Measuring global health R&D for the post-2015 development agenda

CONSULTATION DRAFT

June 2015

This report was prepared by Policy Cures through a project supported by the GHTC, PATH, TB Alliance, IAVI, MMV, FIND and COHRED

www.policycures.org

**CONTENTS**

[EXECUTIVE SUMMARY 2](#_Toc421879226)

[GLOBAL HEALTH R&D IS ESSENTIAL FOR SUSTAINABLE DEVELOPMENT 3](#_Toc421879227)

[Health is fundamental to sustainable development 3](#_Toc421879228)

[Innovation is critical to achieving health targets 3](#_Toc421879229)

[Global health R&D relies on public and philanthropic support 4](#_Toc421879230)

[GLOBAL HEALTH R&D IS MISSING FROM THE SUSTAINABLE DEVELOPMENT GOALS 5](#_Toc421879231)

[A snapshot of the SDG and indicator development timeline 5](#_Toc421879232)

[Global health R&D treated as an afterthought 5](#_Toc421879233)

[Currently proposed SDG indicators do not measure global health R&D 6](#_Toc421879234)

[DEVELOPING THE MISSING R&D INDICATORS 7](#_Toc421879235)

[Indicator inclusion criteria 7](https://pcures.sharepoint.com/Shared%20Documents/Projects/Open/Post-2015%20indicators/5.%20Report/2.%20Consultation%20draft/Consultation%20draft%20update.docx#_Toc421879236)

[PROPOSED INDICATORS FOR GLOBAL HEALTH R&D 8](#_Toc421879237)

[Global indicators 9](#_Toc421879238)

[Complementary national indicators 11](#_Toc421879239)

[CONCLUSION 13](#_Toc421879240)

[REFERENCES 14](#_Toc421879241)

## EXECUTIVE SUMMARY

Health is fundamental to achieving the SDGs. In particular, the health burden that falls disproportionately on low- and middle-income countries must be addressed if we are to ensure sustainable economic prosperity.

This 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.

But because the burden of communicable disease and maternal and infant mortality falls overwhelmingly in the developing world, there is no profitable commercial market drive research and development (R&D) for new products. 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 towards – 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.

Policy Cures has been commissioned by a group of global health R&D stakeholders to recommend a set of indicators to monitor R&D for health in the SDGs. Based on extensive landscaping, consultation and analysis, we have proposed a set of indicators for inclusion in the SDG monitoring framework (outlined below).

**Globally monitored indicators**

*Globally collected:*

1. Public, private and NFP investment in R&D for the health needs of developing countries
2. Number of new registered health technologies targeting the health needs of developing countries (compared to 2015)

*Nationally collected:*

1. Gross domestic expenditure on R&D (GERD)

**Complementary national indicators**

1. Number of new health technologies registered by the National Medicines Regulatory Authority and/or recommended by national guidelines (compared to 2015)
2. Number of registered clinical trials that meet international quality and safety standards
3. Number of clinical trial sites that meet international quality and safety standards
4. National Medicines 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
5. Number of formal coordination and collaboration initiatives aimed at increasing and facilitating transfer of health-related technology, including between public and private entities

This document is intended to inform stakeholders of the importance of including robust indicators for global health R&D, and advise on the most suitable indicators for inclusion. 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 sustainable development**

The health burden that falls disproportionately on low- and middle-income countries 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 amongst 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 R&D for global health as the most effective form of international collective action to help achieve this ‘grand convergence’.3

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

The ambitious targets that make up the health goal will not be achieved without research and development (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 haemorrhage (which is currently responsible for 30% 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 TB (MDR-TB).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

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.

**Matching global strategies and their reliance on R&D**

**Target**

**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

**WHO** **draft** **Global Health Sector Strategy on HIV, 2016-2021**

Reduce global AIDS deaths to below 200,000 by 2030

“**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

**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

“I**n 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

**WHO global technical strategy for malaria (2016-2030)**

Reduce malaria [mortality and incidence] rates by 90% globally compared with 2015

“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

**London Declaration on Neglected Tropical Diseases**

Control, eliminate or eradicate 10 NTDs by 2020

"**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

### **Global health R&D relies on public and philanthropic support**

Because the burden of communicable disease and maternal and infant mortality falls overwhelmingly in the developing world, 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 incentivising the essential role of the biomedical industry in this global effort.

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

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 towards – 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&Din 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:

**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.

* In its current form, Target 3.b conflates the need for R&D with the need for fair pricing of essential medicines (access). 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 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 developing countries; 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).

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

No current SDG indicator proposals include any indicators that can adequately measure global health R&D. Even the 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 UNSC list of preliminary indicators that was sent 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), and even this appears to have been dropped from the group’s latest proposal.

The health thematic group focus on the access element of Target 3.b has persisted into the initial deliberations of the Inter-Agency and Expert Group on Sustainable Development Goal Indicators (IAEG-SDGs), which is responsible for identifying global indicators and an monitoring framework for the SDGs. In the updated list of preliminary indicators presented at the first meeting of the IAEG-SDGs in June 2015, only an access indicator was proposed under Target 3.b.

Not a single indicator has been proposed that will measure progress towards Target 3.b

The Sustainable Development Solutions Network (SDSN) has proposed ‘Public and private expenditure on health R&D’10, but even this is not specific enough to measure progress towards Target 3.b, as it cannot distinguish health research that is being conducted for the needs of developing countries.

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.

## DEVELOPING THE MISSING R&D INDICATORS

Policy Cures was commissioned by a group of global health R&D stakeholders (GHTC, PATH, TB Alliance, IAVI, MMV, FIND and COHRED) to review and recommend a set of indicators that could be used to monitor progress towards 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 UN Statistical Commission (UNSC), and those proposed by the WHO-led health thematic group and 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 responses, with respondents representing a broad range of sectors, organisations and geographies. 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 analysed 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 prioritised, as were cross-cutting indicators (since these are favoured 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

## PROPOSED INDICATORS FOR GLOBAL HEALTH R&D

As outlined in the synthesis report of 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**

Global indicators are intended to be the primary foundation to track the progress of all countries towards 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 line agencies) and then reported to the HLPF, but some (such as those for global public goods) will need to be collected by specialised agencies at the global level.

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

Some of these globally and nationally monitored indicators will also lend themselves to being monitored at the regional level, and countries may also choose to develop additional region-specific 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 specialised set of indicators that would complement the official set of SDG indicators.

Based on the scoping exercise, stakeholder consultation and subsequent analysis, we recommend the following indicators for inclusion in the SDG monitoring framework:

* **3 global indicators**. These indicators are presented in two tiers:
	+ Two that are collected by a specialised organisation at the global level and which are 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 Target 3.b.
	+ One that is collected at the national level. This is an established indicator with a well-defined methodology that can be used to measure domestic research capacity, international support for research in developing countries, and as a proxy for the existence of an enabling policy environment for R&D.
* **5 complementary national indicators** that countries should monitor if appropriate to their national circumstances. As well as measuring progress in global health R&D, these indicators also provide a useful measurement of domestic research capacity, the existence of an enabling policy environment for R&D, and the transfer of technology.

### Global indicators

Around 100-120 indicators has been proposed 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, but equally important is that the global indicator list should not be arbitrarily limited to this number if additional, globally-important and appropriate indicators are identified that create no additional burden on national statistical offices.

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. As a result, they are ideally suited to being collected and reported at the global level, and to inclusion in the global SDG monitoring framework.

The proposal below is designed 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 NFP investment in R&D for the health needs of developing countries**

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

**Number of new registered health technologies targeting the health needs of developing countries (compared to 2015)**

(Disaggregated by disease and product type)

**Targets addressed:** 3.b

**Rationale for inclusion:** Because global health R&D is fundamental to achieving the health targets of the SDGs, a measure of global health R&D progress should 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) are inadequate. With no capacity to identify the purpose of the R&D, they cannot distinguish R&D directed at the health needs of developing countries from all other kinds of health R&D. Indicators specific to Target 3.b are required.

The fact that these indicators could be collected directly at the global level – through collection mechanisms that already exist – rather than from national statistical offices would allow them to be included in the global indicator framework without increasing the reporting burden on national statistical systems.

Tracking global health R&D expenditure provides a clear measure of global support to R&D for the health needs of developing countries that is easily comparable over time, and was identified in the stakeholder consultation as the most appropriate indicator for measuring Target 3.b (and is supported for this target by the SDSN). Tracking the registration of new health technologies measures the effectiveness of this support, and is based on a WHO-endorsed indicator.

**Data status:** No standardised international methodology or official reporting agency currently exists for these indicators, but the World Health Assembly has mandated the WHO to establish a Global Observatory on Health R&D, to act as a centralised source of data on R&D for “diseases that disproportionately affect the world’s poorest countries.”11

There is also existing data from established data collection mechanisms, including from specialised organisations. This includes the G-FINDER survey of global funding for R&D into neglected diseases that predominantly affect the developing world, which has been run annually since 200812, as well as regulatory authority databases, such as that of the US FDA.

The WHO Global Observatory on Heath R&D is due to be established by January 2016, and would be well placed to act as data custodian and lead technical agency for collating and reporting on these globally collected indicators, including by incorporating existing data from sources such as the G-FINDER survey and established databases.13 Data from these sources is also available on an annually updated basis, unlike much current GERD data for example.

#### Nationally collected

**Gross domestic expenditure on R&D (GERD)**

(Disaggregated by sector of performance, source of funds, field of science and socio-economic objective)

**Targets addressed:** 9.5, 9.b, 17.9

**Rationale for inclusion:** Gross expenditure on R&D (GERD) is an established indicator with broad coverage, has the support of the UNSC and SDSN as in indicator for Target 9.5, and was strongly supported as a cross-cutting indicator for multiple SDG targets during the stakeholder consultation. If fully disaggregated by sector of performance, source of funds, field of science and socio-economic objective, GERD can provide a detailed understanding of all R&D that is carried out within a country’s borders, including measuring international support for R&D in low- and middle-income countries. Health R&D is not directly measured by GERD, but it can be estimated, provided that data is at least disaggregated by source of funds, field of science and socio-economic objective.14

However, as noted, even when perfectly reported and fully disaggregated, **GERD 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.

**Data status:** Existing indicator, currently reported by national statistical offices to supra-national organisations including the UNESCO Institute for Statistics, OECD, EUROSTAT and RICYT (and increasingly the African Science Technology and Innovation Indicators initiative). Consistently reported data for this indicator is available for 100+ countries.

However, the quality of GERD data from existing sources deteriorates significantly when disaggregated. This is particularly true for many low- and middle- income countries (LMICs), who often do not report data for field of science or socio-economic objective, or adequately capture non-government sectors. Inclusion in the global SDG monitoring framework would help focus attention on improving the capacity of all countries to report expenditure on R&D conducted on their territories.

### Complementary national indicators

In addition to the indicators recommended for inclusion in the global monitoring framework, a number of important additional indicators were identified. These indicators are not necessarily applicable to all countries, but we recommend that countries should monitor them if appropriate for their national circumstances.

**Number of new health technologies registered by the National Medicines Regulatory Authority and/or recommended by national guidelines (compared to 2015)**

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

Targets addressed: 3.1, 3.2, 3.3, 3.4, 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 Medicines Regulatory Authorities (NRMAs) and health agencies.

**National Medicines 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 low- and middle-income countries where regulatory capacity is often strained. This indicator is based on a metric currently used by the African Medicines Regulatory Harmonization (AMRH) initiative, and would be well suited to additional monitoring at the regional level.

**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.

**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, 17.9

Technology transfer is 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 developing countries (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 standardised international methodology or data exists, tracking this indicator would be an important step in monitoring progress towards the aims set out in this document.

## CONCLUSION

Health is fundamental to achieving the SDGs. In particular, the health burden that falls disproportionately on low- and middle-income countries must be addressed if we are to ensure sustainable economic prosperity.

As recognised by the ambitious targets that make up the health goal, this will require ending the epidemics of 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 towards – 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 inclusion in the SDG monitoring framework. Without them, support for the innovation that will secure the future of global health risks being ignored in 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. Policy Cures. G-FINDER public search tool. 2015. Available from: https://gfinder.policycures.org/PublicSearchTool/
13. Terry RF, Salm JF, Nannei C, Dye C. Creating a global observatory for health R&D. Science. 2014 Sep 12;345(6202):1302–4.
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.

BLANK