the WHO, NCD Global Monitoring Framework, or International Consortium for Health Outcomes Measurement. • Surface the ways in which your metrics could capture progress against gaps in health systems that have been quantified and agreed by the international community, such as Africa's million-person gap in health workers.
Adopt a cross-functional governance model	• Seek support and involvement from corporate functions with a stake in the planning and design of interventions and subsequent measurement. • Understand the needs of multiple internal stakeholders vertically and horizontally so that relevant business interests are represented.
Invest in measurement and monitoring design and relevant staff skills	• Incorporate design of measurement and data capture into up-front strategic planning, taking into account the desired outcomes and the story you want to be able to tell. The better the ongoing data capture and monitoring, the easier it is to improve ongoing performance, and the less onerous the impact measurement and reporting becomes. • Consider which types of data relevant to your monitoring plan could be captured during routine project operations (such as during community/HCP training sessions or health screenings) to minimize the extent to which additional stand-alone M&E interventions need to be conducted. • Ensure that the company has sufficient staff capacity, tools, and skills to design, capture, and analyze outcomes metrics.
Use consistent methodologies and metrics across programs when possible	• Build on existing work, methodologies, and metrics, rather than developing a new measurement approach for each program, in order to support comparability and consistency. • Consider using a number of core metrics—spanning inputs, outputs, and outcomes when relevant—that are used across all access programs.
Leverage existing data when possible[3]	• Make use of relevant existing databases to include public health and demographic data collected by the WHO, World Bank, governments, NGOs, or peer companies. Suggested resources are provided in Appendix 4. • Collaborate with peers and stakeholders in other sectors, such as government and NGOs, in order to share data, spread efforts across a wider base, and facilitate better data collection and analysis.
Integrate predictive modeling to limit the need for field-level measurement[4]	• For health outcome metrics, consider using predictive modeling to limit the resource requirement for field-level impact studies.[5] Invest in field-level measurement only when the situation requires it (for example, if existing system- or country-level data is insufficient, the strength and consistency of efficacy data is limited, or the level of reasonable attribution is tenuous) or when the benefit of measurement outweighs the investment required.

[3] Recommendation adapted from "Measuring Shared Value Innovation and Impact in Health," a report by the Shared Value Initiative. The SVI provides a number of insights and recommendations, some of which this working paper builds upon.

[4] Recommendation adapted from the Shared Value Initiative report.

[5] If modeling is used, refer to related guidance in the "Reporting and Communications" section below, and the "Recommendation for Health Outcomes" section.

IMPLEMENTATION

Recommendation	Suggested Tactics
Conduct a baseline assessment and/or assess comparison groups	• Conduct a baseline assessment to understand the pre-existing state of the relevant population(s), community(ies), and/or health system(s) in which the company seeks to measure outcomes. A baseline assessment will enable more effective measurement of new access programs, Monitoring progress in intervention and control sites will help determine whether changes are attributable to the company's program. • Consider partnering with government, NGOs, peers, or academics in order to conduct these M&E activities.
Prioritize health outcomes measurement in strategically important situations	• Measuring non-disease-specific health outcomes can require a significant investment of human and financial resources, and so is not feasible for application across all company access programs. Where there is a desire to measure this type of health outcome, it is advisable to prioritize certain programs to maximize the value and minimize the resource requirements of these efforts. Prioritization criteria may include: - **Strategic importance:** Programs in which the value of measuring and reporting outcomes is high, whether flagship programs or situations with high external stakeholder scrutiny. - **Feasibility**: Programs in which the feasibility of calculating health outcomes is highest due to the nature of the disease, treatment efficacy, and the extent to which health outcomes can be attributed to treatment, such as childhood vaccines. - **Data availability and quality**: Programs in markets where country-level data collection is more mature.
Use pilot projects to gain experience	• Conduct pilots of proposed projects to experiment and test access approaches and companion measurement systems. Because pilots require fewer resources and enable iteration and program improvement, they are an ideal testing ground for piloting outcomes metrics.  **CASE STUDY:** Novo Nordisk's Blueprint for Change program creates a customized approach to improving access to diabetes therapy in each country in which the program is deployed. The program includes outcomes metrics, such as the percent improvement in diabetes health indicators among people treated by general practitioners who participated in company-sponsored education programs. The programs also include outcomes projections to quantify the potential effects of decreasing gaps in awareness and treatment, such as heart attacks prevented and life-years gained.[6]

[6] Novo Nordisk, "Where Economics and Health Meet: Changing Diabetes in Indonesia," 2013, www.novonordisk.com/content/dam/Denmark/HQ/Sustainability/documents/blueprint-changing-diabetes-in-indonesia.pdf.

Make use of innovative technology for data monitoring and impact assessment	• Consider capturing data on low-cost mobile devices rather than paper to enable quicker monitoring and instantaneous standardized reports, which are less cost- and labor-intensive. • Consider customizable open-source software platforms that provide database, electronic medical records (EMR), stock monitoring, and SMS push/pull communications functionality to complement mobile data capture (see the Conclusions and Recommendations section for examples)

CASE STUDY: Novartis' Roll Back Malaria partnership initiative "SMS for Life" uses text-message technology to provide visibility about medicine stock levels and diagnostics at the health-facility level. Workers send information about stock levels to a central database, allowing real-time information to be presented weekly to the District Medical Officer and mobilizing supplies to the areas that need them the most. The company and its partners encourage participation by rewarding workers with free mobile phone credit. A pilot study in Tanzania has shown that stock-outs of malaria medicines were drastically reduced using this system.[7]

CASE STUDY: More than 35,000 children in Mozambique have now been registered in GSK's mVacciNation pilot program with Vodafone, which seeks to improve vaccination rates using mobile phones. Parents and caregivers receive updates on their phones to remind them when vaccinations are due, and more than 55,000 vaccination visits have been recorded. In addition, healthcare workers are responsible for recording vaccination stock levels and refrigerator temperatures on a weekly basis through the phone. The 17 facilities enrolled in the pilot recorded an average of five stock updates and three cold-chain updates per week. In December 2015 the service was expanded to 76 facilities.

With funding from USAID and GAVI, a randomized control trial will measure the impact of the pilot and assess cost effectiveness to inform decisions about scaling up the program in Mozambique and other African countries.

INTERNAL AND EXTERNAL REPORTING & COMMUNICATION

Recommendation	Suggested Tactics
Provide supporting context	• Providing context in the narrative that accompanies metrics is essential to enable the user or reader to understand and interpret the data provided. • The need for context is especially salient to support health outcomes and health systems outcomes metrics. For example, in which target population were the outcomes measured? What income band, specific geography, gender, or age characterized the target population?

[7] Novartis, "Stepping Stones: From Malaria Control to Elimination," 2011, http://www.malaria.novartis.com/downloads/nmcp-reports/nmcp-highlighter-benin.pdf.

	• For training interventions, it is helpful to provide narrative on the purpose and nature of intervention. For instance, was it interactive, who delivered it, did follow-up take place, what were the outcomes?
Report transparently the data sources, assumptions, and limitations to the approach used to calculate health outcomes	• The need for transparency on assumptions, scope, and methodology are important for metrics across the board, and especially for health outcomes metrics such as DALYs and QALYs. • To support the credibility of your data, and to allow for interpretation and comparison, provide the key assumptions and data sources that underpin data. • For outcomes metrics, specific questions to consider include: Are there extrapolations of data from other countries embedded in your metrics? Is data compiled from predictive modeling or field-level measurement? Is there significant uncertainty in demographic data used in calculations, in efficacy data, or another dimension that represents a critical assumption?
Acknowledge data quality limitations, and find ways to improve upon it or use simpler measures	• Challenges around data quality for datasets needed to calculate QALYs, DALYs, and Lives Saved are widespread in LMICs, in both private- and public-sector contexts. • Where data quality is a concern, it is important to acknowledge this when communicating health outcomes. Public health audiences face similar challenges and are therefore unlikely to be critical of the accuracy of outcomes data, as long as the companies providing the data are transparent. • Expert interviewees suggest that company efforts can be a platform for stakeholder dialogue and engagement, and promote shared learning and improved data-collection methods in the future.
Share results internally if external communication is sensitive	• Companies can choose to test new measurement approaches and share results internally prior to—or, where appropriate, instead of—reporting results externally. • This can help companies to gain experience and feel more comfortable externally reporting metrics.
Use results to inform program strategy and resource allocation	• Results provide a measure of program effectiveness and can be used to provide critical insights to decision makers within companies. • Comparative analysis of results across programs can inform program strategy and resource allocation.

Recommended Metrics

This research is based on the recognition of the healthcare sector's strong opportunity to improve the consistency of its access monitoring and evaluation. This section builds on existing work and recommends a set of core metrics in three categories: input, output, and outcome metrics. This set of metrics has been designed to provide performance and impact measurement for the majority of access to healthcare programs that the healthcare industry is working on.

As introduced earlier, the underlying driver for conducting this research is the recognition, both by healthcare companies and external stakeholders, of a need and opportunity for improved consistency of access metrics and approaches.

While the intent of this paper is to set out recommended metrics and also to propose accompanying guidance, this section focuses on recommending a short set of core metrics in three categories: input, output, and outcome metrics.

The set of metrics that is proposed has been carefully crafted to demonstrate broad applicability. It was developed to align with key frameworks (including the GPAH), and designed to cover metrics that can be used across multiple therapeutic areas. We believe that these broad-based metrics will be used alongside program-specific metrics that reflect the therapeutic focus and nature of the interventions conducted.

Input and Output Metrics

Phase 2 of this project[8] highlighted three key findings:

- Metrics currently used for enterprise-wide reporting on access consist solely of inputs (28 percent) and outputs (72 percent)
- Stakeholders have a clear appetite and shared expectation for standardizing input and output metrics and methodologies.
- The GPAH framework provides a suitable thematic architecture to organize a set of consistent inputs and outputs metrics.

The proposed set of harmonized metrics is organized under the GPAH principles and sub-principles that healthcare companies most often report on: R&D, Pricing, Commercialization, and Capacity-Building. These core metrics can be used across companies and across projects.

KEY INFORMATION: For metrics that refer to the volume of products or are calculated by deriving from volume of products (such as the number of patients reached), the number of pills or packs is often not meaningful or comparable due to variance in pack sizes or number of pills needed by patients, so standard denominators should be used. For acute diseases, a course of treatment based on the WHO Defined Daily Dose (DDD) is the recommended unit.

[8] More information about the phases of this research is available in Appendix 3.

For chronic diseases, the WHO uses 30 days' consumption of the DDD as the standard measure.

KEY INFORMATION: While it is not within the scope of this paper, we believe that these metrics will be augmented by additional metrics that provide additional context by geography, portfolio, and/or that may have value from an internal management and/or external communication standpoint.

OVERARCHING METRICS

Inputs	Outputs
• Expenditure on all access programs (financial, in-kind, and product; cost to company)	• Number of people reached by all access programs

R&D

The most critical R&D issue from an access perspective is the pipeline of new and adapted products with direct relevance to critically unmet health needs in underserved patient populations. There is also growing recognition of the varying epidemiologies and responses to treatment among different underserved populations, highlighting the need for more local R&D capacity—including clinical trials—in LMICs.

The proposed R&D metrics are as follow:

Inputs	Outputs
• Percentage of total R&D expenditure spent on new or adapted products for ATMI-indexed diseases and other priority health topics[9] • Expenditure on R&D capacity building in LMICs • Number of products provided to product-development partnerships, patent pools, and other open research platforms	• Number of products in the pipeline that address ATMI-indexed diseases and other priority health topics • Number of clinical trials in LMICs • Number of active clinical trial sites (conducted by the company and through third parties) in LMICs

EXPANDING AVAILABILITY OF HEALTHCARE SERVICES

Pricing

The proposed Pricing metrics are as follow:

Inputs	Outputs
• Number of countries in which products are available through equitable pricing schemes (absolute number and percent of total number of countries operated in) • Financial value and volume of products donated or provided on an at-cost basis (cost to the company) • Volume of products sold through equitable pricing in LMICs (absolute and as a percentage of total LMIC sales)	• Number of patients reached with products through equitable pricing • Number of patients reached with products through donations

[9] As defined by the WHO Global Health Observatory (http://apps.who.int/gho/data/node.resources).

KEY INFORMATION: Equitable pricing is a term used broadly to include inter- and intra-country pricing strategies such as tiered pricing (including at-cost), dual branding, patient access programs, non-exclusive voluntary licensing agreements, and managed entry agreements (MEAs). In some cases MEAs may have a demonstrable access benefit to disadvantaged groups due to the profile of the patients served by the partner institution, such as a national Ministry of Health or a hospital chain. In other cases, MEAs may principally benefit higher-income patient populations, including premium-segment healthcare-delivery companies, so caution should be applied to ensure that such situations are not included within the scope of access reporting.

KEY INFORMATION: All types of donations are included in the above metrics, including ad hoc short- and long-term donation programs. External stakeholders such as ATMI and NGOs particularly value longer-term sustained donation programs.

Commercialization

Commercialization as defined in the GPAH refers to commercial activities that have a key bearing on the accessibility of products and services to patient populations. In practice, this includes patent enforcement and new business models, as well as registration, distribution, and sales mechanisms.

The proposed Commercialization metrics are as follow:

Input	Output
• Number (and list) of Least Developed Countries in which products for ATMI-indexed diseases and other priority health topics are registered • Volume of products sold through public sector tender in LMICs	—

Capacity-Building

Capacity-building refers to programs that strengthen health systems through a variety of means, such as training health practitioners or other health system personnel, advancing patient education, investing in health infrastructure, and improving supply chain efficiency and integrity. These programs improve the accessibility, affordability, quality, and rational use of healthcare provisions.

The proposed Capacity-Building metrics are as follow:

Inputs	Outputs
• Expenditure on activities that strengthen health systems	• Number of people (community) reached through Health Systems Strengthening initiatives (such as disease awareness programs) • Number of patients reached with Health Systems Strengthening initiatives (e.g., screening, education, or infrastructure) • Number of healthcare and government personnel trained through programs and partnerships

KEY INFORMATION: The list of metrics proposed is deliberately short, with a high degree of aggregation. It is possible to disaggregate to a much more granular level in order to accommodate program-level requirements. For example, the number of health workers can be broken down by type (community health worker, nurse, physician, specialist, pharmacist), region, and by therapeutic area. These more-detailed metrics should be used at the program level where this aligns with the program's M&E strategy, but can then be aggregated across programs using the metrics recommended in this working paper.

Outcomes Metrics

Outcome indicators measure the changes or benefits that result from the program intervention, such as access to, use of, and satisfaction with public services or access to products or services. Based on interviews with working-group members and external stakeholders, including public-health experts and responsible investors, we identified three categories of outcomes metrics that represent the most useful and achievable types for companies to consider implementing.

The three types of outcomes metrics are:

- Health outcomes
- Health systems outcomes
- Business outcomes

Outcomes metrics are widely regarded as challenging metrics to develop, yet necessary for companies and their stakeholders to understand the extent to which their efforts lead to positive results related to patients, communities, and overall disease burdens. Furthermore, companies that are committed to increasing access desire outcomes metrics as a way to measure and track the success of various approaches to increasing access to healthcare.

However, recognizing the challenges inherent in designing and implementing outcomes metrics, companies should carefully consider and prioritize when and how to undertake the development of outcomes metrics (see the Implementation table on page 8 for some illustrative prioritization criteria). At present, none of the companies surveyed reported using outcomes metrics at an enterprise-wide level, though some companies are reporting outcomes at the country or program level (see the Novo Nordisk case on page 8 for an example).

This section assesses some of the most promising approaches to capturing access outcomes, as well as the challenges and opportunities that characterize each approach.

HEALTH OUTCOMES

Non-disease-specific health outcomes are challenging metrics to implement due to their methodological complexity, data needs, and attribution issues, making them resource-intensive to deploy. Furthermore, the general public may not easily understand some metrics, and healthcare company decision makers—who are accustomed to more-tangible impact measures—may not readily prefer them.

Furthermore, companies reporting health-outcomes metrics should transparently communicate the relevant assumptions, limitations, methodologies, and external stakeholders consulted in developing and calculating the metrics. This will provide needed context and credibility to support companies as they integrate health-outcomes metrics into the suite of access metrics that they track and report.

Leading institutions and public health thought leaders use and recommend two health-outcomes metrics, which we explore in more detail below: quality-adjusted life years (QALYs) gained / disability-adjusted life years (DALYs) averted, and mortality avoided / lives saved. While disease-specific health-outcomes metrics can be simpler and less costly to measure than these proposed metrics, they cannot be aggregated across therapeutic areas. The two health-outcomes metrics were selected on the basis of recommendations by experts, their widespread use in the public health community, and because they represent metrics that have the potential to be used across disease types.

However, QALYs and DALYs are complex, resource-intensive, and not accepted by all public health or development stakeholders. We therefore recommend their use only where there are compelling internally or externally driven reasons for investing in measuring health outcomes across multiple health conditions, such as for strategic, high-visibility programs. One methodological challenge is the difficulty in attributing changed health outcomes to company interventions. There are situations where attribution may be less difficult—as with geographies or health topics for which minimal health-worker training is being conducted, or for highly efficacious vaccines—however, we recommend engagement with public health stakeholders to address these issues at a program-specific level. In the following table, we describe the high-level opportunities and challenges associated with each type of health-outcomes metric.

Recommended Metric	Opportunity	Challenge
QALYs gained / DALYs averted	• Aligns with outcomes metrics used by WHO, regulators, policy-makers, and leaders in the public health community • Provides a framework for measuring performance of access initiatives over time • Enables companies to take a more robust approach to assessing social returns on investment • Provides another lens through which companies can make decisions about resource allocation • Metric design can include the use of modeling to reduce the burden of field-level data collection	• Varied availability and quality of data (for example, background morbidity) to underpin calculations • Resource-intensive to track and manage data collection and calculation • Data may be challenging to compare across different environments, countries, and patient types • Challenging to attribute measured changes to the company's intervention • Some stakeholders may not be familiar with this concept, potentially making it less resonant and powerful than inputs/outputs measures such as patients treated. Using these metrics may require education and explanation
Mortality avoided / Lives saved	• Provides a clear and intelligible metric for stakeholders to understand • Like QALYs and DALYs, provides a more robust way to understand and compare impacts of different access approaches	• Like QALYs and DALYs, the availability of high-quality data to underpin calculations is a challenge, the resources needed can be significant, and the metric may be applicable to only a subset of diseases and contexts • Company legal teams may be unwilling to disclose these metrics externally

HEALTH SYSTEMS OUTCOMES

Interviewees highlighted three main types of health system outcomes that represent promising opportunities to improve the measurement and reporting of health systems strengthening. These include supply chain management metrics, health-worker training, and patient education.

Some working-group member companies are tracking supply chain management metrics at the programmatic level, albeit only in certain countries and product areas. Therefore, there is an opportunity to learn from and adapt these methodologies and approaches for expanded use.

CASE STUDY: Merck's "Merck for Mothers" program tracks the stock-out rate in facilities covered through the program, as well as the number of health facilities strengthened to improve the supply of modern contraceptives. A key element of the program's approach to data collection is shifting responsibility for data collection to suppliers. Suppliers are incentivized to record data on deliveries and payments using an electronic data-collection system that enables Merck to track health systems strengthening.

Furthermore, other industries are working to develop methodologies for measuring supply chain outcomes. Healthcare companies may be able to benefit from the work of other collaborative initiatives and individual companies as they consider integrating supply chain metrics as one approach to measuring health systems strengthening.

Determining end-user affordability of products is a key metric of interest to public health stakeholders, and is also critical for evaluating price competitiveness compared to competitors' products. There are several ways in which affordability can be calculated. The WHO/HAI methodology uses a reference income level per country and is widely used in public health circles (see Appendix 4 for more detail). It has the advantage of being relatively cheap and simple, and enables comparing results with third-party assessments, but is not specific to individual market segments or populations within a country, which can limit the value of the commercial insights it generates. Alternative approaches include household surveys and market research (such as to assess ability to pay, willingness to pay, and elasticity of demand), which provide more insights tailored to a target population as defined by income group, region, or another characteristic—although it is important to note that household expenditure rather than income is a more appropriate reference point for these two approaches.[10] Household surveys can yield rich insights, but are costly to conduct, whereas market research can be less costly.

Experts highlight that reporting on patient and health-worker education is poor. This type of reporting often lacks context, does not adequately describe the educational approach used, does not characterize the trainers or how the training was delivered, and does not capture the training outcomes. Providing qualitative context of this nature alongside the metrics listed below will be important to ensure that the reported content is meaningful to the target audience.

In the development community, the outcome of health-education interventions is often measured through pre- and post-project evaluations (both on completion of the project and after an extended interval) and through percentage change in the desired knowledge and/or behavior. For training interventions, these desired changes should be predefined and measured based on the theory of change that underpins the program.

Measurement of patient-education outcomes is a nascent area of corporate reporting. There is an opportunity to develop cost-effective data-collection approaches in order to demonstrate the effectiveness of patient-education efforts.

In the following table, we describe the high-level opportunities and challenges associated with each type of health systems outcome metric. As many of these are being used in a small number of programs among a number of leading companies, they will often be better suited to country- or program-level rather than global implementation.

Recommended Metric	Opportunity	Challenge
Supply chain management metrics: **Facility-level availability** • **Percentage of facilities with products in stock** **End-user price** • **Average end-user price per course of treatment for products in LMICs** • **Affordability of treatments for low-**	• Already tracked at a program or regional level by some companies, creating an opportunity to expand on existing methodologies and learn from experienced practitioners • Innovative tracking and management solutions have been developed for healthcare and other industries	• Stock levels at the facility level may be difficult to monitor • Stock-outs can be attributable to many factors • End-user price is influenced not only by company efforts, but also by government policy, mark-ups, and the prevalence of corruption in the value chain

[10] SR Reddy et al., "Health care payments in the Asia Pacific: Validation of five survey measures of economic burden," *Int J Equ in Health* (2013), doi: 10.1186/1475-9276-12-49.

Recommended Metric	Opportunity	Challenge
income patients in LMICs[11]	• Opportunity to create a direct link between business value and positive health outcomes (for instance, reducing stock-outs has direct commercial impact and improves access) • Simpler and cheaper to track than health outcomes • May provide greater comparability across disease types, populations, and geography • Recommended by prominent public health thought leaders	
Health-worker training • **Percentage of health-system workers receiving training that achieve predefined training goals (such as increased knowledge of symptoms or treatment protocols, application of that knowledge, or improved quality of care)**	• Collecting this data can reveal which training interventions have lasting impact, and thus indicate their cost-effectiveness • There is an opportunity to leverage NGO and public-sector know-how	• Corporate measurement and reporting on training and education is nascent, and companies will face methodological and practical challenges, such as cost-effective data collection and analysis
Patient/community education • **Percentage of patients/ community members receiving training that achieve predefined training goals (such as increased knowledge of symptoms, change in health-seeking behavior, or adherence)**	• Collecting this data can reveal which training interventions have lasting impact, and thus indicate their cost-effectiveness	• Corporate measurement and reporting on education interventions, health-seeking behavior, and adherence is nascent, and companies will face methodological and practical challenges, such as cost-effective data collection and analysis • Adherence is typically costly to track

[11] See the discussion of alternative methodologies for calculating affordability on page 17

BUSINESS OUTCOMES

Business outcomes measure the value to the business of commercial activities that have strong access benefits. Boundary-setting is critically important to ensure that the commercial activities included in the reporting scope have a clear link to achieving access goals. In practice, this can involve segmenting the unit of analysis by:

- **Country income level**: Least Developed Countries, Low-Income Countries, Lower-Middle Income Countries
- **Sales channels**: public sector tenders, GAVI/UN sales, self-pay patients.
- **Product type**: for instance, where dedicated second brands or alternative versions of existing brands exist for sale at lower prices
- **Program type**: patient assistance programs, access-driven MEAs

There are a number of ways companies may measure and report the business outcomes of commercial activities with access benefits. Interviewees noted that sales, profitability, and market-share measures at a country level communicate a powerful story in executive presentations. Volume measures may also unify executive leadership around a central access message, such as delivering more products to patients with the most need.

Corporate leaders are wrestling with how to link bottom-up and top-down analysis of business outcomes. In short, how do access programs in one sub-region or city affect measures of business success at a country or regional level? Companies taking a more ambitious approach are reporting up to board-level management on sales of access-related products; however, many reporting structures take a traditional approach to reporting sales, profitability, share, and volume without an access lens.

Recommended Metric	Opportunity	Challenge
Sales and profits generated through equitable pricing initiatives	• Companies may slice markets by market archetype and income level, funding model, and product type	• Companies face a perennial risk of greenwashing their impact. Namely, stakeholders will view measures of business success with caution if they do not see rigorous management and oversight of those measures. Governance in this instance is important to communicate authenticity
Market share of key products for ATMI-indexed diseases and other priority health topics in low- and middle-income countries	• A key business metric at the brand and portfolio level for country affiliates, market share is an important measure of the business value of inclusive business strategies	• Differentiating between market share contributions of access strategies and business-as-usual sales may prove to be challenging in some cases. Companies do well to disclose their methodologies and definitions to ensure that stakeholders—internal and external—understand the rigor behind the reporting

Conclusions and Recommendations

A number of conclusions emerged from the study:

Moving toward a core list of metrics to enable more consistency and comparability
From a baseline of more than 60 input and output metrics used by the 11 companies surveyed, we propose a core list of 19 input and output metrics, and nine outcomes metrics. If adopted, the proposed metrics should contribute to greater consistency and comparability of measurement and reporting of access activities.

Measuring health outcomes should be carefully considered but used with discretion
It is desirable for companies to measure health outcomes using metrics that are not disease-specific. However, the resource implications of doing so are considerable, particularly when compared with a number of disease-specific health-outcomes metrics that can be accurately and readily measured. Companies should therefore carefully consider the case for investing in metrics such as QALY/DALYs in specific situations, considering a range of decision criteria, including those set out in this document. Enterprise-wide use of such metrics remains a distant prospect, and below we discuss the further research needed on leaner, lower-cost approaches for their implementation.

Health systems measurement is critically important
Expert stakeholders see health systems outcomes metrics as a critically important area in which the healthcare sector needs to improve performance and reporting. This aligns with the central importance of capacity-building and health-system strengthening (acknowledged in the GPAH, ATMI, and elsewhere). The healthcare sector's progress on reporting to date has been patchy, and this remains an opportunity for company innovation and leadership. These metrics are also strongly relevant to—and indicative of—overcoming market-access barriers, and consequently have the potential to be valuable for commercial teams in their attempt to drive sales growth, especially in LMICs.

Business outcomes remain at a nascent stage
As demonstrated by this study, business outcomes remain at a nascent stage of development and implementation internally within healthcare companies, and do not appear to be reported externally at present. Given the growing company interest and activity in inclusive or shared-value business models that can drive sales growth and patient access, there is a need and opportunity for companies to innovate and show leadership. As this trend continues, the already-tenuous distinction between access programs and commercial operations will blur even further. This presents challenges with boundary-setting and places a premium on defining clear criteria for what types of initiative can be included in the access category, whether beneficiaries, program longevity, or certain sales channels.

Recommended Further Research

Suggestion 1: Low-cost methodologies for performance measurement

- **Background**: As companies continue to develop and professionalize their reporting of access performance—particularly in the outcomes realm—the associated financial and human-resource implications will become increasingly challenging. Health outcomes and health systems outcomes in particular are resource-intensive. Tools or platforms that enable companies to measure or model health in a leaner, more resource-efficient manner would help expand the adoption of outcomes measurement and reporting.

- **Opportunities**:
    - First, many low-cost ICT solutions have emerged in recent years that can enable companies and their implementation partners to collect data in a systematic and structured manner on an ongoing basis during a program's lifecycle. Examples include DHIS 2, Medic Mobile, Dimagi and ClickMedix.
    - Second, health systems outcomes such as facility-level availability and pricing can provide valuable insights for commercial teams that want to understand the competitive positioning of their products in the market and barriers to achieving greater sales penetration in mass-market segments. Some country affiliates already collect this type of data, though it tends to be on an ad hoc basis.

Suggestion 2: Improved training outcomes measurement

- **Background**: There is a resounding need to measure training outcomes beyond the number of patients and health-workers trained. However, there are methodological and resource challenges associated with assessing the training outcomes, such as the time interval between the training interventions and the outcomes to which they contribute.

- **Opportunities**: Measuring training outcomes is a priority not only for the healthcare industry; there are also opportunities to learn from best practices in other industries and sectors, such as development agencies.

Suggestion 3: Company research on improved business outcomes metrics

- **Background**: This area of reporting is nascent. Even the leading exponents of internal reporting of business outcomes metrics demonstrate patchy coverage in terms of their portfolios and geographic footprints. As a result, they are failing to capture the full business value of their access strategies. Companies therefore need to define criteria to determine which commercial operations should be included within the scope of their internal reporting of the business value of commercially embedded access activities. Once this is in place, companies can consider when and how to report externally.

- **Opportunities**: Companies that define such criteria will be able to demonstrate to senior management the business value of inclusive business strategies to promote access, which in turn can create a more favorable environment for expanding these strategies. Reporting this information externally will help demonstrate the degree to which access is being integrated into the fabric of commercial operations. This is important, as external stakeholders are growing increasingly dissatisfied with philanthropy-dominated performance; they want to see that this agenda is an integral part of how companies go to market.

Appendices

Appendix 1: Glossary of Terms

access to healthcare The ability of a person to receive healthcare services, which is a function of accessibility, availability, and affordability.

accessibility The degree to and ease with which a population can reach health services and supplies.

Access to Medicine Index (ATMI) The Access to Medicine Index independently ranks pharmaceutical companies' efforts to improve access to medicine in developing countries. Funded by the Bill & Melinda Gates Foundation and the UK and Dutch governments, the Index has been published every two years since 2008.

affordability A measure of the payer's ability to pay for a product, whether or not they are the end user.[12]

availability As defined in the GPAH, the practice of ensuring that innovations are available to patients.

bottom of the pyramid (BoP, also known as base of the pyramid) A socioeconomic concept that groups the world's poorest citizens. A member of the BoP lives on less than $2.50 a day.

capacity-building The process by which individuals, groups, organizations, institutions, and societies increase their abilities to perform core functions, solve problems, define and achieve objectives, and understand and deal with their development needs in a broad context and sustainable manner.

collaboration As defined in the GPAH, the participation and cooperation of numerous diverse stakeholders, with complementary responsibilities and capabilities, to solve systemic challenges.

commercialization Launch of a new product or introduction of an existing product into a new market

communicable disease An illness caused by an infectious agent or its toxins that occurs through direct or indirect transmission of an infectious agent or its products from an infected individual or via an animal, vector, or the inanimate environment to a susceptible animal or host.[13]

defined daily dose (DDD) The DDD is the assumed average maintenance dose per day for a drug used for its main indication in adults. The DDD should be used when calculating the number of patients treated based on volumes of products delivered. For chronic diseases, the WHO uses 30 days' consumption of the DDD as the standard measure.

differential pricing Where companies determine pricing tiers and pricing strategy at the country level or within a country based on the socioeconomic profiles of different population segments, taking into account affordability for populations in need.[14]

Disability-Adjusted Life Years (DALY) A summary measure that combines time lost through premature death and time lived in states of less-than-optimal health, loosely referred to as "disability."[15]

equitable pricing A targeted pricing strategy that aims to improve access to medicine for those in need by taking affordability of individuals and healthcare systems into account in a manner that is locally appropriate.[16] This can be achieved through numerous approaches, including differential pricing and non-exclusive voluntary licensing.

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[12] ATMI, 2016 Methodology

[13] CDC, 2012

[14] Adapted from ATMI, 2016 Methodology

[15] Ibid.

[16] Ibid.

health system resources As defined in the GPAH, the strength and capacity of local health systems to meet the health needs of a population. Includes capacity-building, detection, prevention and awareness of health threats, and investing in employees and suppliers.

health systems strengthening Initiatives and strategies that improve one or more of the functions of the health system and that lead to better health through improvements in access, coverage, quality, or efficiency.[17]

International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) A global nonprofit, nongovernmental organization that represents the research-based pharmaceutical industry, including the biotechnology and vaccine sectors.[18]

least developed countries (LDCs) As defined by the UN, low-income countries suffering from structural impediments to sustainable development. These handicaps are manifested in a low level of human-resource development and a high level of structural economic vulnerability.[19]

managed entry agreement (MEA) An arrangement that provides coverage for a drug, subject to certain conditions, typically additional research or price reductions; the price reduction may or may not be linked to a specific health outcome.

Medicines Patent Pool (MPP) A UN-backed organization that aims to improve access to appropriate, affordable HIV medicines and technologies for people living with HIV in developing countries.

neglected tropical diseases (NTDs) A group of parasitic and bacterial diseases that cause substantial illnesses for more than 1 billion people globally and can impair physical and cognitive development, make it hard to earn a living, and contribute particularly to illness and death in mothers and young children.[20]

noncommunicable diseases (NCDs) Also known as chronic diseases, these do not result from an (acute) infectious process and therefore are not contagious. These diseases are rarely cured completely.[21]

Organisation for Economic Cooperation and Development (OECD) A forum where the governments of 34 democracies with market economies work with each other, as well as with more than 70 non-member economies, to promote economic growth, prosperity, and sustainable development.

Quality-Adjusted Life Years (QALY) A measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. One QALY is equal to one year of life in perfect health.[22]

registration According to the WHO, the publication of internationally agreed-upon information about the design, conduct, and administration of clinical trials.

tiered pricing A pricing scheme in which a company adapts product prices based on the purchasing power of consumers in different geographic or socioeconomic segments. Tiered pricing takes into account affordability of medicines and other products for low-income segments, and is therefore a form of equitable pricing.

World Health Organization (WHO) The directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries, and monitoring and assessing health trends.

[17] WHO

[18] IFPMA, 2014.

[19] UN, 2013.

[20] CDC, 2014.

[21] Ibid.

[22] NICE, 2016

Appendix 2: Contributors

The authors wish to thank the following people—as well as other supporting members of their organizations—for their help in developing this working paper:

- Katharine Jensen, AbbVie
- Tara Prasad, Access to Medicines Foundation
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- Maryam Bigdeli, WHO
- William Reidhead, WWF

Appendix 3: Methodology

The methodology used to conduct this research involved three main phases:

Phase 1: Mapping

Phase 1 consisted of understanding existing company practice and existing access frameworks.

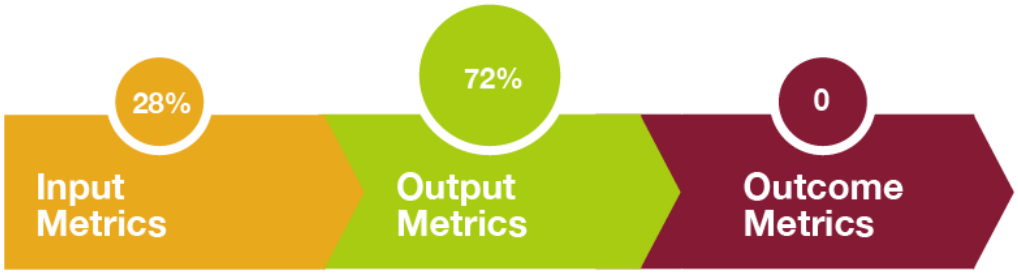
- This phase included data collection of publicly reported enterprise-wide company metrics, interviews with company and non-company representatives, a review of publicly available frameworks (including ATMI, GPAH, and several access frameworks from academic papers provided by the WHO).
- The purpose of this phase was to create an inventory of access to healthcare metrics currently used by healthcare companies in order to understand how they align from company to company and in relation to relevant access frameworks. A second goal was to understand the relative representation of each impact spectrum level (input, output, and outcome) among currently reported metrics.

Phase 2: Data analysis

Phase 2 consisted of a thorough analysis of the data collected in Phase 1, providing insights into the current state of access to healthcare reporting and metrics, and valuable findings that guided Phase 3.

Key findings included:

- **Output metrics are the most common; outcome metrics are absent**



- **Metrics are relatively evenly spread across the major GPAH principles.**
  - The most common metrics relate to the availability principle
  - The most common sub-principles addressed are pricing and capacity-building
  - A number of companies are also reporting on commercialization, developing and adapting products, and promoting innovation and IP rights

- There is a lack of metrics related to local R&D and investing in employees and suppliers

Reported metrics by GPAH Principle and Sub-principle

Availability	40%	Health System	34%	R&D	26%

Availability	#
Pricing	16
Commercialization	7
Registration	2
Policy	0

Health System Resources	#
Capacity Building	16
Detection, Prevention and Awareness	4
Investing in our employees & suppliers	1

R&D	#
Developing and Adapting Products	7
Promoting Innovation & IP Rights	6
Building Local R&D Capacity	2
Clinical Trials	1

The main conclusions of this analysis phase were:
- The GPAH framework constitutes the most suitable thematic architecture around which to organize a set of consistent access metrics
- There is an opportunity to review the relative proportions of input vs. output vs. outcomes metrics that are commonly reported

Phase 3: Recommendations

This phase consisted of crafting recommendations based on the results obtained in Phase 2:
- Developing recommendations for M&E
- Developing a set of recommended metrics
- Identifying opportunities for further research

More specifically, based on findings of the previous phases, developing the proposed set of metrics consisted of four key steps:
- Starting with a long list of metrics collected in Phase 1, focusing on the areas where companies currently mostly report (Capacity-Building, Commercialization, Pricing, and R&D)
- Eliminating metrics lacking specificity or measurability, and highly company- or program-specific metrics that lack broad applicability
- Identifying comparable metrics across companies, proposing alternative metrics with broader applicability, reframing and strengthening existing metrics wherever possible
- Developing or adding new metrics where a gap was identified

For outcomes metrics, based on the initial findings that none of the selected companies' reporting included enterprise-wide outcomes metrics, the focus was to:
- Refine and map outcomes metrics into three types:
  - Health outcomes
  - Health systems outcomes
  - Business value
- Assess the pros and cons for their use
- Provide qualitative guidance on their implementation

Appendix 4: Resources

There are a number of existing resources that companies can use to build a credible, manageable approach to monitoring and evaluation of access to healthcare interventions.

Access Frameworks

- Penchansky, R., and J.W. Thomas. "The Concept of Access: Definition and Relationship to Consumer Satisfaction." *Medical Care* 19 (Feb. 1981): 127-40. www.ncbi.nlm.nih.gov/pubmed/7206846.
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Population demographics

- UN Population Division mortality estimates: http://esa.un.org/unpd/wpp/.
- WHO Global Health Observatory
    - Cause-specific mortality by country: http://www.who.int/healthinfo/global_burden_disease/estimates/en/index1.html.
    - Cause-specific DALYs, years of life lost (YLL), and years lost due to disability by region and income groups: http://www.who.int/healthinfo/global_burden_disease/estimates/en/index2.html.
    - Child causes of death; cause-specific mortality estimates for major causes of child deaths: http://www.who.int/healthinfo/global_burden_disease/estimates/en/index3.html.
- UCSF's Social Franchising Metrics Working Group (SFMWG) advocates for the use of wealth indices adapted from the Demographic and Health Survey (DHS). The wealth indices measure equity in terms of asset ownership and household characteristics. www.sf4health.org/measuring-performance/equity.
- *Community Drug Management for Childhood Illness, Assessment Manual*. This manual from Management Sciences for Health is a useful source for household indicators focused on child health. http://erc.msh.org/toolkit/toolkitfiles/file/C-DMCI Assessment Manual English.pdf.

Quality

- UCSF's Social Franchising Metrics Working Group has compiled a long list of tools to support quality-assessment activities, including sample tools to gauge client perception of services, quality of drugs, and adherence to clinical standards. www.sf4health.org/measuring-performance/quality.

Health Impact

- PSI has developed a health impact calculator to estimate and compare the potential impact of health interventions. http://impactcalculator.psi.org.
- The International Consortium for Health Outcomes Measurement (ICHOM) is a non-profit organization with the purpose to measure and report patient outcomes in a standardized way. By 2017, ICHOM aims to have published Standard Sets covering more than 50 percent of the global disease burden. http://www.ichom.org/
- The Shared Value Initiative published "Measuring Shared Value Innovation and Impact in Health" in September 2014, a useful and complementary resource to this working paper. http://sharedvalue.org/sites/default/files/resource-files/Guide%20to%20Shared%20Value%20Measurement%20for%20Health%20Solutions.pdf.

Pharmaceutical supply system

- WHO guidance on assessing, monitoring, and evaluating country-level pharmaceutical systems. http://apps.who.int/medicinedocs/documents/s14877e/s14877e.pdf.
- WHO and HAI guidance on measuring medicine prices, availability, affordability, and price components. www.who.int/medicines/areas/access/OMS_Medicine_prices.pdf.

Mortality avoided / Lives saved

- Johns Hopkins Bloomberg School of Public Health has developed the Lives Saved Tool in partnership with a number of partners including UNICEF, GAVI, and the Bill & Melinda Gates Foundation. The tool models the impact of health interventions aimed at reducing morbidity and mortality of mothers and children. http://livessavedtool.org/research/scientific-basis-of-list.

Cost-Effectiveness

- UCSF's Social Franchising Metrics Working Group (SFMWG) designed an approach to calculating the cost-effectiveness of access programs. The SFMWG designed this approach after testing it in three programs and considering the variability across accounting systems. www.sf4health.org/measuring-performance/cost-effectiveness.

ABOUT BSR

BSR is a global nonprofit organization that works with its network of more than 250 member companies to build a just and sustainable world. From its offices in Asia, Europe, and North America, BSR develops sustainable business strategies and solutions through consulting, research, and cross-sector collaboration. Visit www.bsr.org for more information about BSR's more than 20 years of leadership in sustainability.

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This working paper has been prepared on behalf of the Healthcare Working Group, a group of 15 global healthcare companies hosted by BSR, as part of an ongoing work program initiated by the launch of the Guiding Principles on Access to Health (GPAH) in 2013. The GPAH is a set of five principles that frame and describe the healthcare industry's approach to reducing the global burden of disease and advancing access to healthcare.

The objective of this working paper is to help pharmaceutical and medical device companies improve their performance measurement and reporting on access to healthcare. To achieve this objective, this paper proposes a set of core metrics to improve the consistency, comparability, and outcomes focus of companies' performance measurement and reporting. It also provides related guidance on Monitoring and Evaluation methodology.

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