

MEASURING GLOBAL HEALTH R&D FOR THE POST-2015 DEVELOPMENT AGENDA

August 2015

As the world agrees on a new development framework for the post-2015 era in the form of the Sustainable Development Goals, a group of concerned organizations with interest and expertise in research for health came together to support the global development agenda by identifying a set of indicators capable of measuring progress in global and national health research. With this publication, we want to call on all countries and global health institutions to help monitor investments in, and use of, research to promote health, equity, and development—both globally and in low- and middle-income countries.

The partners in this initiative are the Council on Health Research for Development, the Foundation for Innovative New Diagnostics, the Global Health Technologies Coalition, the International AIDS Vaccines Initiative, the Medicines for Malaria Venture, PATH, and the TB Alliance, who collectively commissioned Policy Cures to prepare this report.

We would like to thank all of the individuals, organizations, and member state representatives who contributed their time and expertise throughout the stakeholder consultation process that shaped the recommendations presented in this report.

Australia

Suite 206, 68 York Street
Sydney NSW 2000
Tel: +61 (2) 9262 5211

www.policycures.org

Published by Policy Cures
Graphic design by Shigemi Nakamura-Simms of Polkadot Graphic
August 2015

This report was prepared by Policy Cures through a project supported by the Council on Health Research for Development, the Foundation for Innovative New Diagnostics, the Global Health Technologies Coalition, the International AIDS Vaccines Initiative, the Medicines for Malaria Venture, PATH, and the TB Alliance.

The views expressed are those of the authors.



CONTENTS

EXECUTIVE SUMMARY	3
GLOBAL HEALTH R&D IS ESSENTIAL FOR SUSTAINABLE DEVELOPMENT	5
Health is fundamental to sustainable development	5
Innovation is critical to achieving health targets	5
Global health R&D relies on public and philanthropic support	6
GLOBAL HEALTH R&D IS MISSING FROM THE SUSTAINABLE DEVELOPMENT GOALS	7
A snapshot of the SDG and indicator development timeline	7
Global health R&D treated as an afterthought	7
Currently proposed SDG indicators do not measure global health R&D	8
DEVELOPING THE MISSING R&D INDICATORS	9
Indicator inclusion criteria	9
THE SDG MONITORING FRAMEWORK	10
PROPOSED INDICATORS FOR GLOBAL HEALTH R&D	11
Global indicators	12
Complementary national indicators	15
CONCLUSION	17
REFERENCES	18



EXECUTIVE SUMMARY

The Sustainable Development Goals (SDGs) set out an ambitious global agenda to achieve “the future we want.” But despite widespread recognition outside of the SDG process that innovation is central to achieving these goals, and the health goal in particular, research and development (R&D) for global health has largely been ignored in the SDG process.

This document sets out the rationale for the inclusion of robust indicators for global health R&D in the SDG monitoring framework and identifies the most suitable indicators to be included. Without them, support for the innovation that will secure the future of global health risks being ignored in the post-2015 development agenda.

Global health R&D is essential for sustainable development

Health is fundamental to achieving the SDGs. In particular, the health burden that falls disproportionately on low- and middle-income countries (LMICs) must be addressed if we are to ensure sustainable economic prosperity. As recognized by the ambitious targets that make up the health goal, this will require ending the epidemics of HIV/AIDS, tuberculosis, malaria, and neglected tropical diseases, as well as reducing maternal mortality and ending preventable deaths in newborns and children.

But these targets will not be achieved without R&D to develop new health technologies—such as new and improved drugs, vaccines, diagnostics, and other critical innovations—and to improve our understanding of how to best target the tools we already have. And because the burden of poverty-related and neglected diseases and conditions falls overwhelmingly in LMICs, there is no profitable commercial market to drive R&D for new products. Without public and philanthropic funding, the new health technologies necessary for achieving the SDGs will not be developed.

Global health R&D is missing from the Sustainable Development Goals

If the SDGs are to be successful, it is vital that they acknowledge the importance of—and measure progress toward—R&D for global health. But current SDG discussions have largely overlooked the importance of R&D in reaching the health targets.

Only one of the 17 SDGs focuses on health, and the only target under this goal that refers specifically to R&D for the health needs of “developing countries” conflates two distinct problems—access and R&D—excludes important health R&D product areas, and has generally been overlooked throughout the SDG indicator development process. In addition, none of the SDG indicator proposals include any indicators that can adequately measure global health R&D. Even the World Health Organization (WHO)-led health thematic group failed to include a health R&D indicator in its proposed monitoring framework.

Developing the missing indicators

On behalf of a group of global health R&D organizations, Policy Cures has conducted an in-depth analysis and stakeholder consultation to evaluate the SDG indicator landscape and recommend indicators that could be used to monitor progress toward global health R&D in the post-2015 development agenda.

Proposed indicators for global health R&D

Based on extensive landscaping, we are proposing the following indicators for inclusion in the SDG monitoring framework.

Global indicators

We recommend **three indicators** for inclusion in the global SDG monitoring framework. These indicators are presented in two tiers:

Globally collected:

- Public, private, and not-for-profit investment in R&D for the health needs that disproportionately affect people living in low- and middle-income countries
- Number of new registered health technologies targeting the health needs that disproportionately affect people living in low- and middle-income countries

These are the most appropriate for measuring progress in global health R&D and are collected by specialized organizations through existing mechanisms—rather than by national statistical offices—meaning there is no additional reporting burden on national statistical systems. At least one of these two indicators *must be included* in order to measure the global health R&D target (target 3.b).

Nationally collected:

- R&D expenditure as a percentage of GDP [Gross Domestic Product]

This is an established indicator with a well-defined methodology, with data available for more than 135 countries. It can be used to measure domestic research investment, international support for research in LMICs, and as a proxy for research capacity and the existence of an enabling policy environment for R&D.

Complementary national indicators

In addition to the recommended globally monitored indicators, we are proposing **five complementary indicators** for possible inclusion in national SDG monitoring frameworks:

- Number of new health technologies registered by the National Regulatory Authority and/or recommended by national guidelines
- National Regulatory Authorities participating in harmonized registration initiatives based on internationally recognized policies and standards; and sharing regulatory policies, legislation, guidelines, and information on registered products
- Number of formal coordination and collaboration initiatives aimed at increasing and facilitating transfer of health-related technology, including between public and private entities
- Number of registered clinical trials that meet international quality and safety standards
- Number of clinical trial sites that meet international quality and safety standards

Not all of these complementary national indicators will be applicable to every country. But they provide an opportunity for countries—especially LMICs—to ensure their ownership of the post-2015 development agenda. Countries should identify indicators relevant to their national situation and on which they can act and include these in their national monitoring frameworks.

These indicators can play an important role in focusing the attention of all countries on increasing domestic resource mobilization for health R&D, which will be critical to achieving the SDGs. They can also provide a useful measurement of domestic research capacity in general, the existence of an enabling policy environment for R&D, and the transfer of technology.



GLOBAL HEALTH R&D IS ESSENTIAL FOR SUSTAINABLE DEVELOPMENT

Health is fundamental to sustainable development

The health burden that falls disproportionately on low- and middle-income countries (LMICs) must be addressed in order to ensure sustainable economic prosperity, as rightly acknowledged by the current Sustainable Development Goal (SDG) proposal.¹

Health interventions are also among the most cost-effective for poverty alleviation. The Copenhagen Consensus Centre identified 19 of the 169 proposed SDG targets that will be most likely to deliver the best value-for-money. Eight of these “smartest” targets were for health.²

Innovation is critical to achieving health targets

The Lancet Commission on Investing in Health recently outlined an investment framework for achieving the dramatic health gains envisioned for the post-2015 agenda, which would see us reduce infectious, child, and maternal mortality rates to low levels universally within a generation. It highlights investment in research and development (R&D) for global health as the most effective form of international collective action to help achieve this “grand convergence.”³

The ambitious targets that make up the health goal will not be achieved without R&D to develop new health technologies—such as new and improved drugs, vaccines, diagnostics, and other critical innovations—and to improve our understanding of how to best target the tools we already have.

For example, the goal to “By 2030, reduce the global maternal mortality ratio to less than 70 per 100,000 live births” is very unlikely to be achieved while we do not have suitable tools to address post-partum hemorrhage—which is currently responsible for 30 percent of maternal deaths in sub-Saharan Africa and Asia.⁴

Similarly, the goal to “By 2030, end the epidemic of ... tuberculosis” will not be possible without new, effective drugs for the treatment of multi-drug resistant tuberculosis.⁵ And in the absence of new and improved tools to treat, and particularly to prevent HIV transmission, the scale-up of existing treatment and prevention tools for HIV infection will remain insufficient to achieve the end of HIV/AIDS by 2030 as envisaged by the SDGs.⁶



Achieving the health goal is unlikely without continued investment in R&D to develop new and better tools.

The reality of the importance of global health R&D to achieving the health goal is clearly acknowledged in multiple disease-specific global strategies whose targets are aligned with those of the SDGs.

TARGET	MATCHING GLOBAL STRATEGIES AND THEIR RELIANCE ON R&D	
<p>Target 3.3: By 2030, end the epidemics of AIDS, tuberculosis, malaria, and neglected tropical diseases and combat hepatitis, water-borne diseases, and other communicable diseases</p>	<p>WHO draft Global Health Sector Strategy on HIV, 2016-2021 Reduce global AIDS deaths to below 200,000 by 2030</p>	<p>"It is unlikely that the ambitious HIV targets set for 2020 and 2030 can be achieved if we rely only on existing HIV technologies and service delivery approaches."⁷</p>
	<p>WHO global strategy and targets for tuberculosis prevention, care, and control after 2015 (WHO End TB Strategy) Reduce TB deaths by 95% and cut new cases by 90% between 2015 and 2035</p>	<p>"In order to ... achieve by 2035 a reduction in tuberculosis deaths of 95% and a 90% reduction in the incidence rate ..., there must be additional tools available by 2025."⁵</p>
	<p>WHO global technical strategy for malaria (2016-2030) Reduce malaria [mortality and incidence] rates by 90% globally compared with 2015</p>	<p>"A powerful and coordinated global response together with continued investment in research and development will rid entire continents of the disease and eventually eradicate malaria from the world."⁸</p>
	<p>London Declaration on Neglected Tropical Diseases Control, eliminate, or eradicate 10 NTDs by 2020</p>	<p>"We commit to doing our part to: advance R&D through partnerships and provision of funding to find next-generation treatments and interventions for neglected diseases."⁹</p>

If the SDGs are to be successful, it is vital that they acknowledge the importance of—and measure progress toward—R&D for global health.

Global health R&D relies on public and philanthropic support

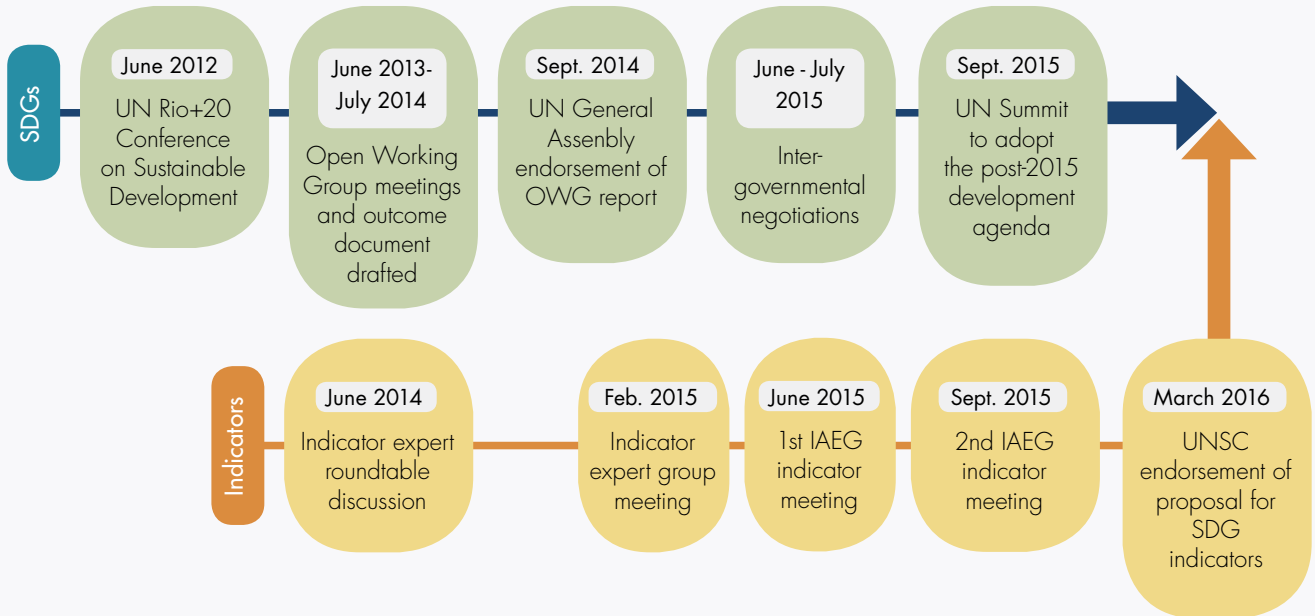
Because the burden of poverty-related and neglected diseases and conditions falls overwhelmingly in LMICs, there is no profitable commercial market to naturally stimulate the development of new health technologies for these conditions. This makes government and philanthropic leadership and funding critical to the development of these technologies as global public goods, including by encouraging and incentivizing the essential role of the biomedical industry in this global effort.

Without public and philanthropic funding, the new health technologies necessary for achieving the SDGs will not be developed. If the SDGs are to be successful, it is therefore vital that they acknowledge the importance of—and measure progress toward—R&D for global health.



GLOBAL HEALTH R&D IS MISSING FROM THE SUSTAINABLE DEVELOPMENT GOALS

A snapshot of the SDG and indicator development timeline



Global health R&D treated as an afterthought

Despite its critical importance, there is limited recognition of health R&D in the proposed goals and targets. One goal (goal 3) out of the 17 SDGs focuses on health, and under this is one target (3.b) that refers specifically to R&D for the health needs of “developing countries.”

However, there are three major issues with target 3.b:

- In its current form, target 3.b conflates the need for R&D with the need for access (i.e., fair pricing of essential medicines). These are two distinct problems with distinct solutions, which require **completely different indicators** to track progress.
- The current wording excludes many important R&D areas including diagnostics, vector control products, microbicides, and other health technologies.
- Target 3.b was only moved to the health goal in the final session of the year-long United Nations (UN) Open Working Group (OWG) discussions. Along with its status as a “means of implementation” indicator, this has meant that target 3.b has been seen as less important than the nine “core” health targets and ignored in indicator development efforts.

There are two other goals that are relevant to innovation: goal 9, which aims to enhance scientific research and technological capabilities in LMICs, and goal 17, which focuses on the means of implementation for sustainable development and strengthening global partnerships. But these are related to innovation generally—health is not specifically mentioned in any of the targets under either of these two goals—and all of the targets for goal 17 are soft rather than concrete targets—in contrast to the “core” targets of the other 16 goals.

Target 3.b:
Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries [and] provide access to affordable... medicines for all.

Currently proposed SDG indicators do not measure global health R&D

Not a single indicator has been proposed that will adequately measure progress in global health R&D—particularly as outlined in target 3.b. The World Health Organization (WHO)-led health thematic group failed to include either a health R&D or access indicator in its initial proposal for the SDG monitoring framework. As a result, **no** indicator for target 3.b was included in the list of preliminary indicators sent by the UN Statistical Commission (UNSC) to member states for review in early 2015.

The subsequent shortlist of indicators prepared by the health thematic group focused only on the access element of the target—ignoring R&D entirely. This has persisted into the initial deliberations of the Inter-Agency and Expert Group on Sustainable Development Goal Indicators (IAEG-SDGs)—the group responsible for identifying global indicators and a monitoring framework for the SDGs. In both the updated list of preliminary indicators presented at the first meeting of the IAEG-SDGs in June 2015 and the subsequent list shared in July 2015, the only indicator proposed under target 3.b was one related to access.

The UNESCO Institute of Statistics (UNESCO-UIS) and the Sustainable Development Solutions Network (SDSN) have respectively proposed “Expenditure on R&D as a percentage of GDP [gross domestic product] (disaggregated by field of science)” and “Public and private expenditure on health R&D” as indicators that could potentially measure progress toward target 3.b.¹⁰ But neither of these indicators can actually do so, as they cannot distinguish health research that is being conducted for the needs of LMICs from any other type of health research.

Goals 9 and 17 relate generally to science and technology and international partnerships, and so understandably no specific global health R&D targets have been proposed for targets under these goals. However, there is an opportunity for countries to include specific measures of global health research capacity or policy support that are relevant to these targets in their national monitoring efforts.

Not a single indicator has been proposed that will measure progress toward target 3.b.



Kibae Park(UN Photo) – Photo has been cropped to fit page – https://www.flickr.com/photos/un_photo/5370298016



DEVELOPING THE MISSING R&D INDICATORS

Policy Cures was commissioned by a group of global health R&D stakeholders—including the Council on Health Research for Development, the Foundation for Innovative New Diagnostics, the International AIDS Vaccine Initiative, the Medicines for Malaria Venture, PATH, and the TB Alliance—to review and recommend a set of indicators that could be used to monitor progress toward global health R&D in the post-2015 development agenda.

As an initial step, Policy Cures identified relevant indicators being proposed specifically for the SDG monitoring framework, including those circulated by the UNSC and those proposed by the WHO-led health thematic group and/or the SDSN.

A broader landscaping effort identified additional indicators which are in use—or have been proposed—elsewhere for the measurement of R&D, particularly in relation to health.

Policy Cures then conducted an open stakeholder consultation in March 2015 to seek feedback from the global health and development community on the indicators identified during the landscaping process. The consultation was conducted online and received 50 submissions from high-level respondents representing a range of sectors—including funders, policymakers, scientists and researchers, program implementers, academics, and advocates—from low-, middle-, and high-income countries. Respondents were asked to select their preferred indicators for each target and were given the opportunity to suggest amended or entirely new indicators.

The indicators identified by stakeholders as being the most important were included on a shortlist. These highest priority indicators were then analyzed to identify those most suitable for inclusion in the SDG monitoring framework and where in this framework they would best fit (e.g. global or national—see following page). This analysis used criteria aligned to those proposed by the UNSC and IAEG-SDGs. For instance, indicators for which measurement mechanisms already exist or that would be simple to measure were prioritized, as were cross-cutting indicators since these are favored in the SDG process as a way to limit the total number of indicators required.

The broad criteria used for this analysis are outlined below:

Indicator inclusion criteria

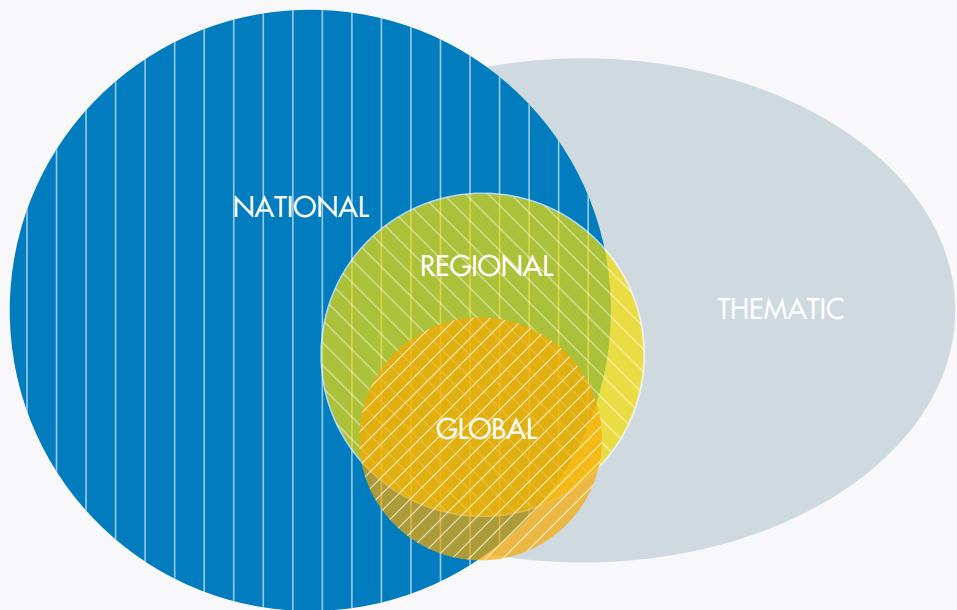
- Feasibility/data availability
 - Source
 - Quality
- Level of endorsement
- Appropriateness
 - For target
 - For global health
- Cross-cutting potential





THE SDG MONITORING FRAMEWORK

As outlined in the synthesis report of the UN secretary-general, there will be four levels of SDG monitoring: global, thematic, regional, and national.¹⁰



Source: Indicators and a Monitoring Framework for the Sustainable Development Goals, SDSN, 2015

Some global indicators—such as those for global public goods—will need to be collected by specialized agencies at the global level.

Global indicators are intended to be the primary foundation to track the progress of all countries toward the SDGs and represent the core set of indicators that will be monitored on a regular basis by the High-Level Political Forum (HLPF). Most global indicators will be collected at the national level by national statistical offices or other government agencies and reported to the HLPF, but some—such as those for global public goods—will need to be collected by specialized agencies at the global level.

Complementary **national indicators** provide an opportunity for more in-depth monitoring of the SDGs targeted to national needs and priorities, allowing countries the opportunity to “define the nature of the indicators, their specifications, timing, data collection methods, and disaggregation.”¹⁰ These indicators are not universally monitored—countries will choose what they monitor based on their national circumstances and their monitoring capacity. And although the final selection of global indicators will be decided in March 2016, the conversation around national indicators will continue into the SDG process, allowing countries to commence tracking relevant national indicators as their national resources grow and their monitoring capacity improves.

Some of the globally and nationally monitored indicators will also lend themselves to being monitored at the regional level, and countries may also choose to develop additional **regional indicators** in response to their shared challenges, priorities, and infrastructure. In addition, it is expected that thematic communities—such as for health—would identify and monitor a specialized set of **thematic indicators** that would complement the official set of SDG indicators.



PROPOSED INDICATORS FOR GLOBAL HEALTH R&D

Based on the scoping exercise, stakeholder consultation, and subsequent analysis, we are proposing the following indicators for inclusion in the SDG monitoring framework. Many other indicators were considered, but these indicators are the most appropriate given the criteria outlined above.

We recommend **three indicators** for inclusion in the **global** SDG monitoring framework. These indicators are presented in two tiers:

Globally collected:

- Public, private, and not-for-profit investment in R&D for the health needs that disproportionately affect people living in low- and middle-income countries
- Number of new registered health technologies targeting the health needs that disproportionately affect people living in low- and middle-income countries

These global indicators are collected by specialized organizations and are the most appropriate for measuring progress in global health R&D. At least one of these two indicators *must be included* in order to be able to measure the global health R&D target (target 3.b).

Nationally collected:

- R&D expenditure as a percentage of GDP

This is an established indicator with a well-defined methodology that is collected at the national level. It can be used to measure domestic research investment, international support for research in LMICs, and as a proxy for research capacity and the existence of an enabling policy environment for R&D.

In addition, we are proposing **five complementary indicators** for possible inclusion in **national** SDG monitoring frameworks:

- Number of new health technologies registered by the National Regulatory Authority and/or recommended by national guidelines
- National Regulatory Authorities participating in harmonized registration initiatives based on internationally recognized policies and standards; and sharing regulatory policies, legislation, guidelines, and information on registered products
- Number of formal coordination and collaboration initiatives aimed at increasing and facilitating transfer of health-related technology, including between public and private entities
- Number of registered clinical trials that meet international quality and safety standards
- Number of clinical trial sites that meet international quality and safety standards

It is important that the number of indicators included in the global indicator list should not be arbitrarily limited.

Not all of these complementary national indicators will be applicable to every country. But they provide an opportunity for countries—especially LMICs—to ensure their ownership of the post-2015 development agenda. Countries should identify indicators relevant to their national situation and on which they can act and include these in their national monitoring frameworks.

As well as measuring progress in global health R&D, these indicators can help measure domestic research capacity in general, the existence of an enabling policy environment for R&D, and the transfer of technology. The following pages provide more detail on each of the proposed indicators and the rationale for including them in the SDG monitoring framework.

Global indicators

Experts have suggested 100-120 indicators as the maximum number that could feasibly be incorporated into the global SDG monitoring framework, so as not to overburden national statistical systems. This is an important principle, and minimizing the reporting burden and limiting the number of indicators has been a key premise of this work. But it is equally important that the number of indicators included in the global indicator list should not be arbitrarily limited if additional, globally-important, and appropriate indicators are identified that create no additional burden on national statistical offices—or if this limit means that some targets are left without an acceptable indicator.

The outputs of global health R&D—such as new health technologies—are global public goods. Their development commonly involves input from multiple international collaborators, and their benefits accrue to multiple countries—not all of which will necessarily fund or conduct R&D themselves. As a result, data on global health R&D is ideally suited to being collected and reported at the global level and for inclusion in the global SDG monitoring framework.

The indicators proposed below have been chosen to ensure the right mix between the importance of global health R&D and the development of a manageable list of indicators for the global monitoring framework.

Globally collected

Public, private, and not-for-profit investment in R&D for the health needs that disproportionately affect people living in low- and middle-income countries

(Disaggregated by funding sector, performing sector, country, disease, and product type)

Number of new health technologies developed that target the health needs that disproportionately affect people living in low- and middle-income countries

(Disaggregated by disease or health priority and product type)

Targets addressed: 3.b

Data status: Data exists for both of these indicators, and there is an established and broadly accepted methodology for the collection and classification of investment data and a defined scope that could be directly adopted or further refined. Furthermore, the World Health Assembly has mandated the WHO to establish the WHO Global Observatory on Health Research and Development to act as a centralized source of data on R&D for “diseases that disproportionately affect the world’s poorest countries,” and this body would be ideally placed to act as data custodian and lead technical agency for collating and reporting on these globally collected indicators.¹¹ The global observatory is due to be established by January 2016.

The observatory would draw from established data collection mechanisms such as the G-FINDER survey of global funding for R&D into neglected diseases that predominantly affect LMICs, which has been run annually since 2008, and regulatory authority databases such as those of the US Food and Drug Administration and the European Medicines Agency.^{12,13} Data from these sources is available on an annually, or more frequently, updated basis, unlike much current R&D expenditure data collected from standard national research surveys.

Rationale for inclusion: Global health R&D is fundamental to achieving the health targets of the SDGs, so a measure of global health R&D progress *must be included* in the global indicator framework.

However the R&D element of target 3.b cannot be measured with any of the indicators currently being considered by the key groups involved in developing the SDG indicators. Even seemingly specific indicators like “Public and private expenditure on health R&D”—as proposed by SDSN—or “Expenditure on R&D as a percentage of GDP (disaggregated by field of science)” —as proposed by UNESCO-UIS—are inadequate because they cannot distinguish R&D that is being done specifically for “diseases that primarily affect developing countries” from any other type of health research. For this reason, **R&D indicators specific to target 3.b are required.**

There are many specific indicators that could be used to measure progress in global health R&D. The two indicators above have been chosen after extensive stakeholder consultation and analysis and are based on indicators or definitions endorsed by the WHO. Other elements—including non-financial contributions, the existence of an enabling policy environment, and the uptake of new health technologies once they have been developed—are all critically important, but are covered in other indicators.

Because data for the two indicators proposed above can be collected by specialized international agencies directly from the organizations that fund and conduct relevant research, their inclusion in the global indicator framework would place no additional burden on national statistical systems in low-resource countries. These are existing, already funded mechanisms—funding for the operation of the WHO R&D observatory has already been secured from member states—meaning that their inclusion in the SDG monitoring framework would not result in an additional cost.

Nationally collected

R&D expenditure as a percentage of GDP

(Disaggregated by sector of performance, source of funds, field of science, and socioeconomic objective)

Targets addressed: 9.5, 9.b, and 17.9



WHO – Photo has been cropped to fit page – <https://www.flickr.com/photos/pathphotos/5225166724/in/photolist-8Zd5PF-cbkyjy-8Xjm2s-cbkA2m-9Mtzfj>

Data status: This is an existing indicator with an established methodology. This indicator is currently collected by national statistical offices or other government agencies through R&D surveys and reported to supra-national organizations including UNESCO-UIS, the Organisation for Economic Co-operation and Development (OECD), Eurostat, and the Ibero-American Network on Science and Technology Indicators, as well as increasingly to the African Science Technology and Innovation Indicators Initiative. Consistently reported data for this indicator is available for 135-140 countries from UNESCO-UIS.

However, the quality of R&D data from existing sources deteriorates significantly when disaggregated. This is particularly true for many LMICs, who often do not report data by field of science or socioeconomic objective or adequately capture nongovernment sectors.

Rationale for inclusion: As an existing indicator with an established methodology and broad coverage, this indicator already has the support of UNSC, UNESCO, and SDSN as an indicator for target 9.5 and the potential to be a cross-cutting indicator for multiple other SDG targets—for which it was strongly supported during the stakeholder consultation.

If fully disaggregated by sector of performance, source of funds, field of science, and socioeconomic objective, this indicator can provide a relatively detailed understanding of all R&D that is carried out within a country's borders and can measure international support for R&D carried out in LMICs.

Health R&D cannot be directly measured using the existing methodology for this indicator¹³, but it can be estimated provided that data is at least disaggregated by source of funds, field of science, and socioeconomic objective.¹⁴

However, as noted above, even when perfectly reported and fully disaggregated, **this indicator cannot be used to monitor the global health R&D target (target 3.b)**, because it cannot distinguish R&D that is being done specifically for “diseases that primarily affect developing countries” from any other type of health research. This is why additional indicators specific to target 3.b are also necessary.

¹³ The internationally adopted standard for the collection and classification of R&D expenditure data through national surveys is the OECD's “Frascati Manual” (*Proposed Standard Practice for Surveys on Research and Experimental Development*).¹⁵

Complementary national indicators

In addition to the universal indicators recommended for inclusion in the global monitoring framework, a number of additional important indicators were identified. These indicators were strongly supported by stakeholders for measuring progress in global health R&D, but not all of them will be applicable to every country. Because of this fact—and the need to limit the number of indicators included in the global monitoring framework—we are proposing these as complementary national indicators, which countries can opt to monitor if appropriate for their national circumstances and monitoring capacity.

As well as measuring progress in global health R&D, a well-constructed indicator framework can both provide useful proxy measurements of LMIC research capacity and help guide the efforts of external researchers and funders to ensure their efforts are locally relevant. Credibly set, regularly updated, and well-communicated priorities for health research such as these promote synergies between all actors working to improve global health through research and innovation.

Number of new health technologies registered by the National Regulatory Authority and/or recommended by national guidelines

(Disaggregated by SDG target [disease or health priority])

Targets addressed: 3.1, 3.2, 3.3, 3.4, and 3.7

The first global registration of a new health technology by a stringent regulatory authority is an important measure of global health R&D progress. But access to—and likely impact of—new health technologies is also dependent on them being registered and recommended for use in the countries in which they are most needed. A reporting framework would need to be developed to allow disaggregation according to the SDG targets, but data should be readily reportable to national statistical offices from National Regulatory Authorities and health agencies.

National Regulatory Authorities participating in harmonized registration initiatives based on internationally recognized policies and standards; and sharing regulatory policies, legislation, guidelines, and information on registered products

Targets addressed: 9.b

Effective national regulatory authorities speed up the introduction and uptake of important new health technologies, but differing capacities and standards between countries are a major impediment to access to new health technologies, particularly in many LMICs where regulatory capacity is often strained. This indicator is based on a metric currently used by the African Medicines Regulatory Harmonization Initiative and would be well-suited to additional monitoring at the regional level.

Number of formal coordination and collaboration initiatives aimed at increasing and facilitating transfer of health-related technology, including between public and private entities

Targets addressed: 9.5, 9.a, 17.6, and 17.9

Technology transfer is a key focus of the means of implementation goal (goal 17) of the SDGs and is also a fundamental component of international support for innovation capacity in LMICs (goal 9). This indicator was proposed in the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, and while no standardized international methodology or data exists, tracking this indicator would be an important step in monitoring progress toward the aims set out in this document.

Number of registered clinical trials that meet international quality and safety standards

Targets addressed: 9.b

Number of clinical trial sites that meet international quality and safety standards

Targets addressed: 9.5

Clinical trials are an essential aspect of R&D for new health products. Tracking the number and quality of both trials and trial sites would provide targeted but useful proxy measures of the existence of an enabling policy environment for health research and of domestic health research infrastructure and would be relevant to any countries looking to track progress in these areas. Global and regional trial registries exist, of varying quality, but little monitoring is done at the national level.



CONCLUSION

Health is fundamental to achieving the SDGs. In particular, the health burden that falls disproportionately on LMICs must be addressed if we are to ensure sustainable economic prosperity.

As recognized by the ambitious targets that make up the health goal, this will require ending the epidemics of HIV/AIDS, tuberculosis, malaria, and neglected tropical diseases, as well as reducing maternal mortality and ending preventable deaths in newborns and children.

These goals will not be achieved without R&D to develop new health technologies—such as new and improved drugs, vaccines, diagnostics, and other critical innovations—and to improve our understanding of how to best target the tools we already have. And this R&D will not happen without public and philanthropic investment and leadership.

If the SDGs are to be successful, it is therefore vital that they acknowledge the importance of—and measure progress toward—R&D for global health. But current SDG discussions have largely overlooked the importance of R&D in reaching the health targets, and no current SDG indicator proposals include any indicators that can adequately measure global health R&D.

Based on extensive landscaping, consultation, and analysis, we have proposed a set of indicators for measuring progress in global health R&D. Including these indicators in the SDG monitoring framework is essential if we are to track the innovation that is fundamental to achieving the health goals of the post-2015 development agenda.

REFERENCES

1. United Nations General Assembly. Report of the Open Working Group of the General Assembly on Sustainable Development Goals. 2014 Aug. Report No.: A/68/970.
2. Copenhagen Consensus Centre. Post-2015 Consensus. Available from: <http://www.copenhagenconsensus.com/post-2015-consensus/nobel-laureates-guide-smarter-global-targets-2030>
3. Jamison DT, Summers LH, Alleyne G, Arrow KJ, Seth S, Binagwaho A. Global health 2035: a world converging within a generation. *The Lancet*. 2013 Dec 7;382(9908):1898, 1921.
4. Khan K, Wojdyla D, Say L, Gülmezoglu A, Van Look P. WHO analysis of causes of maternal death: A systematic review. *Lancet*. 2006 Apr 1;367(9516):1066–74.
5. World Health Organization. Global strategy and targets for tuberculosis prevention, care and control after 2015. EB134/12. 2013.
6. Wilson DP, Stoové MA, Hellard M. A reality check for aspirational targets to end HIV. *Lancet HIV*. 2015 Jan;2(1):e11.
7. World Health Organization. Global Health Sector Strategy on HIV, 2016–2021. Draft for consultation. 2015.
8. World Health Organization. Global Technical Strategy for Malaria 2016-2030. 2015.
9. Uniting to Combat NTDs. London Declaration on Neglected Tropical Diseases. London; 2013.
10. Sustainable Development Solutions Network. Indicators and a monitoring framework for sustainable development goals: launching a data revolution for the SDGs. 2015 May.
11. World Health Organization. WHA resolution 66.22: Follow up of the report of the Consultative Expert Working Group on Research and Development: financing and coordination. 2013.
12. Terry RF, Salm JF, Nannei C, Dye C. Creating a global observatory for health R&D. *Science*. 2014 Sep 12;345(6202):1302–4.
13. Policy Cures. G-FINDER public search tool. 2015. Available from: <https://gfinder.policycures.org/PublicSearchTool/>
14. Røttingen J-A, Regmi S, Eide M, Young AJ, Viergever RF, Ardal C, et al. Mapping of available health research and development data: what's there, what's missing, and what role is there for a global observatory? *Lancet*. 2013 Oct 12;382(9900):1286–307.
15. Organisation for Economic Co-operation and Development. The Measurement of scientific and technological activities : proposed standard practice for surveys on research and experimental development : Frascati manual 2002. Paris: Organisation for Economic Co-operation and Development; 2002.

